UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/813,695	06/18/2013	8465500	630666.00074	6073

26710 7590 05/29/2013

QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 811 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Giovanni Speziali, Pittsburgh, PA;

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/813,695	07/11/2007	Giovanni Speziali	630666.00074	6073

26710 7590 05/24/2013
QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER	
TEMPLETON, CHRISTOPHER L	
ART UNIT	**PAPER NUMBER**
3773	

NOTIFICATION DATE	DELIVERY MODE
05/24/2013	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Response to Rule 312 Communication	Application No. 11/813,695	Applicant(s)
	Examiner	Art Unit

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

1. ☒ The amendment filed on *21 May 2013* under 37 CFR 1.312 has been considered, and has been:

a) ☒ entered.

b) ☐ entered as directed to matters of form not affecting the scope of the invention.

c) ☐ disapproved because the amendment was filed after the payment of the issue fee.
Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

d) ☐ disapproved. See explanation below.

e) ☐ entered in part. See explanation below.

Publishing Division

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use as many sheets as necessary)

Complete if Known	
Application Number	11/813,695
Filing Date	July 11, 2007
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher Templeton
Attorney Docket Number	630666.00074

Sheet	1	of	14

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number / Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-3,667,474	06-06-1972	Konstantin V. Lapkin et al.
		US-3,842,840	10-22-1974	Edward E. Schweizer
		US-4,351,345	09-28-1982	Andrew L. Carney
		US-4,972,874	11-27-1990	Harold E. Jackson
		US-5,059,201	10-22-1991	Stanely E. Asnis
		US-5,336,229	08-09-1994	Wayne A. Noda
		US-5,452,733	09-26-1995	Wesley D. Sterman et al.
		US-5,571,215	11-05-1996	Wesley D. Sterman et al.
		US-5,653,716	08-05-1997	Cheryne M. Malo et al.
		US-5,693,091	12-02-1997	Carl O. Larson Jr. et al.
		US-5,762,613	06-09-1998	Gregg S. Sutton et al.
		US-5,772,672	06-30-1998	Frederick K. Toy et al.
		US-5,797,960	08-25-1998	John H. Stevens et al.
		US-5,839,639	11-24-1998	Jude S. Sauer et al.
		US-5,919,128	07-06-1999	Joseph P. Fitch
		US-5,961,440	10-05-1999	Cyril J. Schweich Jr. et al.
		US-5,972,030	10-26-1999	Michi E. Garrison et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document / Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
Change(s) applied to document, /A.L.G./ 1/22/2013		EP 1 039 851 B1	07-20-2005	Todd J. Mortier et al.	
		EP 1 408 850 B1	09-23-2009	Eric A. Goldfarb et al.	
		EP 1 637 091 A2	03-22-2006	Todd J. Mortier et al.	
		EP 1 845 861 A2	10/2007		
		EP 1 845 861 A4	12/2009		
		WO 1999/00059	01-07-1999	Mehmet C. Oz	

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use as many sheets as necessary)

Complete if Known	
Application Number	11/813,695
Filing Date	July 11, 2007
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher Templeton
Attorney Docket Number	630666.00074

Sheet	8	of	14

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-2005/0075727 A1	04-07-2005	David J. Wheatley
		US-2005/0075723 A1	04-07-2005	Richard Schroeder et al.
		US-2005/0101975 A1	05-12-2005	John D. Nguyen et al.
		US-2005/0125011 A1	06-09-2005	Paul A. Spence et al.
		US-2005/0131277 A1	06-16-2005	~~06-16-2005~~ Schweich, Jr. et al.
		US-2005/0131533 A1	06-16-2005	Ottavio Alfieri et al.
		US-6,908,424 B2	06-21-2005	Todd J. Mortier et al.
		US-2005/0143620 A1	06-30-2005	Todd J. Mortier et al.
		US-2005/0148815 A1	07-07-2005	Todd J. Mortier et al.
		US-2005/0149014 A1	07-07-2005	Wallace N. Hauck et al.
		US-6,918,917 B1	07-19-2005	John D. Nguyen et al.
		US-6,921,407 B2	07-26-2005	John D. Nguyen et al.
		US-2005/0171601 A1	08-04-2005	Delos M. Cosgrove et al.
		US-6,929,715 B2	08-16-2005	Gerdt Fladda et al.
		US-2005/0216039 A1	09-29-2005	Robert J. Lederman
		US-6,955,175 B2	10-18-2005	John H. Stevens et al.
		US-2005/0240202 A1	10-27-2005	Hani Shennib et al.
		US-6,962,605 B2	11-08-2005	Delos M. Cosgrove et al.
		US-2005/0251187 A1	11-10-2005	Richard M. Beane et al.
		US-6,978,176 B2	12-20-2005	Omar M. Lattouf

Change(s) applied to document, /A.J.P./ 2/12/2013

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 09/052528 A2	04-23-2009	John Zentgraf	
		WO 09/052528 A3	04-23-2009	John Zentgraf	

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	11/813,695
				Filing Date	July 11, 2007
				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	4	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,443,922 B1	09-03-2002	Craig P. Roberts et al.
		US-6,451,054	09-17-2002	John H. Stevens
		US-6,461,366	10-08-2002	Jacques Seguin
		US-2002/0169359 A1	11-14-2002	Patrick M. McCarthy et al.
		US-2002/0173694 A1	11-21-2002	Todd J. Mortier et al.
		US-2002/0183766 A1	12-05-2002	Jacques Sequin
		US-6,508,777 B1	01-21-2003	John Macoviak et al.
		US-6,514,194 B2	02-04-2003	Cyril J. Schweich Jr. et al.
		US-2003/0032979 A1	02-13-2003	Todd J. Mortier et al.
		US-2003/0050529 A1	03-13-2003	Robert M. Vidlund et al.
		US-2003/0050693 A1	03-13-2003	Rodolfo C. Quijano et al.
		US-6,537,198 B1	03-25-2003	Robert M. Vidlund et al.
		US-6,537,314 B2	03-25-2003	Jonathan J. Langberg et al.
		US-6,551,331 B2	04-22-2003	Anthony A. Nobles et al.
		US-2003/0078600 A1	04-24-2003	Philip S. O'Quinn et al.
		US-6,558,416 B2	05-06-2003	Delos M. Cosgrove et al.
		US-6,562,052 B2	05-13-2003	Anthony A. Nobles et al.
		US-6,564,805 B2	05-20-2003	Michi E. Garrison et al.
Change(s) applied to document, /A.J.P./ 2/12/2013		US-6,582,388 B1	06-24-2003	Coleman et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 03/082157 A2	10-09-2003	Stefan Schreck	
		WO 03/082157 A3	10-09-2003	Stefan Schreck	
		WO 04/043265 A2	05-27-2004	Robert M. Vidlund et al.	
		WO 04/043265 A3	05-27-2004	Robert M. Vidlund et al.	
		WO 05/039428 A2	05-06-2005	Jan Lan	
		WO 05/039428 A3	05-06-2005	Jan Lan	

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	11/813,695
				Filing Date	July 11, 2007
				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	10	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)* 2006016104O	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
Change(s) applied to document, /A.J.P./ 2/14/2013		US-~~2006/016040 A~~1	07-20-2006	Patrick M. McCarthy et al.
		US-2006/0161193 A1	07-20-2006	Richard M. Beane et al.
		US-7,083,628 B2	08-01-2006	Alan Bachman
		US-7,083,638 B2	08-01-2006	Seth A. Foerster
		US-7,090,686 B2	08-15-2006	Anthony A. Nobles et al.
		US-2006/0184203 A1	08-17-2006	Brian B. Martin et al.
		US-7,094,244 B2	08-22-2006	Stefan Schreck
		US-2006/0195012 A1	08-31-2006	Todd J. Mortier et al.
		US-2006/0195134 A1	08-31-2006	James F. Crittenden
		US-7,100,614 B2	09-05-2006	John H. Stevens et al.
		US-7,112,207 B2	09-26-2006	William J. Allen et al.
		US-7,112,219 B2	09-26-2006	Robert M. Vidlund et al.
		US-2006/0287657 A1	12-21-2006	Alan B. Bachman
		US-2007/0002627 A1	01-04-2007	Tae Un Youn
		US-2007/0027451 A1	02-01-2007	Kai Desinger et al.
		US-7,179,291 B2	02-20-2007	Jonathan M. Rourke et al.
		US-2007/0049952 A1	03-01-2007	Steven J. Weiss
		US-2007/0050022 A1	03-01-2007	Robert M. Vidlund et al.
		US-7,186,264 B2	03-06-2007	John R. Liddicoat et al.
		US-2007/0055303 A1	03-08-2007	Robert M. Vidlund et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [3]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Docket No.: 630666.00074

I hereby certify that this correspondence is being electronically transmitted to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
Date of Signature
and Transmission: May 21, 2013

/ Richard T. Roche /
Richard T. Roche, Reg. No. 38,599

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Giovanni Speziali
Application No.:	11/813,695
Filed:	July 11, 2007
For:	THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS
Group Art Unit:	3773
Examiner:	Christopher L. Templeton

Amendment Under 37 C.F.R. 1.312 In
Response To Notice To File Corrected Application Papers

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Notice to File Corrected Application Papers mailed on April 19, 2013. This amendment is being filed after payment of the issue fee; however, it is limited to the correction of informalities noted in the Notice to File Corrected Application Papers mailed on April 19, 2013. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004) and M.P.E.P. § 714.16(d) III.

Amendments to the Specification begin on page 2 of this paper.

Remarks begin on page 6 of this paper.

Amendments to the Specification

Please insert the following paragraphs after paragraph [0013] and before "DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT" on page 4 of the specification:

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a cut-out view of a patient's chest showing an instrument embodying the invention being inserted into a patient's chest cavity through a thorascopic port that is inserted into the patient's chest.

Figure 2 is a cut-out view of a patient's chest showing an instrument embodying the invention grasping a prolapsing segment of the mitral valve inside the patient's chest cavity and securing an artificial chorda to the free edge of the prolapsing segment of the mitral valve.

Figure 3 is a cut-out view of a patient's chest cavity showing an instrument embodying the invention tensioning the neo-implanted chorda.

Figure 4 is an isometric view of an instrument embodying the invention.

Figure 5 is a detailed isometric view of the distal end of an instrument embodying the invention.

Figure 6A is a detailed side elevation view of the distal end of an instrument embodying the invention showing the tip in a closed position.

Figure 6B is a detailed side elevation view of the distal end of an instrument embodying the invention showing rods inside the instrument that are capable of sliding to move the tip to an open position.

Figure 7 is a detailed isometric view of the distal end of an instrument embodying the invention showing the needle lumen and four fiberoptic channels that are disposed around the needle lumen.

Figure 8A is a detailed isometric view of the preferred embodiment of the suture deployment system showing the positioning of a heart valve leaflet with respect to the instrument.

Figure 8B is a detailed isometric view of the preferred embodiment of the suture deployment system showing the tip of the distal end of the instrument closing on the leaflet to grasp the leaflet such that the needle can puncture and push the suture through the leaflet.

Figure 8C is a detailed isometric view of the preferred embodiment of the suture deployment system showing the needle retracting back through the leaflet to pull the suture loop back through the puncture opening in the leaflet.

Figure 8D is a detailed isometric view of the preferred embodiment of the suture deployment system showing the distal end of the instrument releasing the leaflet and pulling both ends and the midpoint of the suture as the instrument withdraws from the patient's heart.

Figure 8E is a detailed side elevation view of the preferred embodiment of the suture deployment where the suture is released from the instrument and the two suture ends are inserted through the loop.

Figure 8F is a detailed side elevation view of the preferred embodiment of the suture deployment system wherein the ends of the suture are pulled and the loop of the

suture slides back along the suture to form a Larks head around the edge of the valve leaflet.

Figure 9A is a detailed isometric view of a second embodiment of the suture deployment system showing the tip of the distal end of the instrument grasping the heart valve leaflet and showing a suture that is a closed loop with one end of the loop disposed in the tip of the instrument and the other end disposed in the lumen and wrapped around the needle.

Figure 9B is a detailed isometric view of a second embodiment of the suture deployment system showing the needle puncturing the leaflet and pushing the suture through the leaflet.

Figure 9C is a detailed isometric view of a second embodiment of the suture deployment system showing the needle retracting back through the leaflet to pull the looped suture back through the opening in the leaflet and showing the instrument releasing the leaflet.

Figure 9D is a detailed isometric view of a second embodiment of the suture deployment system showing the instrument withdrawing to slide the unhooked end of the suture along the length of the needle towards the leaflet to form a Larks head around the leaflet's edge.

Figure 10A is a detailed isometric view of a third embodiment of the suture deployment system showing the tip of the distal end of the instrument grasping the heart valve leaflet and showing the midpoint of the suture being looped around the lumen and the two loose ends of the suture being coiled up in the tip of the distal end of the instrument.

Figure 10B is a detailed isometric view of a third embodiment of the suture deployment system showing the needle puncture and push the suture through the leaflet and through the loop of the free ends of the suture wherein the needle then hooks the free ends of the suture.

Figure 10C is a detailed isometric view of a third embodiment of the suture deployment system showing the needle retracting back through the leaflet and showing the instrument releasing the leaflet.

Figure 10D is a detailed isometric view of a third embodiment of the suture deployment system showing the instrument withdrawing from the heart to pull the free ends of the suture back through the valve leaflet and forming a Larks head around the leaflet's edge by the midpoint of the suture.

REMARKS

In the Notice to File Corrected Application Papers mailed on April 19, 2013, it was requested that a brief description of the drawings be added to the specification. As requested, the specification has been amended to include a brief description of the drawings. No new matter has been added.

No fees are believed to be due for this amendment. However, if any fees are due, please charge them to Deposit Account No. 17-0055.

Respectfully Submitted,

Giovanni Speziali

Dated: May 21, 2013

By: /Richard T. Roche/

Richard T. Roche
QUARLES & BRADY LLP
411 East Wisconsin Avenue
Milwaukee, WI 53202
Reg. No.: 38,599
(414) 277-5805

Electronic Acknowledgement Receipt

EFS ID:	15830731
Application Number:	11813695
International Application Number:	
Confirmation Number:	6073
Title of Invention:	THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS
First Named Inventor/Applicant Name:	Giovanni Speziali
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	630666.00074
Receipt Date:	21-MAY-2013
Filing Date:	11-JUL-2007
Time Stamp:	14:30:39
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		amendment-NOA-5-21-13.pdf	93553 6ca08dbd61ad3c3d1b77320ffcf879af2bfec5b5	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment after Notice of Allowance (Rule 312)	1	1
	Specification	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	6
Warnings:			
Information:			
	Total Files Size (in bytes):	93553	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/813,695	07/11/2007	Giovanni Speziali	630666.00074	6073

26710 7590 04/19/2013

QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER	
TEMPLETON, CHRISTOPHER L	
ART UNIT	**PAPER NUMBER**
3773	

NOTIFICATION DATE	DELIVERY MODE
04/19/2013	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 11813695
Applicant : Speziali
Filing Date : 07/11/2007
Date Mailed : 04/19/2013

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given 2 month(s) from the mail date of this Notice, or the time remaining from the Notice of Allowance and Fee(s) Due, whichever is longer, within which to respond.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED. **This period for reply is NOT extendable under 37 CFR 1.136(a).**

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee,Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Marty Willis/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 11813695

IDENTIFICATION OF SPECIFICATION/DRAWING INCONSISTENCIES

☐ On Page of the specification there is a brief description of FIG. , but the drawings filed do not include a drawing with that designation. Applicant must respond either by supplying the omitted drawing or by amending the specification to remove all references to that drawing.

☐ The drawings filed include FIG. , but the specification's brief description of the drawings does not describe a drawing with that designation. Applicant must respond either by amending the specification to add a brief description of that drawing or by correcting the drawings to remove the drawing in question.

☒ Drawings are present in the application and are referred to in the detailed description of the invention, but the specification does not contain a brief description of the drawings as required by 37 CFR 1.74 and 37 CFR 1.77(b)(8).

☐ Page of the specification refers to FIG. , but no drawing with that designation is described in the brief description of the drawings and no drawing with that designation is present in the application. Applicant must respond either by amending the specification to remove all references to that drawing, or by supplying that drawing and amending the specification to add a brief description of it.

☐ OTHER:

☐ COMMENTS:

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26710 7590 01/02/2013
QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/813,695	07/11/2007	Giovanni Speziali	630666.00074	6073

TITLE OF INVENTION: THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$885	$300	$0	$1185	04/02/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
TEMPLETON, CHRISTOPHER L	3773	606-139000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Quarles & Brady LLP
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Mayo Foundation for Medical Education and Research

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Rochester, Minnesota

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
- ☒ Issue Fee
- ☒ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 170055 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
- ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /Richard T. Roche/ Date March 29, 2013

Typed or printed name Richard T. Roche Registration No. 38,599

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Electronic Patent Application Fee Transmittal

Application Number:	11813695
Filing Date:	11-Jul-2007
Title of Invention:	THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS
First Named Inventor/Applicant Name:	Giovanni Speziali
Filer:	Richard T. Roche
Attorney Docket Number:	630666.00074

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	2501	1	890	890
Publ. Fee- Early, Voluntary, or Normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1190**

Electronic Acknowledgement Receipt

EFS ID:	15386739
Application Number:	11813695
International Application Number:	
Confirmation Number:	6073
Title of Invention:	THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS
First Named Inventor/Applicant Name:	Giovanni Speziali
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	630666.00074
Receipt Date:	29-MAR-2013
Filing Date:	11-JUL-2007
Time Stamp:	10:44:19
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1190
RAM confirmation Number	8446
Deposit Account	170055
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Issue Fee Payment (PTO-85B)	IssueFee.PDF	960055 329baa21a7790e3758ee5c6e019efb1577f3b0fa	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	31909 1942ebb827e76bf2006935477617c17367d52e9e	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	991964	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket No.: 630666.00074

I hereby certify that this correspondence is being electronically transmitted to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Date of Signature
and Transmission: March 27 ,2013

/ Richard T. Roche /
Richard T. Roche, Reg. No. 38,599

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Giovanni Speziali

Application No.: 11/813,695

Filed: July 11, 2007

For: THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

Group Art Unit: 3773

Examiner: Christopher L. Templeton

AMENDMENT UNDER 37 C.F.R. 1.312

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Notice of Allowance dated January 2, 2013. Please amend the above-identified application as follows.

Amendments to the Drawings begin on page 2 of this paper.

Remarks begin on page 3 of this paper.

An Appendix including an amended drawing figure is attached following page 3 of this paper.

Amendments to the Drawings

An annotated sheet showing the drawing change is attached.

Drawing Figure 3A has been cancelled.

REMARKS

In the Notice of Allowance dated January 2, 2013, it was requested that Figure 3A be deleted. This amendment deletes Figure 3A.

Should any issues remain outstanding, the Examiner is invited to contact the undersigned at the telephone number appearing below.

No fees are believed to be due for this amendment. However, if any fees are due, please charge them to Deposit Account No. 17-0055.

Respectfully Submitted,

Giovanni Speziali

Dated: March 27, 2013

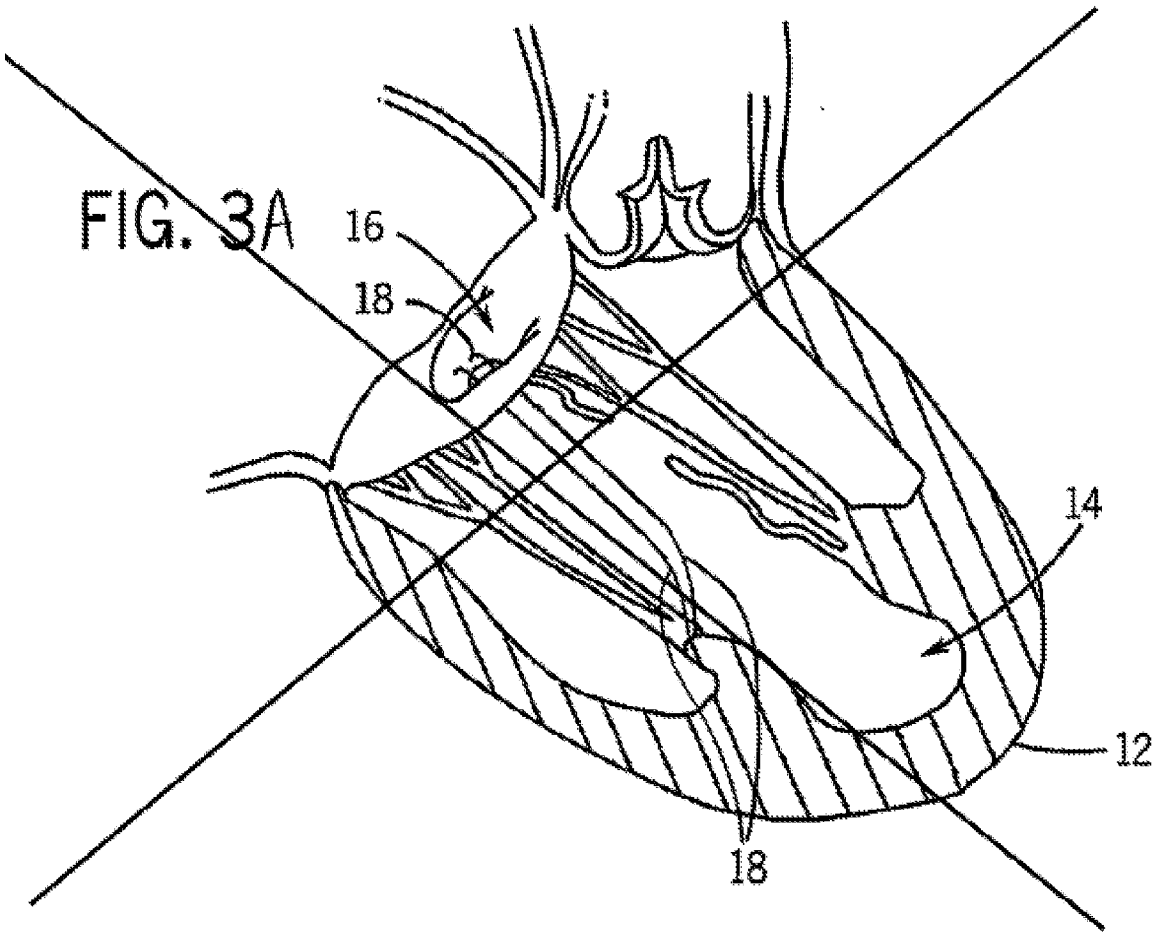
By: /Richard T. Roche/

Richard T. Roche
QUARLES & BRADY LLP
411 East Wisconsin Avenue
Milwaukee, WI 53202
Reg. No.: 38,599
(414) 277-5805

20285972

Annotated Sheet

FIG. 3A



Electronic Acknowledgement Receipt

EFS ID:	15362571
Application Number:	11813695
International Application Number:	
Confirmation Number:	6073
Title of Invention:	THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS
First Named Inventor/Applicant Name:	Giovanni Speziali
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	630666.00074
Receipt Date:	27-MAR-2013
Filing Date:	11-JUL-2007
Time Stamp:	10:23:36
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		amendment-3-27-13.pdf	1546916 01adecc453099c90ac4fef557e5ea860c5a37ad3	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment after Notice of Allowance (Rule 312)	1	1
	Applicant Arguments/Remarks Made in an Amendment	2	3
	Drawings-only black and white line drawings	4	4
Warnings:			
Information:			
	Total Files Size (in bytes):	1546916	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

26710 7590 01/02/2013

QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER
TEMPLETON, CHRISTOPHER L

ART UNIT	PAPER NUMBER
3773	

DATE MAILED: 01/02/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/813,695	07/11/2007	Giovanni Speziali	630666.00074	6073

TITLE OF INVENTION: THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$885	$300	$0	$1185	04/02/2013

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26710 7590 01/02/2013

QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/813,695	07/11/2007	Giovanni Speziali	630666.00074	6073

TITLE OF INVENTION: THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$885	$300	$0	$1185	04/02/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
TEMPLETON, CHRISTOPHER L	3773	606-139000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/813,695	07/11/2007	Giovanni Speziali	630666.00074	6073

26710 7590 01/02/2013

QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER	
TEMPLETON, CHRISTOPHER L	
ART UNIT	PAPER NUMBER
3773	

DATE MAILED: 01/02/2013

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 683 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 683 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No.	Applicant(s)	
	11/813,695	SPEZIALI, GIOVANNI	
	Examiner	Art Unit	
	CHRISTOPHER L. TEMPLETON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed 1 October 2012*.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are *1-6,18,20,21,24,25 and 27-29*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 10/25/12
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20121206* .
5. ☒ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Julian W. Woo/
Primary Examiner, Art Unit 3773

Examiner-Initiated Interview Summary	**Application No.** 11/813,695	**Applicant(s)** SPEZIALI, GIOVANNI	
	Examiner CHRISTOPHER L. TEMPLETON	**Art Unit** 3773	

All participants (applicant, applicant's representative, PTO personnel):

(1) *CHRISTOPHER L. TEMPLETON*. (3)_____.

(2) *Richard Roche*. (4)_____.

Date of Interview: *05 December 2012*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1,19,22-24,26,27,30 and 31*.

Identification of prior art discussed: *N/A*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicant's representative agreed to the amendments set forth in the Examiner's Amendment.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/CHRISTOPHER L TEMPLETON/ Examiner, Art Unit 3773	

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Richard Roche on 5 December 2012.

The application has been amended as follows:

In the specification, paragraph 16, lines 4 and 5, *delete* "In another embodiment shown in Figure 3A, the chorda 18 can be anchored to a papillary muscle in the heart."

Cancel claims 19, 22, 23, 26, 30 and 31.

In claim 1, line 12 after "proper attachment of a suture to the leaflet;" insert, --wherein confirming capture and proper positioning of the leaflet between the distal end and the movable element using a fiber optic visualization system includes using a fiber optic visualization system having at least one illumination fiber optic that provides the light and at least one sensor fiber optic that conveys the reflected light from the distal end; wherein the fiber optic visualization system includes a plurality of illumination fiber optics and a plurality of sensor fiber optics, at least one illumination fiber optic and at least one sensor fiber optic positioned within each of a plurality of channels extending longitudinally through the instrument and terminating adjacent the distal end such that each channel provides an independent indication of whether the leaflet is captured between the movable element and the distal end, and wherein the step of confirming

capture and proper positioning of the leaflet includes viewing each of the independent indications;--.

In claim 24, line 13, after "leaflet to the visualization monitor", insert --wherein the instrument includes a plurality of geometrically arranged illuminating fibers in optical communication with the visualization monitor and the exposed surface of the distal end, at least one illuminating fiber in each of a plurality of separate channels extending longitudinally through the instrument, each of the channels corresponding to one of the colored dots--.

In claim 27, line 15, after "element and the distal end for proper attachment of a suture to the leaflet;" insert --wherein confirming capture and proper positioning of the leaflet between the distal end and the movable element using a fiber optic visualization system includes using a fiber optic visualization system having at least one illumination fiber that provides the light and at least one sensor fiber that conveys the reflected light from the distal end; wherein the fiber optic visualization system includes a plurality of illumination fiber optics and a plurality of sensor fiber optics, at least one illumination fiber optic and at least one sensor fiber optic positioned within each of a plurality of channels extending longitudinally through the instrument and terminating adjacent the distal end such that each channel provides an independent indication of whether the leaflet is captured between the movable element and the distal end, and wherein the step of confirming capture and proper positioning of the leaflet includes viewing each of the independent indications;--.

2. The following changes to the drawings have been approved by the examiner and agreed upon by applicant: Delete figure 3A. **In order to avoid abandonment of the application, applicant must make these above agreed upon drawing changes.**

Reasons for Allowance

3. The following is an examiner's statement of reasons for allowance: With respect to base claims 1 and 27, the prior art of record fails to disclose a method of repairing a heart valve in a patient with an instrument having a distal end and a movable element or providing instructions with the same instrument comprising: inserting the instrument through a patient's chest wall and into the patient's chest cavity; inserting the distal end and movable element through an exterior heart wall; grasping a single leaflet on the heart valve; confirming capture and proper positioning of the leaflet between the movable element and the distal end using a fiber optic visualization system; puncturing the leaflet with a needle after confirming proper positioning of the leaflet and then drawing the suture to connect the suture to the leaflet; capturing the suture with the needle; anchoring the suture to another structure within the heart; and withdrawing the instrument, inter alia, and in combination with the fiber optic visualization system having a plurality of illumination fiber optics that provide light and a plurality of sensor fiber optic that convey reflected light from the distal end and wherein at least one illumination fiber optic and at least one sensor fiber optic is positioned within each of a plurality of channels extending longitudinally through the instrument and terminating adjacent the distal end such that each channel provides an independent indication, and wherein the step of confirming capture and proper positioning includes viewing each of the plurality of independent indications.

4. With respect to base claim 24, the prior art of record fails to disclose: a method of confirming capture and proper positioning of a valve leaflet of a patient's heart comprised of providing an instrument having a distal end, a movable element, a plurality of illuminating fibers in optical communication with a visualization monitor; inserting the instrument through the patient's chest wall and into the patient's chest cavity; grasping a leaflet on a heart valve and conveying a plurality of distinct and independent colored dots to the visualization monitor corresponding to a capture status and positioning of the leaflet, inter alia, in combination with at least one illuminating fiber in each of a plurality of separate channels extending longitudinally through the instrument, each of the channels corresponding to one of the colored dots.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER L. TEMPLETON whose telephone number is (571) 270-1477. The examiner can normally be reached on Monday - Thursday 7 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact*** **the examiner's supervisor, Corrine M. McDermott, *at* (571) 272-4754**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. L. T./
Examiner, Art Unit 3773

/Julian W. Woo/
Primary Examiner, Art Unit 3773

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11813695	SPEZIALI, GIOVANNI
	Examiner	Art Unit
	CHRISTOPHER L TEMPLETON	3773

SEARCHED

Class	Subclass	Date	Examiner
606	139, 144, 145, 15, 16, 205-211	12/6/2012	CT
128	898	12/6/2012	CT
623	11.11, 13.11, 2.11-2.35	4/7/2010	CT
600	478,473,476,16, 37, 160, 182, 104	12/6/2012	CT

SEARCH NOTES

Search Notes	Date	Examiner
EAST search (see attached)	12/6/2012	CT
Inventor name search	4/7/2010	CT
Consulted with Julian Woo with class search help	12/10/2012	CT
Consulted with Corrine McDermott with allowable subject matter	12/12/2012	CT

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner
606	139,144,145,15,16, 205-209	12/6/2012	CT
128	898	12/6/2012	CT
600	478,473,476, 104	12/6/2012	CT

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	31	606/205-211.ccls. and @ad<="20050121" and dot$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/14 08:13
L2	6	606/205-211.ccls. and @ad<="20050121" and dot$1 and fiber and optic$2	US-PGPUB; USPAT	ADJ	OFF	2012/12/14 08:15
L3	0	606/205-211.ccls. and @ad<="20050121" and fiber and optic$2 and (grasp) same indication	US-PGPUB; USPAT	ADJ	OFF	2012/12/14 08:17
L4	13	@ad<="20050121" and fiber same optic$2 and (grasp) same indication	US-PGPUB; USPAT	ADJ	OFF	2012/12/14 08:17
L5	1	606/205-211.ccls. and @ad<="20050121" and fiber same optic$2 and (grasp) same light	US-PGPUB; USPAT	ADJ	OFF	2012/12/14 08:18
L6	0	606/205-211.ccls. and @ad<="20050121" and fiber same optic$2 and (grasp) same alarm	US-PGPUB; USPAT	ADJ	OFF	2012/12/14 08:19
L7	137	606/205-211.ccls. and @ad<="20050121" and fiber same optic$2	US-PGPUB; USPAT	ADJ	OFF	2012/12/14 08:19
L8	4	606/205-211.ccls. and @ad<="20050121" and fiber same optic$2 and dot$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/14 08:19
L9	47	606/205-211.ccls. and @ad<="20050121" and fiber same optic$2 and (monitor or screen)	US-PGPUB; USPAT	ADJ	OFF	2012/12/14 08:20
L10	295	128/898.ccls. and @ad<="20050121" and fiber same optic$2 and (monitor or screen)	US-PGPUB; USPAT	ADJ	OFF	2012/12/14 08:32
L11	12	128/898.ccls. and @ad<="20050121" and fiber same optic$2 and (monitor or screen) and dot$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/14 08:32
L12	1	606/139,144,145.ccls. and @ad<="20050121" and fiber same optic$2 and (monitor or screen) and dot$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/14 08:32
L13	40	606/139,144,145.ccls. and @ad<="20050121" and fiber same optic$2 and (monitor or screen)	US-PGPUB; USPAT	ADJ	OFF	2012/12/14 08:33
L14	35	606/139,144,145.ccls. and @ad<="20050121" and fiber same optic$2 and (monitor or screen) and channel$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/14 08:34
L15	32	("20030004562" | "20030195529" | "20040087978" | "20050021055" | "20050165419" | "20070232941" | "4935027" | "4957498" | "5297536" | "5304185" | "5312423" | "5547455" | "5667473" | "5667478" | "5762458" |	US-PGPUB; USPAT	ADJ	OFF	2012/12/14 08:42

		"5772597" | "5785658" | "5897564" | "6129683" | "6152934" | "6178346" | "6270508" | "6419626" | "6533796" | "6893448" | "6936054" | "7118583" | "7122040" | "7381210" | "7815654" | "7879048" | "7887552").PN.				
S253	0	wo "2009094188"	US-PGPUB; USPAT	ADJ	OFF	2012/12/03 13:08
S254	2	wo "2009094188"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2012/12/03 13:08
S255	0	wo "2009094188" and figures	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2012/12/03 13:09
S256	36	606/139,144.ccls. and grasp and @ad<="20050121" and proper positioning	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2012/12/03 13:21
S257	3	606/139,144.ccls. and grasp and @ad<="20050121" and proper positioning and fiber optics	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2012/12/03 13:22
S258	9	606/139,144.ccls. and grasp and @ad<="20050121" and proper positioning and fiber	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2012/12/03 13:22
S259	66	("20030004562" | "20030195529" | "20040087978" | "20050021055" | "20050165419" | "20070232941" | "4935027" | "4957498" | "5297536" | "5304185" | "5312423" | "5547455" | "5667473" | "5667478" | "5762458" | "5772597" | "5785658" | "5897564" | "6129683" | "6152934" | "6178346" | "6270508" | "6419626" | "6533796" | "6893448" | "6936054" | "7118583" | "7122040" | "7381210" | "7815654" | "7879048" | "7887552").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2012/12/03 14:02
S260	32	("20030004562" | "20030195529" | "20040087978" | "20050021055" | "20050165419" | "20070232941" | "4935027" | "4957498" | "5297536" | "5304185" | "5312423" | "5547455" | "5667473" | "5667478" | "5762458" |	US-PGPUB; USPAT	ADJ	OFF	2012/12/03 14:09

		"5772597" | "5785658" | "5897564" | "6129683" | "6152934" | "6178346" | "6270508" | "6419626" | "6533796" | "6893448" | "6936054" | "7118583" | "7122040" | "7381210" | "7815654" | "7879048" | "7887552").PN.				
S261	12	S260 and fiber	US-PGPUB; USPAT	ADJ	OFF	2012/12/03 14:25
S262	40	("3889662" | "4699463" | "4846154" | "4873572" | "5025778" | "5166787" | "5301061" | "5335662" | "5398685").PN. OR ("5547455").URPN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 14:52
S263	121	(US-20040225300-$ or US-20070112425-$ or US-20050021057-$ or US-20030105519-$ or US-20090088837-$ or US-20100042147-$ or US-20100023118-$ or US-20040143323-$ or US-20040210303-$ or US-20030078653-$ or US-20050075727-$ or US-20060167541-$ or US-20060100698-$ or US-20100030242-$ or US-20090198324-$ or US-20050021056-$ or US-20080243150-$ or US-20070049952-$ or US-20090043153-$ or US-20040044365-$ or US-20010005787-$ or US-20060287716-$ or US-20030120341-$ or US-20070118154-$ or US-20070118213-$ or US-20050070999-$).did. or (US-20080228223-$ or US-20040024414-$ or US-20030078600-$ or US-20050216039-$ or US-20040122448-$ or US-20020099389-$ or US-20100022823-$ or US-20070197858-$ or US-20030032979-$ or US-20040133063-$ or US-20070299468-$ or US-20070112422-$ or US-20050149093-$ or US-20030195529-$ or US-20030065338-$ or US-20060095025-$ or US-20040138531-$ or US-20080188873-$ or US-20020055748-$ or US-20040092962-$ or US-20070232941-$).did. or (US-6997950-$ or US-6358277-$ or US-4960424-$ or US-7513908-$ or US-6332893-$ or US-6074417-$ or US-6797002-$ or US-6840246-$ or US-6978176-$ or US-7563273-$ or US-7431692-$ or US-6746471-$ or US-7527647-$ or US-6149660-$ or US-5908428-$ or US-5059201-$ or US-6936054-$ or US-7118583-$ or US-6893448-$ or US-5312423-$ or US-4493323-$ or US-5522820-$ or US-6702835-$ or US-6743239-$ or US-5810847-$ or US-7559936-$).did. or (US-7794474-$ or US-6260552-$ or US-5762613-$ or US-5891160-$ or US-6464707-$ or US-7063710-$ or US-6991635-$ or US-6551330-$ or US-6575971-$ or US-5316479-$ or US-5836894-$ or US-	US-PGPUB; USPAT; DERWENT	ADJ	OFF	2012/12/03 15:37

		7083571-$ or US-6626917-$ or US-5609598-$ or US-6178346-$ or US-5336229-$ or US-6419626-$ or US-5593405-$ or US-5785658-$ or US-5772597-$ or US-6129683-$ or US-5730702-$ or US-8118206-$ or US-5908429-$ or US-5667472-$ or US-4759348-$).did. or (US-6730076-$ or US-7235089-$ or US-5441507-$ or US-5667473-$ or US-5667478-$ or US-5746770-$ or US-7122040-$ or US-5667517-$ or US-5547455-$ or US-5025778-$).did. or (US-20040143323-$ or US-20030105519-$ or WO-02102237-$ or WO-2006089236-$ or US-20040210303-$ or WO-03037227-$ or US-20020161378-$ or WO-03049619-$ or US-7635386-$ or WO-9829041-$).did.				
S264	54	S263 and fiber	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:37
S265	62	S263 and indicat$3	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:39
S266	6	S263 and indicat$3 same grasp	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:39
S267	5	S263 and 606/205.ccls.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:41
S268	28	("20050203562" | "5762613" | "6419626" | "7306559" | "6010516" | "6796939" | "5879289" | "5336232" | "6558333" | "6711429" | "5667473" | "6882875" | "5785658" | "20050033556" | "6129683" | "20040054270" | "20060235279" | "5941822" | "5674230" | "6324418" | "7310547" | "7615002" | "20070078484" | "6226543" | "20060161055" | "5569300" | "5800350" | "5772597").PN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:43
S269	3	"11473296"	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:50
S270	0	(("2005033556") or ("2005203562")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/12/03 15:52
S271	2	(("20050033556") or ("20050203562")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/12/03 15:52
S272	2	S271 and fiber	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:53
S273	18	S268 and fiber	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:54
S274	7	"11773388" and kinematic$4	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 16:14

S275	94	606/139,144,145.ccls. and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 12:13
S276	109	606/205-209.ccls. and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 12:13
S277	28	128/898.ccls. and @ad<="20050121" and fiber optic$1 and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 12:13
S278	6	623/2.11.ccls. and @ad<="20050121" and fiber optic$1 and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 12:14
S279	11	606/139,144,145.ccls. and @ad<="20050121" and fiber optic$1 and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 12:14
S280	3	606/205-209.ccls. and @ad<="20050121" and indication same grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 12:31
S281	2	606/205-209.ccls. and @ad<="20050121" and confirm$5 same grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:04
S282	29	606/205-209.ccls. and @ad<="20050121" and indicat$3 same grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:05
S283	0	606/205-209.ccls. and @ad<="20050121" and alarm same grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:21
S284	0	"227".clas. and @ad<="20050121" and confirm$5 same grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:21
S285	32	"227".clas. and @ad<="20050121" and indicat$3 same grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:22
S286	0	"227".clas. and @ad<="20050121" and alarm same grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:22
S287	0	"227".clas. and @ad<="20050121" and fiber optic$1 same grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:25
S288	46	"227".clas. and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:25
S289	9	606/205-209 and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:31
S290	109	606/205-209.ccls. and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:31
S291	85	("6149660" | "5762613" | "4960424" | "6997950" | "6419626" | "20030004562" | "5312423" | "7815654" | "7887552" | "20040044365" | "6165119" | "20050154402" | "4935027" | "5547455" | "6129683" | "6178346" | "6270508" | "3667474" | "5059201" | "6022360" | "6177144" | "6245079" | "20010005787" | "6978176" | "7666204" | "5431666" | "20050021056" | "5667472" | "5667478" | "20050021055" | "5772597" | "6419626" | "6893448" | "7381210" | "5667472" | "5693091" | "6050936" | "6234995" | "6260552" | "6840246" | "5667473" | "5785658" | "7118583" | "5336229" | "5571215" | "5839639" | "6162168" | "6264602" | "20030105519" | "20030195529" | "20040122448" | "4957498" | "5304185" | "5336229" | "20030195529" | "5667478" | "5452733" | "6077214" | "6183411" |	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:54

		"20070232941" | "5667473" | "5785658" | "6936054" | "7122040" | "20030078600" | "4972874" | "5653716" | "5772672" | "5919128" | "5961440" | "6045497" | "6165120" | "6190357" | "6261222" | "5830231" | "5908429" | "6178346" | "5297536" | "5762458" | "5897564" | "6152934" | "6533796" | "7879048" | "5908428" | "3842840" | "4351345" | "5797960" | "5972030" | "6059715" | "6197052" | "6626917" | "5772597" | "20040087978" | "20050165419").PN.				
S292	20	606/205-209 and @ad<="20050121" and indicat$3 and grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 14:14
S293	1	"8052699".pn.	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 14:44
S294	21	("20030065402" | "20050245965" | "20060085034" | "20060135992" | "20060212050" | "20060271104" | "20070175963" | "20070203510" | "20070246505" | "20080110959" | "20080140115" | "5395030" | "5919232" | "6210439" | "6258107" | "7175591" | "7547312" | "7670361" | "7744627" | "7823592" | "7845536").PN. OR ("8052699").URPN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/06 14:50
S295	1	"12666235"	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/06 14:59
S296	0	606/15,16 and @ad<="20050121"	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:43
S297	1283	606/15,16.ccls. and @ad<="20050121"	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:44
S298	21	606/15,16.ccls. and @ad<="20050121" and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:44
S299	710	606/15,16.ccls. and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:44
S300	49	606/15,16.ccls. and @ad<="20050121" and fiber optic$1 and forceps	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:47
S301	11	606/15,16.ccls. and @ad<="20050121" and fiber optic$1 and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:50
S302	44	606/15,16.ccls. and @ad<="20050121" and fiber optic$1 and sensor and illuminat$3	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:51
S303	133	606/15,16.ccls. and @ad<="20050121" and fiber optic$1 and sensor	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:52
S304	1	606/15,16.ccls. and @ad<="20050121" and fiber optic$1 and (confirm$5 or indicat$3) same (grasp or pinch or grip)	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:57
S305	0	606/15,16.ccls. and @ad<="20050121" and fiber optic$1 (grasp or pinch or grip)	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:58
S306	85	606/15,16.ccls. and @ad<="20050121" and fiber optic$1 and (grasp or pinch or grip)	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:58
S307	6	600/478.ccls. and @ad<="20050121" and fiber optic$1 and (grasp or pinch or	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:01

		grip)				
S308	158	600/478.ccls. and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:01
S309	0	600/478.ccls. and @ad<="20050121" and fiber optic$1 and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:02
S310	1	600/473,476.ccls. and @ad<="20050121" and fiber optic$1 and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:02
S311	604	600/473,476,478.ccls. and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:02
S312	182	600/473,476,478.ccls. and @ad<="20050121" and fiber optic$1 and sensor and illuminat$3	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:02
S313	63	128/898.ccls. and @ad<="20050121" and fiber optic$1 and sensor and illuminat$3	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:11
S314	13	128/898.ccls. and @ad<="20050121" and fiber optic$1 and sensor and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:12
S330	8	606/210,211.ccls. and @ad<="20050121" and (grip or grasp) and (signal or alarm)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/07 08:20
S331	1	606/210,211.ccls. and @ad<="20050121" and fiber optic$1 and (confirm$5 or indicat$3) same (grasp or pinch or grip)	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 08:22
S333	3350	@ad<="20050121" and fiber optic$1 and (grasp or pinch or grip) and (signal or alarm)	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 08:23
S334	238	@ad<="20050121" and fiber optic$1 and (grasp or pinch or grip) and (signal or alarm) and forceps	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 08:23
S335	28	@ad<="20050121" and fiber optic$1 and (grasp or pinch or grip) same (signal or alarm) and forceps	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 08:24
S336	96	@ad<="20050121" and fiber optic$1 and (grasp or pinch or grip) same (detection)	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 08:52
S337	11415	@ad<="20050121" and (grasp or pinch or grip) same (detect$3 or alarm)	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 08:59
S338	706	@ad<="20050121" and (grasp or pinch or grip) same (detect$3 or alarm) and tissue	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 09:00
S339	568	@ad<="20050121" and (grasp or pinch or grip) same (detect$3 or alarm) and (surgery or surgical)	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 09:04
S340	191	@ad<="20050121" and (grasp or pinch or grip) same (detect$3 or alarm) and (surgery or surgical) and heart	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 09:05
S342	2	"11813695"	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 15:28
S343	237	606/145.ccls.	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 15:32
S344	58	("5762613" | "20040044365" | "20040236353" | "20070049952" | "5762458" | "6270508" | "7666204" |	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 16:02

		"6162233" | "6991635" | "4935027" | "5059201" | "5571215" | "6436107" | "5626607" | "5665100" | "5972004" | "3667474" | "5059201" | "5304185" | "6858003" | "20070179511" | "6053933" | "5693091" | "4967498" | "5830231" | "20070232941" | "5336229" | "5571215" | "5839639" | "5908429" | "20050021055" | "7887552" | "20020013571" | "20090105729" | "20030187457" | "5211650" | "5984939" | "6629984" | "5452733" | "5897564" | "20030004562" | "7635386" | "4972874" | "5653716" | "5772672" | "5919128" | "5961440" | "6533796" | "20040087978" | "20080027468" | "20080188873" | "6626917" | "3842840" | "4351345" | "5797960" | "5972030" | "5431666" | "20050165419" | "6152934" | "4935027" | "5993467").PN.				
S345	49	S344 and @ad<="20050121"	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 16:04
S346	11	S345 and fiber and optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 16:04
S347	124	("20030050693" | "20030181928" | "20040003819" | "20040049207" | "20040049552" | "20040127983" | "20040133063" | "20050033446" | "20050143620" | "20050240202" | "20060149123" | "20060195134" | "20070002627" | "20070118154" | "20070197858" | "20090131880" | "5762613" | "6332863" | "6355050" | "6443922" | "6451054" | "6514194" | "6585727" | "6589160" | "6622730" | "6626930" | "6764510" | "6921407" | "7094244" | "20080027468" | "6419626" | "5626607" | "5665100" | "5972004" | "6053933" | "6858003" | "20010016675" | "20020183766" | "20040267083" | "20050065396" | "20050075723" | "20060058871" | "20060074485" | "20060100699" | "20070027451" | "20070118155" | "20070299468" | "20080228223" | "20090259304" | "6117144" | "6165119" | "6165183" | "6283993" | "6402781" | "6564805" | "6616684" | "6733509" | "6793618" | "6986775" | "7226467" | "4935027" | "20030004562" | "20050021055" | "6270508" | "20020029080" | "20030032979" | "20030166992" | "20040039442" | "20040044350" | "20040167539" | "20050021056" | "20050125011" | "20050149014" | "20050216039" | "20060036317" | "20060135993" | "20060287657" | "20070055303" | "20070088375" | "20070239272" | "20080065205" | "20080097489" | "3667474" | "5059201" | "6022360" | "6245079" | "6269819" | "6619291" | "6629534" | "6679268" | "6695866" | "6740107" | "6802860" |	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 16:07

		"6978176" | "7077862" | "7090686" | "7247134" | "7288097" | "7666204" | "20020049402" | "20040092962" | "20040243229" | "20050044365" | "20050131533" | "20050148815" | "20070049952" | "20080051703" | "20080091264" | "20080188873" | "5693091" | "6050936" | "6234995" | "6260552" | "6746471" | "6752813" | "6770084" | "6918917" | "7179291" | "7217240" | "7563273" | "7604646" | "5830231" | "5762458" | "6936054").PN.				
S348	143	("20070179511" | "20090105729" | "20020169359" | "20030050529" | "20030130731" | "20040122448" | "20050075727" | "20050131277" | "20060020275" | "20060195012" | "20070265643" | "20080183194" | "20090105751" | "5336229" | "5571215" | "5839639" | "6162168" | "6264602" | "6406420" | "6558416" | "6989028" | "7112207" | "5908429" | "20040087978" | "20070232941" | "7887552" | "5984939" | "6162233" | "6629984" | "20010021872" | "20020013571" | "20030167071" | "20030171641" | "20040087975" | "20060016040" | "20060161193" | "20070100356" | "20070112244" | "5452733" | "6077214" | "6183411" | "6197052" | "6402680" | "6461366" | "6551331" | "6718985" | "6723038" | "6770083" | "6955175" | "0658238" | "7004176" | "7011669" | "7048754" | "7186264" | "7250028" | "7464712" | "5897564" | "20040044365" | "20040236353" | "6991635" | "20030199975" | "20040030382" | "20040167374" | "20040225300" | "20050021057" | "20050101975" | "20060052868" | "20060089671" | "20060127509" | "20060184203" | "20070129737" | "20070203391" | "20080065011" | "20090156995" | "4972874" | "5653716" | "5772672" | "5919128" | "6045497" | "6165120" | "6190357" | "6261222" | "6312447" | "6402679" | "6508777" | "6537198" | "6602288" | "6629921" | "6709456" | "6755777" | "6808488" | "6810882" | "6875224" | "6929715" | "7083628" | "7112219" | "7608091" | "6997950" | "6533796" | "5211650" | "5993467" | "7635386" | "20020077524" | "20020173694" | "20030078600" | "20040225304" | "20040236354" | "20050171601" | "20050251187" | "20060041306" | "20060241340" | "20070050022" | "20080065156" | "20080091059" | "20080167714" | "20080195200" | "20080208006" | "20090163934" | "4351345" | "5797960" | "5972030" | "6059715" | "6332864" | "6332893" | "6401720" | "6436107" |	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 16:07

		"6537314" | "6562052" | "6645205" | "6908424" | "6962605" | "7004952" | "7044905" | "7083638" | "7100614" | "7189199" | "7294148" | "7563267" | "5431666" | "20050165419" | "6152934" | "6626917" | "20030187457").PN.				
S349	91	S347 and @ad<="20050121"	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 16:08
S350	107	S348 and @ad<="20050121"	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 16:08
S351	21	S349 and fiber and optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 16:08
S352	8	S350 and fiber and optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 16:08
S353	0	"5919128".pn. and sensor and optic$2 and fiber	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 16:14
S354	0	"5919128".pn. and sensor	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 16:14
S355	1	"5919128".pn. and fiber	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 16:14
S356	1	"8052699".pn.	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 16:37
S357	2	"11813695"	US-PGPUB; USPAT	ADJ	OFF	2012/12/10 07:50
S358	6	(("5037433") or ("5741271") or ("5746694") or ("6808491") or ("7261728") or ("8206284")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/12/10 16:47
S359	5	S358 and fiber	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/10 16:47
S360	152	600/104.ccls. and @ad<="20050121" and fiber and optic$1	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/10 16:52
S361	161	600/104.ccls. and @ad<="20050121" and fiber and optic$2 and channel$1	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/10 16:59
S362	87	600/104.ccls. and @ad<="20050121" and fiber and optic$2 and channels	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/10 16:59
S363	14	600/104.ccls. and @ad<="20050121" and fiber and optic$2 and channels and suture and needle	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/10 17:15
S364	19	600/104.ccls. and @ad<="20050121" and fiber same optic$2 same channels	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/11 07:58
S365	571	"600".clas. and @ad<="20050121" and fiber same optic$2 same channels	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/11 08:16
S366	220	600/101-183.ccls. and @ad<="20050121" and fiber same optic$2 same channels	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/11 08:17
S374	3	(("2137710") or ("5226426")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/12/11 10:41
S375	3	(("20070156175") or ("20030149447") or ("20080082113")).PN.	US-PGPUB; USPAT;	OR	OFF	2012/12/11 12:43

			USOCR			
S376	4	(("20070156175") or ("20030149447") or ("20080082113") or ("5139511")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/12/11 12:55
S377	90	("4899729").PN. OR ("5139511").URPN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/11 15:27

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S315	0	"606139,144,145".ccls. and @ad<="20050121" and fiber optic$1 and sensor	USPAT; UPAD	ADJ	OFF	2012/12/06 16:14
S316	16	"606/139,144,145".ccls. and @ad<="20050121" and fiber optic$1 and sensor	USPAT; UPAD	ADJ	OFF	2012/12/06 16:14
S317	108	"606/15,16".ccls. and @ad<="20050121" and fiber optic$1 and sensor	USPAT; UPAD	ADJ	OFF	2012/12/06 16:14
S318	185	"600/478,473,476".ccls. and @ad<="20050121" and fiber optic$1 and sensor	USPAT; UPAD	ADJ	OFF	2012/12/06 16:14
S319	1	"600/478,473,476".ccls. and @ad<="20050121" and fiber optic$1 and sensor and heart valve	USPAT; UPAD	ADJ	OFF	2012/12/06 16:14
S320	1	"600/478,473,476".ccls. and @ad<="20050121" and fiber optic$1 and sensor and heart valve	USPAT; UPAD	ADJ	OFF	2012/12/06 16:14
S321	4	"606/15,16".ccls. and @ad<="20050121" and fiber optic$1 and sensor and heart valve	USPAT; UPAD	ADJ	OFF	2012/12/06 16:14
S322	9	"606/15,16".ccls. and @ad<="20050121" and fiber optic$1 and heart valve	USPAT; UPAD	ADJ	OFF	2012/12/06 16:15
S323	1	"600/478,473,476".ccls. and @ad<="20050121" and fiber optic$1 and heart valve	USPAT; UPAD	ADJ	OFF	2012/12/06 16:15
S324	3	606/205-209.ccls. and @ad<="20050121" and fiber optic$1 and heart valve	USPAT; UPAD	ADJ	OFF	2012/12/06 16:15
S325	7	"606/139,144,145".ccls. and @ad<="20050121" and fiber optic$1 and heart valve	USPAT; UPAD	ADJ	OFF	2012/12/06 16:18
S326	53	"606/139,144,145".ccls. and @ad<="20050121" and fiber optic$1 and needle	USPAT; UPAD	ADJ	OFF	2012/12/06 16:18
S327	98	606/205-209.ccls. and @ad<="20050121" and fiber optic$1	USPAT; UPAD	ADJ	OFF	2012/12/06 16:20
S328	1	"20040044365"	USPAT; UPAD	ADJ	OFF	2012/12/06 16:44
S329	78	("20020049402" | "20030130571" | "3805793" | "4350160" | "5080663" | "5242456" | "5267958" | "5374275" | "5403326" | "5443446" | "5458131" | "5474573" | "5540704" | "5569274" | "5573540" | "5575800" | "5578044" | "5601574" | "5662664" | "5685867" | "5695457" | "5700272" | "5713910" | "5716367" | "5741277" | "5741279" |	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:46

		"5766183" | "5792094" | "5836956" | "5839639" | "5860992" | "5885238" | "5891159" | "5891160" | "5924424" | "5928224" | "5928250" | "5968059" | "5972020" | "6010531" | "6015427" | "6029671" | "6047700" | "6056760" | "6080182" | "6083219" | "6117159" | "6149660" | "6157852" | "6162233" | "6165183" | "6190357" | "6234995" | "6312447" | "6443922" | "6508777" | "6582388" | "6626930" | "6645205").PN. OR ("7083628").URPN.				
S341	4	606/210,211.ccls. and @ad<="20050121" and fiber optic$1	USPAT; UPAD	ADJ	OFF	2012/12/07 08:18

12/14/2012 8:46:48 AM
C:\Users\ctempleton\Documents\EAST\Workspaces\11813695.wsp

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11813695
Filing Date	2007-07-11
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher L. Templeton
Attorney Docket Number	630666.00074

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4935027		1990-06-19	Yoon	
	2	4957498		1990-09-18	Caspari et al.	
	3	5297536		1994-03-29	Wilk	
	4	5304185		1994-04-19	Taylor	
	5	5312423		1994-05-17	Rosenbluth	
	6	5547455		1996-08-20	McKenna et al.	
	7	5667473		1997-09-16	Finn et al.	
	8	5667478		1997-09-16	McFarlin et al.	

	9	5762458		1998-06-09	Wang et al.	
	10	5772597		1998-06-30	Goldberger et al.	
	11	5785658		1998-07-28	Benaron et al.	
	12	5897564		1999-04-27	Schulze et al.	
	13	6129683		2000-10-10	Sutton et al.	
	14	6152934		2000-11-18	Harper et al.	
	15	6178346		2001-01-23	Amundson et al.	
	16	6270508		2001-08-07	Klieman et al.	
	17	6419626		2002-07-16	Yoon	
	18	6533796		2003-03-18	Sauer et al.	
	19	6893448		2005-05-17	O'Quinn et al.	

Receipt date: 10/25/2012	Application Number	11813695	11813695 - GAU: 3773
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2007-07-11	
	First Named Inventor	Giovanni Speziali	
	Art Unit	3773	
	Examiner Name	Christopher L. Templeton	
	Attorney Docket Number	630666.00074	

	20	6936054		2005-08-30	Chu	
	21	7118583		2006-10-10	O'Quinn et al.	
	22	7122040		2006-10-17	Hill et al.	
	23	7381210		2008-06-03	Zarbatany et al.	
	24	7815654		2010-10-19	Chu	
	25	7879048		2011-02-01	Bain et al.	
	26	7887552		2011-02-15	Bachman	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030004562		2003-01-02	DiCarlo	
	2	20030195529		2003-10-16	Takamoto et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Receipt date: 10/25/2012	Application Number	11813695	11813695 - GAU: 3773
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2007-07-11	
	First Named Inventor	Giovanni Speziali	
	Art Unit	3773	
	Examiner Name	Christopher L. Templeton	
	Attorney Docket Number	630666.00074	

	3	20040087978		2004-05-06	Velez et al.	
	4	20050021055		2005-01-27	Toubia et al.	
	5	20050165419		2005-07-28	Sauer et al.	
	6	20070232941		2007-10-04	Rabinovich	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	06142114	JP		1994-05-24	Masahiro et al.		☐
	2	2004021893	WO	A1	2004-03-18	Bachman		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	US Patent Application No. 12/254,807. Image File Wrapper.	☐

Receipt date: 10/25/2012	Application Number	11813695	11813695 - GAU: 3773
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2007-07-11	
	First Named Inventor	Giovanni Speziali	
	Art Unit	3773	
	Examiner Name	Christopher L. Templeton	
	Attorney Docket Number	630666.00074	

	2	US Patent Application No. 12/254,808. Image File Wrapper.	☐
	3	US Patent Application No. 11/813,695. Image File Wrapper.	☐
	4	US Patent Application No. 12/709,220. Image File Wrapper.	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Christopher Templeton/	Date Considered	12/14/2012

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	"11813695"	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 15:28
S260	32	("20030004562" | "20030195529" | "20040087978" | "20050021055" | "20050165419" | "20070232941" | "4935027" | "4957498" | "5297536" | "5304185" | "5312423" | "5547455" | "5667473" | "5667478" | "5762458" | "5772597" | "5785658" | "5897564" | "6129683" | "6152934" | "6178346" | "6270508" | "6419626" | "6533796" | "6893448" | "6936054" | "7118583" | "7122040" | "7381210" | "7815654" | "7879048" | "7887552").PN.	US-PGPUB; USPAT	ADJ	OFF	2012/12/03 14:09
S261	12	S260 and fiber	US-PGPUB; USPAT	ADJ	OFF	2012/12/03 14:25
S262	40	("3889662" | "4699463" | "4846154" | "4873572" | "5025778" | "5166787" | "5301061" | "5335662" | "5398685").PN. OR ("5547455").URPN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 14:52
S263	121	(US-20040225300-$ or US-20070112425-$ or US-20050021057-$ or US-20030105519-$ or US-20090088837-$ or US-20100042147-$ or US-20100023118-$ or US-20040143323-$ or US-20040210303-$ or US-20030078653-$ or US-20050075727-$ or US-20060167541-$ or US-20060100698-$ or US-20100030242-$ or US-20090198324-$ or US-20050021056-$ or US-20080243150-$ or US-20070049952-$ or US-20090043153-$ or US-20040044365-$ or US-20010005787-$ or US-20060287716-$ or US-20030120341-$ or US-20070118154-$ or US-20070118213-$ or US-20050070999-$).did. or (US-20080228223-$ or US-20040024414-$ or US-20030078600-$ or US-20050216039-$ or US-20040122448-$ or US-20020099389-$ or US-20100022823-$ or US-20070197858-$ or US-20030032979-$ or US-20040133063-$ or US-20070299468-$ or US-20070112422-$ or US-20050149093-$ or US-20030195529-$ or US-20030065338-$ or US-20060095025-$ or US-20040138531-$ or US-20080188873-$ or US-	US-PGPUB; USPAT; DERWENT	ADJ	OFF	2012/12/03 15:37

		20020055748-$ or US-20040092962-$ or US-20070232941-$).did. or (US-6997950-$ or US-6358277-$ or US-4960424-$ or US-7513908-$ or US-6332893-$ or US-6074417-$ or US-6797002-$ or US-6840246-$ or US-6978176-$ or US-7563273-$ or US-7431692-$ or US-6746471-$ or US-7527647-$ or US-6149660-$ or US-5908428-$ or US-5059201-$ or US-6936054-$ or US-7118583-$ or US-6893448-$ or US-5312423-$ or US-4493323-$ or US-5522820-$ or US-6702835-$ or US-6743239-$ or US-5810847-$ or US-7559936-$).did. or (US-7794474-$ or US-6260552-$ or US-5762613-$ or US-5891160-$ or US-6464707-$ or US-7063710-$ or US-6991635-$ or US-6551330-$ or US-6575971-$ or US-5316479-$ or US-5836894-$ or US-7338434-$ or US-7083571-$ or US-6626917-$ or US-5609598-$ or US-6178346-$ or US-5336229-$ or US-6419626-$ or US-5593405-$ or US-5785658-$ or US-5772597-$ or US-6129683-$ or US-5730702-$ or US-8118206-$ or US-5908429-$ or US-5667472-$ or US-4759348-$).did. or (US-6730076-$ or US-7235089-$ or US-5441507-$ or US-5667473-$ or US-5667478-$ or US-5746770-$ or US-7122040-$ or US-5667517-$ or US-5547455-$ or US-5025778-$).did. or (US-20040143323-$ or US-20030105519-$ or WO-02102237-$ or WO-2006089236-$ or US-20040210303-$ or WO-03037227-$ or US-20020161378-$ or WO-03049619-$ or US-7635386-$ or WO-9829041-$).did.				
S264	54	S263 and fiber	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:37
S265	62	S263 and indicat$3	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:39
S266	6	S263 and indicat$3 same grasp	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:39
S267	5	S263 and 606/205.ccls.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:41
S268	28	("20050203562" | "5762613" | "6419626" | "7306559" | "6010516" | "6796939" | "5879289" | "5336232" | "6558333" | "6711429" | "5667473" | "6882875" | "5785658" | "20050033556" | "6129683" | "20040054270" |	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:43

		"20060235279" | "5941822" | "5674230" | "6324418" | "7310547" | "7615002" | "20070078484" | "6226543" | "20060161055" | "5569300" | "5800350" | "5772597").PN.				
S269	3	"11473296"	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:50
S270	0	(("2005033556") or ("2005203562")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/12/03 15:52
S271	2	(("20050033556") or ("20050203562")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/12/03 15:52
S272	2	S271 and fiber	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:53
S273	18	S268 and fiber	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 15:54
S274	7	"11773388" and kinematic$4	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/03 16:14
S275	94	606/139,144,145.ccls. and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 12:13
S276	109	606/205-209.ccls. and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 12:13
S277	28	128/898.ccls. and @ad<="20050121" and fiber optic$1 and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 12:13
S278	6	623/2.11.ccls. and @ad<="20050121" and fiber optic$1 and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 12:14
S279	11	606/139,144,145.ccls. and @ad<="20050121" and fiber optic$1 and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 12:14
S280	3	606/205-209.ccls. and @ad<="20050121" and indication same grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 12:31
S281	2	606/205-209.ccls. and @ad<="20050121" and confirm$5 same grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:04
S282	29	606/205-209.ccls. and @ad<="20050121" and indicat$3 same grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:05
S283	0	606/205-209.ccls. and @ad<="20050121" and alarm same grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:21
S284	0	"227".clas. and @ad<="20050121" and confirm$5 same grasp	US-PGPUB;	ADJ	OFF	2012/12/06 13:21

			USPAT			
S285	32	"227".clas. and @ad<="20050121" and indicat$3 same grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:22
S286	0	"227".clas. and @ad<="20050121" and alarm same grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:22
S287	0	"227".clas. and @ad<="20050121" and fiber optic$1 same grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:25
S288	46	"227".clas. and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:25
S289	9	606/205-209 and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:31
S290	109	606/205-209.ccls. and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:31
S291	85	("6149660" | "5762613" | "4960424" | "6997950" | "6419626" | "20030004562" | "5312423" | "7815654" | "7887552" | "20040044365" | "6165119" | "20050154402" | "4935027" | "5547455" | "6129683" | "6178346" | "6270508" | "3667474" | "5059201" | "6022360" | "6177144" | "6245079" | "20010005787" | "6978176" | "7666204" | "5431666" | "20050021056" | "5667472" | "5667478" | "20050021055" | "5772597" | "6419626" | "6893448" | "7381210" | "5667472" | "5693091" | "6050936" | "6234995" | "6260552" | "6840246" | "5667473" | "5785658" | "7118583" | "5336229" | "5571215" | "5839639" | "6162168" | "6264602" | "20030105519" | "20030195529" | "20040122448" | "4957498" | "5304185" | "5336229" | "20030195529" | "5667478" | "5452733" | "6077214" | "6183411" | "20070232941" | "5667473" | "5785658" | "6936054" | "7122040" | "20030078600" | "4972874" | "5653716" | "5772672" | "5919128" | "5961440" | "6045497" | "6165120" | "6190357" | "6261222" | "5830231" | "5908429" | "6178346" | "5297536" | "5762458" | "5897564" | "6152934" | "6533796" | "7879048" | "5908428" | "3842840" | "4351345" | "5797960" | "5972030" | "6059715" | "6197052" | "6626917" | "5772597" | "20040087978" | "20050165419").PN.	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 13:54
S292	20	606/205-209 and @ad<="20050121" and indicat$3 and grasp	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 14:14
S293	1	"8052699".pn.	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 14:44
S294	21	("20030065402" | "20050245965" |	US-	ADJ	OFF	2012/12/06

		"20060085034" | "20060135992" | "20060212050" | "20060271104" | "20070175963" | "20070203510" | "20070246505" | "20080110959" | "20080140115" | "5395030" | "5919232" | "6210439" | "6258107" | "7175591" | "7547312" | "7670361" | "7744627" | "7823592" | "7845536").PN. OR ("8052699").URPN.	PGPUB; USPAT; USOCR			14:50
S295	1	"12666235"	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/06 14:59
S296	0	606/15,16 and @ad<="20050121"	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:43
S297	1283	606/15,16.ccls. and @ad<="20050121"	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:44
S298	21	606/15,16.ccls. and @ad<="20050121" and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:44
S299	710	606/15,16.ccls. and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:44
S300	49	606/15,16.ccls. and @ad<="20050121" and fiber optic$1 and forceps	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:47
S301	11	606/15,16.ccls. and @ad<="20050121" and fiber optic$1 and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:50
S302	44	606/15,16.ccls. and @ad<="20050121" and fiber optic$1 and sensor and illuminat$3	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:51
S303	133	606/15,16.ccls. and @ad<="20050121" and fiber optic$1 and sensor	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:52
S304	1	606/15,16.ccls. and @ad<="20050121" and fiber optic$1 and (confirm$5 or indicat$3) same (grasp or pinch or grip)	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:57
S305	0	606/15,16.ccls. and @ad<="20050121" and fiber optic$1 (grasp or pinch or grip)	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:58
S306	85	606/15,16.ccls. and @ad<="20050121" and fiber optic$1 and (grasp or pinch or grip)	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 15:58
S307	6	600/478.ccls. and @ad<="20050121" and fiber optic$1 and (grasp or pinch or grip)	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:01
S308	158	600/478.ccls. and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:01
S309	0	600/478.ccls. and @ad<="20050121" and fiber optic$1 and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:02
S310	1	600/473,476.ccls. and @ad<="20050121" and fiber optic$1 and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:02

S311	604	600/473,476,478.ccls. and @ad<="20050121" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:02
S312	182	600/473,476,478.ccls. and @ad<="20050121" and fiber optic$1 and sensor and illuminat$3	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:02
S313	63	128/898.ccls. and @ad<="20050121" and fiber optic$1 and sensor and illuminat$3	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:11
S314	13	128/898.ccls. and @ad<="20050121" and fiber optic$1 and sensor and heart valve	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:12
S330	8	606/210,211.ccls. and @ad<="20050121" and (grip or grasp) and (signal or alarm)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/12/07 08:20
S331	1	606/210,211.ccls. and @ad<="20050121" and fiber optic$1 and (confirm$5 or indicat$3) same (grasp or pinch or grip)	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 08:22
S333	3350	@ad<="20050121" and fiber optic$1 and (grasp or pinch or grip) and (signal or alarm)	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 08:23
S334	238	@ad<="20050121" and fiber optic$1 and (grasp or pinch or grip) and (signal or alarm) and forceps	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 08:23
S335	28	@ad<="20050121" and fiber optic$1 and (grasp or pinch or grip) same (signal or alarm) and forceps	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 08:24
S336	96	@ad<="20050121" and fiber optic$1 and (grasp or pinch or grip) same (detection)	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 08:52
S337	11415	@ad<="20050121" and (grasp or pinch or grip) same (detect$3 or alarm)	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 08:59
S338	706	@ad<="20050121" and (grasp or pinch or grip) same (detect$3 or alarm) and tissue	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 09:00
S339	568	@ad<="20050121" and (grasp or pinch or grip) same (detect$3 or alarm) and (surgery or surgical)	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 09:04
S340	191	@ad<="20050121" and (grasp or pinch or grip) same (detect$3 or alarm) and (surgery or surgical) and heart	US-PGPUB; USPAT	ADJ	OFF	2012/12/07 09:05

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S315	0	"606139,144,145".ccls. and @ad<="20050121" and fiber optic$1 and sensor	USPAT; UPAD	ADJ	OFF	2012/12/06 16:14
S316	16	"606/139,144,145".ccls. and @ad<="20050121" and fiber optic$1 and sensor	USPAT; UPAD	ADJ	OFF	2012/12/06 16:14
S317	108	"606/15,16".ccls. and @ad<="20050121" and fiber optic$1 and sensor	USPAT; UPAD	ADJ	OFF	2012/12/06 16:14

S318	185	"600/478,473,476".ccls. and @ad<="20050121" and fiber optic$1 and sensor	USPAT; UPAD	ADJ	OFF	2012/12/06 16:14
S319	1	"600/478,473,476".ccls. and @ad<="20050121" and fiber optic$1 and sensor and heart valve	USPAT; UPAD	ADJ	OFF	2012/12/06 16:14
S320	1	"600/478,473,476".ccls. and @ad<="20050121" and fiber optic$1 and sensor and heart valve	USPAT; UPAD	ADJ	OFF	2012/12/06 16:14
S321	4	"606/15,16".ccls. and @ad<="20050121" and fiber optic$1 and sensor and heart valve	USPAT; UPAD	ADJ	OFF	2012/12/06 16:14
S322	9	"606/15,16".ccls. and @ad<="20050121" and fiber optic$1 and heart valve	USPAT; UPAD	ADJ	OFF	2012/12/06 16:15
S323	1	"600/478,473,476".ccls. and @ad<="20050121" and fiber optic$1 and heart valve	USPAT; UPAD	ADJ	OFF	2012/12/06 16:15
S324	3	606/205-209.ccls. and @ad<="20050121" and fiber optic$1 and heart valve	USPAT; UPAD	ADJ	OFF	2012/12/06 16:15
S325	7	"606/139,144,145".ccls. and @ad<="20050121" and fiber optic$1 and heart valve	USPAT; UPAD	ADJ	OFF	2012/12/06 16:18
S326	53	"606/139,144,145".ccls. and @ad<="20050121" and fiber optic$1 and needle	USPAT; UPAD	ADJ	OFF	2012/12/06 16:18
S327	98	606/205-209.ccls. and @ad<="20050121" and fiber optic$1	USPAT; UPAD	ADJ	OFF	2012/12/06 16:20
S328	1	"20040044365"	USPAT; UPAD	ADJ	OFF	2012/12/06 16:44
S329	78	("20020049402" | "20030130571" | "3805793" | "4350160" | "5080663" | "5242456" | "5267958" | "5374275" | "5403326" | "5443446" | "5458131" | "5474573" | "5540704" | "5569274" | "5573540" | "5575800" | "5578044" | "5601574" | "5662664" | "5685867" | "5695457" | "5700272" | "5713910" | "5716367" | "5741277" | "5741279" | "5766183" | "5792094" | "5836956" | "5839639" | "5860992" | "5885238" | "5891159" | "5891160" | "5924424" | "5928224" | "5928250" | "5968059" | "5972020" | "6010531" | "6015427" | "6029671" | "6047700" | "6056760" | "6080182" | "6083219" | "6117159" | "6149660" | "6157852" | "6162233" | "6165183" | "6190357" | "6234995" | "6312447" | "6443922" | "6508777" | "6582388" | "6626930" | "6645205").PN. OR ("7083628").URPN.	US-PGPUB; USPAT	ADJ	OFF	2012/12/06 16:46
S341	4	606/210,211.ccls. and @ad<="20050121" and fiber optic$1	USPAT; UPAD	ADJ	OFF	2012/12/07 08:18

12/7/2012 3:49:31 PM
C:\Users\ctempleton\Documents\EAST\Workspaces\11813695.wsp

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
11813695	SPEZIALI, GIOVANNI
Examiner	**Art Unit**
CHRISTOPHER L TEMPLETON	3773

ORIGINAL		INTERNATIONAL CLASSIFICATION															
CLASS	SUBCLASS	CLAIMED										NON-CLAIMED					
606	139	A	6	1	B	17 / 04 (2006.0)											

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
606	144				

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1		17												
2	2	7	18												
3	3		19												
4	4	8	20												
5	5	9	21												
6	6		22												
	7		23												
	8	10	24												
	9	11	25												
	10		26												
	11	12	27												
	12	13	28												
	13	14	29												
	14		30												
	15		31												
	16														

/CHRISTOPHER L TEMPLETON/ Examiner.Art Unit 3773	12/6/2012	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	14	
/JULIAN WOO/ Primary Examiner.Art Unit 3773	12/14/2012	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	8C

Docket No.: 630666.00074

I hereby certify that this correspondence is being electronically transmitted to the United States Patent and Trademark Office on the date set forth below.
Date of Transmission: December 5, 2012 /Richard T. Roche/
Richard T. Roche, Reg. No. 38,599

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Giovanni Speziali
Application No.	11/813,695
Filed:	July 11, 2007
For:	Thorascopic Heart Valve Repair Method And Apparatus
Confirmation No.:	6073
Examiner:	Christopher L. Templeton
Art Unit:	3773

APPLICANTS' SUMMARY OF EXAMINER INTERVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants wish to thank Examiner Templeton for the courtesy of an interview on December 5.

In the Examiner interview, Examiner Templeton stated that he could enter the following amendments by way of an Examiner's Amendment:

(1) incorporate claims 22 and 23 into claim 1 to place claim 1 in allowable form;

(2) incorporate claim 26 into claim 24 to place claim 24 in allowable form;

(3) incorporate claims 30 and 31 into claim 27 to place claim 27 in allowable form;

(4) cancel the following language at the last sentence of paragraph [0016] specification: "In another embodiment shown in Figure 3A, the chorda 18 can be anchored to a papillary muscle in the heart";

(5) cancel Figure 3A; and

(6) cancel claim 19.

Applicant authorized these Examiner Amendments. The Examiner's Amendments would place the application in condition for allowance.

Applicant authorized these amendments solely to advance prosecution and specifically reserves the right to seek claims of a similar scope to the previous independent claims as well as present and argue support for claims reciting anchoring to a papillary muscle in a continuation application.

No other fees are believed to be needed. However, if fees are needed, then please charge them to Deposit Account No. 17-0055.

Respectfully submitted,

Giovanni Speziali

Dated: December 5, 2012

By: /Richard T. Roche/

Richard T. Roche
Registration No. 38,599
Quarles and Brady LLP
411 East Wisconsin Ave.
Milwaukee, WI 53202
(414) 277-5805

18864668

Electronic Acknowledgement Receipt

EFS ID:	14392476
Application Number:	11813695
International Application Number:	
Confirmation Number:	6073
Title of Invention:	Thorascopic Heart Valve Repair Method and Apparatus
First Named Inventor/Applicant Name:	Giovanni Speziali
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	630666.00074
Receipt Date:	05-DEC-2012
Filing Date:	11-JUL-2007
Time Stamp:	16:49:11
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant summary of interview with examiner	interview-summary-12-5-12.pdf	70410 9e9b5ff4cae819c9cccd14b63fba911721a2f9be	no	2

Warnings:	
Information:	

Total Files Size (in bytes):	70410

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11813695
Filing Date	2007-07-11
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher L. Templeton
Attorney Docket Number	630666.00074

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4935027		1990-06-19	Yoon	
	2	4957498		1990-09-18	Caspari et al.	
	3	5297536		1994-03-29	Wilk	
	4	5304185		1994-04-19	Taylor	
	5	5312423		1994-05-17	Rosenbluth	
	6	5547455		1996-08-20	McKenna et al.	
	7	5667473		1997-09-16	Finn et al.	
	8	5667478		1997-09-16	McFarlin et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11813695
	Filing Date	2007-07-11
	First Named Inventor	Giovanni Speziali
	Art Unit	3773
	Examiner Name	Christopher L. Templeton
	Attorney Docket Number	630666.00074

	9	5762458		1998-06-09	Wang et al.	
	10	5772597		1998-06-30	Goldberger et al.	
	11	5785658		1998-07-28	Benaron et al.	
	12	5897564		1999-04-27	Schulze et al.	
	13	6129683		2000-10-10	Sutton et al.	
	14	6152934		2000-11-18	Harper et al.	
	15	6178346		2001-01-23	Amundson et al.	
	16	6270508		2001-08-07	Klieman et al.	
	17	6419626		2002-07-16	Yoon	
	18	6533796		2003-03-18	Sauer et al.	
	19	6893448		2005-05-17	O'Quinn et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11813695
	Filing Date	2007-07-11
	First Named Inventor	Giovanni Speziali
	Art Unit	3773
	Examiner Name	Christopher L. Templeton
	Attorney Docket Number	630666.00074

	20	6936054		2005-08-30	Chu	
	21	7118583		2006-10-10	O'Quinn et al.	
	22	7122040		2006-10-17	Hill et al.	
	23	7381210		2008-06-03	Zarbatany et al.	
	24	7815654		2010-10-19	Chu	
	25	7879048		2011-02-01	Bain et al.	
	26	7887552		2011-02-15	Bachman	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030004562		2003-01-02	DiCarlo	
	2	20030195529		2003-10-16	Takamoto et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11813695
	Filing Date	2007-07-11
	First Named Inventor	Giovanni Speziali
	Art Unit	3773
	Examiner Name	Christopher L. Templeton
	Attorney Docket Number	630666.00074

	3	20040087978		2004-05-06	Velez et al.	
	4	20050021055		2005-01-27	Toubia et al.	
	5	20050165419		2005-07-28	Sauer et al.	
	6	20070232941		2007-10-04	Rabinovich	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	06142114	JP		1994-05-24	Masahiro et al.		☐
	2	2004021893	WO	A1	2004-03-18	Bachman		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	US Patent Application No. 12/254,807. Image File Wrapper.	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11813695
	Filing Date	2007-07-11
	First Named Inventor	Giovanni Speziali
	Art Unit	3773
	Examiner Name	Christopher L. Templeton
	Attorney Docket Number	630666.00074

	2	US Patent Application No. 12/254,808. Image File Wrapper.	☐
	3	US Patent Application No. 11/813,695. Image File Wrapper.	☐
	4	US Patent Application No. 12/709,220. Image File Wrapper.	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11813695
	Filing Date	2007-07-11
	First Named Inventor	Giovanni Speziali
	Art Unit	3773
	Examiner Name	Christopher L. Templeton
	Attorney Docket Number	630666.00074

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2012-10-25
Name/Print	Richard T. Roche	Registration Number	38,599

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	11813695
Filing Date:	11-Jul-2007
Title of Invention:	Thorascopic Heart Valve Repair Method and Apparatus
First Named Inventor/Applicant Name:	Giovanni Speziali
Filer:	Richard T. Roche
Attorney Docket Number:	630666.00074

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	14076788
Application Number:	11813695
International Application Number:	
Confirmation Number:	6073
Title of Invention:	Thorascopic Heart Valve Repair Method and Apparatus
First Named Inventor/Applicant Name:	Giovanni Speziali
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	630666.00074
Receipt Date:	25-OCT-2012
Filing Date:	11-JUL-2007
Time Stamp:	15:44:22
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	2331
Deposit Account	170055
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Foreign Reference	JP-H06-142114.PDF	627890 2e266b6b2078f280effb196e8c2e8b167bfc16f3	no	9
Warnings:					
Information:					
2	Foreign Reference	WO-2004-021893.PDF	1413084 4e6cea4f7fbab7679215a27d16843740704 54ee3	no	42
Warnings:					
Information:					
3	Non Patent Literature	11813695_IFW.PDF	12831426 f4cabdb9d8e2b78258a475ec9752e9c87a6fd964	no	300
Warnings:					
Information:					
4	Non Patent Literature	12254807_IFW.PDF	22415100 17f0685cdb7a59e3bf444bd9723f5646d8a26411	no	430
Warnings:					
Information:					
5	Non Patent Literature	12709220_IFW.PDF	14209993 c8360def1fdf514315a4f0b18a16e32e89f212e6	no	333
Warnings:					
Information:					
6	Non Patent Literature	12254808_IFW.PDF	22585168 8c661ebb764a15ba0f4780f4cbbbb6d39ec3155a	no	435
Warnings:					
Information:					
7	Information Disclosure Statement (IDS) Form (SB08)	US-IDS-10-25-12.PDF	529045 3e9f19a7cf53febac2b3fd5546e19d8c2142162c	no	7
Warnings:					
Information:					
8	Fee Worksheet (SB06)	fee-info.pdf	30255 0076c1632d3acc636dc947be2bcd566a1d4c3c08	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	74641961		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Ref. 2

PATENT ABSTRACTS OF JAPAN

(11)Publication number : **06-142114**
(43)Date of publication of application : **24.05.1994**

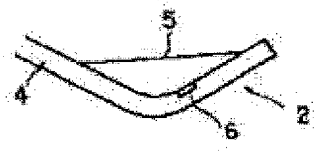
(51)Int.Cl. **A61B 17/39**
A61B 1/00

(21)Application number : **04-293400**
(22)Date of filing : **30.10.1992**

(71)Applicant : **OLYMPUS OPTICAL CO LTD**
(72)Inventor : **KUDO MASAHIRO**
KOSAKA YOSHIHIRO
YAMAGUCHI TATSUYA
KAMI KUNIAKI
TAKAYAMA SHUICHI
HIBINO HIROKI
MIZUNO HITOSHI
UEDA YASUHIRO
YOSHINO KENJI

(54) IN-CELOM TREATING DEVICE

(57)Abstract:
PURPOSE: To provide an in-celom treating device by which an operating surgeon can recognize more clearly the state of a treatment in a celom and can execute safely and surely the treatment.
CONSTITUTION: In the in-celom treating device for executing a treatment by inserting a treating implement into a celom, this device is provided with a microphone 6 for detecting a sound generated at the time of executing the treatment in the celom, and by informing an operating surgeon of a sound detected by the microphone 6, the operating surgeon executes a work, while recognizing the state of the treatment in the celom by the sound generated at the time of its treatment.



(19)日本国特許庁（ＪＰ）　(12) **公開特許公報**（Ａ）　(11)特許出願公開番号

特開平6－142114

(43)公開日　平成６年(1994)５月24日

(51)Int.Cl.[5]	識別記号	庁内整理番号	ＦＩ	技術表示箇所
Ａ６１Ｂ　17/39	３１０	8718－4C		
1/00	３３４　Ｄ	8119－4C		

審査請求　未請求　請求項の数１(全　８　頁)

(21)出願番号　特願平4－293400

(22)出願日　平成４年(1992)10月30日

(71)出願人　000000376
オリンパス光学工業株式会社
東京都渋谷区幡ヶ谷２丁目43番２号

(72)発明者　工藤　正宏
東京都渋谷区幡ヶ谷２丁目43番２号　オリンパス光学工業株式会社内

(72)発明者　小坂　芳広
東京都渋谷区幡ヶ谷２丁目43番２号　オリンパス光学工業株式会社内

(72)発明者　山口　達也
東京都渋谷区幡ヶ谷２丁目43番２号　オリンパス光学工業株式会社内

(74)代理人　弁理士　鈴江　武彦

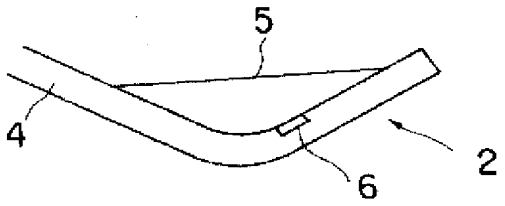
最終頁に続く

(54)【発明の名称】　体腔内処置装置

(57)【要約】

【目的】本発明は、術者が体腔内の処置の状況をより明確に把握でき、安全かつ確実な処置を行うことができる体腔内処置装置を提供することを目的とする。

【構成】処置具を体腔内に挿入して処置を行う体腔内処置装置において、体腔内で処置を行う際に発生する音を検出するマイクロホン６を設け、このマイクロホン６によって検出した音を術者に知らせることによって、術者が体腔内の処置の状況を、その処置する際に発生する音で把握しながら作業を行う。



1

【特許請求の範囲】

【請求項１】　処置具を体腔内に挿入して処置を行う体腔内処置装置において、体腔内で処置を行う際に発生する音を検出する手段と、この音検出手段によって検出した音を術者に知らせる告知手段とを具備したことを特徴とする体腔内処置装置。

【発明の詳細な説明】

【０００１】

【産業上の利用分野】本発明は、処置具等を用いて体腔内の部位に治療等の処置を施す体腔内処置装置に関する。

【０００２】

【従来の技術】生体への侵襲度の小さな処置法として、経内視鏡、経腹腔鏡的に体腔内へ処置具を導入して治療等の処置が行われる。この場合、術者は内視鏡を通じての観察情報と処置具を操作する際に手が受ける感覚（押すと突き当たる、挟むと抵抗がある等）によってその処置する状況を把握しているが、オープン手術に比べると、術者にとって処置状況を充分に把握できにくい。このため、かなりの経験と熟練が必要であるなどの問題があった。

【０００３】

【発明が解決しようとする課題】本発明は前記課題に着目してなされたもので、その目的とするところは、術者が、体腔内の処置の状況をより明確に把握でき、安全かつ確実な処置を行うことができる体腔内処置装置を提供することにある。

【０００４】

【課題を解決するための手段および作用】本発明は、処置具を体腔内に挿入して処置を行う体腔内処置装置において、体腔内で処置を行う際に発生する音を検出する手段と、この音検出手段によって検出した音を術者に知らせる告知手段とを具備したものである。この体腔内処置装置によれば、術者が体腔内の処置状況を処置音で把握しながら作業を行うことができる。

【０００５】

【実施例】図１ないし図４は本発明の第１の実施例を示すものである。図１は側視型内視鏡１を用いて高周波切開具（パピロトミーナイフ）２を経内視鏡的に導入し、十二指腸乳頭部３を切除する状況を示している。高周波切開具２は、そのシース４の先端側周部に切開用電極ワイヤ５を露出して設けてなり、その電極ワイヤ５をある程度、引き込むことにより、図１および図２で示すように、シース４の先端部を湾曲させながら直線的に張るようになっている。この状態で電極ワイヤ５を十二指腸乳頭部３に押し当てて高周波電流を流すことによりその十二指腸乳頭部３を切除することができる。

【０００６】この高周波切開具２におけるシース４の先端側周部には、前記切開用電極ワイヤ５側に向けた単一の超小型マイクロホン６が取り付けられている。この超

2

小型マイクロホン６はシース４に挿通された図示しない信号線を通じて図４の（ａ）で示すような体外の増幅器７に接続され、また、増幅器７はスピーカ８に接続されている。マイクロホン６で検出した音の信号は増幅器７で増幅し、スピーカ８から音を流して処置音を聞く方式となっている。

【０００７】図３で示すように、内視鏡１の先端部における観察光学系９、照明光学系１０及び鉗子口１１を設けた面部と同一面には、その視野方向に向けて左右一対の超小型マイクロホン６，６が取り付けられている。この超小型マイクロホン６，６は、その内視鏡１の挿入部に挿通される図示しない信号線を通じて図４の（ｂ）で示すような体外の増幅器７に接続されている。また、増幅器７は左右一対のスピーカ８，８に接続されている。そして、各マイクロホン６，６で検出した音の信号を増幅器７で増幅して左右一対のスピーカ８，８から音を流し、処置する際に発生する音をステレオで聞く方式となっている。

【０００８】しかして、内視鏡１の処置具挿通用チャンネルを経て、高周波切開具２を十二指腸乳頭部３に導き、十二指腸乳頭部３を切除すると、その際に発生する音が各マイクロホン６，６で検出され、術者はスピーカ８，８で聞ける。スピーカ８，８は例えば、観察モニタの近くに置かれ、体腔内での音を術者に伝達する。高周波切開具２に設けた超小型マイクロホン６では処置音を発生源近くで検出でき、正確な処置音が確実に得られる。また、内視鏡１の先端部に設けた左右一対の超小型マイクロホン６，６によって処置部位から発生する処置音の状況を立体的に聞くことができる。例えば、内視鏡先端での左右一対のスピーカ８，８と観察光学系と対応で左右一対のスピーカ８，８をモニタ画面の左右に対応させて設置すれば、処置している音を立体的に認識できる。

【０００９】図５ないし図６は本発明の第２の実施例に係る結石破砕用バスケット鉗子１３を示すものである。これはシース１４の先端部にワイヤバスケット１５が操作ワイヤ１６によって突没自在に設けられている。また、図５で示すように、シース１４の先端部には超小型マイクロホン６が取着されている。この超小型マイクロホン６は前述したようにシース１４に挿通された図示しない信号線を通じて体外の増幅器に接続され、また、この増幅器はスピーカに接続される。マイクロホン６で検出した音の信号を増幅器で増幅し、スピーカから音を流して聞けるようになっている。

【００１０】図６はそのバスケット鉗子１３の使用状況である。すなわち、このバスケット鉗子１３は十二指腸までは経内視鏡的に導入され、この後、図６で示す胆・膵管１７内に挿入される。そして、ワイヤバスケット１５をシース１４から押し出してこの内部に結石１８を取り込み、ワイヤバスケット１５をシース１４内に引き込

3

むことによりその結石１８を押し潰して破砕する。一方、この結石１８の取り込み作業や破砕音等がマイクロホン６で検出され、術者はスピーカからその処置音が聞けるため、これを処置状況の判断材料として状況を判別する。したがって、手探りでのみ作業を行う場合に比べてより確実に状況が把握でき、確実かつ容易に作業を行うことができる。

【００１１】図７ないし図８は本発明の第３の実施例に係り、生検鉗子を経内視鏡的に使用する体腔内処置装置の例である。この生検鉗子２０はシース２１の先端部に開閉自在な一対の生検カップ２２，２２を設け、この生検カップ２２，２２はシース２１内に挿通した図示しない操作ワイヤを介して手元側での押引き操作によって開閉される。この生検鉗子２０は内視鏡２３の鉗子チャンネル２４を通じて体腔内に導入される。

【００１２】図８で示すように、内視鏡２３の先端面には、鉗子チャンネル２４の先端開口の他に照明光学系２５と観察光学系２６が設けられ、さらに、その視野方向に向けて左右一対の超小型マイクロホン６，６が取り付けられている。この超小型マイクロホン６，６は、その内視鏡２３の挿入部に挿通される図示しない信号線を通じて、体外の増幅器に接続されている。また、増幅器は左右一対のスピーカに接続されている。そして、各マイクロホン６，６で検出した音の信号を増幅器で増幅して左右一対のスピーカから音を流し、処置する際に発生する音をステレオで聞ける方式になっている。

【００１３】しかして、図８で示すように、経内視鏡的に生検鉗子２０を体腔内に導入し、体腔内におけるポリープ２７の生体組織を採取する。また、この採取時に生じる音はマイクロホン６，６によって検出し、術者は一対のスピーカからその処置する際に発生する音をステレオで聞ける。そして、手探りでのみ作業を行う場合に比べてより確実に状況が把握でき、確実かつ容易に作業を行うことができる。

【００１４】なお、この実施例における生検鉗子２０の先端に力覚センサを設け、その生検鉗子２０が体腔内の生体組織に当たってそれに加える力を検出し、その検出した力に応じて生検鉗子２０の手元操作部に設けた振動子を振動するようになっている。

【００１５】これによると、生検鉗子２０の先端が生体組織に当たる力の程度に応じて生検鉗子２０の手元操作部が振動し、術者にその力の程度を伝達する。鉗子先端と操作部が離れている場合、術者にその反力が伝わらなくなるが、その力の程度に応じて生検鉗子２０の手元操作部が振動するため、術者に処置時の情報を伝え、安全に処置が行える。

【００１６】また、この生検鉗子２０にも前述したようなマイクロホンを取り付け、処置する際に発生する音を検出してスピーカによってその音を聞けるようにしてある。

4

【００１７】図９は本発明の第４の実施例に係り、処置具として高周波スネアを経内視鏡的に使用する体腔内処置装置の例である。高周波スネア３０はシース３１の先端部に突没自在なループ状のスネアワイヤ３２を設けてなり、このスネアワイヤ３２はシース３１内に挿通した図示しない操作ワイヤを介して手元側での押引き操作によって突没操作される。この高周波スネア３０は内視鏡３３の鉗子チャンネル３４を通じて体腔内に導入される。

【００１８】また、内視鏡３３の先端面には、鉗子チャンネル３４の先端開口の他に照明光学系３５と観察光学系３６が設けられ、さらに、その視野方向に向けて左右一対の超小型マイクロホン６，６が取り付けられている。この超小型マイクロホン６，６は、その内視鏡３３の挿入部に挿通される図示しない信号線を通じて、体外の増幅器に接続されている。また、増幅器は左右一対のスピーカに接続されている。そして、各マイクロホン６，６で検出した音の信号を増幅器で増幅して左右一対のスピーカから音を流し、処置する際などに発生する音をステレオで聞ける方式になっている。

【００１９】しかして、図９で示すように、経内視鏡的に高周波スネア３０を体腔内に導入し、体腔内におけるポリープ３７の切除する。また、この採取時に生じる音はマイクロホン６，６によって検出し、術者は一対のスピーカからその処置する音をステレオで聞ける。このため、手探りでのみ作業を行う場合に比べてより確実に状況が把握でき、確実かつ容易に作業を行うことができる。

【００２０】なお、高周波スネア３０のシース３１における先端部にマイクロホンを設けて処置する際などに発生する音を検出するようにしてもよい。

【００２１】図１０は本発明の第５の実施例に係り、処置具としてレーザプローブを経内視鏡的に使用する体腔内処置装置の例である。第４の実施例の場合と同様にレーザポローブ４０のシース４１の先端部又は／及び内視鏡４２の先端面にマイクロホンを設けてレーザポローブ４０を使用する際の処置音を検出してこれを体外で術者が聞くようにしたものである。このため、手探りでのみ作業を行う場合に比べてより確実に状況が把握でき、また、体腔内のポリープ４３などの患部をレーザ光で焼灼する作業を確実かつ容易に作業を行うことができる。

【００２２】図１１は本発明の第６の実施例に係り、経腹腔鏡的処置（胆嚢摘出術、産婦人科術等を含む腹腔鏡下手術）を行う場合の例である。（ａ）はその処置状況を示しており、硬性鏡４５と剥離用鉗子４６はそれぞれ別のトラカール４７，４８を介して腹腔４９内に挿入されている。硬性鏡４５の光学系設置（先端）面には、（ｂ）で示すように、１つの超小型マイクロホン６が設けられている。そして、このマイクロホン６は、前述したように硬性鏡４５のシースに挿通された図示しない信

5

号線を通じて体外の増幅器に接続され、また、この増幅器にはスピーカが接続されている。そして、処置部の観察像検出部と同じ面でマイクロホン６により処置する際に発生する音を検出し、この音の信号を増幅器で増幅し、スピーカから音を流して、腹腔鏡下手術において処置する際に発生する音を術者が聞けるようになっている。

【００２３】しかして、術者はスピーカからその処置音が聞けるため、これを処置状況の判断材料として状況をより明確に判別できる。したがって、術者はよりよい臨場感が得られ、確実かつ容易に作業を安全に行うことができる。

【００２４】また、図１１の（ｃ）はそのバスケット鉗子４６の代わりに組織切開と剥離のために使用する高周波プローブ５０を用いて処置する例を示している。

【００２５】この場合に使用する処置具にマイクロホンを設けて処置する際の音を検出してこれを聞くようにしてもよい。また、処置対象も腹腔だけでなく、胸腔等体腔内処置を行う場合についても同様である。

【００２６】なお、設けるマイクロホンの数は、前述した各実施例のものに限定されるものではなく、さらに、多く設けてもよいものである。また、以下に述べるような処置具や内視鏡に前述したようなマイクロホンを取り付け、処置する際に発生する音を検出してそれをスピーカによって聞けるようにしてもよいものである。

【００２７】図１２は管腔狭窄部を拡張するためのバルーンカテーテル５１の例である。このバルーン５２の外周には前面にわたり分散して複数の圧力センサ５３が取り付けられている。圧力センサ５３は、例えば半導体センサ・感圧ゴム等からなっている。各圧力センサ５３は、図示しない信号線を通じて体外の圧力－音声変換器に接続されている。

【００２８】そこで、例えば血管５４における狭窄部５５を拡張する場合、図１２で示すように、バルーンカテーテル５１を血管５４内に導入し、そのバルーン５２を狭窄部５５に位置させて膨張させる。この血管５４の狭窄部５５を拡張するとき、圧力センサ５３は、バルーン５２が接触する管壁から受ける圧力を検出する。この検出する圧力に応じて体外の圧力－音声変換器は発生する音の大きさ・高さ・音色等を変えることで、術者にその圧力状態を知らせるとともに、過剰に圧力が管腔にかかり、管腔にダメージを与えることを防止する操作を行わせることができる。この手技は、胆管、尿道、食道等の管腔における狭窄部位のバルーンダイレーションにも同様に適用することができる。

【００２９】図１３ないし図１５は血流検知機能付把持具６０の例である。この把持具６０は図１３で示すように、シース６１の先端には、開閉自在な一対の把持片６２，６３からなる先端把持部が設けられ、シース６１の手元端には操作ハンドル６４が取り付けられている。そして、先端把持部の把持片６２，６３は操作ハンドル６４により前記シース６１内に挿通した図示しない操作ワイヤを介して開閉操作される。

6

【００３０】図１４で示すように、先端把持部の一方の把持片６２の内面には、超小型のマイクロホン６６が取着されている。このマイクロホン６６は、シース６１に挿通された図示しない信号線を通じて体外の信号検出器６７に接続される。この場合の信号検出器６７は、増幅器を含むスピーカであり、マイクロホン６６で検出した音の信号を増幅器で増幅し、そのスピーカから音を出力し、これを術者が聞けるようになっている。

【００３１】この血流検知機能付把持具６０は、例えば胆嚢摘出術などの腹腔鏡下手術において、鈍的な剥離血管６８の把持等を行う場合に使用される。図１４の（ｂ）で示すように把持具６０における先端把持部の把持片６２，６３の間に血管６８を挟み込み、その血管６８を把持した場合、その血管６８に血液の流れがあると、その流れる音がマイクロホン６６で検出できる。血液の流れる音がスピーカから聞こえれば、血流があることが知れ、安全に対処できる。また、把持する生態組織の内部に血管があっても同じくその血流を検出して血管の存在が知れ、知らないまま処置する事態を回避し安全な処置ができる。

【００３２】図１６ないし図１７はその把持具６０の変形例を示すものである。これは先端把持部の一方の把持片６２の内面に超音波発信用振動子７１を設け、これに対向して他方の把持片６３の内面に超音波受信用振動子７２を設ける。図１７で示すように、超音波受信用振動子７２は前述したと同じくシース６１に挿通された図示しない信号線を通じて体外の信号検出器６７に接続される。超音波発信用振動子７１は振動子ドライバ７３によって駆動される。

【００３３】しかして、これの把持具６０によれば、その把持片６２，６３の間に挟み込んだ組織中に血管があり、それに血流があると、超音波発信用振動子７１から発信した超音波が受信用振動子７２に受信された状態で、受信周波数がドプラーシフトを受ける。その受信周波数のドプラーシフトを検出することにより、血流の有無を知る。例えば血管をクリップで止血する手技が確実に行われたかを確認することもできる。また、血管が豊富な組織を把持することで、その内部の血流の状態を大まかに知ることができ、多大な出血を未然に防ぐ処置ができ、安全な手術を行うことができる。

【００３４】なお、この超音波発信用振動子７１の代わりにレーザ光を発するレーザダイオード、超音波受信用振動子７２の代わりにレーザ光を受信するレーザ検出器を設けてもよく、この場合も、その受信するレーザ光の周波数が、血流があると、ドプラーシフトを受ける。その受信周波数のドプラーシフトを検出することにより、血流の有無が知れる。

7

【００３５】図１８は前述した血流検知機能付把持具６０の先端把持部の各把持片６２，６３の内面にそれぞれ感圧ゴムを貼り付けて触覚センサ７５を構成したものである。マイクロホン６６はその一方の把持片６２における中央部分に埋め込まれている。触覚センサ７５は図示しない信号線を介して同じく図示しない検出器に接続される。このようにすれば、その把持片６２，６３の間に挟む組織のかたさも検出することができる。

【００３６】この把持具６０によれば、把持組織部分の血量の検出に加え、そのかたさ情報も検出することができる。血管・組織の性状に関しての情報の多様化により、よりよい診断を行うことができる。なお、図１９で示すように前述した他の各血流検知機能付把持具６０についても、同様に触覚センサ７５を組み付けてもよい。

【００３７】図２０ないし図２５は内視鏡の挿入部の例を示すものである。この挿入部８０は図２０で示すように可撓管８１の先端に湾曲管部８２を連結し、その湾曲管部８２の先端には先端部８３が連結されている。湾曲管部８２の芯材は、複数の湾曲駒８４を挿入部８０の長手軸方向へ並べて配置し、隣接する湾曲駒８４同志を回動自在に連結してなる。また、その回動枢支位置は１つ置きに左右と上下に入れ替る。このため、芯材全体として前後左右に湾曲することができる。また、この湾曲管部８２における複数の湾曲駒８４の側周面には、歪みゲージが張り付けられている。

【００３８】この歪みゲージの数とその張り付ける向きは、測定目的とする曲げモーメント、引張り圧縮荷重、及び捩じモーメント等の外力によって選択がなされる。例えば図２１で示すように、湾曲駒８４の中心線に対し、平行な方向に表裏各１個ずつと、垂直な方向に表裏各１個ずつ張り付けた場合、その歪みゲージR_1，R_2，R_3，R_4は、図２２で示すようなブリッジ回路に組み込まれる。Ｅはブリッジ電圧、e_1，e_2は出力電圧である。この結果により湾曲駒８４の中心線に対して平行な方向の表裏各歪み量が計測される。この両者の歪み量から湾曲駒８４に作用する曲げモーメントと引張り圧縮荷重が計算される。

【００３９】また、図２３で示すように、湾曲駒８４の中心線に対し、交互に十４５度、－４５度の角度で表裏各２個ずつ張り付けた場合、その歪みゲージR_1，R_2，R_3，R_4は、図２４で示すようなブリッジ回路に組み込まれる。これにより湾曲駒８４の中心線回りの捩り歪み量が計測される。この歪み量から湾曲駒８４に作用する捩りモーメントが計算される。

【００４０】さらに、前述した図２１と図２３でそれぞれ示される各歪みゲージR_1，R_2，R_3，R_4を同じ湾曲駒８４に張り付けると、その湾曲駒８４に作用する曲げモーメント、引張り圧縮荷重、および捩りモーメントを求めることができる。

【００４１】そして、このような検出手段で外力を求めることができる結果、この外力を操作者に伝えることによって、過大な外力が働いた場合に危険を知らせる警告機能が得られる。また、その検出した外力を制御対象として使用することもできる。例えば、図２５で示すように大腸９０等の管腔内に内視鏡の挿入部８０を挿入する場合において、湾曲管部８２が屈曲した管腔部分にあるとき、湾曲駒８４に作用する曲げモーメントを減少させる方向へ湾曲管部８２を動作させることにより、湾曲管部８２を挿入していく方向へ向けさせることが可能である。

8

【００４２】

【発明の効果】以上説明したように本発明は、処置具を体腔内に挿入して処置を行う体腔内処置装置において、体腔内で処置を行う際に発生する音を検出する手段と、この音検出手段によって検出した音を術者に知らせる告知手段とを具備したものであるから、術者が体腔内の処置の状況を音で把握しながら作業を行うことができる。したがって、術者は、体腔内の処置の状況をより明確に把握でき、安全かつ確実な処置を行うことができる。

【図面の簡単な説明】

【図１】本発明の第１の実施例に係る、側視型内視鏡と高周波切開具の使用状態の説明図。

【図２】前記高周波切開具の先端部の斜視図。

【図３】前記側視型内視鏡の先端部の平面図。

【図４】同じく本発明の第１の実施例に係る音検出システムのブロック図。

【図５】本発明の第２の実施例に係る結石破砕用バスケット鉗子の先端部付近を示す斜視図。

【図６】同じく本発明の第２の実施例に係る結石破砕用バスケット鉗子の使用状態を示す説明図。

【図７】本発明の第３の実施例に係る生検鉗子を経内視鏡的に使用する状況を示す説明図。

【図８】同じく本発明の第３の実施例に係る生検鉗子を経内視鏡的に使用する状況の拡大斜視図。

【図９】本発明の第４の実施例に係る高周波スネアを経内視鏡的に使用する状況を示す説明図。

【図１０】本発明の第５の実施例に係るレーザプローブを経内視鏡的に使用する状況を示す斜視図。

【図１１】本発明の第６の実施例に係り、経腹腔鏡的処置を行う場合の例であって、（ａ）はその処置状況を示す説明図、（ｂ）は硬性鏡の先端部の斜視図、（ｃ）は他の作業状態の状況を示す説明図。

【図１２】管腔狭窄部を拡張するためのバルーンカテーテルの使用状況の説明図。

【図１３】血流検知機能付把持具を示す側面図。

【図１４】同じくその血流検知機能付把持具の先端把持部の側面図。

【図１５】同じくその血流検知機能付把持具の検出システムのブロック図。

【図１６】前記把持具の変形例を示すその先端把持部の

9

側面図。

【図１７】同じくその把持具の検出システムのブロック図。

【図１８】他の血流検知機能付把持具の先端把持部の側面図。

【図１９】さらに、他の血流検知機能付把持具の先端把持部の側面図。

【図２０】内視鏡における挿入部の斜視図。

【図２１】同じくその挿入部における湾曲部の湾曲駒に歪みゲージを取り付ける態様の説明図。

10

【図２２】前記歪みゲージを組み込むブリッジ回路図。

【図２３】挿入部における湾曲部の湾曲駒に歪みゲージを取り付ける態様の説明図。

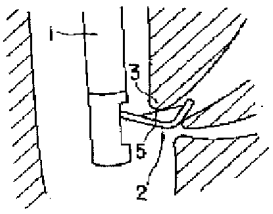
【図２４】前記歪みゲージを組み込むブリッジ回路図。

【図２５】内視鏡の挿入部の挿入使用状態の説明図。

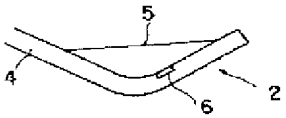
【符号の説明】

１…側視型内視鏡、２…高周波切開具、３…十二指腸乳頭部、４…シース、５…切開用電極ワイヤ、６…マイクロホン、７…増幅器、８…スピーカ、１２…バスケット鉗子。

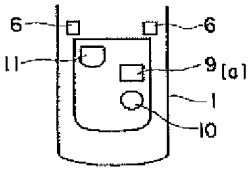
【図１】



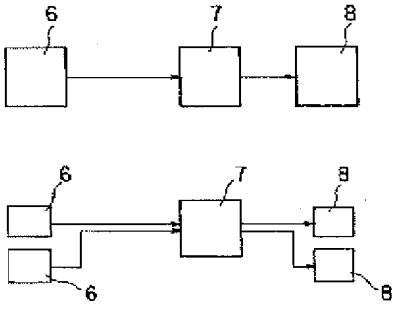
【図２】



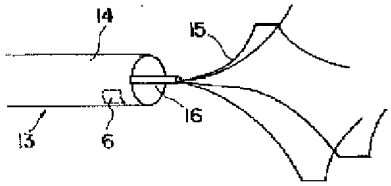
【図３】



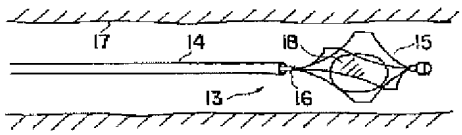
【図４】



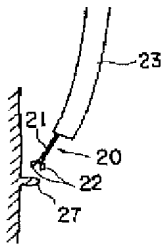
【図５】



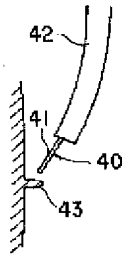
【図６】



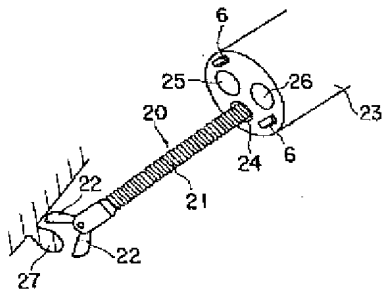
【図７】



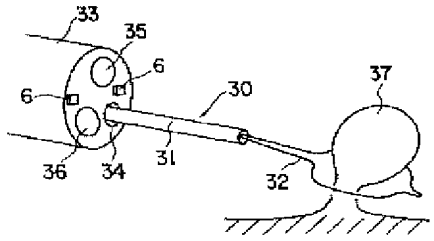
【図１０】



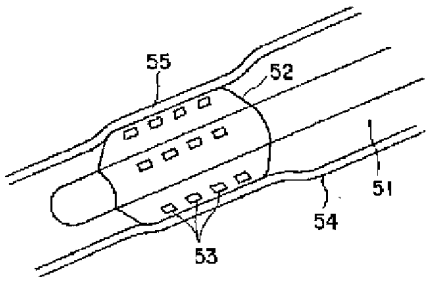
【図８】



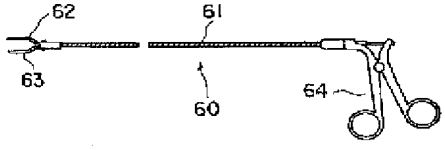
【図９】



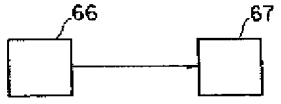
【図１２】



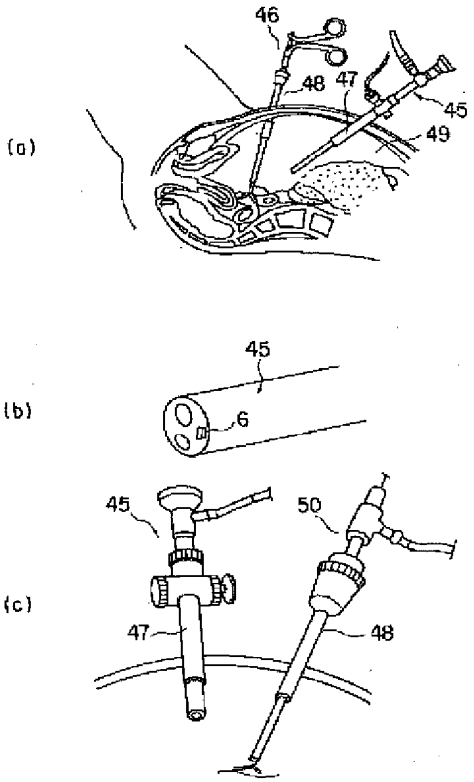
【図１３】



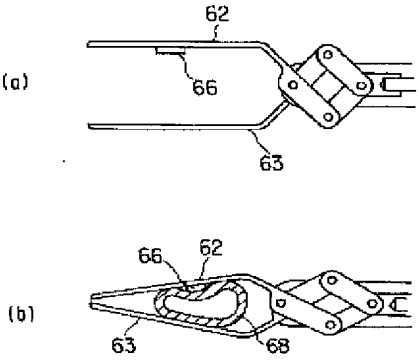
【図１５】



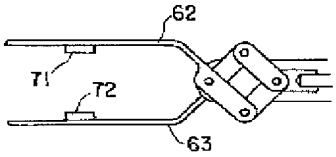
【図１１】



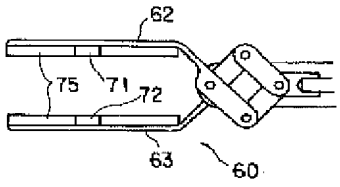
【図１４】



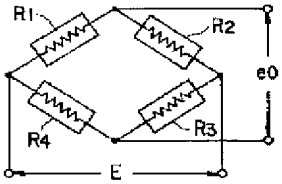
【図１６】



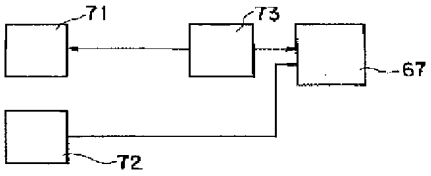
【図１９】



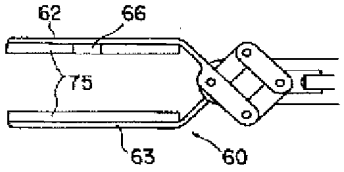
【図２４】



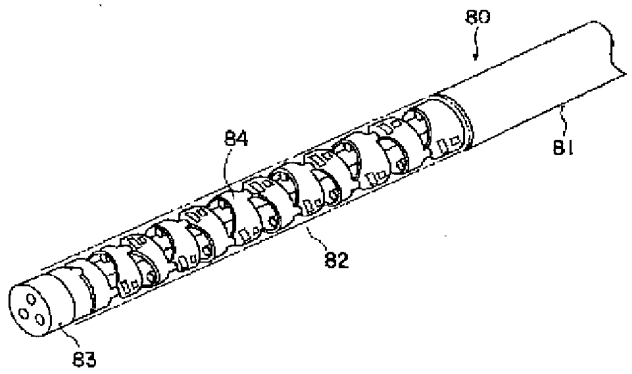
【図１７】



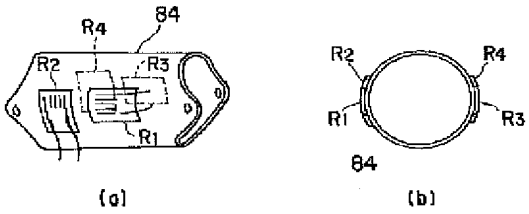
【図１８】



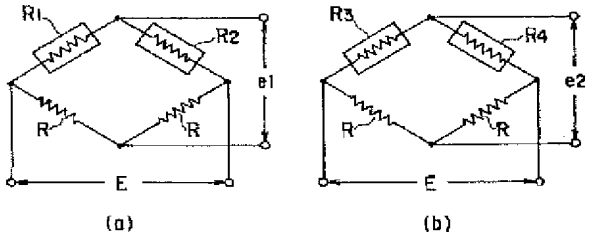
【図２０】



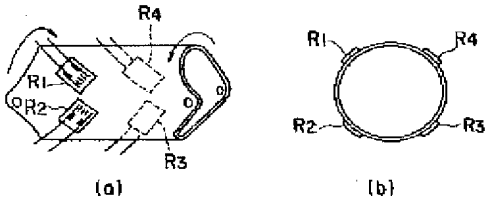
【図２１】



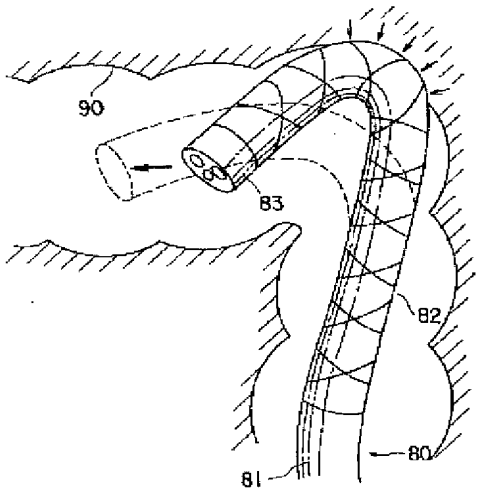
【図２２】



【図２３】



【図２５】



フロントページの続き

(72)発明者　上　邦彰
東京都渋谷区幡ヶ谷２丁目43番２号　オリンパス光学工業株式会社内
(72)発明者　高山　修一
東京都渋谷区幡ヶ谷２丁目43番２号　オリンパス光学工業株式会社内
(72)発明者　日比野　浩樹
東京都渋谷区幡ヶ谷２丁目43番２号　オリンパス光学工業株式会社内
(72)発明者　水野　均
東京都渋谷区幡ヶ谷２丁目43番２号　オリンパス光学工業株式会社内
(72)発明者　植田　康弘
東京都渋谷区幡ヶ谷２丁目43番２号　オリンパス光学工業株式会社内
(72)発明者　吉野　謙二
東京都渋谷区幡ヶ谷２丁目43番２号　オリンパス光学工業株式会社内

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 March 2004 (18.03.2004)

PCT

(10) International Publication Number
WO 2004/021893 A1

(51) International Patent Classification[7]: A61B 17/04

(21) International Application Number:
PCT/US2003/027661

(22) International Filing Date:
2 September 2003 (02.09.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/233,879 3 September 2002 (03.09.2002) US

(71) Applicant: **EDWARDS LIFESCIENCES CORPORATION** [US/US]; One Edwards Way, Irvine, CA 92614 (US).

(72) Inventor: **BACHMAN, Alan, B.**; 111 Nicole Avenue, Milford, CT 06460 (US).

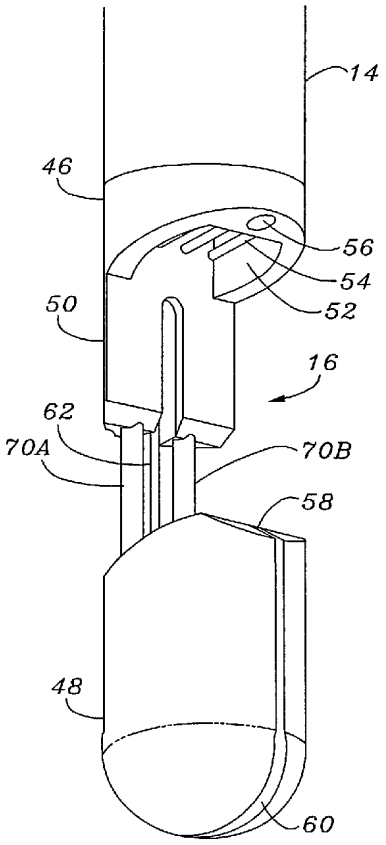
(74) Agents: **JAMES, John, Christopher** et al.; Edwards Lifesciences LLC, One Edwards Way, Irvine, CA 92614 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: MITRAL VALVE REPAIR DEVICE AND METHOD FOR USE



(57) Abstract: A single catheter mitral valve repair device for stabilizing a tissue portion and selectively applying a tissue fastener thereto. The single catheter mitral valve repair device of the present invention includes an extendable engagement tip having at least one vacuum port formed thereon, at least one deployable fastener in communication with the engagement tip, and at least one actuator member in communication with the port. The deployable fastener is capable of controllably engaging and fastening a tissue segment located proximal to the engagement tip.

WO 2004/021893 A1

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

MITRAL VALVE REPAIR DEVICE AND METHOD FOR USE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application discloses subject matter related to our co-pending United States Patent Application No. 09/562,406, filed May 1, 2000, entitled Minimally Invasive Mitral Valve Repair Method and Apparatus. The disclosure of the aforementioned United States patent application is incorporated by reference herein in its entirety.

BACKGROUND OF THE INVENTION

[0002] In vertebrate animals, the heart is a hollow muscular organ having four pumping chambers: the left atrium, the left ventricle, the right atrium and the right ventricle. The atria are isolated from their respective ventricles by one-way valves located at the respective atrial-ventricular junctions. These valves are identified as the mitral (or bicuspid) valve on the left side of the heart, and tricuspid valve on the right side of the heart. The exit valves from the left and right ventricles are identified as the aortic and pulmonary valves, respectively.

[0003] The valves of the heart are positioned in valvular annuluses that comprise dense fibrous rings attached either directly or indirectly to the atrial and ventricular muscle fibers. Valve leaflets comprising flexible collagenous structures are attached to, and extend inwardly from, the annuluses to meet at coapting edges. The aortic, tricuspid and pulmonary valves each have three leaflets, while the mitral valve only has two. In normal operation, the leaflets of the mitral valve open as left ventricle dilates thereby permitting blood to flow from the left atrium into the left ventricle. The leaflets then coapt (i.e. close) during the contraction cycle of the left ventricle, thereby preventing the blood from returning to the left atrium and forcing the blood to exit the left ventricle

through the aortic valve. Similarly, the tricuspid valve regulates flow from the right atrium into the right ventricle, and the pulmonary valve regulates blood exiting the right ventricle.

[0004] For a number of clinical reasons various problems with heart valves can develop. One common form of heart disease involves the deterioration or degradation of the heart valves, which leads to stenosis and/or insufficiency. Heart valve stenosis is a condition in which the valve does not open properly. Insufficiency is a condition in which the valve does not close properly. Insufficiency of the mitral valve, most common because of the relatively high fluid pressures in the left ventricle, results in mitral valve regurgitation ("MR"), a condition in which blood reverses its intended course and flows "backward" from the left ventricle to the left atrium during heart contractions.

[0005] A number of surgical techniques have been developed to repair degraded or otherwise incompetent heart valves. A common procedure involves replacement of a native aortic or mitral valve with a prosthetic heart valve. Such procedures require the surgeon to access the heart through the patient's chest (or possibly percutaneously), surgically remove the incompetent native heart valve and associated tissue, remodel the surrounding valve annulus, and secure a replacement valve in the remodeled annulus. While these procedures can be very effective, there are associated shortcomings. For example, the highly invasive nature of the implantation procedure typically results in substantial patient discomfort and requires patients to remain hospitalized for extended recovery periods. In addition, the two basic types of commercially available replacement valves, mechanical valves, and tissue valves, have shortcomings of their own. Mechanical replacement valves typically offer extended operational lifetimes, but the patient is usually required to maintain a regimen of anti-coagulant drugs

for the remainder of his or her life. Tissue valves typically offer a higher degree of acceptance by the body thereby reducing or eliminating the need for anti-coagulants, but the operational lifetimes of tissue valves is typically shorter than mechanical valves and thus may require a subsequent replacement(s).

[0006] As an alternative to prosthetic heart valve replacement, it is often preferable to remodel the native heart valve and/or surrounding tissue. Remodeling procedures often preserve left ventricular function better than mitral valve replacement because the subvalvular papillary muscles and chordae tendineae are preserved (most prosthetic valves do not utilize these muscles). Typically, valvular remodeling is accomplished by implanting a prosthetic ring ("annuloplasty ring") into the valve annulus to reduce and/or stabilize the structure of the annulus. Annuloplasty rings are typically constructed of a resilient core covered with a fabric sewing material. Annuloplasty procedures can be performed alone, or they can be performed in conjunction with other procedures such as leaflet repair. Although annuloplasty procedures have become popular and well accepted, reshaping the surrounding annulus and traditional leaflet repairs do not always lead to optimum leaflet coaptation. As a result, some patients may still experience residual mitral valve regurgitation following annuloplasty procedures.

[0007] A recently developed technique known as a "bow-tie" repair has also been advocated for repairing insufficient heart valves, in particular the mitral valve. The mitral valve bow-tie technique involves, in its simplest form, suturing the anterior and posterior leaflets together near the middle of their coapting edges, thereby causing blood to flow through two newly formed side openings. While this does reduce the volume of blood that flows from the atrium to the ventricle, this loss is more than compensated by improved leaflet coaptation, which reduces

mitral regurgitation. As originally developed by Dr. Ottavio Alfieri, this process involved arresting the heart, and placing the patient on extra corporeal bypass and required invasive surgery to access and suture the leaflets together. More recently, however, some have advocated a "beating heart" procedure in which the leaflets are accessed remotely and the heart remains active throughout the procedure.

[0008] A particular method for performing a beating heart bow-tie procedure (i.e. without extra corporeal bypass) has been proposed by Dr. Mehmet Oz, of Columbia University. The method and devices for performing the method are described in PCT publication WO 99/00059, published January 7, 1999. In one embodiment of the disclosed procedure, the associated device consists of a forceps-like grasper used to grasp and hold the mitral valve leaflets in a coapted position for suturing. Since the mitral valve leaflets meet and curve toward and slightly into the left ventricular cavity at their mating edges, the grasper device is passed through a sealed aperture in the apex of the left ventricle. The edges of the mating mitral valve leaflets are then grasped and held together, and a fastening device such as a clip or suture is utilized to fasten them. The fastening device should be applied to the leaflet tissue with sufficient tissue purchase to prevent tear out or other failure, but close enough to the edges to ensure that the newly created side holes are as large as possible. The Mehmet Oz disclosure thus illustrates that teeth of the grasper device can be linearly slidable with respect to one another so as to permit alignment of the mitral valve leaflets prior to fastening. Since the procedure is done on a beating heart, it will be readily understood that the pressures and motions within the left ventricle and mitral valve leaflets are severe. Thus the procedure taught by Dr. Mehmet Oz is very skill-intensive.

[0009] The bow-tie technique has proved to be a viable alternative for treating otherwise incompetent heart valves. Nonetheless, several shortcomings associated with current bow-tie procedures have been identified. Current systems include devices having mechanical graspers, barbed members, and vacuum devices that simultaneously capture and retain the valve leaflets prior to applying a fastening device thereto. Often, use of these devices results in the less than optimal leaflet stabilization and fastener placement. Many of these problems arise from the fact that the surgeon is required to capture, retain and fasten the leaflets in one relatively inflexible procedure. These difficulties are compounded when the leaflets are small or calcified making them difficult to pull together, and in beating heart procedures in which the leaflets are actively functioning throughout the surgery. In light of the foregoing, there is presently a need for improved systems for stabilizing multiple tissue heart valve leaflets and placing a fastening device there between. More specifically, there is a present need for an improved bow-tie procedure for repairing a patient's mitral valve.

BRIEF SUMMARY OF THE INVENTION

[0010] The single catheter mitral valve repair device of the present invention may be used to repair tissue throughout a patient's body. However, it is particularly useful in repairing dysfunctional mitral valve tissue by stabilizing discreet valvular tissue pieces and deploying a fastening device therethrough, thereby coapting the tissue pieces. The present invention may also be used to repair arterial septal defects (ASD), ventricular septal defects (VSD), and defects associated with patent foramen ovale (PFO).

[0011] In one aspect, the repair device of the present invention comprises an extendable engagement tip having at least one port

formed thereon, at least one deployable fastener in communication with the engagement tip, and one or more actuator members in communication with the port(s). The deployable fastener is capable of controllably engaging and fastening tissue located proximal to the engagement tip.

[0012] In another aspect of the present invention, the repair device comprises a handle, an elongated body, and an extendable engagement tip. The handle comprises a stationary handle body, an engagement tip actuator in communication with the stationary handle body, a fastener deployment housing in communication with the stationary handle body, and a vacuum connector capable of placing a vacuum source in communication with the stationary handle body. The elongated body comprises a flexible body member, at least one vacuum lumen, one or more actuation lumens and one or more fastener lumens. Optionally, the elongated body can also comprise one or more auxiliary lumens. The one or more actuation lumens are capable of receiving one or more actuation members therein. Similarly, the one or more fastener lumens are capable of receiving at least one deployable fastener therein. The extendable engagement tip comprises a fastener deployment housing capable of attaching to the elongated body, an actuation flange attached to the fastener deployment housing, an extendable tip attached to the actuation flange and in communication with the engagement tip actuator, a vacuum port in communication with the vacuum connector, and at least one deployable fastener in communication with the fastener deployment housing.

[0013] The present invention also discloses a method of repairing tissue using the repair device of the present invention and comprises grasping a first tissue portion with a vacuum force, stabilizing the first tissue portion with a mechanical force, deploying a tissue fastener into

the stabilized first tissue portion, disengaging the first tissue portion, grasping at least a second tissue portion with a vacuum force, stabilizing at least a second tissue portion with a mechanical force, deploying at least a second tissue fastener into at least the second stabilized tissue portion, disengaging at least the second tissue portion, and coapting the first tissue portion and at least the second tissue portion with the first tissue fastener and at least the second tissue fastener.

[0014] Other objects, features, and advantages of the present invention will become apparent from a consideration of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The apparatus of the present invention will be explained in more detail by way of the accompanying drawings, wherein:

[0016] Fig.1 shows a perspective view of the mitral valve repair device of the present invention;

[0017] Fig. 2 shows a perspective view of the handle portion of the mitral valve repair device of the present invention;

[0018] Fig. 3 shows a cross-sectional view of the handle portion of the mitral valve repair device of the present invention;

[0019] Figs. 4A and 4B show alternate cross-sectional views of the elongated body of the mitral valve repair device of the present invention;

[0020] Figs. 5A and 5B show alternate perspective views of the engagement tip of the mitral valve repair device of the present invention;

[0021] Fig. 6 shows a cross-sectional view of the engagement tip of the mitral valve repair device of the present invention;

[0022] Figs. 7A and 7B show alternate perspective views of the engagement tip of the mitral valve repair device of the present invention in an extended position;

[0023] Fig. 8 shows a cross-sectional view of the engagement tip of the mitral valve repair device of the present invention in a retracted position wherein the deployable needle is deployed;

[0024] Fig. 9 shows a cross-sectional view of the engagement tip of the mitral valve repair device of the present invention in a retracted position wherein the deployable needle is retracted and is engaging a needle catch;

[0025] Fig. 10 shows a perspective view of the mitral valve repair device of the present invention having attached fastener material to a first tissue portion;

[0026] Fig. 11 shows a perspective view of the mitral valve repair device of the present invention having attached fastener material to a second tissue portion;

[0027] Fig. 12 shows a perspective view of discreet tissue portions having fastener material positioned therethrough; and

[0028] Fig. 13 shows a perspective view of discreet tissue portions being coapted with fastener material.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0029] Disclosed herein is a detailed description of various embodiments of the present invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the invention. The overall organization of the description is for the purpose of clarity only and is not intended to limit the present invention.

[0030] The single catheter mitral valve repair device of the present invention is designed for use in a surgical treatment of bodily tissue. As those skilled in the art will appreciate, the exemplary single catheter mitral repair device disclosed herein is designed to minimize trauma to the patient before, during, and after a minimally invasive surgical procedure while providing improved tissue stabilization and enhanced placement of a fastening device thereon. While the single catheter mitral valve repair device of the present invention may be used to repair tissue throughout a patient's body, it is particularly useful in repairing dysfunctional mitral valve tissue by stabilizing discreet valvular tissue pieces and deploying a fastening device therethrough, thereby coapting the tissue pieces. The present invention may also be used to repair arterial septal defects (ASD), ventricular septal defects (VSD), and defects associated with patent foramen ovale (PFO).

[0031] Figure 1 shows the single catheter mitral valve repair device of the present invention. As shown, the repair device 10 comprises a handle portion 12 attached to an elongated body 14. An engagement tip 16 is positioned on the distal portion of the elongated body 14. A vacuum connector 18 is attached to the handle 12. As those skilled in the art will appreciate, the present invention may be manufactured from a variety of materials including, without limitation, various metals, plastics, thermoplastics, silicones, elastomers, ceramics, composite

materials, or various combinations of the aforementioned materials. For example, the handle 12 may be manufactured from polyethylene, while the elongated body 14 is manufactured by an elastomer. In an alternate embodiment the elongated body 14, the engagement tip 16, or both may incorporate radio-opaque or echogenic materials, thereby enabling the surgeon to precisely position the repair device 10 within the patient's body.

[0032] Figure 2 shows a perspective view of the handle 12 of the present invention. As shown in Figure 2, the handle 12 comprises a stationary handle body 20 having a tip actuator 22 and a fastener deployment actuator 24 in communication therewith. The tip actuator 22 and fastener deployment actuator 24 are movable relative to the stationary handle body 20. Exemplary tip actuator members or fastener deployment housings may include, for example, buttons, levers, slidable fixtures, or toggles. The distal portion of the stationary handle body 20 includes a coupling orifice 26 capable of receiving the elongated body 14 therein. In addition, the stationary handle body 20 may include a handle flange 28 located thereon. The stationary handle body 20, fastener deployment actuator 24, or tip actuator 22, may include at least one grip member 30 positioned thereon. As shown in Figure 2, a vacuum connector 18 is in communication with the handle 12.

[0033] Figure 3 shows a cross sectional view of the handle 12 of the present invention. As shown in Figure 3, the stationary handle body 20 defines an actuation channel 32, which is in communication with the coupling orifice 26 formed on the distal portion of the stationary handle body 20. The actuation channel 32 formed inside the stationary handle body 20 is capable of receiving the tip actuator 22 and the fastener deployment actuator 24 independently and in telescoping relation therein. Those skilled in the art will appreciate that the present invention

permits a user to actuate the tip actuator 22 or the fastener deployment actuator 24 independently. As shown, a bias member 34 may be positioned within the actuation channel 32 and may communicate in biasing relation with the fastener deployment actuator 24. The tip actuator 22 is in communication with at least one actuator extension member (see Fig. 7) positioned within one or more actuation lumens (see Fig. 4) formed in the elongated body 14. Similarly, the fastener deployment actuator 24 is in communication with at least one fastener extension member (see Fig. 6) positioned within one or more fastener lumens (see Fig. 4) formed in the elongated body 14. The vacuum connector 18 is to be connected to an external vacuum source and is in fluid communication with the vacuum lumen 36 formed in the elongated body 14.

[0034] The elongated body 14 of the present invention may be manufactured in a variety of lengths or diameters as desired by the user. Figures 4A and 4B show cross-sectional views of two embodiments of the elongated body 14 of the present invention. As shown in Figure 4, the elongated body 14 of the present invention may comprise at least one vacuum lumen 36. In the illustrated embodiment, the vacuum lumen 36 is disposed in the center of the device; although those skilled in the art will appreciate that the present invention may be easily manufactured with the vacuum lumen 36 positioned at various locations within or alongside the elongated body 14. The body member 38 may further include one or more tip actuation lumens 40a, 40b, one or more auxiliary lumens 42, and one or more fastener lumens 44 formed therein. For example, Figure 4B shows an alternate embodiment of the present invention wherein the body member 38 forms a vacuum lumen 36, tip actuation lumens 40a, 40b, auxiliary lumens 42, and two fastener lumens 44a, 44b therein. Those skilled in the art will appreciate that the

one or more auxiliary lumens 42 of the present invention are capable of receiving a guidewire, thereby enabling the present invention to be directed to an area of interest in vivo with a guidewire. The elongated body 14 of the present invention may be attached to the handle 12 in a variety of manners, including, for example, adhesively attached or in snap-fit relation.

[0035] Figure 5A shows a perspective view of the engagement tip 16 attached to the elongated body 14 of the present invention. The engagement tip 16 comprises a fastener deployment housing 46, an extendable tip 48, and an actuation flange 50 in communication with the fastener deployment housing 46 and the extendable tip 48. The fastener deployment housing 46 further includes at least one vacuum port 52 having a tissue support 54 located therein, and a fastener deployment port 56 located thereon. The tissue support 54 may comprise a series of vanes or other supports positioned across or proximate to the vacuum port 52. The vacuum port 52, positioned on the fastener deployment housing 46, is in fluid communication with the vacuum connector 18 positioned on the handle 12 through the vacuum lumen 36 formed in the elongated body 14. Similarly, the fastener deployment port 56 is in communication with the fastener deployment actuator 24 located on the handle 12 through fastener lumen 44 formed in the elongated body 14. In an alternate embodiment illustrated in Figure 5B, a plurality of fastener deployment ports 56 may be formed on the fastener deployment housing 46 and may be in communication with a plurality of fastener lumens 44 formed in the elongated body 14 (see Figure 4B). The extendable tip 48 of the present invention is in communication with the tip actuator 22 located on the handle 12 through the actuation lumens 40a, 40b formed in the elongated body 14. The extendable tip 48 may include a fastener receiver port 58 capable of receiving the

deployable needle 64 therein (see Fig. 6). The fastener receiver port 58 is coaligned with or positioned proximate to the fastener deployment port 56 formed on the fastener deployment housing 46. The fastener receiving port 58 is capable of receiving the deployable needle 64 therein and includes a needle catch 68 attached to fastener material 62 (see Fig. 6). The needle catch 68 may comprise a variety of devices capable of engaging and retaining the deployable needle 64 therein, including, for example, a ferruled or sized ring. In addition, the extendable tip 48 may include a fastener channel 60 capable of receiving fastener material 62 therein. Preferably the fastener channel 60 is open on the distal end of extendable tip 48, as illustrated. Exemplary fastener materials include, for example, thread, wire, monofilament, braided filament, suture material, needles, sutures, staples, buttons, tissue-graspers, tissue clasps, barbs, and other tissue-coaption devices.

[0036] Figure 6 shows a cross sectional view of the engagement tip 16. The vacuum port 52 is in fluid communication with the vacuum lumen 36. A deployable needle 64 is in communication with the deployment housing 66 positioned within the fastener lumen 44. The receiver port 58 is in communication with the auxiliary lumen 42 located in the elongated body 14. A needle catch 68, which is capable of engaging and retaining the deployable needle 64, is attached to fastener material 62 which is positioned within the receiver port 58 and which extends through the auxiliary lumen 42 around the distal end of the engagement tip 16 and back towards the handle 12.

[0037] Figures 7A and 7B show the engagement tip 16 of the present invention in an extended configuration, thereby enabling the present invention to grasp and stabilize tissue located proximate thereto with a vacuum force. As shown in Figure 7A, actuation members 70a,

70b are slidably received in the fastener deployment housing 46 and the extendable tip 48, thereby permitting the extendable tip 48 to be moved, in telescoping relation, relative to the fastener deployment housing 46. Exemplary actuation members 70a, 70b may include, for example, rods, shafts, or conduits. The actuation members 70a, 70b communicate with the tip actuator 22 positioned on the handle 12 through the actuation lumens 40a, 40b positioned in the elongated body 14. To actuate the extendable tip 48, the user advances the tip actuator 22 towards the stationary handle body 20, thereby advancing the actuation members 70a, 70b and resulting in the extendible tip 48 extending from the fastener deployment housing 46. To retract the extendible tip 48, the user retracts the tip actuator 22 away from the stationary handle body 20, thereby retracting the actuation members 70a, 70b and resulting in the extendible tip 48 retracting towards the fastener deployment housing 46. Those skilled in the art will appreciated that actuation of the tip actuator 22 results in the longitudinal movement of the actuation member 70a, 70b positioned in the tip actuator lumens 40a, 40b of the elongated body 14, thereby resulting in the longitudinal extension and retraction of the extendable tip 48. Figure 7B shows and alternate embodiment in which there are a plurality (two in the illustrated case) of deployment ports 56, fastener receiver ports 58 and corresponding fastener channels 60. Figure 7B illustrates another alternate embodiment in which the faster material is stored within the vacuum lumen 36 (as opposed to the auxiliary lumen 42, see figure 6).

[0038] Figures 8 and 9 show cross sectional views of the engagement tip 16 of the present invention during use wherein a mechanical stabilization force may be applied to captured tissue. Figure 8 shows a cross sectional view of the engagement tip 16 wherein the deployable needle 64 has been deployed from the fastener deployment

port 56 located on the fastener deployment housing 46 through the fastener receiver port 58 and into the extendable tip 48. The deployable needle 64 is attached to the deployment housing 66 positioned within the one or more fastener lumens 44 of the elongated body 14. The deployment housing 66 is coupled to the fastener deployment actuator 24 positioned on the handle 12. To deploy the deployable needle 64, the user advances the fastener deployment actuator 24 on the handle 12 towards the stationary handle body 20, which results in the longitudinal movement of the deployment housing 66 within the fastener lumen 44 of the elongated body 14. Longitudinal movement of the deployment housing 66 results in the deployable needle 64 advancing through the fastener deployment port 56 into the fastener receiving port 58 and engaging the needle catch 68 located therein. As shown in Figure 8, the deployable needle 64 has engaged the needle catch 68. The needle catch 68 is attached to the fastener material 62 located within the auxiliary lumen 42.

[0039] Figure 9 shows a cross sectional view of the engagement tip 16 of the present invention wherein the deployable needle 64, having engaged and been retained by the needle catch 68 attached to the fastener material 62, is positioned within the fastener lumen 44 of the elongated body 14. To retract the deployable needle, the user moves the fastener deployment actuator 24 rearwardly away from the stationary handle body 20. As a result, the deployment housing 66 moves in a reward longitudinal motion which results in the deployable needle 64, which is attached to the deployment housing 66, moving rearwardly. The deployable needle 64, having the needle catch 68 and the fastener material 62 attached thereto, retracts through the fastener receiving port 58 and enters the fastener deployment port 56. As shown in Figure 9, the fastener material 62 is in communication with the auxiliary lumen 42

and the fastener lumen 44, thereby traversing the actuation flange 50. In an alternate embodiment of the present invention the extendable tip 48, the fastener deployment housing 46, or the elongated body 14 may include at least one guidewire retaining device or lumen therein or attach thereto. In yet another alternate embodiment, the positions of the needles and needle catch are reversed (i.e. the needle moves from the extendable tip 48 to engage the needle catch in the port 56).

[0040] The present invention also discloses a method of using the single catheter mitral valve repair device of the present invention to repair discreet tissue portions in vivo. The description below describes a method of repairing dysfunctional heart valves, however, those skilled in the art will appreciate that the present invention may be adapted for use in other tissue repair procedures.

[0041] To repair a dysfunctional or otherwise incompetent heart valve, a guidewire capable of traversing the circulatory system and entering the heart of the patient is introduced into the patient through an endoluminal entry point. For example, an endoluminal entry point may be formed in a femoral vein or right jugular vein of a patient. Thereafter, the guidewire may be introduced into the patient through the endoluminal entry point and advanced through the circulatory system, eventually arriving at the heart. Upon arriving at the heart, the guidewire is directed into the right atrium of the heart, traverses the right atrium and is made to puncture the atrial septum, thereby entering the left atrium. The guidewire may then be advanced through the mitral valve while the heart is in diastole and traverses the left ventricle. The guidewire traverses the aortic valve into the aorta and is made to emerge from the left femoral artery through an endoluminal exit point. This methodology of positioning a guidewire is known to physicians skilled in the art of interventional cardiology. Once the guidewire is

positioned, the endoluminal entry or exit port is dilated to permit entry of a catheter therethrough. A protective sheath may be advanced in the venous area to protect the vascular structure.

[0042] With the guidewire suitably anchored, the distal portion of the mitral valve repair device of the present invention may be attached to the guidewire. Thereafter, the elongated body 14 having the engagement tip 16 attached thereto is advanced through the dilated guidewire entry port to a point proximate the cusp portion of the mitral valve. Those skilled in the art will appreciate that the mitral valve repair device 10 of the present invention may approach the cusp of the mitral valve from an antegrade position or from a retrograde position as desired by the user. For a retrograde approach, the user attaches the repair device 10 to the guidewire emerging from the left femoral artery. The device is then advanced along the guidewire to a position proximate the retrograde aspect of the mitral valve. The engagement tip 16 of the mitral valve repair device 10 may be positioned proximate the tissue portion 72 of the mitral valve. Once suitably positioned, the tip actuator 22 positioned on the handle 12 may be actuated, thereby resulting in the extendable tip 48 of the engagement tip 16 extending distally from the fastener deployment housing 46. Thereafter, an external vacuum source (not shown) may be activated to apply a vacuum force to the mitral valve repair device 10 through the vacuum connector 18. The external vacuum source (not shown) communicates with the vacuum port 52 located on the engagement tip 16 through the at least one vacuum lumen 36 in the elongated body 14. With the extendable tip 48 distally extended from the fastener deployment housing 46, the tissue portion 72 located proximate to the vacuum port 52 is grasped and retained by the vacuum force applied by the external vacuum source (not shown). Once the tissue portion 72 is captured by the vacuum force supplied through

the vacuum port 52, the tip actuator 22 located on the handle 12 is actuated to retract the extendable tip 48 toward the fastener deployment housing 46 thereby mechanically retaining and stabilizing the tissue portion 72 therebetween. Once the tissue is sufficiently stabilized, the fastener deployment actuator 24 located on the handle 12 may be actuated to deploy a fastening device through the tissue portion 72. To deploy the fastener device the user advances the fastener deployment actuator 24 toward the handle flange 28 positioned on the stationary handle body 20 of the handle 12, thereby causing the deployable needle 64 to exit the deployment port 56 and traverse the tissue positioned within the actuation flange 50. Thereafter, the deployable needle 64 enters the receiver port 58 formed on the extendable tip 48 and engages the needle catch 68 which is attached to the fastener material 62 positioned within the fastener channel 60. The fastener deployment housing 46 is returned to a non-deployed position by the user, thereby resulting in the deployable needle 64, which has retained the needle catch 68 attached to the fastener material 60, returning to a non-deployed position within the fastener lumen 44 of the elongated body 14, and resulting in the tissue portion 72 having fastener material 62 positioned therethrough. As shown in Figure 10, with the fastener material 62 positioned through the tissue portion 72, the external vacuum source may be deactivated which results in the release of the captured tissue portion 72. Thereafter, the mitral valve repair device 10 of the present invention is removed from the patient's body leaving a fastener material 62 attached to the tissue portion 72.

[0043] Once removed from the body of the patient, the mitral valve repair device 10 may be reloaded with deployable need and fastener material, rotated, and reintroduced into the patient thereby permitting the device to apply additional tissue fasteners to bodily tissue adjacent that

already fastened. At least the distal portion of the mitral valve repair device of the present invention is re-attached to the guidewire. Thereafter, the elongated body 14 having the engagement tip 16 attached thereto is again advanced through the dilated guidewire entry port to a point proximate the cusp portion of the mitral valve. The engagement tip 16 of the mitral valve repair device 10 may be positioned proximate to another tissue portion 74 of the mitral valve. The preceding process is then repeated to secure suture material 62' to tissue portion 74. Figure 11 shows the mitral valve repair device 10 positioned proximate to a second tissue portion 74 located near the first tissue portion 72. As shown, the fastener material 62' is positioned through the tissue portion 74 and the external vacuum source may be deactivated which results in the release of the captured tissue portion 74. Thereafter, the mitral valve repair device 10 of the present invention is removed from the patient's body and may be removed from the patient's body leaving a fastener material 62' attached to the tissue portion 74. Thereafter, the fastener material portions 62, 62' may be joined to coapt the individual tissue portions 72, 74. As shown in Figure 12-13, a knot 76 is formed in the fastener material 62, 62' and advanced to the tissue portions 72, 74. In one embodiment, the knot 76 is formed external the patient's body and advanced to the repair site with a knot-pushing device.

[0044] In the alternative embodiments of figures 4B, 5B and 7B, the repair device need not be removed from the patient between the steps of securing the first and second tissue pieces. The dual fastening system of these alternate embodiments permits the faster material to be placed sequentially in both pieces of tissue simply by rotating the device after securing the first piece of tissue. Lastly, one of skill in the art will understand that if the vacuum source is strong enough, and the needle

64 sharp enough, extendable tip 64 need not translate relative to the deployment housing 46 to mechanically hold the tissue in place. The pieces of tissue can be held together in place with vacuum and punctured without use of mechanical retention.

[0045] In closing, it is understood that the embodiments of the invention disclosed herein are illustrative of the principals of the invention. Other modifications may be employed which are within the scope of the present invention. Accordingly, the present invention is not limited to that precisely as shown and described in the present disclosure.

What is claimed is:

1. An apparatus for fastening a tissue segment within the heart of a patient in vivo, comprising:

an elongated body having a proximal end and a distal end;

a fastener deployment housing at the distal end of the elongated body, the fastener deployment housing having at least one vacuum port and at least one fastener deployment port formed thereon;

an extendable engagement tip capable of moving in telescopic relation to the fastener deployment housing, the extendable engagement tip having at least one fastener receiving port formed thereon;

at least one deployable fastener disposed within the fastener deployment housing, the deployable fastener capable of engaging the tissue segment when positioned proximal to the engagement tip; and

at least one fastener deployment actuator in communication with the deployable fastener and capable of causing the fastener to engage the tissue segment.

2. The apparatus of claim 1 wherein the engagement tip further comprises:

an actuation flange that telescopically couples the fastener deployment housing with the extendable tip.

3. The apparatus of claim 2 further comprising an extendable tip actuator in communication with the extendable tip, wherein the extendable tip actuator is capable of causing the extendable tip to move in telescopic relation to the fastener deployment housing.

4. The apparatus of claim 1 wherein the vacuum port and fastener port are one in the same.

5. The apparatus of claim 1 further comprising multiple vacuum ports formed on the fastener deployment housing.

6. The apparatus of claim 1 wherein the vacuum port further comprises at least one tissue support traversing the vacuum port.

7. The apparatus of claim 1 wherein the at least one fastener deployment port is capable of receiving the deployable fastener therein.

8. The apparatus of claim 1 wherein the fastener receiving port is capable of receiving the deployable fastener therein.

9. The apparatus of claim 1 wherein the fastener receiving port further comprises at least one fastener catch the capable of engaging and retaining the deployable fastener.

10. The apparatus of claim 9 wherein the fastener catch is in communication with a fastener material.

11. The apparatus of claim 10 wherein the fastener material is selected from the group consisting of thread, wire, monofilament, braided filament, and suture material.

12. The apparatus of claim 1 wherein the deployable fastener is selected from the group consisting of a needles, sutures, staples, buttons, tissue-graspers, tissue clasps, and barbs.

13. The apparatus of claim 1 further comprising a handle in communication with the engagement tip.

14. The apparatus of claim 13 wherein the handle comprises a engagement tip actuator in communication with the engagement tip, a fastener deployment actuator in communication with the deployable fastener, and a vacuum actuator in communication with the vacuum port.

15. The apparatus of claim 1 wherein the elongated body is flexible.

16. The apparatus of claim 15 wherein the elongated body contains one or more actuation members therein.

17. The apparatus of claim 16 wherein each actuation member is in communication with at least one device selected from the group consisting of the engagement tip, the port, the deployable fastener, the actuator, the handle, and an external vacuum source.

18. The apparatus of claim 17 wherein the external vacuum source is in communication with at least one vacuum lumen located within the elongated body, wherein the vacuum lumen communicates with the actuation members and the vacuum port.

19. The apparatus of claim 1 further comprising at least one lumen formed within the elongated body.

20. The apparatus of claim 19 wherein the auxiliary lumen is capable of receiving at least one device therein, the device selected from the group consisting of a fastener, fastener material, and a guidewire.

21. A system for repairing tissue within the body of a patient, comprising

a handle comprising:

a stationary handle body;

a engagement tip actuator connected to the stationary handle body;

a fastener deployment actuator coupled to the stationary handle body; and

a vacuum connector;

an elongated body comprising:

a flexible body member;

at least one vacuum lumen integral with the body member;

at least one actuation lumen integral with the body member, wherein the actuation lumen is

capable of receiving at least one actuation member therein; and

at least one fastener lumen integral with the body member, wherein the fastener lumen is capable of receiving at least one deployable fastener therein; and,

an engagement tip comprising:

a fastener deployment housing capable of attaching to the elongated body;

an actuation flange attached to the fastener deployment housing;

an extendable tip attached to the actuation flange and in communication with the engagement tip actuator;

a vacuum port in communication with the vacuum connector; and,

at least one deployable fastener in communication with the fastener deployment actuator.

22. A method of repairing tissue within the heart of a patient in vivo, comprising:

grasping a first tissue portion with a vacuum force;

stabilizing the first tissue portion with a mechanical force;

deploying a tissue fastener into the stabilized first tissue portion;

disengaging the first tissue portion;

grasping a second tissue portion with a vacuum force;

stabilizing the second tissue portion with a mechanical force;

deploying a second tissue fastener into the second stabilized tissue portion;

disengaging the second tissue portion; and

coapting the first tissue portion and the second tissue portion by coupling the first and second tissue fasteners.

23. The method of claim 22 further comprising coapting the first and second tissue portions with sutures.

Fig. 1

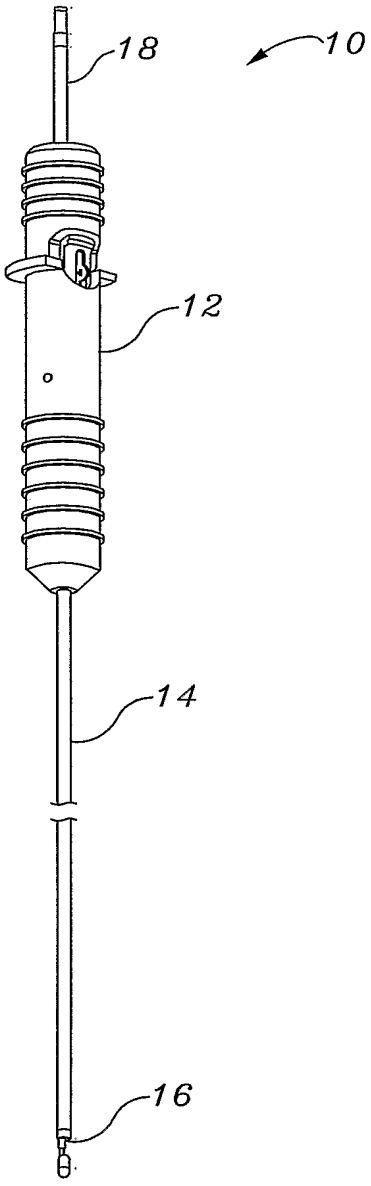


Fig. 2

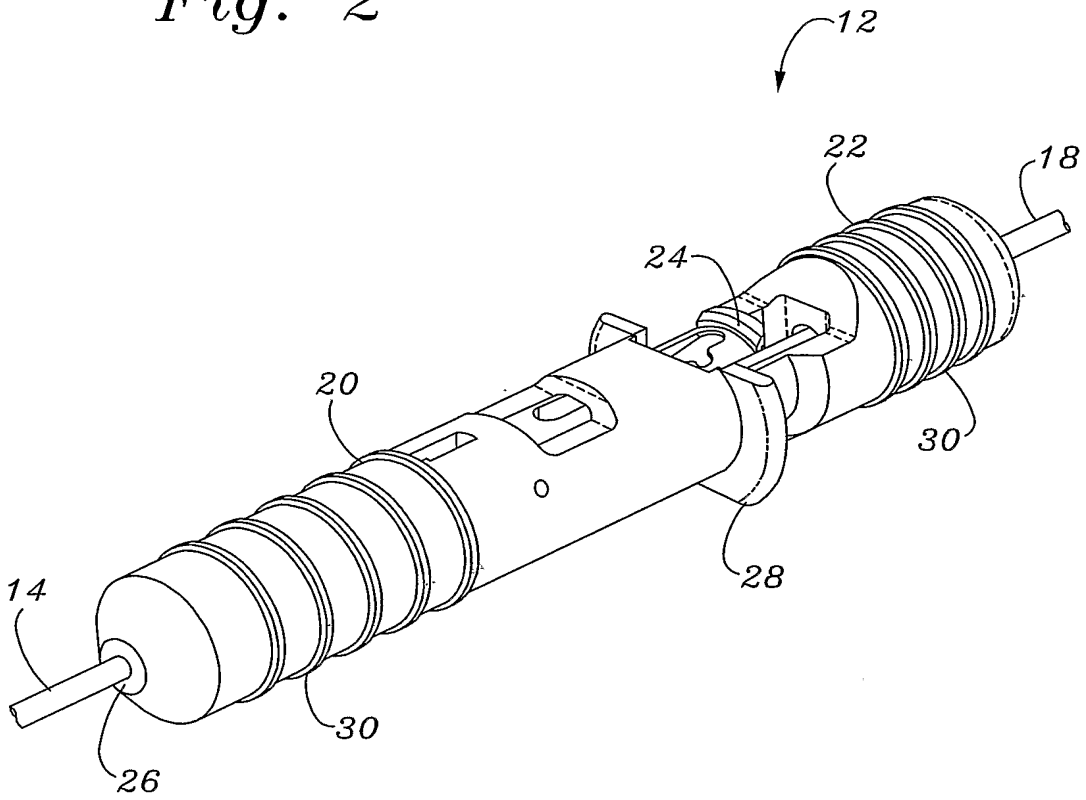


Fig. 3

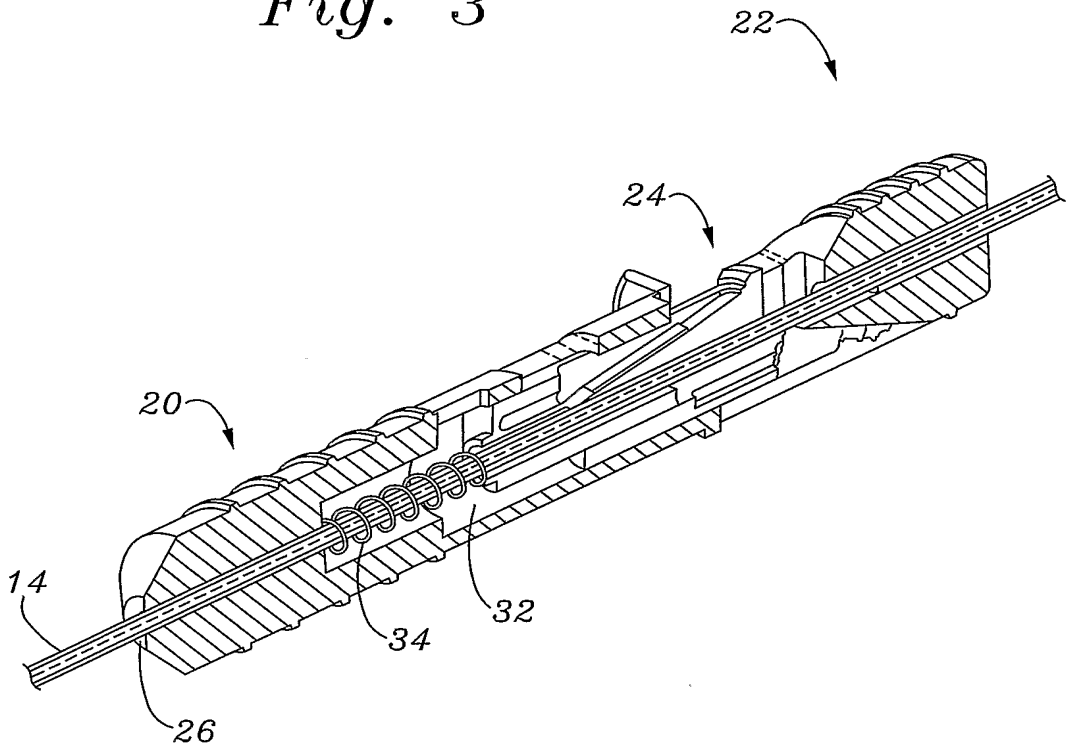


Fig. 4A

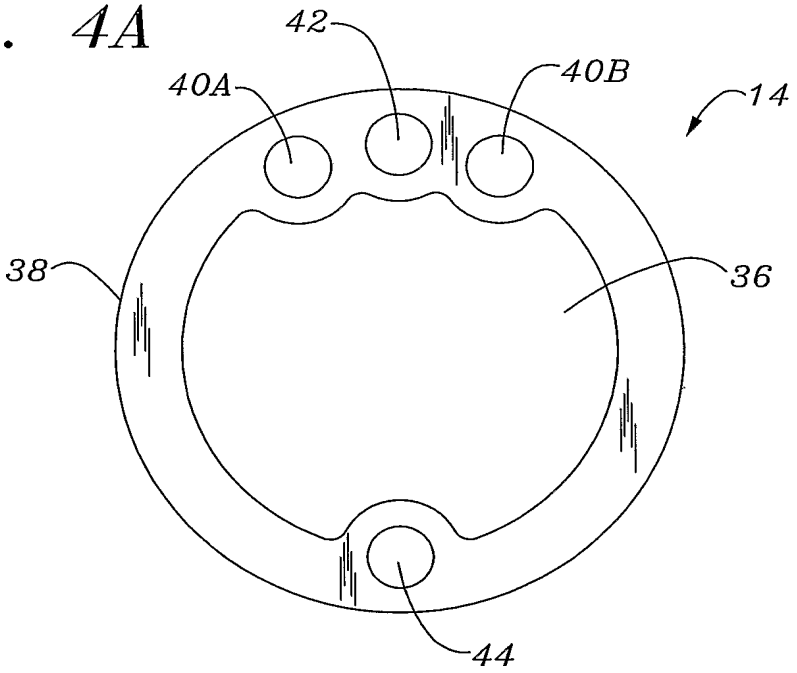


Fig. 4B

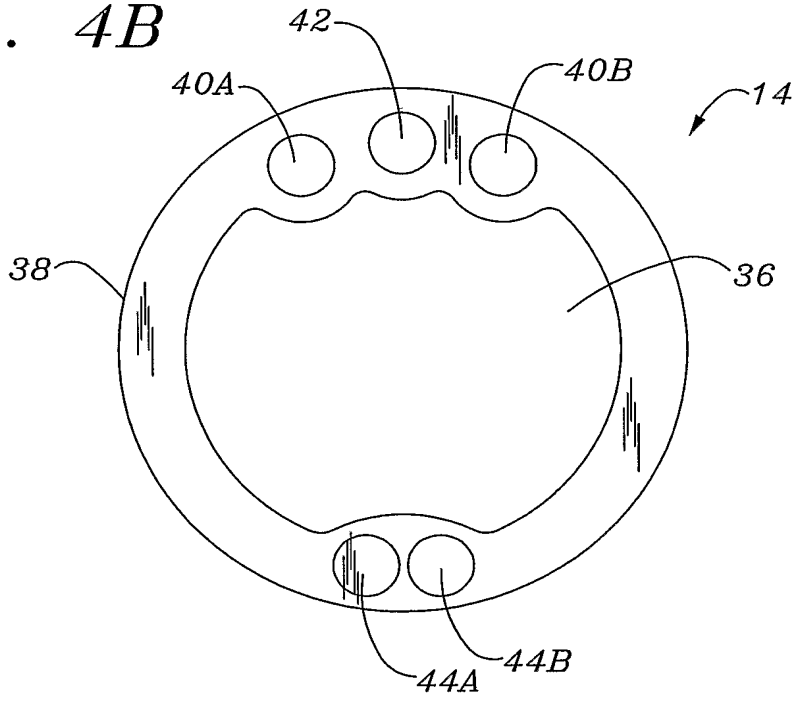


Fig. 5A

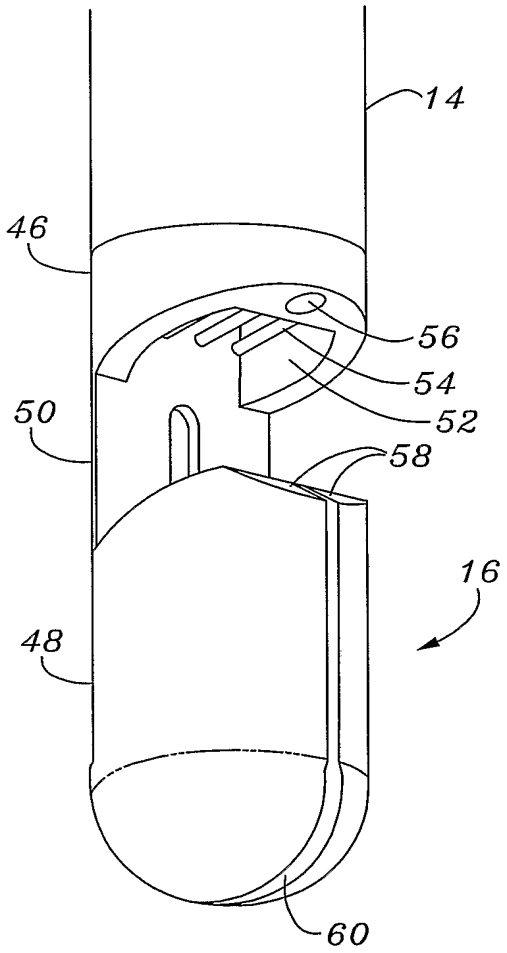


Fig. 5B

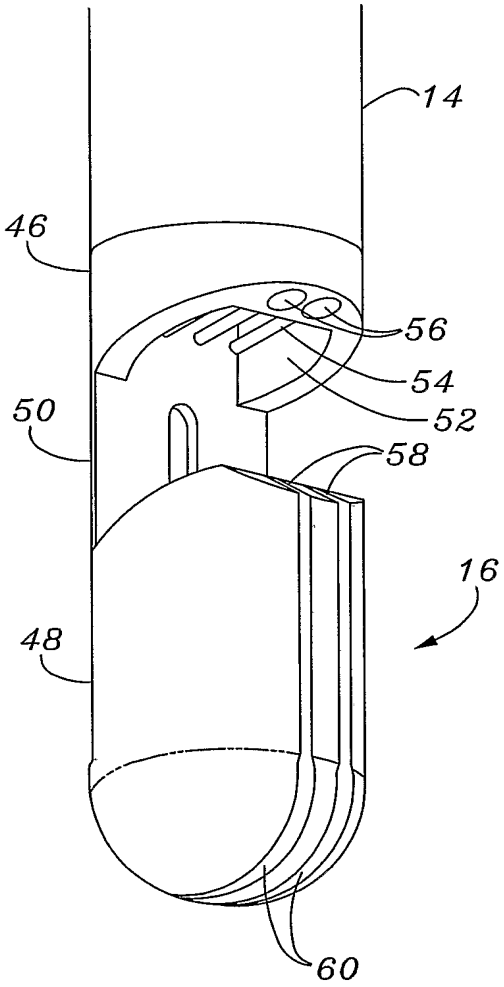


Fig. 6

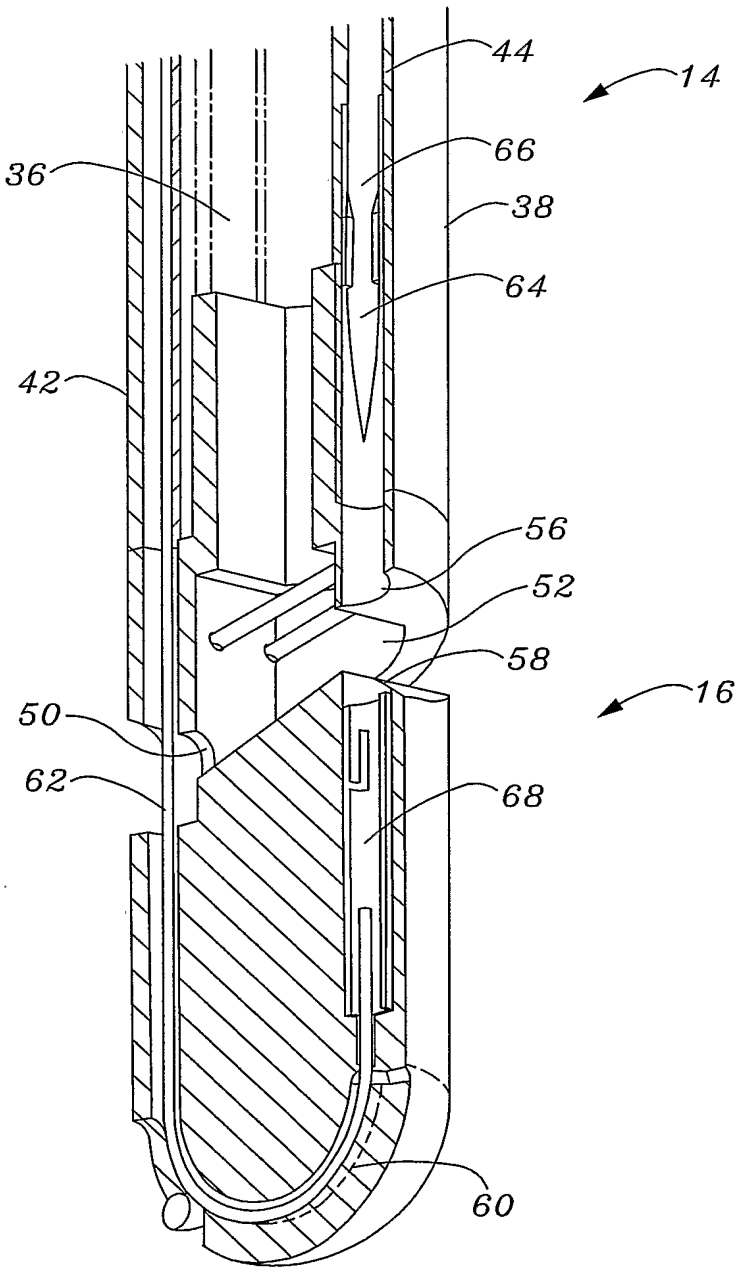


Fig. 7B

Fig. 7A

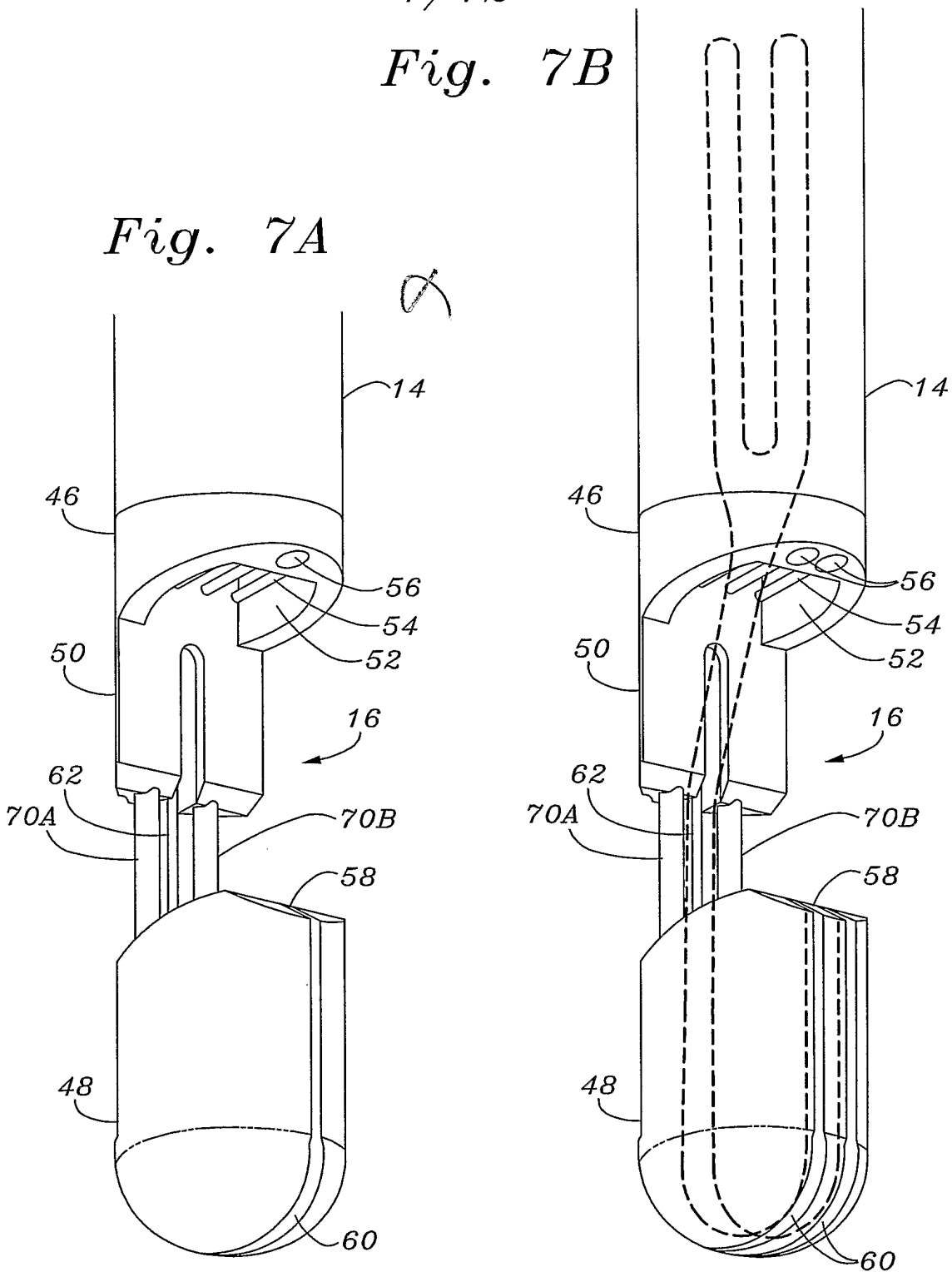

14
46
56
54
52
50
16
62
70A
70B
58
48
60
14
46
56
54
52
50
16
62
70A
70B
58
48
60

Fig. 8

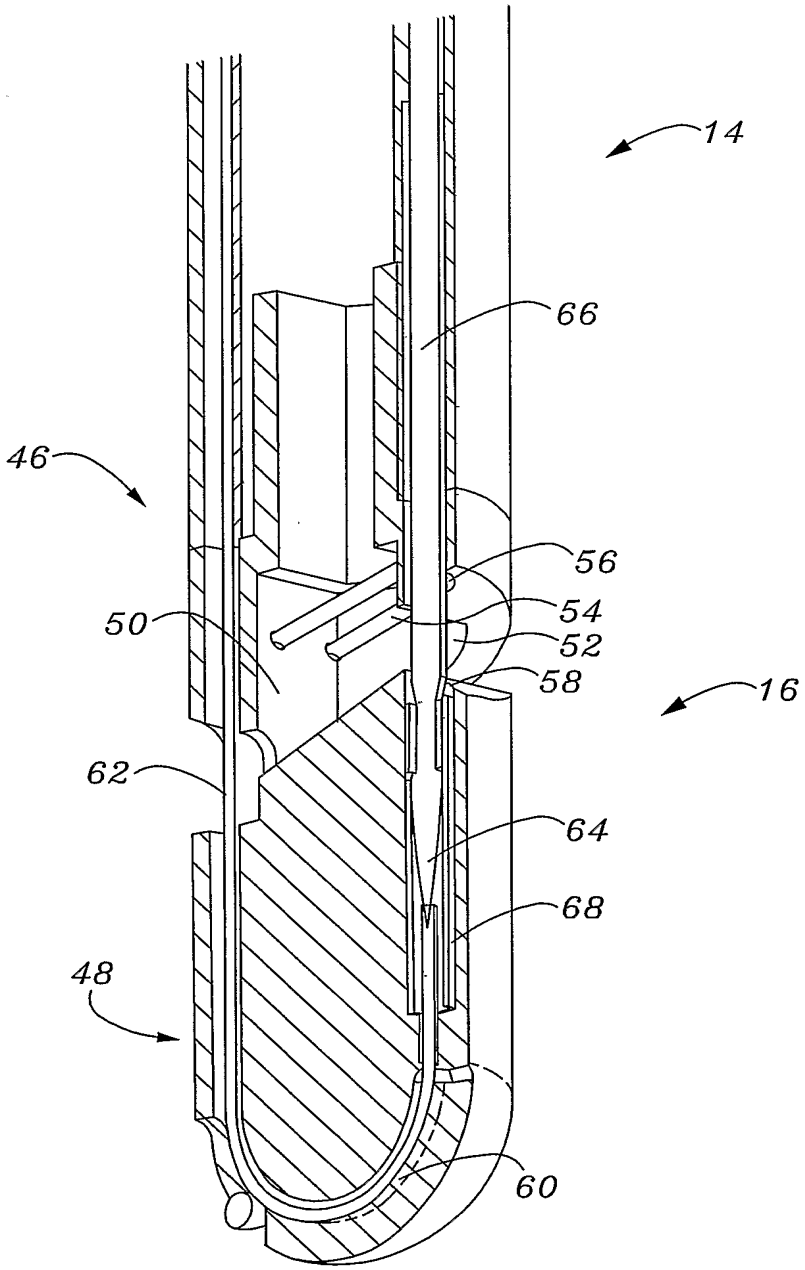


Fig. 9

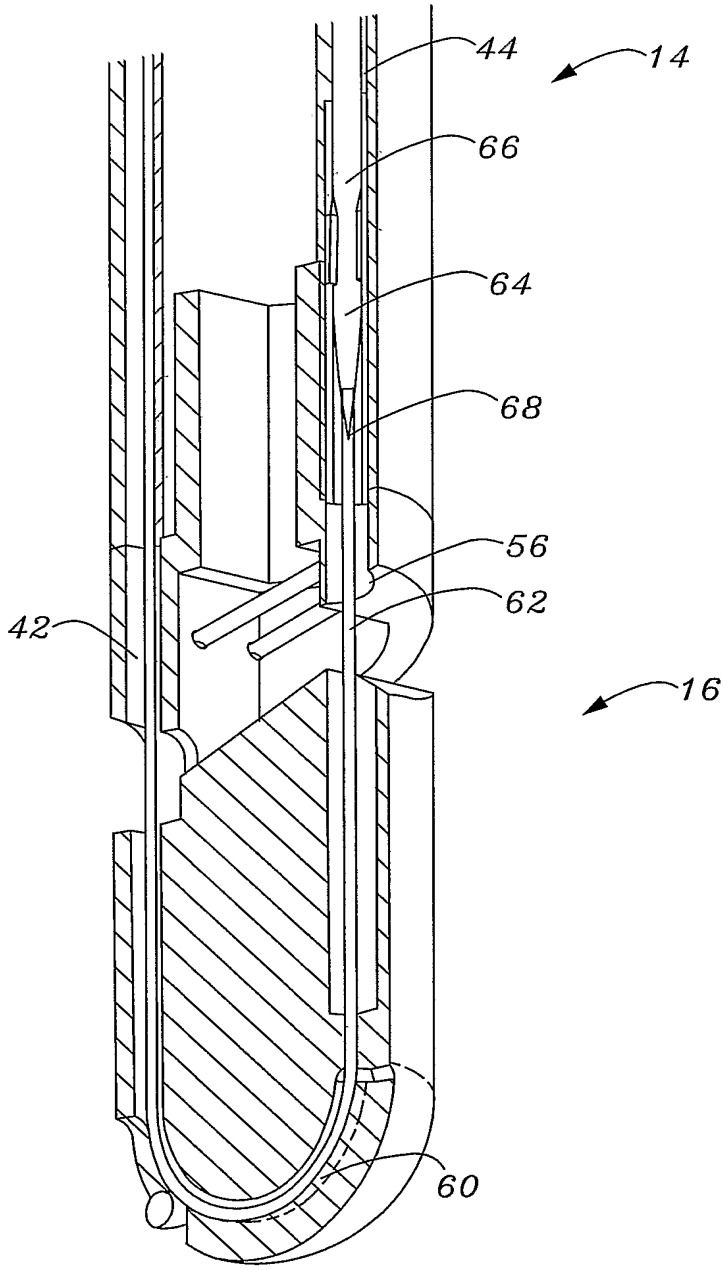


Fig. 10

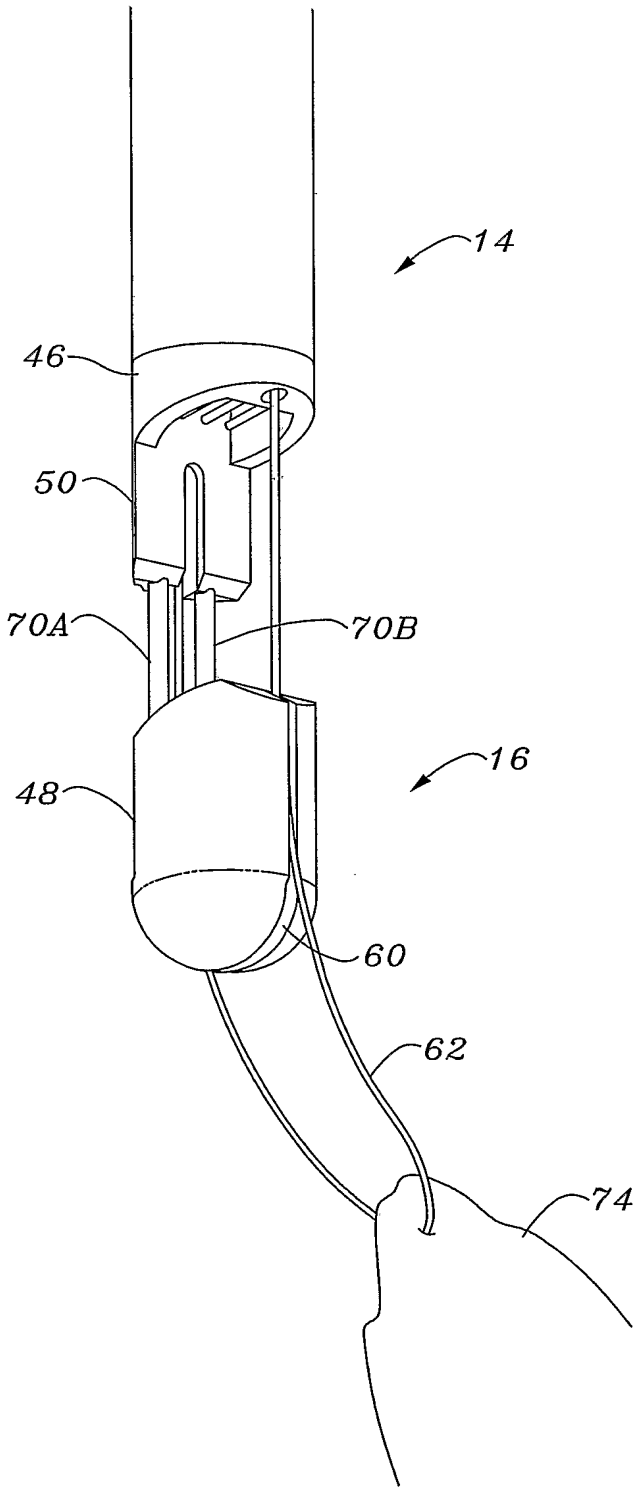


Fig. 11

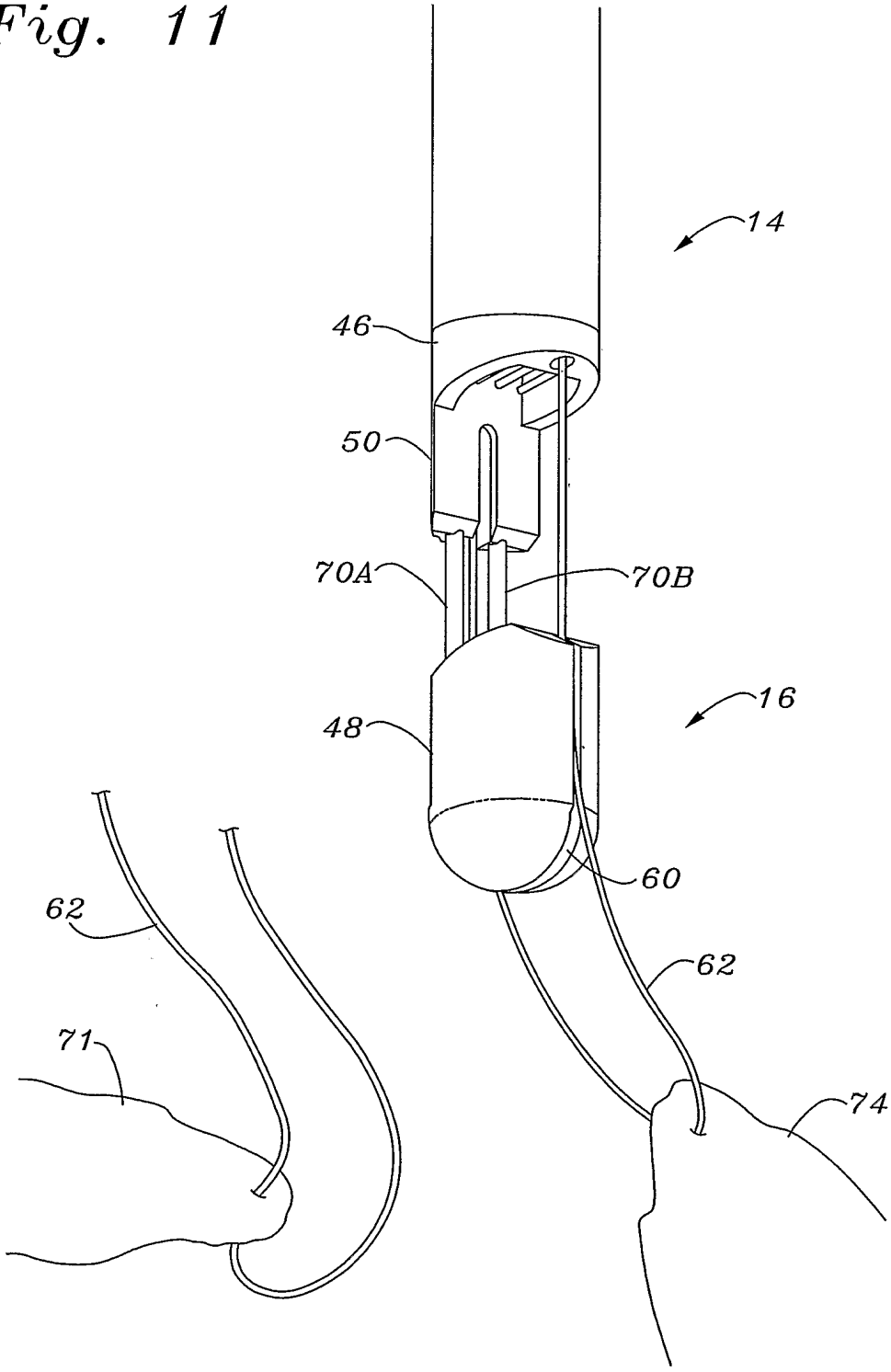


Fig. 12

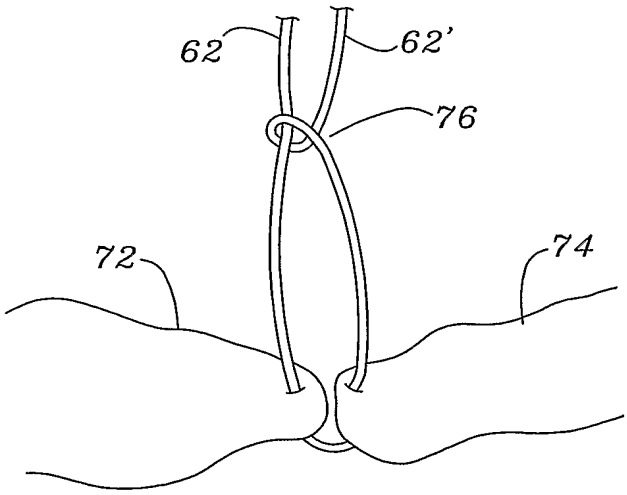
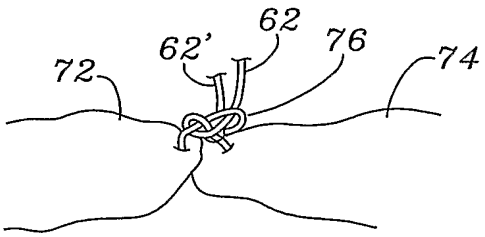


Fig. 13



INTERNATIONAL SEARCH REPORT

Internat pplication No
PCT/US 03/27661

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/04

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 7 A61B

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 02 24078 A (OPUS MEDICAL, INC.) 28 March 2002 (2002-03-28) abstract; figures page 21, line 19 -page 24, line 29	1-15, 19-21
Y	WO 95 25468 A (UNIVERSITY COLLEGE LONDON) 28 September 1995 (1995-09-28) abstract; figures page 4, line 25-28	1-15, 19-21
A	WO 97 27807 A (HEARTPORT, INC.) 7 August 1997 (1997-08-07) page 33, line 8 -page 34, line 6; figures 34,35	1,21
A	US 5 766 183 A (SAUER) 16 June 1998 (1998-06-16) abstract; figures	1,21

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° 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 document 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	Date of mailing of the international search report
7 January 2004	15/01/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Giménez Burgos, R

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int application No.
PCT/US 03/27661

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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. [X] Claims Nos.: 22,23
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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 II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

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 an additional fee, this Authority did not invite payment of any additional fee.

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.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internati cation No
PCT/US 03/27661

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 0224078	A	28-03-2002	US	6551330 B1	22-04-2003
			AU	9505001 A	02-04-2002
			WO	0224078 A1	28-03-2002
			US	2003181925 A1	25-09-2003
WO 9525468	A	28-09-1995	AU	3245995 A	09-10-1995
			DE	69509641 D1	17-06-1999
			DE	69509641 T2	16-09-1999
			EP	0751745 A1	08-01-1997
			WO	9525468 A1	28-09-1995
			JP	10500318 T	13-01-1998
			US	5792153 A	11-08-1998
WO 9727807	A	07-08-1997	US	5860992 A	19-01-1999
			AU	1754097 A	22-08-1997
			WO	9727807 A1	07-08-1997
US 5766183	A	16-06-1998	US	6368334 B1	09-04-2002
			US	2002123756 A1	05-09-2002

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 630666.00074
Speziali	Confirmation No.: 6073
Application No.: 11/813,695	Examiner: Christopher L. Templeton
Filed: July 11, 2007	Group Art Unit: 3773

For: THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INTRODUCTORY COMMENTS

In response to the Office Action of July 2, 2012, amendment to the above-identified patent application is requested.

The present amendment comprises the following sections:

A. Amendments to the Specification

B. Amendments to the Claims

C. Amendments to the Drawings

D. Remarks

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 17-0055.

AMENDMENTS TO THE SPECIFICATION

In the Abstract

Please substitute the following amended paragraph(s) and/or section(s) (deleted matter is shown by strikethrough and added matter is shown by underlining):

An instrument for performing thorascopic repair of heart valves includes a shaft for extending through the chest cavity and into a heart chamber providing access to a valve needing repair. A movable tip on the shaft is operable to capture a valve leaflet and a needle is operable to penetrate a captured valve leaflet and draw the suture ~~there~~through the leaflet. The suture is thus fastened to the valve leaflet and the instrument is withdrawn from the heart chamber transporting the suture outside the heart chamber. The suture is anchored to the heart wall with proper tension as determined by observing valve operation with an ultrasonic imaging system.

In the Specification

Please substitute the following amended paragraph(s) and/or section(s) (deleted matter is shown by strikethrough or double brackets and added matter is shown by underlining):

At paragraph [0016] on page 5 of the specification as filed:

While a single chorda 18 is implanted in the above description, additional chorda, or sutures, can be implanted and attached to the apex 12 of the heart wall with optimal tension. In this case the tensions in all the neo-implanted chorda 18 are adjusted until optimal valve operation is achieved. In another embodiment shown in Figure 3A, the chorda 18 can be anchored to a papillary muscle in the heart.

AMENDMENTS TO THE CLAIMS

A detailed listing of all claims that are, or were, in the present application, irrespective of whether the claim(s) remain(s) under examination in the application is presented below. The claims are presented in ascending order and each includes one status identifier. Those claims not cancelled or withdrawn but amended by the current amendment utilize the following notations for amendment: 1. deleted matter is shown by strikethrough for six or more characters and double brackets for five or fewer characters; and 2. added matter is shown by underlining.

1. (Currently Amended) A method of repairing a heart valve in a patient with an instrument having a distal end and a movable element, the method comprising:

inserting the instrument through the patient's chest wall and into the patient's chest cavity;

inserting the distal end and the movable element of the instrument through an exterior heart wall;

grasping a single leaflet on the heart valve between the movable element and the distal end of the instrument;

confirming capture and proper positioning of the leaflet between the movable element and the distal end using a fiber optic visualization system that detects light reflected off of the leaflet when the leaflet is properly positioned between the movable element and the distal end for proper attachment of a suture to the leaflet;

puncturing the leaflet with a needle disposed on the distal end of the instrument after confirming proper positioning of the leaflet to form a puncture opening and drawing [[a]] the suture through the puncture opening to connect the suture to the leaflet;

capturing the suture with the needle;

anchoring the suture to another structure in the heart;

withdrawing the instrument through the heart wall; and

withdrawing the instrument from the chest cavity.

2. (Currently Amended) The method of claim 1, wherein the step of anchoring the suture includes withdrawing the suture with the instrument through the heart wall and anchoring the suture to [[the]] an outer surface of the heart wall.

3. (Currently Amended) The method of claim 2, further comprising adjusting [[the]] a tension on the suture before anchoring the suture by observing operation of the heart valve using a medical imaging system.

4. (Currently Amended) The method of claim 1, further comprising placing a purse-string suture in the heart wall around [[the]] a location of the instrument insertion.

5. (Currently Amended) The method of claim 1, wherein inserting the distal end and the movable element of the instrument through [[a]] the heart wall comprises inserting the distal end and the movable element of the instrument transapically.

6. (Previously Presented) The method of claim 5, wherein the step of anchoring the suture includes withdrawing the suture with the instrument through the heart wall and anchoring the suture to an outer surface of the heart wall near the heart's apex.

7-17. (Canceled).

18. (Previously Presented) The method of claim 1, wherein the another structure is the heart wall.

19. (Previously Presented) The method of claim 1, wherein the another structure is a papillary muscle.

20. (Previously Presented) The method of claim 1, wherein the another structure is not a valve leaflet.

21. (Previously Presented) The method of claim 1, wherein the step of inserting an instrument through the patient's chest wall comprises inserting a rigid metal shaft through the patient's chest wall.

22. (Previously Presented) The method of claim 1, wherein confirming capture of the leaflet between the distal end and the movable element using a fiber optic visualization system includes using a fiber optic visualization system having at least one illumination fiber optic that provides the light and at least one sensor fiber optic that conveys the reflected light from the distal end.

23. (Currently Amended) The method of claim 22, wherein the fiber optic visualization system includes a plurality of illumination fiber optics and a plurality of sensor fiber optics, at least one illumination fiber optic and at least one sensor fiber optic positioned within each of a plurality of channels extending longitudinally through the instrument and terminating adjacent the distal end such that each channel provides an independent indication of whether the leaflet is captured between the movable element and the distal end, and wherein the step of confirming

capture and proper positioning of the leaflet includes viewing each of the plurality of independent indications.

24. (Currently Amended) A method of confirming capture and proper positioning of a valve leaflet of a patient's heart, the method comprising:

providing an instrument having a distal end, a movable element movable with respect to the distal end, and ~~an at least one~~ a plurality of illuminating fibers in optical communication with a visualization monitor and an exposed surface of the distal end;

inserting the instrument through the patient's chest wall and into the patient's chest cavity;

grasping [[the]] a leaflet on [[the]] a heart valve between the movable element and the distal end of the instrument; and

conveying a plurality of distinct and independent colored dots to the visualization monitor corresponding to a capture status and positioning of the leaflet, wherein when the capture status of the leaflet is positive, light from the illuminating fibers is reflected off of the leaflet to the visualization monitor.

25. (Currently Amended) The method of claim 24, wherein [[the]] a color of each of the colored dots is substantially red when the capture status of the leaflet is negative and substantially white when the capture status of the leaflet is positive due to the light from the illuminating fibers being reflected off of the leaflet and conveyed back to the visualization monitor by [[a]] one or more sensor fiber optics.

26. (Currently Amended) The method of claim 24, wherein the instrument includes a plurality of geometrically arranged illuminating fibers in optical communication with the visualization monitor and an exposed surface of the distal end, at least one illuminating fiber in each of a plurality of separate channels extending longitudinally through the instrument, each of the channels corresponding to one of the colored dots.

27. (Currently Amended) A method, comprising:

providing an instrument having a distal end, a movable element and a needle disposed on the distal end; and

providing instructions for repairing a heart valve of a patient with the instrument, the instructions comprising:

inserting the instrument through the patient's chest wall and into the patient's chest cavity;

inserting the distal end and the movable element of the instrument through an exterior heart wall;

grasping a single leaflet on the heart valve between the movable element and the distal end of the instrument;

confirming capture and proper positioning of the leaflet between the movable element and the distal end using a fiber optic visualization system that detects light reflected off of the leaflet when the leaflet is properly positioned between the movable element and the distal end for proper attachment of a suture to the leaflet;

puncturing the leaflet with the needle of the instrument after confirming proper positioning of the leaflet to form a puncture opening and drawing [[a]] the suture through the puncture opening to connect the suture to the leaflet;

capturing the suture with the needle;

anchoring the suture to another structure in the heart;

withdrawing the instrument through the heart wall; and

withdrawing the instrument from the chest cavity.

28. (Currently Amended) The method of claim 27, wherein the step of anchoring the suture includes withdrawing the suture with the instrument through the heart wall and anchoring the suture to [[the]] an outer surface of the heart wall.

29. (Currently Amended) The method of claim 28, wherein the instructions further comprise[[ing]] adjusting [[the]] a tension on the suture before anchoring the suture by observing operation of the heart valve using a medical imaging system.

30. (Previously Presented) The method of claim 27, wherein confirming capture of the leaflet between the distal end and the movable element using a fiber optic visualization system includes using a fiber optic visualization system having at least one illumination fiber that provides the light and at least one sensor fiber that conveys the reflected light from the distal end.

31. (Currently Amended) The method of claim 30, wherein the fiber optic visualization system includes a plurality of illumination fiber optics and a plurality of sensor fiber optics, at least one illumination fiber optic and at least one sensor fiber optic positioned within each of a plurality of channels extending longitudinally through the instrument and terminating adjacent the distal end such that each channel provides an independent indication of whether the leaflet is captured between the movable element and the distal end, and wherein the step of confirming capture and proper positioning of the leaflet includes viewing each of the plurality of independent indications.

AMENDMENTS TO THE DRAWINGS

New figure 3A is added in response to the Drawings Objection.

Attachment: Figure 3A

REMARKS

Claims 1-6 and 18-31 are pending. By this Amendment, claims 1-5, 23-29 and 31 are amended.

Drawings

The drawings stand objected to under 37 C.F.R. § 1.83 because the Office Action contends that the feature of the "another structure" being a papillary muscle in claim 19 is not shown in the drawings. New Figure 3A has been added by this amendment depicting sutures anchored to a papillary muscle. No new matter is added by this amendment as discussed below with respect to the 35 U.S.C. § 112 rejections. See MPEP § 2163.06 ("[I]nformation contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter.")

Specification

The abstract stands objected to because the Office Action contends that the word "capture" should be changed to "captured" in line 3 and for the use of legal phraseology such as the word therethrough. By this Amendment, the abstract has been amended as suggested in the Office Action.

Claim Objections

Claims 5 and 29 stand objected to due to informalities in claim language. By this Amendment, these claims have been amended as suggested in the Office Action. It is therefore respectfully requested that these objections be withdrawn.

Claims Rejections – 35 U.S.C. § 112

Claim 19 stands rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement because the Office Action contends that the specification does not disclose anchoring the suture to a papillary muscle and only discloses anchoring at the heart apex. However, paragraph 10 of the application states that "[a] commonly used technique to surgically correct mitral valve regurgitation is the implantation of artificial chordate (usually 4-0 or 5-0 Gore-Tex sutures) between the prolapsing segment of the valve and the papillary muscle." Although this statement is presented in the Background section of the application, the sutures/chordae of the disclosed invention are also described, in one embodiment, as 4-0 or 5-0 Gore-Tex sutures. As such, although the Detailed Description only expressly describes anchoring the sutures at the heart apex, it should be apparent from the Background section that one skilled in the art would understand that it is inherent from the disclosure that the sutures could also be anchored to a papillary muscle. It is therefore respectfully requested that this rejection be withdrawn.

Claims 2-4, 22, 23, 24-26 and 28-31 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite because the Office Action contends that various terms in the claims lack sufficient antecedent basis. With regard to claims 2-4, 23, 24-26, 28-29 and 31 the claims

have been amended to provide antecedent basis for the limitations noted in the Office Action. As to claims 22 and 30, Applicant notes that the parent claims recite "a fiber optic visualization system that detects **light reflected** off of the leaflet," and therefore the recitations of "the light" and "the reflected light" in claim 22 have sufficient antecedent basis in the parent claim. It is therefore respectfully requested that these rejections be withdrawn.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 2, 5, 6, 18, 20, 22, 23, 27, 28, 30 and 31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S. Publication No. 2004/0044365) and further in view of Benaron et al. (U.S. Patent No. 5,785,658). Claims 3 and 29 stand rejected as being unpatentable over Lattouf in view of Bachman and Benaron and further in view of St. Gaor et al (U.S. Publication No. 2005/0021506). Claim 4 stands rejected as being unpatentable over Lattouf in view of Bachman in view of Benaron and further in view of Oz et al (U.S. Publication No. 2001/0005787). Claim 19 stands rejected as being unpatentable over Lattouf in view of Bachman and Benaron et al and further in view of Fasol et al. (U.S. Publication No. 2003/0105519). Claim 21 stands rejected as being unpatentable over Lattouf in view of Bachman and further in view of Sauer et al. (U.S. Publication No. 2005/0154402). These rejections are respectfully traversed.

The Office Action admits that that neither Lattouf nor Bachman teaches confirming capture of a valve leaflet with a fiber optic visualization system that detects light reflected off of the leaflet when the leaflet is properly captured, but cites to Benaron as teaching this limitation, stating that it would have been obvious to combine the feature with the method of Lattouf "for

the purpose of nondestructive interrogation of tissue grasped in order to discriminate tissue types."

Although Applicant does not acquiesce in these rejections as it is Applicant's position that they are based on the use of impermissible hindsight, independent claims 1 and 27 have been amended to clarify that both capture and proper positioning of the leaflet between the movable element and the distal end for proper attachment of a suture to the leaflet and that the needle is punctured through the leaflet after confirming proper positioning of the leaflet. As is explained in the present application at least at pargraphs [0029]-[0030], such a procedure provides significant advantages in identifying partially captured leaflets and avoiding false positives that result in improper suture placement. None of the cited references teach or suggest such a configuration.

As acknowledged in the Office Action, Benaron only teaches the use of fiber optics for "nondestructive interrogation of tissue grasped in order to discriminate tissue types." The device of Benaron necessarily indicates the presence of tissue captured by a tool because tissue must be present in order to perform the described analysis to determine the type of tissue. However, Benaron provides no indication of the manner in which the tissue is captured and therefore can provide no information regarding the specific positioning of the suture and, accordingly, whether or not tissue is properly positioned for insertion of a suture. The entire intent of Benaron is simply to determine the type of tissue grasped, and therefore the system teaches one skilled in the art nothing regarding confirming proper positioning of a valve leaflet.

In addition, as noted in the Office Action Lattouf and Bachman both teach nothing regarding confirm leaflet capture and positioning, and neither reference recognizes the potential

issue of improper capture that can lead to poor suture placement that is addressed by the claimed invention. As such, not only do none of the cited references teach or suggest confirming proper positioning of a captured valve leaflet for insertion of a suture prior to penetrating the leaflet with a needle, but there is no reasoned basis provided to one skilled in the art for modifying the reference to meet the claimed limitations. As such, it is respectfully requested that the rejections of claims 1 and 27 be withdrawn.

Dependent claims 23 and 31 have also been amended. These claims recite that there are a plurality of fiber optic channels extending longitudinally through the instrument that each including an illumination fiber optic and a sensor fiber optic to provide an independent indication of whether the leaflet is captured and that the step of confirming capture and proper positioning of the leaflet includes viewing each of the plurality of independent indications. This configuration avoids improper but partial capture of the leaflet by provide a white color from fewer than all of the channels, ensuring that a partial capture is not falsely identified as a confirmed capture as may happen with a single fiber optic view. None of the cited references teach or suggest this limitation and therefore these claims are independently allowable. Although Benaron teaches the use of multiple "windows," the reference teaches that these are provided for tools having multiple functions, not to provide independent indications of the presence and positioning of tissue. (Col. 16, line 67 – col. 17, line 5.) In addition, Benaron teaches that illumination and sensor fiber optics must be in separate windows and channels and therefore teaches away from the claimed limitations. (See col. 20, lines 42-65.)

With regard to claims 2-6 and 18-22 depending from independent claim 1 and claims 28-30 depending from independent claim 27, these claims are allowable at least because the

underlying base claim is allowable, although Applicant does not acquiesce in the positions set forth in the Office Action and specifically reserves the right to make further arguments with respect to these claims. It is therefore respectfully requested that these rejections be withdrawn.

Claims 24-26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Thornton et al. (U.S. Patent No. 7,666,204) in view of Benaron et al. (U.S. Patent No. 5,785,658). This rejection is respectfully traversed.

The Office Action cites to the "color Doppler echo" image of Thornton as providing the claimed color conveyed to the visualization monitor. Claim 24 has therefore been amended to clarify that a plurality of distinct and independent colored dots corresponding to a capture status and positioning of the leaflet are conveyed to the visualization monitor. Color Doppler echocardiography is a visualization technique the utilizes ultrasound waves to create an image of the heart that shows the size, shape and movement of the heart. (See, e.g., http://medical-dictionary.thefreedictionary.com/color+Doppler+echocardiography) and therefore the cited image of Thornton does not provide any kind of teaching of a plurality of colored dots as claimed. Moreover, even if the image could be considered to be comprised of many colored dots, the dots would not be "distinct and independent" because they are inextricably linked to one another to form the Doppler image of the heart. As such, Thornton does not teach or suggest this limitation. Further, as noted above, Benaron does not teach or suggest providing a visual indication of a positioning of the leaflet and although a display panel can display colors, the reference does not disclose displaying a plurality of distinct and independent colored dots

indicative of a capture status and positioning of a leaflet. It is therefore respectfully requested that this rejection be withdrawn.

With regard to claims 25 and 26 depending from independent claim 24, the claims are allowable because the underlying base claim is allowable, although Applicant does not acquiesce in the positions set forth in the Office Action and specifically reserves the right to make further arguments with respect to these claims. However, Applicant additionally notes that claim 26 has been amended to recite that there is at least one illuminating fiber in each of a plurality of separate channels extending longitudinally through the instrument, each of the channels corresponding to one of the colored dots, which is neither taught nor suggested by the cited references and therefore at least this claim is independently allowable. It is therefore respectfully requested that these rejections be withdrawn.

Conclusion

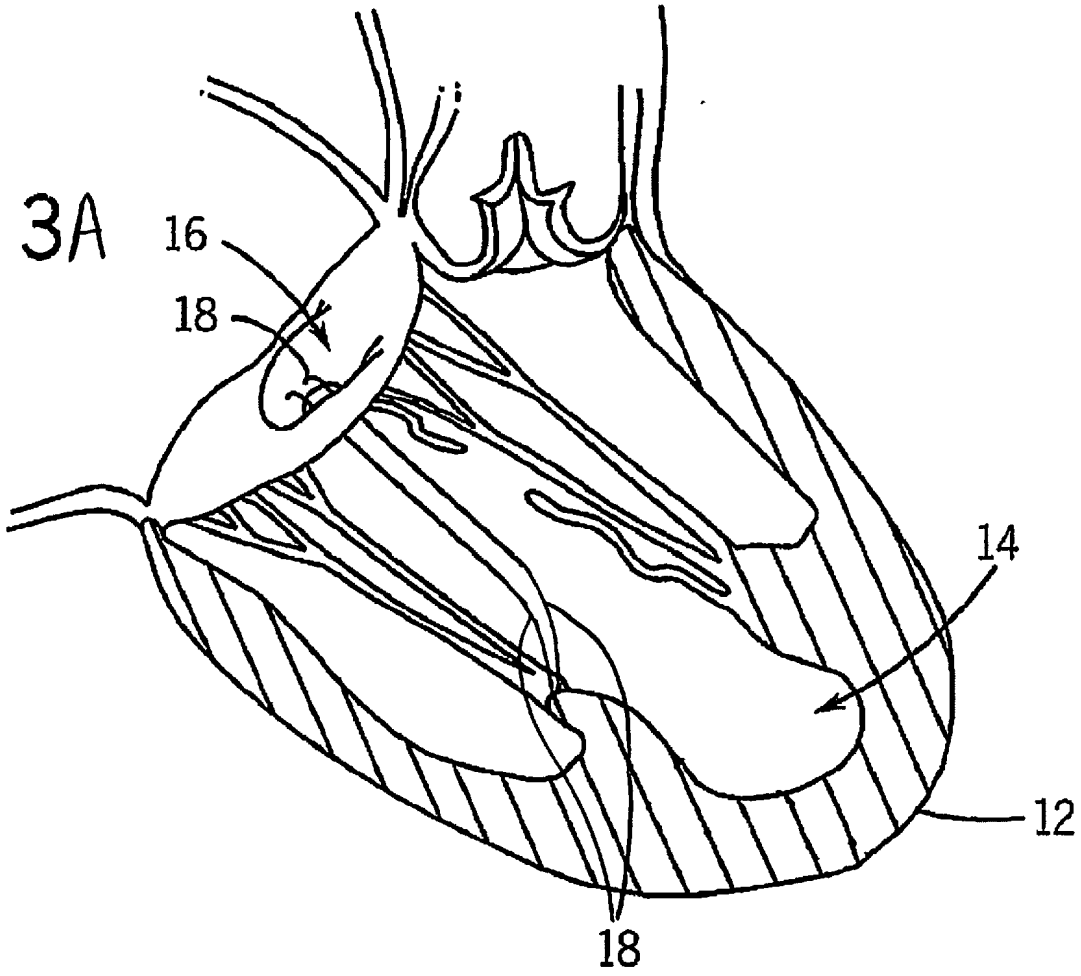
In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

/Richard T. Roche/
Richard T. Roche
Registration No. 38,599
Quarles & Brady LLP
411 E. Wisconsin Ave.
Milwaukee, WI 53202
Telephone: 414-277-5805

FIG. 3A



Electronic Acknowledgement Receipt

EFS ID:	13880509
Application Number:	11813695
International Application Number:	
Confirmation Number:	6073
Title of Invention:	Thorascopic Heart Valve Repair Method and Apparatus
First Named Inventor/Applicant Name:	Giovanni Speziali
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	630666.00074
Receipt Date:	01-OCT-2012
Filing Date:	11-JUL-2007
Time Stamp:	16:10:44
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Response-NFOA-7-2-12.pdf	125949 936f83ca235814b64df5dff441cf18cc45d84e41	yes	18

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Specification	2	2
	Claims	3	10
	Drawings-only black and white line drawings	11	11
	Applicant Arguments/Remarks Made in an Amendment	12	18

Warnings:					
Information:					
2	Drawings-only black and white line drawings	Mayo_00074-Figure-3A.PDF	942093 67b514a46fe8fc687905da0de183f94fc329f17d	no	1
Warnings:					
Information:					
		Total Files Size (in bytes):	1068042		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/813,695	07/11/2007	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	10/01/2012	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $30 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $125 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/AJAY R. DAVID/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/813,695	07/11/2007	Giovanni Speziali	630666.00074	6073

26710 7590 07/02/2012

QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER	
TEMPLETON, CHRISTOPHER L	
ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
07/02/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Office Action Summary	Application No.	Applicant(s)	
	11/813,695	SPEZIALI, GIOVANNI	
	Examiner	Art Unit	
	CHRISTOPHER L. TEMPLETON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-6 and 18-31* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-6 and 18-31* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☒ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *11 July 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/29/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment

This office action is responsive to the amendment filed on 21 February 2011. As directed by the amendment: claims 1, 22-25, 27, 30 and 31 have been amended. Thus, claims 1-6 and 18-31 are presently pending in this application.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 February 2011 has been entered.

Response to Amendment

2. The amendments to claim 24 overcome the previous claim objection and previous 35 U.S.C. 112 second paragraph rejection.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "another structure" being a papillary muscle (claim 19) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The abstract of the disclosure is objected to because:

The word “capture” should be changed to --captured-- in line 3.

Legal phraseology (therethrough) is contained within the abstract.

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Correction is required. See MPEP § 608.01(b).

Claim Objections

6. Claims 5 and 29 are objected to because of the following informalities.

7. As to claim 5, there is already antecedent basis for "a heart wall" in line 2.

Appropriate correction is required.

8. As to claim 29, the word “comprising” in line 2 should be changed to--comprise--.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification does not disclose the “another structure” being a papillary muscle. Figure 3 and paragraphs 11 and 15 only disclose the suture being tied off at the apex of the heart or outside the apex of the heart. Attaching it to a papillary muscle is new matter.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 2-4, 22, 23, 24-26 and 28-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claim 2 recites the limitation "the outer surface" in line 3. There is insufficient antecedent basis for this limitation in the claim.

14. Claim 3 recites the limitation "the tension" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 4 recites the limitation "the location" in line 2. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 22 recites the limitation "the light" in line 4. There is insufficient antecedent basis for this limitation in the claim.

17. Claim 22 recites the limitation "the reflected light" in lines 4 and 5. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 24 recites the limitation "the leaflet" in line 8. There is insufficient antecedent basis for this limitation in the claim.

19. Claim 24 recites the limitation "the heart valve" in line 8. There is insufficient antecedent basis for this limitation in the claim.

20. Claim 25 recites the limitation "the light" in line 3. There is insufficient antecedent basis for this limitation in the claim.

21. Claim 28 recites the limitation "the outer surface" in line 3. There is insufficient antecedent basis for this limitation in the claim.

22. Claim 29 recites the limitation "the tension" in line 2. There is insufficient antecedent basis for this limitation in the claim.

23. Claim 30 recites the limitation "the light" in line 4. There is insufficient antecedent basis for this limitation in the claim.

24. Claim 30 recites the limitation "the reflected light" in lines 4 and 5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

26. Claims 1, 2, 5, 6, 18, 20, 22, 23, 27, 28, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S. Publication No. 2004/0044365) and further in view of Benaron et al (U.S. Patent No. 5,785,658).

27. As to claims 1, 2, 5, 6, 18, 20, 22, 23, Lattouf discloses the claimed method of repairing a heart valve in a patient comprised of inserting an instrument having a distal end and a movable element through the patient's chest wall and into the patient's chest cavity (column 2, lines 34-42); inserting the distal end of the instrument through a heart wall and entering a heart chamber through the apex of the heart, transapically (column 3, line 45-column 4, line 5); withdrawing the suture with the instrument through the heart wall and anchoring the suture to the outer surface of the heart wall implicitly near the

apex of the heart (column 3, line 45-column 4, line 5; Figure 27), and withdrawing the instrument from the chest cavity. Lattouf does not expressly disclose the steps of grasping a single leaflet between a movable element and a distal end of the instrument, capturing the suture with a needle or puncturing the leaflet with the needle, or confirming capture of the leaflet using a fiber optic system.

Bachman teaches, in the same field of endeavor, the steps of grasping a single leaflet on a heart valve between a movable element and the distal end of an instrument (Figure 11; paragraphs 42 and 43), puncturing the leaflet with a needle disposed on the distal end of the instrument and the step of capturing the suture with the needle (paragraph 42; Figure 8).

Benaron teaches using fiber optics (column 4, line 46-column 6, line 13), in the analogous art of surgical instruments for non-destructive interrogation of body tissue, to detect light reflected off of any tissue when the tissue is properly positioned between movable elements (column 5, lines 24-36; column 6, lines 5-13) for confirming capture of any tissue between movable elements (column 5, lines 24-36; column 1, lines 33-45; column 3, line 42-column 4, line 45) for the purpose of nondestructive interrogation of tissue grasped in order to discriminate tissue types (column 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and device of Lattouf and include the instrument with a movable element and needle at the distal end and the steps of grasping a single leaflet between the movable element and a distal end of the instrument, puncturing the leaflet with the needle and capturing the suture with the

needle, as taught by Bachman, for the purpose of applying a suture quickly and stably with the needle and grasping portion (abstract; paragraphs 10 and 13), providing improved tissue stabilization and enhanced placement of a fastening device, and minimizing trauma to the patient before, during and after surgery (paragraph 30). It would have also been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method of Lattouf and include the fiber optic system and step of confirming capture, as taught by Benaron, for the purpose of nondestructive interrogation of tissue grasped in order to discriminate tissue types (column 4).

As to claims 27, 28, 30 and 31, Lattouf discloses the claimed method of providing an instrument having a distal end and a movable element, and providing instructions for repairing a heart valve of a patient with the instrument, the instructions comprised of inserting the instrument through the patient's chest wall and into the patient's chest cavity (column 2, lines 34-42); inserting the distal end of the instrument through a heart wall and entering a heart chamber through the apex of the heart, transapically (column 3, line 45-column 4, line 5); anchoring the suture to another structure in the heart (Figure 27); withdrawing the suture with the instrument through the heart wall and anchoring the suture to the outer surface of the heart wall implicitly near the apex of the heart (column 3, line 45-column 4, line 5; Figure 27), and withdrawing the instrument from the chest cavity. Lattouf does not expressly disclose the steps of providing an instrument having a needle, grasping a single leaflet between the movable element and a distal end of the instrument, capturing the suture with the needle, puncturing the

leaflet with a needle, puncturing the leaflet with the needle, or the step of confirming capture of the leaflet using a fiber optic system.

Bachman teaches, in the same field of endeavor, an instrument with a distal end, a movable element and a needle, and the steps of providing the instrument having a distal end, a movable element and a needle; grasping a single leaflet (Figure 11; paragraphs 42 and 43) on a heart valve between a movable element and the distal end of the instrument and puncturing the leaflet with a needle disposed on the distal end of the instrument and capturing a suture with the needle (paragraph 42; Figure 8).

Benaron teaches using fiber optics (column 4, line 46-column 6, line 13), in the analogous art of surgical instruments for non-destructive interrogation of body tissue, to detect light reflected off of any tissue when the tissue is properly positioned between movable elements (column 5, lines 24-36; column 6, lines 5-13), for confirming capture of any tissue between movable elements (column 5, lines 24-36; column 1, lines 33-45; column 3, line 42-column 4, line 45) and for the purpose of nondestructive interrogation of tissue grasped in order to discriminate tissue types (column 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and device of Lattouf and include the instrument with a movable element and needle at the distal end and include the instructions of grasping a single leaflet between the movable element and a distal end of the instrument, puncturing the leaflet with the needle and capturing the suture with the needle, as taught by Bachman, for the purpose of applying a suture quickly and stably with the needle and grasping portion (abstract; paragraphs 10 and 13), providing

improved tissue stabilization and enhanced placement of a fastening device, and minimizing trauma to the patient before, during and after surgery (paragraph 30). It would have also been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method of Lattouf and include the fiber optic system and step of confirming capture, as taught by Benaron, for the purpose of nondestructive interrogation of tissue grasped in order to discriminate tissue types (column 4).

28. Claims 3 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S. Publication No. 2004/0044365) and Benaron et al (U.S. Patent No. 5,785,658) and further in view of St. Goar et al (U.S. Publication No. 2005/0021056). Lattouf/Bachman/Benaron disclose the claimed invention but are silent on the step of adjusting tension on the suture by observing the operation of the heart valve using a medical imaging system. St. Goar teaches, in the same field of endeavor, the step of adjusting tension on a suture by observing the operation of the heart valve using a medical imaging system (paragraph 24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lattouf/Bachman/Benaron and include the step of adjusting the tension on the suture by observing the operation of the heart valve using a medical imaging system, as taught by St. Goar, in order to ensure the absence of regurgitation by monitoring the valve with an imaging system for the purpose of positioning the leaflet in the right position (paragraph 24).

29. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S. Publication No. 2004/0044365)

and Benaron et al (U.S. Patent No. 5,785,658) and further in view of Oz et al (U.S. Publication No. 2001/0005787). Lattouf/Bachman/Benaron disclose the claimed invention but are silent on the step of placing a purse-string suture in the heart wall around a location of the instrument. Oz teaches, in the same field of endeavor, placing a purse-string suture in the heart wall around the location of an instrument in order to control bleeding (Figure 1; paragraphs 68, 71). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lattouf/Bachman/Benaron and include the step of placing a purse-string suture in the heart around the location of the instrument, as taught by Oz, for the purpose of controlling bleeding around the instrument (paragraphs 68 and 71).

30. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S. Publication No. 2004/0044365) and Benaron et al (U.S. Patent No. 5,785,658) and further in view of Fasol et al (U.S. Publication No. 2003/0105519). Lattouf/Bachman/Benaron disclose the claimed invention except for anchoring the suture to papillary muscle. Fasol teaches, in the same field of endeavor, that it is old and well known in the art to attach a suture to the heart valve and then to the papillary muscle (Figures 8-9). It would have been an obvious matter of design choice to attach the suture to the papillary muscle, as taught by Fasol, for the purpose of repairing a malfunctioning heart valve (paragraph 5). Moreover, paragraph 10 of applicant's specification teaches that attaching a suture to the valve and then to the papillary muscle was a common technique known in the art

and thus it would have been obvious to one of ordinary skill in the art to attach the suture to papillary muscle.

31. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S. Publication No. 2004/0044365) and Benaron et al (U.S. Patent No. 5,785,658) and further in view of Sauer et al (U.S. Publication No. 2005/0154402). Lattouf/Bachman/Benaron disclose the claimed invention but are silent on a rigid metal shaft. Sauer teaches, in the same field of endeavor, a rigid shaft 52 on an instrument (paragraph 122) and teaches that shafts can be either rigid or flexible depending on its application. Therefore, it would have been an obvious matter of design choice to modify the instrument of Lattouf/Bachman/Benaron with a rigid shaft, as taught by Sauer, depending on the location the instrument is being used. Moreover, the official notice statement of it being obvious to make surgical devices out of rigid metal is taken to be prior art since it was not argued.

32. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thornton et al (U.S. Patent No. 7,666,204) in view of Benaron et al (U.S. Patent No. 5,785,658).

33. As to claims 24 and 26, Thornton discloses a method of confirming capture of a valve leaflet of a patient's heart comprised of providing an instrument having a distal end; grasping a leaflet of a heart valve and conveying a color to a visualization monitor corresponding to a capture status of the leaflet (column 19, line 55-column 20, line 15 teaches a color Doppler image showing if regurgitation of the valve has been reduced or not by conveying a color on a visualization monitor which corresponds to a capture

status of the leaflet). Thornton also discloses the instrument having a distal end 16, a movable element 18 movable with respect to the distal end 16, and the step of grasping the leaflet on the heart valve between the movable element 18 and the distal end of the instrument 16 (Figures 3A and B; column 19, lines 26-54), and implicitly inserting the instrument through the patient's chest wall and into the patient's chest cavity (column 4, lines 30-46 discloses inserting the instrument directly through body tissues such as in a direct access procedure to the heart). Thornton does not expressly disclose at least one illuminating fiber in optical communication with a visualization monitor or light being reflected off of the leaflet to the visualization monitor.

Benaron teaches, in the analogous art of surgical instruments for non-destructive interrogation of body tissue, using a plurality of geometrically arranged illuminating fiber optics in communication with a visualization monitor 28 (column 4, line 46-column 6, line 13) to detect light reflected off of any tissue when the tissue is properly positioned between movable elements (column 5, lines 24-36; column 6, lines 5-13) and displaying a color (column 10) for the purpose of nondestructive interrogation of tissue grasped in order to discriminate tissue types (column 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and device of Thornton and include the illuminating fiber optics and step of reflecting light off of tissue to a visualization monitor, as taught by Benaron, for the purpose of nondestructive interrogation of tissue grasped in order to discriminate tissue types (column 4).

34. As to claim 25, Benaron discloses a color change (column 10, lines 16-27) but does not disclose specific colors. It would have been an obvious matter of design choice to make the color change to red when the capture status of the leaflet is negative and to make the color change to white when the capture status is positive, in order to determine the specific type of tissue being grasped or any other information represented by the color (column 10, lines 16-27).

Response to Arguments

35. Applicant's arguments with respect to claims 1, 24 and 27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. McFarlin et al (U.S. Patent No. 5,667,478), Finn et al (U.S. Patent Nos. 5,667,473, 5,667,472, Goldenberger (U.S. Patent No. 5,772,597) and Yoon (U.S. Patent No. 6,419,626) disclose fiber optics.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER L. TEMPLETON whose telephone number is (571) 270-1477. The examiner can normally be reached on Monday - Thursday 7 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Corrine M. McDermott, at* (571) 272-4754**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. L. T./
Examiner, Art Unit 3773

/Julian W. Woo/
Primary Examiner, Art Unit 3773

Notice of References Cited	Application/Control No. 11/813,695	Applicant(s)/Patent Under Reexamination SPEZIALI, GIOVANNI	
	Examiner CHRISTOPHER L. TEMPLETON	Art Unit 3773	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,785,658	07-1998	Benaron et al.	600/473
*	B	US-2005/0021056	01-2005	St. Goar et al.	606/144
*	C	US-2005/0154402	07-2005	Sauer et al.	606/139
*	D	US-5,667,478	09-1997	McFarlin et al.	600/182
*	E	US-5,667,473	09-1997	Finn et al.	600/104
*	F	US-5,667,472	09-1997	Finn et al.	600/104
*	G	US-6,178,346	01-2001	Amundson et al.	600/473
*	H	US-5,772,597	06-1998	Goldberger et al.	600/473
*	I	US-6,419,626	07-2002	Yoon, InBae	600/109
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11813695	SPEZIALI, GIOVANNI
	Examiner	Art Unit
	CHRISTOPHER L TEMPLETON	3773

SEARCHED

Class	Subclass	Date	Examiner
606	139, 144, 145, 15, 16, 205-211	6/26/2012	CT
128	898	6/26/2012	CT
623	11.11, 13.11, 2.11-2.35	4/7/2010	CT
600	16, 37, 160, 182	6/26/2012	CT

SEARCH NOTES

Search Notes	Date	Examiner
EAST search (see attached)	6/26/2012	CT
Inventor name search	4/7/2010	CT

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11813695
Filing Date	2007-07-11
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher L. Templeton
Attorney Docket Number	630666.00074

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4957498		1990-09-18	Caspari et al.	
	2	5304185		1994-04-19	Taylor	
	3	5431666		1995-07-11	Sauer et al.	
	4	5336229		1994-08-09	Noda	
	5	5830231		1998-11-03	Geiges Jr.	
	6	5908429		1999-06-01	Yoon	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Receipt date: 04/29/2011	Application Number	11813695	11813695 - GAU: 3773
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2007-07-11	
	First Named Inventor	Giovanni Speziali	
	Art Unit	3773	
	Examiner Name	Christopher L. Templeton	
	Attorney Docket Number	630666.00074	

	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Christopher Templeton/	Date Considered	06/26/2012

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	277	600/160,182.ccls. and @ad<="20050121" and (fiber optic$1 or fiberoptic$1)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 15:13
L3	170	600/160,182.ccls. and @ad<="20050121" and (fiber optic$1 or fiberoptic$1) and reflect$3	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 15:15
L4	2	(("20020099389") or ("6936054")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/06/26 15:19
L5	0	"5785658".pn. and no tissue	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 15:33
L6	1	"5785658".pn. and tissue	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 15:33
L7	0	"5785658".pn. and doesn't same tissue	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 15:47
L8	1	"5785658".pn. and no same tissue	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 15:47
L9	1	"5785658".pn. and detect same tissue	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 15:48
L10	0	"5785658".pn. and lack same tissue	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 15:50
L16	9	speziali, giovanni.in.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 16:07
L17	1	"7666204".pn.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 16:31
L18	9	(("6936054") or ("7118583") or ("6893448") or ("5312423") or ("7122040") or ("4373530") or ("7063715") or ("5336231") or ("7063710")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/06/26 16:38

S169	1	"7666204".pn.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 10:43
S170	1	"6626917".pn.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 10:46
S171	915	@ad<="20060119" and fiber optic$1 and (heart valve$1 or leaflet$1)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 10:51
S172	16	@ad<="20060119" and fiber optic$1 same (heart valve$1 or leaflet$1)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 10:51
S173	1	"6178346".pn.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 10:58
S174	99	@ad<="20060119" and fiber optic$1 and (heart valve$1 or leaflet$1) and grasp	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 11:00
S175	3	(("7967842") or ("20040153122") or ("20080033459")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/06/25 11:14
S176	4	(("7967842") or ("20040153122") or ("20080033459") or ("5141520")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/06/25 11:22
S177	95	(US-20040225300-$ or US-20070112425-$ or US-20050021057-$ or US-20030105519-$ or US-20090088837-$ or US-20100042147-$ or US-20100023118-$ or US-20040143323-$ or US-20040210303-$ or US-20030078653-$ or US-20050075727-$ or US-20060167541-$ or US-20060100698-$ or US-20100030242-$ or US-20090198324-$ or US-20050021056-$ or US-20080243150-$ or US-20070049952-$ or US-20090043153-$ or US-20040044365-$ or US-20010005787-$ or US-20060287716-$ or US-20030120341-$ or US-20070118154-$ or US-20070118213-$ or US-20050070999-$).did. or (US-20080228223-$ or US-20040024414-$ or US-20030078600-$ or US-20050216039-$ or US-20040122448-$ or US-20020099389-$ or US-20100022823-$ or US-20070197858-$ or US-20030032979-$ or US-20040133063-$ or US-20070299468-$ or US-20070112422-$ or US-20050149093-$ or US-20030195529-$ or US-20030065338-$ or US-20060095025-$).did. or (US-6997950-$	US-PGPUB; USPAT; DERWENT	ADJ	OFF	2012/06/25 11:25

		or US-6358277-$ or US-4960424-$ or US-7513908-$ or US-6332893-$ or US-6074417-$ or US-6797002-$ or US-6840246-$ or US-6978176-$ or US-7563273-$ or US-7431692-$ or US-6746471-$ or US-7527647-$ or US-6149660-$ or US-5908428-$ or US-5059201-$ or US-6936054-$ or US-7118583-$ or US-6893448-$ or US-5312423-$ or US-4493323-$ or US-5522820-$ or US-6702835-$ or US-6743239-$ or US-5810847-$ or US-7559936-$).did. or (US-7794474-$ or US-6260552-$ or US-5762613-$ or US-5891160-$ or US-6464707-$ or US-7063710-$ or US-6991635-$ or US-6551330-$ or US-6575971-$ or US-5316479-$ or US-5836894-$ or US-7338434-$ or US-7083571-$ or US-6626917-$ or US-5609598-$ or US-6178346-$).did. or (US-20040143323-$ or US-20030105519-$ or WO-02102237-$ or WO-2006089236-$ or US-20040210303-$ or WO-03037227-$ or US-20020161378-$ or WO-03049619-$ or US-7635386-$ or WO-9829041-$).did.				
S178	25	S177 and fiber optic$1	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 11:25
S179	28	("20050203562" | "5762613" | "6419626" | "7306559" | "6010516" | "6796939" | "5879289" | "5336232" | "6558333" | "6711429" | "5667473" | "6882875" | "5785658" | "20050033556" | "6129683" | "20040054270" | "20060235279" | "5941822" | "5674230" | "6324418" | "7310547" | "7615002" | "20070078484" | "6226543" | "20060161055" | "5569300" | "5800350" | "5772597").PN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 11:35
S180	5	(("6419626") or ("20040044365") or ("5336229") or ("6936054") or ("5059201")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/06/25 11:42
S181	1408	600/101-183.ccls. and @ad<="20060119" and (fiber optic$1)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 11:44
S182	26	600/101-183.ccls. and @ad<="20060119" and (fiber optic$1) and (heart valve$1 or leaflet$1)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 11:45
S183	1	"5785658".pn.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 12:04
S184	1	"6419626".pn.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 12:06

S185	118	606/205-211.ccls. and @ad<="20060119" and (fiber optic$1)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 12:09
S186	5	606/205-211.ccls. and @ad<="20060119" and (fiber optic$1) and (heart valve$1 or leaflet$1)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 12:10
S187	26	600/101-183.ccls. and @ad<="20060119" and (fiber optic$1) and (heart valve$1 or leaflet$1)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 12:14
S188	171	"600".clas. and @ad<="20060119" and (fiber optic$1) and (heart valve$1 or leaflet$1)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 12:34
S189	50	128/898.ccls. and @ad<="20060119" and (fiber optic$1) and (heart valve$1 or leaflet$1)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 12:48
S190	16	606/139,144,145.ccls. and @ad<="20060119" and (fiber optic$1) and (heart valve$1 or leaflet$1)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 12:51
S191	102	(US-20040225300-$ or US-20070112425-$ or US-20050021057-$ or US-20030105519-$ or US-20090088837-$ or US-20100042147-$ or US-20100023118-$ or US-20040143323-$ or US-20040210303-$ or US-20030078653-$ or US-20050075727-$ or US-20060167541-$ or US-20060100698-$ or US-20100030242-$ or US-20090198324-$ or US-20050021056-$ or US-20080243150-$ or US-20070049952-$ or US-20090043153-$ or US-20040044365-$ or US-20010005787-$ or US-20060287716-$ or US-20030120341-$ or US-20070118154-$ or US-20070118213-$ or US-20050070999-$).did. or (US-20080228223-$ or US-20040024414-$ or US-20030078600-$ or US-20050216039-$ or US-20040122448-$ or US-20020099389-$ or US-20100022823-$ or US-20070197858-$ or US-20030032979-$ or US-20040133063-$ or US-20070299468-$ or US-20070112422-$ or US-20050149093-$ or US-20030195529-$ or US-20030065338-$ or US-20060095025-$ or US-20040138531-$).did. or (US-6997950-$ or US-6358277-$ or US-4960424-$ or US-7513908-$ or US-6332893-$ or US-6074417-$ or US-6797002-$ or US-6840246-$ or US-6978176-$ or US-7563273-$ or US-7431692-$ or US-6746471-$ or US-7527647-$ or US-6149660-$ or US-5908428-$ or US-5059201-$ or US-	US-PGPUB; USPAT; DERWENT	ADJ	OFF	2012/06/25 13:46

		7118583-$ or US-6893448-$ or US-5312423-$ or US-4493323-$ or US-5522820-$ or US-6702835-$ or US-6743239-$ or US-5810847-$ or US-7559936-$).did. or (US-7794474-$ or US-6260552-$ or US-5762613-$ or US-5891160-$ or US-6464707-$ or US-7063710-$ or US-6991635-$ or US-6551330-$ or US-6575971-$ or US-5316479-$ or US-5836894-$ or US-7338434-$ or US-7083571-$ or US-6626917-$ or US-5609598-$ or US-6178346-$ or US-5336229-$ or US-6419626-$ or US-5593405-$ or US-5785658-$ or US-5772597-$ or US-6129683-$).did. or (US-20040143323-$ or US-20030105519-$ or WO-02102237-$ or WO-2006089236-$ or US-20040210303-$ or WO-03037227-$ or US-20020161378-$ or WO-03049619-$ or US-7635386-$ or WO-9829041-$).did.				
S192	31	S191 and fiber optic$1	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 13:46
S193	1408	600/101-183.ccls. and @ad<="20060119" and (fiber optic$1)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 14:11
S194	1006	600/101-183.ccls. and @ad<="20060119" and (fiber optic$1) same light	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 14:37
S195	0	600/101-183.ccls. and @ad<="20060119" and (fiber optic$1) same light same relect	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 14:37
S196	0	600/101-183.ccls. and @ad<="20060119" and (fiber optic$1) same light same relect$3	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 14:37
S197	114	("3938502" | "4224929" | "4418689" | "4470407" | "4539588" | "4621284" | "4685451" | "4917097" | "5147354" | "5400791" | "5445157" | "5517997" | "5690605" | "5769076" | "5865829" | "5876121" | "5879306" | "5919132" | "5931789" | "5983120" | "5997472").PN. OR ("6178346").URPN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 14:47
S198	60	S197 and fiber optic$1	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 14:47
S199	60	S197 and fiber optic$1 and light	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 14:51
S200	12	fiber optic$1 same light same relect$3	US-PGPUB; USPAT;	ADJ	OFF	2012/06/25 14:56

			USOCR			
S201	16338	fiber optic$1 same light same reflect$3	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 14:57
S202	11487	fiber optic$1 same light same reflect$3 and @ad<="20060119"	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 14:57
S203	129	fiber optic$1 same light same reflect$3 same (valve or leaflet)and @ad<="20060119"	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 14:58
S204	1	"600".clas. and fiber optic$1 same light same reflect$3 same (valve or leaflet)and @ad<="20060119"	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 15:00
S205	900	"600".clas. and fiber optic$1 same light same reflect$3 and @ad<="20060119"	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 15:00
S206	3	"600".clas. and fiber optic$1 same light same reflect$3 same sensor fiber and @ad<="20060119"	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 15:00
S207	89	("4784150" | "4975581" | "4981138" | "5199431" | "5348018").PN. OR ("5785658").URPN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/25 15:42
S209	6	(("4957498") or ("5304185") or ("5431666") or ("5336229") or ("5830231") or ("5908429")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/06/26 07:53
S210	1	S209 and fiber optic$1	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 07:54
S211	54	("6149660" | "5762613" | "4960424" | "6997950" | "20040044365" | "6165119" | "3667474" | "5059201" | "6022360" | "6177144" | "6245079" | "20010005787" | "6978176" | "7666204" | "5431666" | "5667472" | "5693091" | "6050936" | "6234995" | "6260552" | "6840246" | "5336229" | "5571215" | "5839639" | "6162168" | "6264602" | "20030105519" | "20030195529" | "20040122448" | "4957498" | "5304185" | "5336229" | "5452733" | "6077214" | "6183411" | "20030078600" | "4972874" | "5653716" | "5772672" | "5919128" | "5961440" | "6045497" | "6165120" | "6190357" | "6261222" | "5830231" | "5908429" | "5908428" | "3842840" | "4351345" | "5797960" | "5972030" | "6059715" | "6197052" | "6626917").PN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 07:55
S212	11	S211 and fiber optic$1	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 07:58

S213	3	S211 and fiberoptic$1	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 08:06
S214	0	S209 and fiberoptic$1	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 08:07
S215	79	606/139,144,145,205-211.ccls. and @ad<="20060119" and fiberoptic$1	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 08:07
S216	200	606/139,144,145,205-211.ccls. and @ad<="20060119" and fiber optic$1	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 08:07
S217	181	S216 not S215	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 08:22
S218	814	606/15,16.ccls. and @ad<="20060119" and (fiberoptic$1 or fiber optic$1)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 08:23
S219	174	606/15,16.ccls. and @ad<="20060119" and (fiberoptic$1 or fiber optic$1) and reflect	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 08:23
S220	471	606/15,16.ccls. and @ad<="20060119" and (fiberoptic$1 or fiber optic$1) and reflect$3	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 08:23
S221	34	606/15,16.ccls. and @ad<="20060119" and (fiberoptic$1 or fiber optic$1) and reflect$3 and (forceps or grasp)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 08:23
S222	2	"11813695" and papillary muscle	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 10:07
S223	2	"20050021056"	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 11:09
S224	82	2001/0005787	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 11:12
S225	1	"20010005787"	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 11:12
S226	1	"20030105519"	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 11:14
S227	1	"6978176".pn. and trocar	US-PGPUB; USPAT;	ADJ	OFF	2012/06/26 11:37

			USOCR			
S228	1	"6978176".pn. and rigid	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 11:47
S229	0	"20040044365".pn. and rigid	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 11:50
S230	0	"20040044365" and rigid	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 11:50
S231	111	(US-20040225300-$ or US-20070112425-$ or US-20050021057-$ or US-20030105519-$ or US-20090088837-$ or US-20100042147-$ or US-20100023118-$ or US-20040143323-$ or US-20040210303-$ or US-20030078653-$ or US-20050075727-$ or US-20060167541-$ or US-20060100698-$ or US-20100030242-$ or US-20090198324-$ or US-20050021056-$ or US-20080243150-$ or US-20070049952-$ or US-20090043153-$ or US-20040044365-$ or US-20010005787-$ or US-20060287716-$ or US-20030120341-$ or US-20070118154-$ or US-20070118213-$ or US-20050070999-$).did. or (US-20080228223-$ or US-20040024414-$ or US-20030078600-$ or US-20050216039-$ or US-20040122448-$ or US-20020099389-$ or US-20100022823-$ or US-20070197858-$ or US-20030032979-$ or US-20040133063-$ or US-20070299468-$ or US-20070112422-$ or US-20050149093-$ or US-20030195529-$ or US-20030065338-$ or US-20060095025-$ or US-20040138531-$ or US-20080188873-$).did. or (US-6997950-$ or US-6358277-$ or US-4960424-$ or US-7513908-$ or US-6332893-$ or US-6074417-$ or US-6797002-$ or US-6840246-$ or US-6978176-$ or US-7563273-$ or US-7431692-$ or US-6746471-$ or US-7527647-$ or US-6149660-$ or US-5908428-$ or US-5059201-$ or US-6936054-$ or US-7118583-$ or US-6893448-$ or US-5312423-$ or US-4493323-$ or US-5522820-$ or US-6702835-$ or US-6743239-$ or US-5810847-$ or US-7559936-$).did. or (US-7794474-$ or US-6260552-$ or US-5762613-$ or US-5891160-$ or US-6464707-$ or US-7063710-$ or US-6991635-$ or US-6551330-$ or US-6575971-$ or US-5316479-$ or US-5836894-$ or US-7338434-$ or US-7083571-$ or US-	US-PGPUB; USPAT; DERWENT	ADJ	OFF	2012/06/26 12:05

		5609598-$ or US-6178346-$ or US-5336229-$ or US-6419626-$ or US-5593405-$ or US-5785658-$ or US-5772597-$ or US-6129683-$ or US-5730702-$ or US-8118206-$ or US-5908429-$ or US-5667472-$ or US-4759348-$).did. or (US-6730076-$ or US-7235089-$ or US-5441507-$).did. or (US-20040143323-$ or US-20030105519-$ or WO-02102237-$ or WO-2006089236-$ or US-20040210303-$ or WO-03037227-$ or US-20020161378-$ or WO-03049619-$ or US-7635386-$ or WO-9829041-$).did.				
S232	58	S231 and rigid	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 12:05
S233	306	606/144,145.ccls. and @ad<="20050121" and rigid	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 13:25
S234	706	606/139,144,145.ccls. and @ad<="20050121" and rigid	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 13:25
S235	247	606/139,144,145.ccls. and @ad<="20050121" and rigid same (metal or steel)	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 13:26
S236	180	606/139,144,145.ccls. and @ad<="20050121" and rigid same (metal or steel) and needle and suture	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 13:26
S237	0	"20050154402" and chest	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 13:32
S238	0	"20050154402" and heart	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 13:32
S239	2	"20050154402" and valve	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/06/26 13:32
S240	2	(("7666204") or ("6626917")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/06/26 13:45

EAST Search History (Interference)

<This search history is empty>

6/26/2012 4:39:58 PM
C:\Users\ctempleton\Documents\EAST\Workspaces\11813695.wsp

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11813695	SPEZIALI, GIOVANNI
	Examiner	**Art Unit**
	CHRISTOPHER L TEMPLETON	3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/15/2010	04/07/2010	11/09/2010	06/26/2012					
	1	÷	✓	✓	✓					
	2	÷	✓	✓	✓					
	3	÷	✓	✓	✓					
	4	÷	✓	✓	✓					
	5	÷	✓	✓	✓					
	6	÷	✓	✓	✓					
	7	÷	-	-	-					
	8	÷	-	-	-					
	9	÷	-	-	-					
	10	÷	-	-	-					
	11	÷	-	-	-					
	12	÷	-	-	-					
	13	÷	-	-	-					
	14	÷	-	-	-					
	15	÷	-	-	-					
	16	÷	-	-	-					
	17	÷	-	-	-					
	18			✓	✓					
	19			✓	✓					
	20			✓	✓					
	21			✓	✓					
	22			✓	✓					
	23			✓	✓					
	24			✓	✓					
	25			✓	✓					
	26			✓	✓					
	27			✓	✓					
	28			✓	✓					
	29			✓	✓					
	30			✓	✓					
	31			✓	✓					

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11813695
Filing Date	2007-07-11
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher L. Templeton
Attorney Docket Number	630666.00074

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4957498		1990-09-18	Caspari et al.	
	2	5304185		1994-04-19	Taylor	
	3	5431666		1995-07-11	Sauer et al.	
	4	5336229		1994-08-09	Noda	
	5	5830231		1998-11-03	Geiges Jr.	
	6	5908429		1999-06-01	Yoon	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11813695
	Filing Date	2007-07-11
	First Named Inventor	Giovanni Speziali
	Art Unit	3773
	Examiner Name	Christopher L. Templeton
	Attorney Docket Number	630666.00074

	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11813695
	Filing Date	2007-07-11
	First Named Inventor	Giovanni Speziali
	Art Unit	3773
	Examiner Name	Christopher L. Templeton
	Attorney Docket Number	630666.00074

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2011-04-29
Name/Print	Richard T. Roche	Registration Number	38599

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	9990608
Application Number:	11813695
International Application Number:	
Confirmation Number:	6073
Title of Invention:	Thorascopic Heart Valve Repair Method and Apparatus
First Named Inventor/Applicant Name:	Giovanni Speziali
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	630666.00074
Receipt Date:	29-APR-2011
Filing Date:	11-JUL-2007
Time Stamp:	17:05:50
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed (SB/08)	Mayo_00074-Supp-IDS-3.pdf	612419 69dd0225d98cd8e0099df351881807d01ccfdc16	no	4

Warnings:	
Information:	

Total Files Size (in bytes):	612419

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	11813695	Filing Date	2007-07-11	Docket Number (if applicable)	630666.00074	Art Unit	3773
First Named Inventor	Giovanni Speziali			Examiner Name	Christopher L. Templeton		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☐ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 170055

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Richard T Roche/	Date (YYYY-MM-DD)	2011-02-21
Name	Richard T Roche	Registration Number	38599

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 630666.00074
Giovanni Speziali	Confirmation No.: 6073
Application No.: 11/813,695	Examiner: Christopher L. Templeton
Filed: July 11, 2007	Group Art Unit: 3773

For: THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

AMENDMENT AND RESPONSE

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INTRODUCTORY COMMENTS

In response to the Office Action of November 22, 2010, and in conjunction with the Request for Continued Examination filed herewith, amendment to the above-identified patent application is requested.

The present amendment comprises the following sections:

A. Amendments to the Claims

B. Remarks

AMENDMENTS TO THE CLAIMS

A detailed listing of all claims that are, or were, in the present application, irrespective of whether the claim(s) remain(s) under examination in the application is presented below. The claims are presented in ascending order and each includes one status identifier. Those claims not cancelled or withdrawn but amended by the current amendment utilize the following notations for amendment: 1. deleted matter is shown by strikethrough for six or more characters and double brackets for five or fewer characters; and 2. added matter is shown by underlining.

1. (Currently Amended) A method of repairing a heart valve in a patient with an instrument having a distal end and a movable element, the method comprising:

inserting the instrument through the patient's chest wall and into the patient's chest cavity;

inserting the distal end and the movable element of the instrument through an exterior heart wall;

grasping a single leaflet on the heart valve between the movable element and the distal end of the instrument;

confirming capture of the leaflet between the movable element and the distal end using a fiber optic visualization system that detects light reflected off of the leaflet when the leaflet is properly positioned between the movable element and the distal end;

puncturing the leaflet with a needle disposed on the distal end of the instrument to form a puncture opening and drawing a suture through the puncture opening to connect the suture to the leaflet;

capturing the suture with the needle;

anchoring the suture to another structure in the heart;

withdrawing the instrument through the heart wall; and

withdrawing the instrument from the chest cavity.

2. (Previously Presented) The method of claim 1, wherein the step of anchoring the suture includes withdrawing the suture with the instrument through the heart wall and anchoring the suture to the outer surface of the heart wall.

3. (Previously Presented) The method of claim 2, further comprising adjusting the tension on the suture before anchoring the suture by observing operation of the heart valve using a medical imaging system.

4. (Previously Presented) The method of claim 1, further comprising placing a purse-string suture in the heart wall around the location of the instrument insertion.

5. (Previously Presented) The method of claim 1, wherein inserting the distal end and the movable element of the instrument through a heart wall comprises inserting the distal end the movable element of the instrument transapically.

6. (Previously Presented) The method of claim 5, wherein the step of anchoring the suture includes withdrawing the suture with the instrument through the heart wall and anchoring the suture to an outer surface of the heart wall near the heart's apex.

7-17. (Canceled).

18. (Previously Presented) The method of claim 1, wherein the another structure is the heart wall.

19. (Previously Presented) The method of claim 1, wherein the another structure is a papillary muscle.

20. (Previously Presented) The method of claim 1, wherein the another structure is not a valve leaflet.

21. (Previously Presented) The method of claim 1, wherein the step of inserting an instrument through the patient's chest wall comprises inserting a rigid metal shaft through the patient's chest wall.

22. (Currently Amended) The method of claim 1, ~~further comprising~~ wherein confirming capture of the leaflet between the distal end and the movable element using a fiber optic visualization system includes using a fiber optic visualization system having at least one illumination fiber optic that provides the light and at least one sensor fiber optic that conveys the reflected light from the distal end.

23. (Currently Amended) The method of claim 22, wherein the ~~step of confirming capture of the leaflet includes using a~~ fiber optic visualization system includes a plurality of illumination fiber optics and a plurality of sensor fiber optics.

24. (Currently Amended) A method of confirming capture of a valve leaflet of a patient's heart, the method comprising:

providing an instrument having[[e]] a distal end, a movable element ~~reversibly, distally shiftable~~ movable with respect to the distal end, and an at least one illuminating fiber in optical communication with a visualization monitor and an exposed surface of the distal end;

inserting the instrument through the patient's chest wall and into the patient's chest cavity;

grasping the leaflet on the heart valve between the movable element and the distal end of the instrument; and

conveying a color to the visualization~~ing~~ monitor corresponding to a capture status of the leaflet, wherein when the capture status of the leaflet is positive, light is reflected off of the leaflet to the visualization monitor.

25. (Currently Amended) The method of claim 24, wherein the color is substantially red when the capture status of the leaflet is negative and substantially white when the capture status of the leaflet is positive due to the light from the illuminating fiber being reflected off of the leaflet and conveyed back to the visualization monitor by a sensor fiber optic.

26. (Previously Presented) The method of claim 24, wherein the instrument includes a plurality of geometrically arranged illuminating fibers in optical communication with the visualization monitor and an exposed surface of the distal end.

27. (Currently Amended) A method, comprising:

providing an instrument having a distal end, a movable element and a needle disposed on the distal end; and

providing instructions for repairing a heart valve of a patient with the instrument, the instructions comprising:

inserting the instrument through the patient's chest wall and into the patient's chest cavity;

inserting the distal end and the movable element of the instrument through an exterior heart wall;

grasping a single leaflet on the heart valve between the movable element and the distal end of the instrument;

confirming capture of the leaflet between the movable element and the distal end using a fiber optic visualization system that detects light reflected off of the leaflet when the leaflet is properly positioned between the movable element and the distal end;

puncturing the leaflet with the needle of the instrument to form a puncture opening and drawing a suture through the puncture opening to connect the suture to the leaflet;

capturing the suture with the needle;

anchoring the suture to another structure in the heart;

withdrawing the instrument through the heart wall; and

withdrawing the instrument from the chest cavity.

28. (Previously Presented) The method of claim 27, wherein the step of anchoring the suture includes withdrawing the suture with the instrument through the heart wall and anchoring the suture to the outer surface of the heart wall.

29. (Previously Presented) The method of claim 28, wherein the instructions further comprising adjusting the tension on the suture before anchoring the suture by observing operation of the heart valve using a medical imaging system.

30. (Currently Amended) The method of claim 27, wherein ~~the instructions further comprise~~ confirming capture of the leaflet between the distal end and the movable element using a fiber optic visualization system includes using a fiber optic visualization system having at least one illumination fiber that provides the light and at least one sensor fiber that conveys the reflected light from the distal end.

31. (Currently Amended) The method of claim 30, wherein the ~~step of confirming capture of the leaflet includes using a~~ fiber optic visualization system includes a plurality of illumination fiber optics and a plurality of sensor fiber optics.

REMARKS

Claims 1-6 and 18-31 are pending. By this Amendment, claims 1, 22-25, 27 and 30-31 are amended. Support for the amendments can be found through the specification. No new matter has been added.

Claim Objections

Claim 24 stands objected to because the Office Action contends the word "have" should be amended to "having" in line 3 of the claim. By this Amendment, the claim has been amended as suggested in the Office Action. It is therefore respectfully requested that this objection be withdrawn.

Claim Rejections – 35 U.S.C. § 112

Claims 24-26 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action contends that it is unclear what is mean in claim 24 by the movable element being "reversibly, distally shiftable." Although Applicants do not acquiesce in this rejection, the limitation has been canceled in this amendment solely to advance prosecution. It is therefore respectfully requested that this rejection be withdrawn.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 2, 5, 6, 18, 20, 27 and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S. Publication No.

2004/0044365). Claims 3 and 29 stand rejected as being unpatentable over Lattouf in view of Bachman and further in view of St. Goar et al (U.S. Publication No. 2005/0021056). Claim 4 stands rejected as unpatentable over Lattouf in view of Bachman further in view of Oz et al. (U.S. Publication No. 2001/0005787). Claim 19 stands rejected as unpatentable over Lattouf in view of Backman and further in view of Fasol et al. (U.S. Publication No. 2003/0105519). Claims 22, 23, 30 and 31 stand rejected as being unpatentable over Lattouf in view of Bachman and further in view of Levine (U.S. Publication No. 2004/0122448). Claim 21 stands rejected as unpatentable over Lattouf in view of Bachman further in view of Takamoto (U.S. Publication No. 2003/0195529). These rejections are respectfully traversed.

Independent claims 1 and 27 have been amended to recite that the methods include confirming capture of the leaflet using a fiber optic visualization system that detects light reflected off of a leaflet when the leaflet is properly positioned between the movable element and the distal end. The Office Action cites Levine as teaching confirming capture of leaflets using a fiber optic system. However, Levine contains only a general reference to use of fiber optics as one type of imaging that can be used to monitor effectiveness of the procedure. Levine does not teach or suggest confirming capture of a leaflet by detecting light reflected off of the leaflet. In addition, none of the other cited references teach or suggest this limitation. It is therefore respectfully requested that the rejection of independent claims 1 and 27, as amended, be withdrawn.

With regard to claims 2-6, 18-21 and 23 depending from claim 1 and claims 28-29 and 31 depending from claim 27, it is respectfully submitted that these claims are allowable because the underlying base claims are allowable, although Applicant does not acquiesce in the positions set

forth in the Office Action and reserves the right to make additional arguments with respect to these claims. As such, Applicant respectfully requests withdrawal of these rejections.

Claims 24-26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Thornton et al (U.S. Patent No. 7,666,204) in view of Craig (U.S. Patent No. 6,626,917). This rejection is respectfully traversed.

Independent claim 24 has been amended to clarify that conveying a color to the visualization monitor corresponding to a capture status of the leaflet includes that when the capture status of the leaflet is positive, light is reflected off of the leaflet to the visualization monitor. The cited references do not teach or suggest this limitation as amended.

The Office Action admits that Thornton does not disclose use of a fiber optic imaging system to confirm leaflet capture and cites to Craig as teaching use of a fiber optic system. However, Craig only teaches use of fiber optics to enhance visualization of a confined space in which a suturing operation is performed. Craig does not teach or suggest receiving a positive capture status of a leaflet by receiving light that is reflected off of the leaflet to the visualization monitor. It is therefore respectfully requested that this rejection be withdrawn.

With regard to claims 25 and 26 depending from claim 24, it is respectfully submitted that these claims are allowable because the underlying base claim is allowable, although Applicant does not acquiesce in the positions set forth in the Office Action and reserves the right to make additional arguments with respect to these claims. As such, Applicant respectfully requests withdrawal of these rejections.

Conclusion

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

Giovanni Speziali

Dated: February 21, 2011

/Richard T. Roche/

Richard T. Roche
Registration No. 38,599
Quarles and Brady LLP
411 East Wisconsin Ave.
Milwaukee, WI 53202
(414) 277-5805

QB\12580239.1

Electronic Patent Application Fee Transmittal

Application Number:	11813695
Filing Date:	11-Jul-2007
Title of Invention:	Thorascopic Heart Valve Repair Method and Apparatus
First Named Inventor/Applicant Name:	Giovanni Speziali
Filer:	Richard T. Roche
Attorney Docket Number:	630666.00074

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	2801	1	405	405
		Total in USD ($)		**405**

Electronic Acknowledgement Receipt

EFS ID:	9486172
Application Number:	11813695
International Application Number:	
Confirmation Number:	6073
Title of Invention:	Thorascopic Heart Valve Repair Method and Apparatus
First Named Inventor/Applicant Name:	Giovanni Speziali
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	630666.00074
Receipt Date:	21-FEB-2011
Filing Date:	11-JUL-2007
Time Stamp:	17:21:44
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$405
RAM confirmation Number	10245
Deposit Account	170055
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	mayo_74_rce.pdf	33436 ce33e1ef5791b6af0dc25fd2ce590de7d2702c66	no	2
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
2	Amendment Submitted/Entered with Filing of CPA/RCE	mayo_74_response.pdf	990050 622e71e47d3ed90c3d9f09316bc1623876a91843	no	12
Warnings:					
Information:					
3	Fee Worksheet (PTO-875)	fee-info.pdf	29993 75ca3b03c4332ff6379106628a53f7dd0b137b88	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1053479		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11813695	07/11/07	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☐ RATE ($)	SMALL ENTITY ☐ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
			TOTAL			TOTAL	

* If the difference in column 1 is less than zero, enter "0" in column 2.

APPLICATION AS AMENDED – PART II

AMENDMENT 2/21/11 (2/22)

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $26 =		OR	X $52=	
Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0	X $110 =		OR	X $220=	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
① 77 (20) (27) 31					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/LISA FULTON/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/813,695	07/11/2007	Giovanni Speziali	630666.00074	6073

26710 7590 11/22/2010

QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI 53202-4497

EXAMINER	
TEMPLETON, CHRISTOPHER L	
ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
11/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Office Action Summary	Application No.	Applicant(s)	
	11/813,695	SPEZIALI, GIOVANNI	
	Examiner	Art Unit	
	CHRISTOPHER L. TEMPLETON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 18-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 18-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/11/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment

This office action is responsive to the amendment filed on 3 September 2010. As directed by the amendment: claims 1-6 have been amended, claims 7-17 have been cancelled and new claims 18-31 have been added. Thus, claims 1-6 and 18-31 are presently pending in this application.

Claim Objections

1. Claim 24 is objected to because of the following informality: The word “have” should be changed to "having” in line 3 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant in claim 24 by the movable element being “reversibly, distally shiftable".

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 2, 5, 6, 18, 20, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S. Publication No. 2004/0044365).

6. As to claims 1, 2, 5, 6, 18 and 20, Lattouf discloses the claimed method of repairing a heart valve in a patient, the method comprised of inserting an instrument through the patient's chest wall and into the patient's chest cavity (column 2, lines 34-42); inserting the distal end of the instrument through a heart wall and entering a heart chamber through the apex of the heart, transapically (column 3, line 45-column 4, line 5); withdrawing the suture with the instrument through the heart wall and anchoring the suture to the outer surface of the heart wall implicitly near the apex of the heart (column 3, line 45-column 4, line 5), and withdrawing the instrument from the chest cavity. Lattouf does not expressly disclose the steps of grasping a single leaflet between a movable element and a distal end of the instrument, and capturing the suture with the needle or puncturing the leaflet with a needle.

Bachman teaches the steps of grasping a single leaflet on a heart valve between a movable element and the distal end of an instrument (Figure 11; paragraphs 42 and 43), puncturing the leaflet with a needle disposed on the distal end of the instrument and the step of capturing (taking control of) the suture with the needle (paragraph 42).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and device of Lattouf to include the instrument with a movable element and needle at the distal end, as taught by Bachman, for the purpose of applying a suture quickly and stably with the needle and grasping

portion (abstract; paragraphs 10 and 13), providing improved tissue stabilization and enhanced placement of a fastening device, and minimizing trauma to the patient before, during and after surgery (paragraph 30).

7. As to claims 27 and 28, Lattouf discloses the claimed method of providing an instrument and providing instructions for repairing a heart valve of a patient with the instrument, the instructions comprised of inserting an instrument through the patient's chest wall and into the patient's chest cavity (column 2, lines 34-42); inserting the distal end of the instrument through a heart wall and entering a heart chamber through the apex of the heart, transapically (column 3, line 45-column 4, line 5); anchoring the suture to another structure in the heart; withdrawing the suture with the instrument through the heart wall and anchoring the suture to the outer surface of the heart wall implicitly near the apex of the heart (column 3, line 45-column 4, line 5), and withdrawing the instrument from the chest cavity. Lattouf does not expressly disclose the steps of providing an instrument having a movable element and a needle; grasping a single leaflet between a movable element and a distal end of the instrument, capturing the suture with the needle or puncturing the leaflet with a needle or puncturing the leaflet with a needle of the instrument.

Bachman teaches the steps of providing an instrument having a distal end, a movable element and a needle; grasping a single leaflet (Figure 11; paragraphs 42 and 43) on a heart valve between a movable element and the distal end of the instrument and puncturing the leaflet with a needle disposed on the distal end of the instrument and capturing (taking control of) the suture with the needle (paragraph 42).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lattouf to include the instrument with a movable element at the distal end and a needle, as taught by Bachman, for the purpose of applying a suture quickly and stably with the needle and grasping portion (abstract; paragraphs 10 and 13), providing improved tissue stabilization and enhanced placement of a fastening device with the grasping portion, and minimizing trauma to the patient before, during and after surgery (paragraph 30).

8. Claims 3 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S. Publication No. 2004/0044365) and further in view of St. Goar et al (U.S. Publication No. 2005/0021056). Lattouf/Bachman disclose the claimed invention but are silent on the step of adjusting the tension on the suture by observing the operation of the heart valve using a medical imaging system. St. Goar teaches the step of adjusting the tension on a suture by observing the operation of the heart valve using a medical imaging system (paragraph 24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lattouf/Bachman to include the step of adjusting the tension on the suture by observing the operation of the heart valve using a medical imaging system, as taught by St. Goar, for the purpose of ensuring the absence of regurgitation by monitoring the valve with an imaging system in order to position the leaflet in the right position.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S. Publication No. 2004/0044365)

and further in view of Oz et al (U.S. Publication No. 2001/0005787). Lattouf/Bachman disclose the claimed invention but are silent on the step of placing a purse-string suture in the heart wall around the location of the instrument. Oz teaches placing a purse-string suture in the heart wall around the location of an instrument in order to control bleeding (Figure 1; paragraphs 68, 71). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lattouf/Bachman to include the step of placing a purse-string suture in the heart around the location of the instrument, as taught by Oz, for the purpose of controlling bleeding around the instrument.

10. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S. Publication No. 2004/0044365) and further in view of Fasol et al (U.S. Publication No. 2003/0105519). Lattouf/Bachman disclose the claimed invention except for anchoring the suture to the papillary muscle. Fasol teaches that it was old and well known in the art to attach a suture to the heart valve and then to the papillary muscle (Figures 8-9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lattouf/Bachman to include the step of attaching the suture to the papillary muscle, as taught by Fasol, in order to prevent regurgitation. Moreover, paragraph 10 of applicant's specification teaches that attaching a suture to the valve and then to the papillary muscle was a common technique known in the art.

11. Claims 22, 23, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S.

Publication No. 2004/0044365) and further in view of Levine (U.S. Publication No. 2004/0122448). Lattouf/Bachman disclose the claimed invention but are silent on confirming capture of the leaflet by fiber optic visualization. Levine teaches confirming capture of leaflets (paragraphs 14 and 15). Levine also teaches confirming capture of leaflets using a fiber optic system in order to facilitate proper positioning of the grasping elements and/or monitoring of effectiveness of the procedure (paragraph 15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lattouf/Bachman to include the steps of monitoring capture of the leaflets by using a fiber optic system, as taught by Levine, for the purpose of providing proper positioning of the grasping elements and/or monitoring of effectiveness of the procedure through fiber optics.

12. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S. Publication No. 2004/0044365) and further in view of Takamoto et al (U.S. Publication No. 2003/0195529). Lattouf implicitly discloses the step of inserting a rigid instrument through the patient's chest wall (Applicant's arguments page 12, line 6 also discloses that Lattouf teaches inserting a rigid instrument through the patient's chest wall). Lattouf does not expressly disclose the instrument as being metal. Bachman teaches that it was old and well known in the art to make suturing instruments out of metal (paragraph 31). Lattouf/Bachman do not expressly disclose inserting a rigid metal shaft through the patient's chest wall. Takamoto teaches inserting a rigid metal shaft through a patient's chest wall (paragraphs 16 and 59 teach inserting a shaft through a patient's chest wall)

(paragraphs 40-49 teach that it was well known in the art to have a suturing instrument, with a movable element at the distal end of the instrument, made of a rigid metal). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Lattouf/Bachman and make the instrument out of rigid metal and insert it through the patient's chest wall, as taught by Takamoto, since it was old and well known in the art to make suturing instruments out of rigid metal for insertion through a patient's chest wall. It also would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Lattouf/Bachman and make the instrument out of rigid metal and insert it through the patient's chest wall, as taught by Takamoto, in order to treat intracardiac defects with a suturing instrument made of a rigid metal shaft so that the instrument can be inserted through a patient's chest wall without bending.

Moreover, it is also old and well known in the art to make surgical devices out of metal, plastics, or ceramics as evidenced by Bachman paragraph 31, and paragraph 40 of Takamoto; therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the device of Lattouf/Bachman out of rigid metal.

13. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thornton et al (U.S. Patent No. 7,666,204) in view of Craig (U.S. Patent No. 6,626,917).

14. As to claim 24, as best understood, Thornton discloses a method of confirming capture of a valve leaflet of a patient's heart, the method comprised of providing an instrument having a distal end; grasping a leaflet of the heart valve and conveying a

color to a visualization monitor corresponding to a capture status of the leaflet (column 19, line 55-column 20, line 15 teaches a color Doppler image showing if regurgitation of the valve has been reduced or not by conveying a color on a visualization monitor which corresponds to a capture status of the leaflet). Thornton also discloses providing an instrument having a distal end 16, a movable element 18 reversibly, distally shiftable with respect to the distal end 16, and the step of grasping the leaflet on the heart valve between the movable element 18 and the distal end of the instrument 16 (Figures 3A and B; column 19, lines 26-54), and implicitly inserting the instrument through the patent's chest wall and into the patient's chest cavity (column 4, lines 30-46 discloses inserting the instrument directly through body tissues such as in a direct access procedure to the heart). Thornton does not expressly disclose at least one illuminating fiber in optical communication with a visualization monitor.

Craig teaches a fiber optic imaging system and light in optical communication with a visualization monitor and an exposed surface of a distal end of the device in order to allow visualization of the operation in a confined space (column 14, lines 38-61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and device of Thornton to include the fiber optic imaging system, as taught by Craig, for the purpose of visualizing the operation in a confined space.

15. As to claim 25, Thornton implicitly discloses the color changing corresponding to a capture status of the leaflet. Thornton does not expressly disclose the color being

substantially red when the capture status of the leaflet is negative and substantially white when the capture status of the leaflet is positive. Thorton does implicitly teach the color changing when the capture status changes (column 19, line 55-column 20, line 15 teaches a color Doppler image showing if regurgitation of the valve has been reduced or not by conveying a color on a visualization monitor). It would have been an obvious matter of design choice to make the color change to red when the capture status of the leaflet is negative and to make the color change to white when the capture status is positive, since applicant has not disclosed that the red and white color on the visualization monitor solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the color Doppler of Thornton.

16. As to claim 26, Thornton/Craig disclose the claimed invention except of a plurality of geometrically arranged illuminating fibers in optical communication with the visualization monitor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a plurality of illuminating fibers, since it has been held that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Response to Arguments

17. Applicant's arguments filed 3 September 2010 have been fully considered but they are not persuasive. Applicant argues that there was no motivation to combine the Lattouf and Bachman references. The examiner disagrees. Lattouf discloses the

claimed method for repairing a heart valve but does not disclose a movable element that grasps a single leaflet between the movable element and the distal end of the instrument. Bachman teaches the steps of grasping a leaflet on a heart valve with an instrument comprised of a movable element on the distal end of the instrument, puncturing the leaflet with a needle disposed on the distal end of the instrument and the step of capturing the suture with the needle (paragraph 42) for the purpose of applying a suture quickly and stably with the needle and grasping portion (abstract; paragraphs 10 and 13), providing improved tissue stabilization and enhanced placement of a fastening device, and minimizing trauma to the patient before, during and after surgery (paragraph 30). Therefore one of ordinary skill in the art would modify the device of Lattouf to include the device of Bachman in order to provide improved tissue stabilization and enhanced placement of the suture- thus giving motivation to combine the references.

18. Applicant also argues that there was not a reasonable expectation of success to combine the references and arrive at the claimed method, due to the total number of different combinations of six different features of Lattouf and Bachman. The examiner again disagrees.

Lattouf discloses the claimed method steps. The method of Lattouf was modified to include the device of Bachman in order to provide improved tissue stabilization and enhanced placement of the suture. The device of Lattouf and the method of inserting the device of Bachman were not used in the rejection; therefore making the argument of the six different features moot. According to applicant's chart on page 11 of applicant's

arguments, Lattouf discloses "Access" and "Anchor Site" features which correspond to the method steps, while Bachman teaches the "Grabbing Means"/"Leaflet Capture Facilitator" (which are the same and are both taught by Bachman), "Suture Deployment" and "No. of Targeted Leaflets" features, which correspond to the device and method of using Bachman's device. One of ordinary skill in the art would modify the method of Lattouf with the device of Bachman in order to provide improved tissue stabilization and enhanced placement of the suture. Therefore, there is a reasonable expectation of success for arriving at the claimed invention, since only the device of Lattouf was modified in the rejection.

19. Applicant also argues that the delivery system of Lattouf would create a host of unintended and potentially lethal or injurious consequences if used to penetrate a patient's septum. The examiner disagrees since penetrating a patient's septum was never claimed. Also in the rejection, the device of Lattouf was modified/replaced with the device of Bachman thus making this argument moot.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER L. TEMPLETON whose telephone number is (571) 270-1477. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie T. Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. L. T./
Examiner, Art Unit 3773

/Julian W. Woo/
Primary Examiner, Art Unit 3773

Notice of References Cited	Application/Control No. 11/813,695	Applicant(s)/Patent Under Reexamination SPEZIALI, GIOVANNI	
	Examiner CHRISTOPHER L. TEMPLETON	Art Unit 3773	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-7,666,204	02-2010	Thornton et al.	606/190
*	B	US-2003/0195529	10-2003	Takamoto et al.	606/145
*	C	US-2003/0105519	06-2003	FASOL et al.	623/2.1
*	D	US-2004/0122448	06-2004	Levine, Robert A.	606/139
*	E	US-6,626,917	09-2003	Craig, H. Randall	606/144
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11813695	SPEZIALI, GIOVANNI
	Examiner	Art Unit
	CHRISTOPHER L TEMPLETON	3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/15/2010	04/07/2010	11/09/2010						
	1	÷	✓	✓						
	2	÷	✓	✓						
	3	÷	✓	✓						
	4	÷	✓	✓						
	5	÷	✓	✓						
	6	÷	✓	✓						
	7	÷	-	-						
	8	÷	-	-						
	9	÷	-	-						
	10	÷	-	-						
	11	÷	-	-						
	12	÷	-	-						
	13	÷	-	-						
	14	÷	-	-						
	15	÷	-	-						
	16	÷	-	-						
	17	÷	-	-						
	18			✓						
	19			✓						
	20			✓						
	21			✓						
	22			✓						
	23			✓						
	24			✓						
	25			✓						
	26			✓						
	27			✓						
	28			✓						
	29			✓						
	30			✓						
	31			✓						

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11813695	SPEZIALI, GIOVANNI
	Examiner	Art Unit
	CHRISTOPHER L TEMPLETON	3773

SEARCHED

Class	Subclass	Date	Examiner
606	139, 144, 145	11/9/2010	CT
128	898	4/7/2010	CT
623	11.11, 13.11, 2.11-2.35	4/7/2010	CT
600	16, 37	4/7/2010	CT

SEARCH NOTES

Search Notes	Date	Examiner
EAST search (see attached)	11/9/2010	CT
Inventor name search	4/7/2010	CT

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S61	1	("20050021056").PN.	US-PGPUB; USPAT	OR	OFF	2010/11/08 10:17
S62	95	606/139,144,145.ccls. and @ay<="2005" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 10:31
S63	4	606/139,144,145.ccls. and @ay<="2005" and fiber optic$1 and chordae	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 10:32
S64	21	606/139,144,145.ccls. and @ay<="2005" and fiber optic$1 and heart and valve	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 11:48
S65	2	"20040122448" and sensor $1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 12:24
S66	64	sensor same grasp same monitor	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 12:29
S67	2565	sensor same grasp	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 12:32
S68	141	sensor same grasp same valve	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 12:32
S69	45547	display monitor	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 12:37
S70	4	display monitor same grasp same detect$3	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 12:37
S71	217	display monitor same detect$3 and surgery	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 12:37
S72	128	600/103.ccls.	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 12:41
S73	1232	600/109.ccls.	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 12:42
S74	790	600/109.ccls. and @ay<="2005"	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 12:43
S75	60	600/109.ccls. and @ay<="2005" and monitor and valve	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 12:43
S76	1810	@ay<="2005" and monitor and heart valve	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 12:46
S77	23	@ay<="2005" and monitor same heart valve same sensor	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 12:47

S78	39	("20030078600" | "20040044365" | "3667474" | "3842840" | "4351345" | "4972874" | "5059201" | "5336229" | "5452733" | "5571215" | "5653716" | "5693091" | "5762613" | "5772672" | "5797960" | "5839639" | "5908428" | "5919128" | "5961440" | "5972030" | "5667472" | "6022360" | "6045497" | "6050936" | "6059715" | "6077214" | "6149660" | "6162168" | "6165119" | "6165120" | "6177144" | "6183411" | "6190357" | "6197052" | "6234995" | "6245079" | "6260552" | "6261222" | "6264602").PN.	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:01
S79	7	S78 and fiber optic	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:01
S80	7	S78 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:01
S81	19	(("6269819") or ("20010016675") or ("6283993") or ("20010021872") or ("6312447") or ("6332863") or ("6332864") or ("6332893") or ("20020013571") or ("20020029080") or ("6355050") or ("20020049402") or ("6402679") or ("6402680") or ("6401720") or ("6402781") or ("6404420") or ("20020077524") or ("6436107")).PN.	US-PGPUB; USPAT	OR	OFF	2010/11/08 13:13
S82	1	S81 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:13

S83	19	(("6443922") or ("6451054") or ("6461366") or ("20020169359") or ("20020173694") or ("20020183766") or ("6508777") or ("6514194") or ("20030032979") or ("20030050529") or ("20030050693") or ("6537198") or ("6537314") or ("6551331") or ("20030078600") or ("6558416") or ("6562052") or ("6564805") or ("6582388")).PN.	US-PGPUB; USPAT	OR	OFF	2010/11/08 13:13
S84	3	S83 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:13
S85	19	(("6585727") or ("6589160") or ("20030130731") or ("6602288") or ("20030166992") or ("20030167071") or ("6616684") or ("20030171641") or ("6619291") or ("6622730") or ("20030181928") or ("6626930") or ("6629534") or ("6629921") or ("20030199975") or ("6645205") or ("20040003819") or ("6679268") or ("20040030382")).PN.	US-PGPUB; USPAT	OR	OFF	2010/11/08 13:15
S86	1	S85 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:15
S87	18	(("6695866") or ("20040039442") or ("20040044350") or ("20040049207") or ("20040049552") or ("6709456") or ("6718985") or ("6723038") or ("20040087975") or ("6733509") or ("20040092962") or ("6740107") or ("6746471") or	US-PGPUB; USPAT	OR	OFF	2010/11/08 13:16

		("6752813") or ("20040122448") or ("6755777") or ("20040127983") or ("20040133063")).PN.				
S88	7	S87 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:16
S89	7	S87 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:20
S90	19	(("6764510") or ("6770083") or ("6770084") or ("20040167374") or ("20040167539") or ("6793618") or ("6802860") or ("6808488") or ("6710882") or ("20040225300") or ("20040225304") or ("20040236354") or ("20040243229") or ("20040267083") or ("20050021056") or ("20050021057") or ("20050033446") or ("20050065396") or ("6875224")).PN.	US-PGPUB; USPAT	OR	OFF	2010/11/08 13:20
S91	1	S90 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:20
S92	20	(("20050075727") or ("20050075723") or ("20050101975") or ("20050125011") or ("20050131277") or ("20050131533") or ("6908424") or ("20050143620") or ("20050148815") or ("20050149014") or ("6918917") or ("6921407") or ("20050171601") or ("6929715") or ("20050216039") or ("6955175") or ("20050240202") or ("6962605") or ("20050251187") or ("6978176")).PN.	US-PGPUB; USPAT	OR	OFF	2010/11/08 13:20
S93	2	S92 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:20

S94	19	(("6986775") or ("6989028") or ("20060020275") or ("20060036317") or ("20060041306") or ("7004176") or ("7004952") or ("20060052868") or ("7011669") or ("20060058871") or ("20060074485") or ("20060089671") or ("20060241340") or ("7044905") or ("7048754") or ("20060127509") or ("20060135993") or ("20060149123") or ("7077862")).PN.	US-PGPUB; USPAT	OR	OFF	2010/11/08 13:20
S95	0	S94 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:20
S96	19	(("2006016040") or ("20060161193") or ("7083628") or ("7083638") or ("7090686") or ("20060184203") or ("7094244") or ("20060195012") or ("20060195134") or ("7100614") or ("7112207") or ("7112219") or ("20060287657") or ("20070027451") or ("20070002627") or ("7179291") or ("20070049952") or ("20070050022") or ("7186264") or ("20070055303")).PN.	US-PGPUB; USPAT	OR	OFF	2010/11/08 13:21
S97	0	S96 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:21

S98	17	(("7189199") or ("20070088375") or ("20070100356") or ("7217240") or ("20070112244") or ("20070118154") or ("20070118155") or ("7226467") or ("20070129737") or ("7247134") or ("7250028") or ("20070197858") or ("20070203391") or ("200702303391") or ("7288097") or ("20070265643") or ("20070299468") or ("20080051703")).PN.	US-PGPUB; USPAT	OR	OFF	2010/11/08 13:21
S99	4	S98 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:21
S100	0	S96 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:41
S101	4	S98 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:41
S102	9	("20030078465" | "20030105519" | "20040193191" | "20050070999" | "20050075727" | "20050125011" | "20050240202" | "20070118213" | "7144363").PN.	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:41
S103	0	S102 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:41
S104	12	(("20080065011") or ("20080065156") or ("20080065205") or ("20080091059") or ("20080091264") or ("20080167714") or ("20080183194") or ("20080188873") or ("20080195200") or ("20080208006") or ("20080228223") or ("7464712")).PN.	US-PGPUB; USPAT	OR	OFF	2010/11/08 13:41
S105	3	S104 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:41

S106	11	(("20090105729") or ("20080097489") or ("20090105751") or ("20090131880") or ("20090156995") or ("20090163934") or ("7563267") or ("7563273") or ("20090259304") or ("7604646") or ("7608091")).PN.	US-PGPUB; USPAT	OR	OFF	2010/11/08 13:43
S107	3	S106 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 13:43
S108	15	606/139,144,145.ccls. and @ay<="2005" and fiber optic$1 and (heart valve or leaflet$1)	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 14:53
S109	1	"20010005787"	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 15:21
S110	2	"11813695" and rigid	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 15:55
S111	1	"6978176".pn. and rigid	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 16:37
S112	2	"11813695" and papillary	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 16:49
S113	1	"6978176".pn. and papillary	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 17:07
S114	76	(US-20040225300-$ or US-20070112425-$ or US-20050021057-$ or US-20030105519-$ or US-20090088837-$ or US-20100042147-$ or US-20100023118-$ or US-20040143323-$ or US-20040210303-$ or US-20030078653-$ or US-20050075727-$ or US-20060167541-$ or US-20060100698-$ or US-20100030242-$ or US-20090198324-$ or US-20050021056-$ or US-20080243150-$ or US-20070049952-$ or US-20090043153-$ or US-20040044365-$ or US-20010005787-$ or US-20060287716-$ or US-20030120341-$ or US-20070118154-$ or US-20070118213-$ or US-20050070999-$).did. or (US-20080228223-$ or US-	US-PGPUB; USPAT; DERWENT	ADJ	OFF	2010/11/08 17:09

		20040024414-$ or US-20030078600-$ or US-20050216039-$ or US-20040122448-$ or US-20020099389-$ or US-20100022823-$ or US-20070197858-$ or US-20030032979-$ or US-20040133063-$ or US-20070299468-$).did. or (US-6997950-$ or US-6358277-$ or US-4960424-$ or US-7513908-$ or US-6332893-$ or US-6074417-$ or US-6797002-$ or US-6840246-$ or US-6978176-$ or US-7563273-$ or US-7431692-$ or US-6746471-$ or US-7527647-$ or US-6149660-$ or US-5908428-$ or US-5059201-$ or US-6936054-$ or US-7118583-$ or US-6893448-$ or US-5312423-$ or US-4493323-$ or US-5522820-$ or US-6702835-$ or US-6743239-$ or US-5810847-$ or US-7559936-$).did. or (US-7794474-$ or US-6260552-$ or US-5762613-$).did. or (US-20040143323-$ or US-20030105519-$ or WO-02102237-$ or WO-2006089236-$ or US-20040210303-$ or WO-03037227-$ or US-20020161378-$ or WO-03049619-$ or US-7635386-$ or WO-9829041-$).did.				
S115	43	S114 and papillary	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 17:09
S116	0	lattouf, omar.in. and suture and metal	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 17:59
S117	3	lattouf, omar.in. and suture	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 17:59
S118	17	lattouf, omar.in.	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 18:00
S119	1	lattouf, omar.in. and metal	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 18:00
S120	12	lattouf, omar.in. and rigid	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 18:01
S121	0	"6978176".pn. and S78	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 18:14

S122	9	(("6010531") or ("6840246") or ("6978176") or ("7294148") or ("20050149093") or ("20060100698") or ("20060167541") or ("20070112422") or ("20090005863")).PN.	US-PGPUB; USPAT	OR	OFF	2010/11/08 18:19
S123	1	"5762613".pn. and metal	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 18:23
S124	59	("20020049402" | "20030130571" | "3805793" | "4350160" | "5766183" | "5839639" | "5080663" | "5242456" | "5267958" | "5374275" | "5403326" | "5443446" | "5458131" | "5474573" | "5540704" | "5569274" | "5573540" | "5575800" | "5578044" | "5601574" | "5662664" | "5685867" | "5695457" | "5700272" | "5713910" | "5716367" | "5741277" | "5741279" | "5792094" | "5836956" | "5860992" | "5885238" | "5891159" | "5891160" | "5924424" | "5928224" | "5928250" | "5968059" | "5972020" | "6626930" | "6645205" | "6010531" | "6015427" | "6029671" | "6047700" | "6056760" | "6080182" | "6083219" | "6117159" | "6149660" | "6157852" | "6162233" | "6165183" | "6190357" | "6234995" | "6312447" | "6443922" | "6508777" | "6582388").PN.	US-PGPUB; USPAT	ADJ	OFF	2010/11/08 18:29
S125	103	606/139,144,145.ccls. and @ay<="2005" and metal and chest	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 09:03
S126	9	("4841888" | "5037433" | "5080663" | "5716367" | "5792153" | "6280460" | "6368334").PN. OR ("7063710").URPN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2010/11/09 09:18
S127	11	("5792153" | "6454777" | "6551330").PN. OR ("6991635").URPN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2010/11/09 09:19

S128	16	("2093145" | "3130418" | "4211241" | "4261342" | "4469101" | "4558520" | "4665951" | "4980424" | "5034009" | "5383904" | "5415667" | "5489296" | "5500015" | "5554184" | "5645568" | "0763076"). PN.	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 10:34
S129	7	fiber same optic same visualization same system and heart and valve and leaflet and color	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 11:07
S130	12	fiber same optic same visualization same system and heart and valve and leaflet	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 11:24
S131	3	fiber same optic same visualization same system and heart and valve and leaflet and sensor	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 11:25
S132	0	sensor same fiber same visualization same system and heart and valve and leaflet	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 11:26
S133	26	sensor same fiber and heart and valve and leaflet	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 11:26
S134	4	606/205-208.ccls. and heart valve and sensor	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 11:33
S135	17	606/139,144,145.ccls. and heart same valve and sensor	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 11:37
S136	1	"6575971".pn.	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 11:43
S137	1091	valve same heart same sensor	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 11:51
S138	4	valve same heart same sensor same grasp$3	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 11:51
S139	51	grasping sensor	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 11:52
S140	1859	600/587.ccls.	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 11:55
S141	12	600/587.ccls. and forceps and sensor	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 11:55
S142	92	600/587.ccls. and grip and sensor	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 12:03
S143	40	600/587.ccls. and grip same sensor	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 12:03
S144	25	600/587.ccls. and grip same sensor and monitor	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 12:13

S145	6	600/587.ccls. and grip same sensor and monitor and color	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 12:13
S146	113	"600".clas. and grip same sensor and monitor and color	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 12:16
S147	0	700/258.ccls. and color and heart same valve same grasp	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 12:18
S148	7	700/258.ccls. and color and monitor and grasp	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 12:18
S149	7	700/258.ccls. and color and monitor and sensor and grasp	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 12:18
S150	34	"700".clas. and grasp same sensor and monitor	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 12:20
S151	765	robot and (grasp$3 or touch$3) sensor	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 12:22
S152	217	robot and (grasp$3 or touch$3) sensor and monitor	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 12:22
S153	409	robot and grasp$3 same sensor and monitor	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 12:24
S154	51	robot and grasp$3 same sensor and monitor and forceps	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 12:24
S155	6	("4515165" | "5833603" | "5860917" | "5987346" | "6163714" | "6631286").PN.	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 12:46
S156	4801	force sensor and monitor	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 13:05
S157	377	force same sensor and monitor and forceps	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 13:05
S158	1	"7666204".pn.	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 13:08
S159	1	"7666204".pn. and color	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 13:08
S160	2	"20040122448"	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 13:24
S161	2	"20040122448" and fiber optics	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 13:24

S162	90	(US-20040225300-$ or US-20070112425-$ or US-20050021057-$ or US-20030105519-$ or US-20090088837-$ or US-20100042147-$ or US-20100023118-$ or US-20040143323-$ or US-20040210303-$ or US-20030078653-$ or US-20050075727-$ or US-20060167541-$ or US-20060100698-$ or US-20100030242-$ or US-20090198324-$ or US-20050021056-$ or US-20080243150-$ or US-20070049952-$ or US-20090043153-$ or US-20040044365-$ or US-20010005787-$ or US-20060287716-$ or US-20030120341-$ or US-20070118154-$ or US-20070118213-$ or US-20050070999-$).did. or (US-20080228223-$ or US-20040024414-$ or US-20030078600-$ or US-20050216039-$ or US-20040122448-$ or US-20020099389-$ or US-20100022823-$ or US-20070197858-$ or US-20030032979-$ or US-20040133063-$ or US-20070299468-$ or US-20070112422-$ or US-20050149093-$ or US-20030195529-$ or US-20030065338-$).did. or (US-6997950-$ or US-6358277-$ or US-4960424-$ or US-7513908-$ or US-6332893-$ or US-6074417-$ or US-6797002-$ or US-6840246-$ or US-6978176-$ or US-7563273-$ or US-7431692-$ or US-6746471-$ or US-7527647-$ or US-6149660-$ or US-5908428-$ or US-5059201-$ or US-6936054-$ or US-7118583-$ or US-6893448-$ or US-5312423-$ or US-4493323-$ or US-5522820-$ or US-6702835-$ or US-6743239-	US-PGPUB; USPAT; DERWENT	ADJ	OFF	2010/11/09 13:28

		$ or US-5810847-$ or US-7559936-$).did. or (US-7794474-$ or US-6260552-$ or US-5762613-$ or US-5891160-$ or US-6464707-$ or US-7063710-$ or US-6991635-$ or US-6551330-$ or US-6575971-$ or US-5316479-$ or US-5836894-$ or US-7338434-$ or US-7083571-$).did. or (US-20040143323-$ or US-20030105519-$ or WO-02102237-$ or WO-2006089236-$ or US-20040210303-$ or WO-03037227-$ or US-20020161378-$ or WO-03049619-$ or US-7635386-$ or WO-9829041-$).did.				
S163	21	S162 and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 13:28
S164	95	606/139,144,145.ccls. and @ay<="2005" and fiber optic$1	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 13:38
S165	1	"7666204".pn.	US-PGPUB; USPAT	ADJ	OFF	2010/11/09 16:06

11/10/2010 7:47:31 AM
C:\Documents and Settings\ctempleton\My Documents\EAST\Workspaces\11813695.wsp

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11813695
Filing Date	2007-07-11
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher L. Templeton
Attorney Docket Number	630666.00074

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6997950		2006-02-14	Chawla	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Receipt date: 11/11/2010	Application Number	11813695	11813695 - GAU: 3773
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2007-07-11	
	First Named Inventor	Giovanni Speziali	
	Art Unit	3773	
	Examiner Name	Christopher L. Templeton	
	Attorney Docket Number	630666.00074	

	1	PCT International Preliminary Report on Patentability for PCT/US2008/080560	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Christopher Templeton/	Date Considered	11/16/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11813695
Filing Date	2007-07-11
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher L. Templeton
Attorney Docket Number	630666.00074

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6997950		2006-02-14	Chawla	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11813695
	Filing Date	2007-07-11
	First Named Inventor	Giovanni Speziali
	Art Unit	3773
	Examiner Name	Christopher L. Templeton
	Attorney Docket Number	630666.00074

	1	PCT International Preliminary Report on Patentability for PCT/US2008/080560	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11813695
	Filing Date	2007-07-11
	First Named Inventor	Giovanni Speziali
	Art Unit	3773
	Examiner Name	Christopher L. Templeton
	Attorney Docket Number	630666.00074

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2010-11-11
Name/Print	Richard T. Roche	Registration Number	38599

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 4069.01WO01	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2008/080560	International filing date *(day/month/year)* 20 October 2008 (20.10.2008)	Priority date *(day/month/year)* 18 October 2007 (18.10.2007)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant NEOCHORD INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 20 April 2010 (20.04.2010)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Simin Baharlou e-mail: pt09.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
PEDERSEN BRAD

PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A.
4800 IDS CENTER 80 SOUTH EIGHTH STREET
MINNEAPOLIS MN 55402-2100 USA

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing *(day/month/year)*	**25 AUGUST 2009 (25.08.2009)**
Applicant's or agent's file reference 4069.01WO01	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2008/080560	**20 OCTOBER 2008 (20.10.2008)**	18 OCTOBER 2007 (18.10.2007)

International Patent Classification (IPC) or both national classification and IPC

A61B 17/068(2006.01)i, A61B 17/04(2006.01)i, A61B 17/29(2006.01)i, A61B 17/34(2006.01)i

Applicant

NEOCHORD INC. et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR	Date of completion of this opinion	Authorized officer
Korean Intellectual Property Office Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302 -701, Republic of Korea Facsimile No. 82-42-472-7140	24 AUGUST 2009 (24.08.2009)	YANG, Seong Ji Telephone No.82-42-481-5624

Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2008/080560

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of :

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____ , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material
   - ☐ a sequence listing
   - ☐ table(s) related to the sequence listing

   b. format of material
   - ☐ on paper
   - ☐ in electronic form

   c. time of filing/furnishing
   - ☐ contained in the international application as filed.
   - ☐ filed together with the international application in electronic form.
   - ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additioanl copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2008/080560

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 38, 39, 49, 50

because:

☒ the said international application, or the said claims Nos. 38, 39, 49, 50 relate to the following subject matter which does not require an international search *(specify)*:

The subject matter of claims 38-39 and 49-50 is directed to the category of methods for treatment of the human (patient) body by surgery for repairing a valve leaflet in a beating heart (Rule 43bis.1(b): Rule 67.1(iv)).

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for said claims Nos. 38, 39, 49, 50

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Istructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Istructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2008/080560

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1 - 37, 40 - 48	YES
	Claims	None	NO
Inventive step (IS)	Claims	1 - 19, 21, 22, 34 - 37, 40 -48	YES
	Claims	20, 23 - 33	NO
Industrial applicability (IA)	Claims	1 - 37, 40 - 48	YES
	Claims	None	NO

2. Citations and explanations :

Reference is made to the following documents:

D1: WO 2006-078694 A2 (MAYO FOUNDATION FOR MEDICLA EDUCATION AND RESEARCH) 27 July 2006
D2: US 2004-0044365 A1 (BACHMAN, ALAN B.) 4 Mar. 2004
D3: US 2007-0049952 A1 (WEISS, STEVEN J.) 1 Mar. 2007

1. Novelty and Inventive Step

1.1 Independent Claims 1, 12, 20, 31, 34, and 40

D1, which is considered to represent the most relevant state of the art, discloses an instrument for performing thorascopic repair of heart valves comprising: a shaft, a movable tip on the shaft is operable to capture a valve leaflet, and a needle.

Claim 1 differs from D1 in that D1 does not disclose a maximum diameter of a capture assembly and two clamping jaws. And, claim 12 differs from D1 in that D1 does not disclose the maximum diameter of a capture assembly and a bifurcated tip. In addition, each feature of claims 1 and 12 is not disclosed in any other documents, nor is it general knowledge of a person skilled in the art. Accordingly, claims 1 and 12 is not anticipated by the prior art, nor is it obvious to the skilled person. Therefore, each subject matter of claims 1 and 12 is novel and involves an inventive step in the sense of PCT Article 33(2)-(3).

Features (a handle assembly, a capture assembly, and a needle) of claim 20 are described in D1 as providing the corresponding advantages as in the present application although an ultrasonic imaging system in D1 is not same to a capture confirmation system. Since a person skilled in the art would regard it a normal design to replace the imaging system by the capture confirmation system, the subject matter of claim 20 lacks an inventive step under PCT Article 33(3).

Features (a handle assembly, a capture assembly, and a needle) of claim 31 are described in D1 as providing the corresponding advantages as in the present application although the handle in D1 does not disclose two channel of shaft. Since a person skilled in the art would regard it a normal design to make two channel by general experimentation alone without exercising any ingenuity, the subject matter of claim 31 lacks an inventive step under PCT Article 33(3).

(Continued on Supplemental Box)

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of :

Box V

Claim 34 differs from D1 in that D1 does not disclose a biasing member. And, claim 40 differs from D1 in that D1 does not disclose a replaceable suture cartridge including a secondary shaft. In addition, each feature of claims 34 and 40 is not disclosed in any other documents, nor is it general knowledge of a person skilled in the art. Accordingly, claims 34 and 40 is not anticipated by the prior art, nor is it obvious to the skilled person. Therefore, each subject matter of claims 34 and 40 is novel and involves an inventive step in the sense of PCT Article 33(2)-(3).

1.2 Dependent Claims 21-30, and 32-33

Claim 21 differs from D1 in that D1 does not disclose a binary indication. In addition, this feature of claim 21 is not disclosed in any other documents, nor is it general knowledge of a person skilled in the art. Accordingly, claim 21 is not anticipated by the prior art, nor is it obvious to the skilled person. Therefore, the subject matter of claim 21 is novel and involves an inventive step in the sense of PCT Article 33(2)-(3).

Since claim 22 depend on claim 21, claim 22 is also considered to be novel and to involve an inventive step under PCT Article 33(2)-(3).

Each additional features (numeric selections) of claims 23 to 28 does not have unexpected effects or properties in relation to the rest of the range. However, no such effects are indicated in the application. Hence, claims 23-28 lack an inventive step under PCT Aticle 33(3).

Each additional features (optic fibers) defined in claims 29-30 is merely a variation of the disclosure of D1 and a person skilled in the art would arrive at the claimed invention by general experimentation alone without exercising any ingenuity. Therefore, each subject matter of claims 29-30 lacks an inventive step under PCT Article 33(3).

The additional feature (needle detent) of claim 32 is a slight constructional change in the D1 which comes within the scope of the customary practice followed by person skilled in the art. And, the additional feature (a hook) of claim 33 is corresponded to notch of D1. Therefore, each subject matter of claims 32-33 lacks an inventive step under PCT Article 33(3).

1.3 Dependent Claims 2-11, 13-19, 35-37, and 41-48

Claims 2-11 consequently depend on claim 1, claims 13-19 consequently depend on claim 12, claims 35-37 consequently depend on claim 34, and claims 41-48 consequently depend on claim 40. Therefore, claims 2-11, 13-19, 35-37, and 41-48 are also considered to be novel and to involve an inventive step under PCT Article 33(2)-(3).

2. Industrial Applicability

All above claims are considered to be industrially applicable under PCT Article 33(4).

Electronic Patent Application Fee Transmittal

Application Number:	11813695
Filing Date:	11-Jul-2007
Title of Invention:	Thorascopic Heart Valve Repair Method and Apparatus
First Named Inventor/Applicant Name:	Giovanni Speziali
Filer:	Richard T. Roche/Beth Erlitz
Attorney Docket Number:	630666.00074

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	8819194
Application Number:	11813695
International Application Number:	
Confirmation Number:	6073
Title of Invention:	Thorascopic Heart Valve Repair Method and Apparatus
First Named Inventor/Applicant Name:	Giovanni Speziali
Customer Number:	26710
Filer:	Richard T. Roche/Beth Erlitz
Filer Authorized By:	Richard T. Roche
Attorney Docket Number:	630666.00074
Receipt Date:	11-NOV-2010
Filing Date:	11-JUL-2007
Time Stamp:	15:55:32
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	12900
Deposit Account	170055
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed (SB/08)	63066600074SupplDS2.PDF	612288 a612a4a6e6a2f2c2432fc16fe0a31c77a4f3dbad	no	4
Warnings:					
Information:					
2	NPL Documents	WO09052528IPRP.PDF	284294 e35d498226c46a6a956a5cafe89f42d125070a07	no	6
Warnings:					
Information:					
3	Fee Worksheet (PTO-875)	fee-info.pdf	30403 bf8479850c92452ebd73a22f5124a8540cca1d01	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	926985		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION

I hereby certify that this correspondence is being electronically transmitted to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Date: September 3, 2010

Richard T. Roche

Richard T. Roche, Reg. No. 38,599

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 630666.00074

Giovanni Speziali Confirmation No.: 6073

Application No.: 11/813,695 Examiner: Christopher L. Templeton

Filed: July 11, 2007 Group Art Unit: 3773

For: THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INTRODUCTORY COMMENTS

In response to the Office Action of April 13, 2010, and in accordance with the automatic extension of time for response provided by 37 CFR § 1.136(a), amendment to the above-identified patent application is requested.

The present amendment comprises the following sections:

A. Amendments to the Claims begin on page 2

B. Remarks begin on page 8

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 17-0055.

AMENDMENTS TO THE CLAIMS

A detailed listing of all claims that are, or were, in the present application, irrespective of whether the claim(s) remain(s) under examination in the application is presented below. The claims are presented in ascending order and each includes one status identifier. Those claims not cancelled or withdrawn but amended by the current amendment utilize the following notations for amendment: 1. deleted matter is shown by strikethrough for six or more characters and double brackets for five or fewer characters; and 2. added matter is shown by underlining.

1. (Currently Amended) A method [[for]] of repairing a heart valve in a patient with an instrument having a distal end and a movable element, the [[steps]] method comprising:

[[a)]]inserting [[an]] the instrument through the ~~subject~~ patient's chest wall and into the patient's chest cavity;

[[b)]]inserting the distal end and the movable element of the instrument through an exterior heart wall ~~and entering a heart chamber~~;

[[c)]]grasping a single leaflet on the heart valve ~~with a movable device on~~ between the movable element and the distal end of the instrument;

[[d)]]puncturing the leaflet with a needle disposed on the distal end of the instrument to form a puncture opening and drawing a suture through the puncture opening to connect the suture ~~thereto~~ to the leaflet;

capturing the suture with the needle;

[[e)]]anchoring the suture to another structure in the heart;

[[f)]]withdrawing the instrument ~~from~~ through the heart wall ~~chamber~~; and

[[g)]]withdrawing the instrument from the chest cavity.

2. (Currently Amended) The method ~~as recited in~~ of claim 1, ~~in which~~ wherein the step [[e)]] of anchoring the suture includes withdrawing the suture with the instrument ~~from~~ through the heart wall ~~chamber as recited in step f)~~ and anchoring the suture to the outer surface of the heart wall.

3. (Currently Amended) The method ~~as recited in~~ of claim 2, ~~in which the~~ further comprising adjusting the tension on the suture ~~is adjusted~~ before anchoring the suture by observing [[the]] operation of the heart valve using a medical imaging system.

4. (Currently Amended) The method ~~as recited in~~ of claim 1, further comprising ~~which includes~~ placing a purse-string suture in the heart wall around the location of the instrument insertion.

5. (Currently Amended) The method ~~as recited in~~ of claim 1, ~~in which~~ wherein inserting the distal end and the movable element of the instrument ~~is inserted in step b)~~ through ~~the apex of the~~ a heart wall comprises inserting the distal end the movable element of the instrument transapically.

6. (Currently Amended) The method ~~as recited in~~ of claim 5, ~~in which~~ wherein the step [[e)]] of anchoring the suture includes withdrawing the suture with the instrument ~~from~~ through the heart wall ~~chamber as recited in step f)~~ and anchoring the suture to [[the]] an outer surface of the heart wall near the ~~apex of the~~ heart's apex.

7-17. (Canceled).

Please add new claims 18-31 as follows:

18. (New) The method of claim 1, wherein the another structure is the heart wall.

19. (New) The method of claim 1, wherein the another structure is a papillary muscle.

20. (New) The method of claim 1, wherein the another structure is not a valve leaflet.

21. (New) The method of claim 1, wherein the step of inserting an instrument through the patient's chest wall comprises inserting a rigid metal shaft through the patient's chest wall.

22. (New) The method of claim 1, further comprising confirming capture of the leaflet between the distal end and the movable element.

23. (New) The method of claim 22, wherein the step of confirming capture of the leaflet includes using a fiber optic visualization system.

24. (New) A method of confirming capture of a valve leaflet of a patient's heart, the method comprising:

providing an instrument have a distal end, a movable element reversibly, distally shiftable with respect to the distal end, and an at least one illuminating fiber in optical communication with a visualization monitor and an exposed surface of the distal end;

inserting the instrument through the patient's chest wall and into the patient's chest cavity;

grasping the leaflet on the heart valve between the movable element and the distal end of the instrument; and

conveying a color to the visualizing monitor corresponding to a capture status of the leaflet.

25. (New) The method of claim 24, wherein the color is substantially red when the capture status of the leaflet is negative and substantially white when the capture status of the leaflet is positive.

26. (New) The method of claim 24, wherein the instrument includes a plurality of geometrically arranged illuminating fibers in optical communication with the visualization monitor and an exposed surface of the distal end.

27. (New) A method, comprising:

providing an instrument having a distal end, a movable element and a needle disposed on the distal end; and

providing instructions for repairing a heart valve of a patient with the instrument, the instructions comprising:

inserting the instrument through the patient's chest wall and into the patient's chest cavity;

inserting the distal end and the movable element of the instrument through an exterior heart wall;

grasping a single leaflet on the heart valve between the movable element and the distal end of the instrument;

puncturing the leaflet with the needle of the instrument to form a puncture opening and drawing a suture through the puncture opening to connect the suture to the leaflet;

capturing the suture with the needle;

anchoring the suture to another structure in the heart;

withdrawing the instrument through the heart wall; and

withdrawing the instrument from the chest cavity.

28. (New) The method of claim 27, wherein the step of anchoring the suture includes withdrawing the suture with the instrument through the heart wall and anchoring the suture to the outer surface of the heart wall.

29. (New) The method of claim 28, wherein the instructions further comprising adjusting the tension on the suture before anchoring the suture by observing operation of the heart valve using a medical imaging system.

30. (New) The method of claim 27, wherein the instructions further comprise confirming capture of the leaflet between the distal end and the movable element.

31. (New) The method of claim 30, wherein the step of confirming capture of the leaflet includes using a fiber optic visualization system.

REMARKS

Claims 1-6 are pending. By this Amendment, claims 1-6 are amended and new claims 18-31 are added. No claims are canceled. Support for the amendments can be found throughout the application as originally filed, such as, for example, at least at page 3, ¶ 0011, page 4, ¶ 0014 – page 6, ¶ 018, and Figures 1-3.

Information Disclosure Statement

The Examiner has requested that Applicant point out any particular references in the IDS which may be of particular relevance to the instant claimed invention in response to this Office Action. Applicant notes that, in addition to the Information Disclosure Statement filed June 5, 2008, a Supplemental Information Disclosure Statement was filed on February 8, 2010.

In response to the Examiner's request, Applicant respectfully states that while the duty of candor and good faith owned to the Office pursuant to 37 CFR 1.56(a) requires the disclosure of all information material to patentability, see MPEP § 2000.01, et al., Applicant is not required to identify references cited in an IDS which may be of "particular relevance." Applicant notes, however, that a general discussion of the relevant art is included in the Background of the Invention section of the Application. In addition, the Examiner has already indicated in the Forms 1449 dated April 14, 2010 (Lists of Reference cited by applicant and consider by examiner), that all referenced identified by Applicant have already been considered.

Claims Rejections – 35 U.S.C. § 103

Claims 1-2 and 5-6 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,978,176 to Lattouf in view of U.S. Patent Publication No. 2004/0044365 to Bachman. Claim 3 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Lattouf in view of Bachman and further in view of U.S. Patent Publication No. 2005/0021056 to St. Goar, et al. Claim 4 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Lattouf in view of Bachman and further in view of U.S. Patent Publication No. 2001/0005787 to Oz. Applicant respectfully traverses the rejection for at least the following reasons.

In determining whether a claimed invention in obvious under 35 U.S.C. § 103, the issue "is not whether the differences *themselves* would have been obvious, but whether the claimed invention *as a whole* would have been obvious." MPEP § 2141.02(I) (emphasis in original) (citing Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fed. Cir. 1983); Schneck v. Nortron Corp., 713 F.2d 782 (Fed. Cir. 1983)). "The mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP § 2143.01(III) (emphasis in original) (citing In re Mills, 916 F.2d 680 (Fed. Cir. 1990). Rather, three basic criteria must be met: (1) there must be some suggestion or motivation to modify or combine the references; (2) there must be a reasonable expectation of success; and (3) the prior art must teach or suggest all the claim limitations."

The rejection should be withdrawn because there was no motivation to combine the Lattouf and Bachman references or a reasonable expectation of success. In particular, the Office Action claims that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lattouf to include the instrument with a movable

device at the distal end and a needle, as taught by Bachman, for the purpose of applying a suture quickly and stably with the needle and grasping portion." (Office Action at 3.) According to the MPEP, however, this type of sweeping, generalized statement is not sufficient to established a *prima facie* case of obviousness under 35 U.S.C. § 103. See MPEP 2143.01(IV) ("A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspect of the claimed invention were individually known in the art *is not sufficient to established a prima facie case of obviousness without some objective reason to combine the teachings of the references*." (emphasis added) (citing ex parte Levengood, 28 U.S.P.Q.2d 1300 (BPAI 1993).) Instead of providing any objective reason to combine the teachings of Lattouf and Bachman as required under the rules, the Office Action has simply made conclusory statements of obviousness which are insufficient under the Patent Office's rules. Therefore, the Office Action has failed to establish a *prima facie* case of obviousness.

A review of the cited references in view of the claim language indicates that there could not have been a reasonable expectation of success to combine the references to disclose the limitations of the claims. As shown in the table below, there are at least six key features of amended claim 1 where Lattouf and Bachman provide different approaches to each other:

Feature	U.S. Patent No. 6,978,176 (Lattouf)	U.S. Patent Publ. No. 2004/0044365 (Bachman)	Amended Claim 1
Access	Transapical	Transseptal	"inserting the distal end and the movable element of the instrument through a heart wall"
Grabbing Means	Jaws	Sandwich	"grasping a single leaflet on the heart valve between the movable element and the distal end of the instrument"
Leaflet Capture Facilitator	Balloon backing	Vacuum	"grasping a single leaflet on the heart valve between the movable element and the distal end of the instrument"
Suture Deployment	Leaflet clip and pusher bar	Single needle retained by needle catch, which is attached to fastener material	"capturing the suture with the needle"
No. of Targeted Leaflets	2	1	"grasping a single leaflet"
Anchor Site	Heart Wall	Leaflet-to-leaflet	"anchoring the suture to a structure in the heart"

Thus, the total number of different combinations of these six different features of Lattouf and Bachman is six factorial, or 720. It cannot be considered reasonable experimentation and there cannot have been a reasonable expectation of success for one skilled in the art to have arrived at the specific claimed combination of features in the claims from the 720 different

combinations of features that are possible by combining the differing features of the cited references. It is therefore respectfully submitted that the rejection be withdrawn.

In addition, there can be no motivation or reasoned basis for combining Lattouf and Bachman because the teachings of the references clearly indicate that the features of the respective instruments cannot be combined. As previously explained, Bachman discloses transeptal access to a patient's left atrium. The rigid delivery system disclosed by Lattouf, however, would create a host of unintended and potentially lethal or injurious consequences if used to penetrate a patient's septum, such as leaving a large septal opening. Therefore, one of ordinary skilled in the art would also not have been motivated to combine the disclosures of Lattouf and Bachman. For this additional reason, it is respectfully requested that the rejection be withdrawn.

With regard to claims 2-6 depending from claim 1, it is respectfully submitted that these claims are allowable because the underlying base claim is allowable, although Applicant does not acquiesce in the positions set forth in the Office Action and reserves the right to make additional arguments with respect to these claims. As such, Applicant respectfully requests withdrawal of these rejections.

New claims

Claims 18-31 have been added to further identify and distinguish the invention. Support for the new claims can be found at least at page 3, ¶ 0011, page 4, ¶ 0014 – page 6, ¶ 018, and in Figures 1-3. It is respectfully submitted that the new claims are allowable for at least the same reasons that claims 1-6 are allowable.

Conclusion

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,
Giovanni Speziali

Dated: September 3, 2010 By: _____

Richard T. Roche
Registration No. 38,599
Quarles and Brady LLP
411 East Wisconsin Ave.
Milwaukee, WI 53202
(414) 277-5805

11207871

Electronic Patent Application Fee Transmittal

Application Number:	11813695
Filing Date:	11-Jul-2007
Title of Invention:	Thorascopic Heart Valve Repair Method and Apparatus
First Named Inventor/Applicant Name:	Giovanni Speziali
Filer:	Richard T. Roche/sara kerstein
Attorney Docket Number:	630666.00074

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 2 months with $0 paid	2253	1	245	245

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**245**

Electronic Acknowledgement Receipt

EFS ID:	8354259
Application Number:	11813695
International Application Number:	
Confirmation Number:	6073
Title of Invention:	Thorascopic Heart Valve Repair Method and Apparatus
First Named Inventor/Applicant Name:	Giovanni Speziali
Customer Number:	26710
Filer:	Richard T. Roche/sara kerstein
Filer Authorized By:	Richard T. Roche
Attorney Docket Number:	630666.00074
Receipt Date:	03-SEP-2010
Filing Date:	11-JUL-2007
Time Stamp:	14:18:40
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$245
RAM confirmation Number	658
Deposit Account	170055
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	response.pdf	428367 479db8cb122f2f48472ab61274484f706e5244c5	no	13
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	30141 7881a041f21878643b778c66dfbb14940b4ec6bf	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	458508		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/813,695	07/11/2007	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 09/03/2010	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/Fennell A. Pearlie/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/813,695	07/11/2007	Giovanni Speziali	630666.00074	6073

26710 7590 04/13/2010

QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI 53202-4497

EXAMINER	
TEMPLETON, CHRISTOPHER L	
ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
04/13/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Office Action Summary	Application No.	Applicant(s)	
	11/813,695	SPEZIALI, GIOVANNI	
	Examiner	Art Unit	
	CHRISTOPHER L. TEMPLETON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/5/08,12/22/09,2/8/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment

This office action is responsive to the amendment filed on 19 February 2010. As directed by the amendment: claims 7-17 have been cancelled. Thus, claims 1-6 are presently pending in this application.

Election/Restrictions

1. Applicant timely traversed the restriction (election) requirement in the reply filed on 19 February 2010.

2. Applicant's election with traverse of group I (claims 1-6) in the reply filed on 19 February 2010 is acknowledged. The traversal is on the ground(s) that species A and B are generic to all of the claims in group I. The **species** restriction requirement as set forth in the office action mailed 26 January 2010 has been withdrawn.

The restriction requirement between group I and group II is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

3. Applicant should note that the large number of references in the attached IDS have been considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S. Publication No. 2004/0044365). Lattouf discloses the claimed method for repairing a heart valve: inserting an instrument through the subject's chest wall and into the chest cavity (column 2, lines 34-42); inserting the distal end of the instrument through a heart wall and entering a heart chamber through the apex of the heart (column 3, line 45-column 4, line 5); puncturing a leaflet with the instrument and drawing a suture through the puncture to connect the suture thereto; withdrawing the suture with the instrument from the heart chamber and anchoring the suture to the outer surface of the heart wall (column 3, line 45-column 4, line 5). Lattouf does not expressly disclose the steps of grasping a leaflet with a movable device on a distal end of an instrument and puncturing the leaflet with a needle. Bachman teaches the steps of grasping a leaflet on a heart valve with a movable device on the distal end of the instrument and puncturing the leaflet with a needle disposed on the distal end of the instrument (paragraph 42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lattouf to include the instrument with a movable device at the distal end and a needle, as taught by Bachman, for the purpose of applying a suture quickly and stably with the needle and grasping portion.

6. Claims 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S. Publication No. 2004/0044365) and further in view of St. Goar et al (U.S. Publication No. 2005/0021056). Lattouf/Bachman disclose the claimed invention but are silent on the step of adjusting the tension on the suture by observing the operation of the heart valve using a medical imaging system. St. Goar teaches the step of adjusting the tension on a suture by observing the operation of the heart valve using a medical imaging system (paragraph 24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lattouf/Bachman to include the step of adjusting the tension on the suture by observing the operation of the heart valve using a medical imaging system, as taught by St. Goar, for the purpose of ensuring the absence of regurgitation by monitoring the valve with an imaging system in order to position the leaflet in the right position.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lattouf (U.S. Patent No. 6,978,176) in view of Bachman (U.S. Publication No. 2004/0044365) and further in view of Oz et al (U.S. Publication No. 2001/0005787). Lattouf/Bachman disclose the claimed invention but are silent on the step of placing a purse-string suture in the heart wall around the location of the instrument. Oz teaches placing a purse-string suture in the heart wall around the location of an instrument in order to control bleeding (Figure 1; paragraphs 68, 71). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lattouf/Bachman to include the step of placing a purse-string suture in the heart around the location of the

instrument, as taught by Oz, for the purpose of controlling bleeding around the instrument.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Downing (U.S. Patent No. 6,840,246) discloses an instrument inserted through a heart, Fasol (U.S. Publication No. 2003/0105519) discloses attaching chordae to a leaflet, Grooters (U.S. Patent No. 4,960,424) and discloses attaching artificial chordae to an external portion of a heart.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER L. TEMPLETON whose telephone number is (571) 270-1477. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie T. Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. L. T./
Examiner, Art Unit 3773

/Julian W. Woo/
Primary Examiner, Art Unit 3773

Notice of References Cited	Application/Control No. 11/813,695	Applicant(s)/Patent Under Reexamination SPEZIALI, GIOVANNI	
	Examiner CHRISTOPHER L. TEMPLETON	Art Unit 3773	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,978,176	12-2005	Lattouf, Omar M.	607/9
*	B	US-4,960,424	10-1990	Grooters, Ronald K.	128/898
*	C	US-6,840,246	01-2005	Downing, Stephen W.	128/898
*	D	US-2003/0105519	06-2003	FASOL et al.	623/2.1
*	E	US-2001/0005787	06-2001	Oz et al.	606/142
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11813695	SPEZIALI, GIOVANNI
	Examiner	Art Unit
	CHRISTOPHER L TEMPLETON	3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/15/2010	04/07/2010							
	1	÷	✓							
	2	÷	✓							
	3	÷	✓							
	4	÷	✓							
	5	÷	✓							
	6	÷	✓							
	7	÷	-							
	8	÷	-							
	9	÷	-							
	10	÷	-							
	11	÷	-							
	12	÷	-							
	13	÷	-							
	14	÷	-							
	15	÷	-							
	16	÷	-							
	17	÷	-							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11813695	SPEZIALI, GIOVANNI
	Examiner	Art Unit
	CHRISTOPHER L TEMPLETON	3773

SEARCHED

Class	Subclass	Date	Examiner
606	139, 144, 145	4/7/2010	CT
128	898	4/7/2010	CT
623	11.11, 13.11, 2.11-2.35	4/7/2010	CT
600	16, 37	4/7/2010	CT

SEARCH NOTES

Search Notes	Date	Examiner
EAST search (see attached)	4/7/2010	CT
Inventor name search	4/7/2010	CT

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

PTO/SB/08a (08-07)
Approved for use through 11/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11813695
Filing Date	2007-07-11
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher Templeton
Attorney Docket Number	630666.00074

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5667472		1997-09-16	Finn et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030078600		2003-04-24	O'Quinn et al.	
	2	20040044365		2004-03-04	Bachman	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	03/001893	WO	A2	2003-01-09	Evalve		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Receipt date: 12/22/2009	Application Number	11813695	11813695 - GAU: 3773
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2007-07-11	
	First Named Inventor	Giovanni Speziali	
	Art Unit	3773	
	Examiner Name	Christopher Templeton	
	Attorney Docket Number	630666.00074	

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Extended European Search Report for EP 06718728.6.	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Christopher Templeton/	Date Considered	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use as many sheets as necessary)

Complete if Known	
Application Number	11/813,695
Filing Date	July 11, 2007
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher Templeton
Attorney Docket Number	630666.00074

Sheet	1	of	14

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number / Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-3,667,474	06-06-1972	Konstantin V. Lapkin et al.
		US-3,842,840	10-22-1974	Edward E. Schweizer
		US-4,351,345	09-28-1982	Andrew L. Carney
		US-4,972,874	11-27-1990	Harold E. Jackson
		US-5,059,201	10-22-1991	Stanely E. Asnis
		US-5,336,229	08-09-1994	Wayne A. Noda
		US-5,452,733	09-26-1995	Wesley D. Sterman et al.
		US-5,571,215	11-05-1996	Wesley D. Sterman et al.
		US-5,653,716	08-05-1997	Cheryne M. Malo et al.
		US-5,693,091	12-02-1997	Carl O. Larson Jr. et al.
		US-5,762,613	06-09-1998	Gregg S. Sutton et al.
		US-5,772,672	06-30-1998	Frederick K. Toy et al.
		US-5,797,960	08-25-1998	John H. Stevens et al.
		US-5,839,639	11-24-1998	Jude S. Sauer et al.
		US-5,919,128	07-06-1999	Joseph P. Fitch
		US-5,961,440	10-05-1999	Cyril J. Schweich Jr. et al.
		US-5,972,030	10-26-1999	Michi E. Garrison et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document / Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		EP 1 039 851 B1	07-20-2005	Todd J. Mortier et al.	
		EP 1 408 850 B1	09-23-2009	Eric A. Goldfarb et al.	
		EP 1 637 091 A2	03-22-2006	Todd J. Mortier et al.	
		EP 1 845 861 A2			
		EP 1 845 861 A4			
		WO 1999/00059	01-07-1999	Mehmet C. Oz	

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	11/813,695
				Filing Date	July 11, 2007
				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	2	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,022,360	02-08-2000	William J. Reimels et al.
		US-6,045,497	04-04-2000	Cyril J. Schweich Jr. et al.
		US-6,050,936	04-18-2000	Cyril J. Schweich Jr. et al.
		US-6,059,715	05-09-2000	Cyril J. Schweich Jr. et al.
		US-6,077,214	06-20-2000	Todd J. Mortier et al.
		US-6,117,144	09-12-2000	Anthony A. Nobles et al.
		US-6,162,168	12-19-2000	Cyril J. Schweich Jr. et al.
		US-6,165,119	12-26-2000	Cyril J. Schweich Jr. et al.
		US-6,165,120	12-26-2000	Cyril J. Schweich Jr. et al.
		US-6,165,183	12-26-2000	Stephen T. Kuehn et al.
		US-6,183,411	02-06-2001	Todd J. Mortier et al.
		US-6,190,357	02-20-2001	Richard M. Ferrari et al.
		US-6,197,052	03-06-2001	Delos M. Cosgrove et al.
		US-6,234,995	05-22-2001	James C. Peacock III
		US-6,245,079	06-12-2001	Anthony A. Nobles et al.
		US-6,260,552	07-17-2001	Todd J. Mortier et al.
		US-6,261,222	07-17-2001	Cyril J. Schweich Jr. et al.
		US-6,264,602	07-24-2001	Todd J. Mortier et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 99/30647	06-24-1999	Todd J. Mortier et al.	
		WO 00/16700	03-30-2000	Todd J. Mortier et al.	
		WO 00/06026 A2 (corrected version)	02-10-2000	Cyril J. Schweich et al.	
		WO 00/06026 A2	02-10-2000	Cyril J. Schweich et al.	
		WO 00/06026 A3	02-10-2000	Cyril Schweich et al.	
		WO 00/06027 A2 (corrected version)	02-10-2000	Todd J. Mortier et al.	
		WO 00/06027 A2	02-10-2000	Todd J. Mortier et al.	

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	11/813,695
Filing Date	July 11, 2007
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher Templeton
Attorney Docket Number	630666.00074

Sheet	3	of	14

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,269,819	08-07-2001	Mehmet C. Oz et al.
		US-2001/0016675	08-23-2001	Todd J. Mortier et al.
		US-6,283,993	09-04-2001	Delos M. Cosgrove et al.
		US-2001/0021872	09-13-2001	Steven R. Bailey et al.
		US-6,312,447	11-06-2001	Randall Y. Grimes
		US-6,332,863	12-25-2001	Cyril J. Schweich Jr. et al.
		US-6,332,864	12-25-2001	Cyril J. Schweich Jr. et al.
		US-6,332,893	12-25-2001	Todd J. Mortier et al.
		US-2002/0013571	01-31-2002	Eric A. Goldfarb et al.
		US-2002/0029080	03-07-2002	Todd J. Mortier et al.
		US-6,355,050	03-12-2002	Bernard H. Andreas et al.
		US-2002/0049402	04-25-2002	James C. Peacock III et al.
		US-6,402,679	06-11-2002	Todd J. Mortier et al.
		US-6,402,680	06-11-2002	Todd J. Mortier et al.
		US-6,401,720	06-11-2002	John H. Stevens et al.
		US-6,402,781	06-11-2002	Jonathan J. Langberg et al.
		US-6,406,420 B1	06-18-2002	Patrick M. McCarthy et al.
		US-2002/0077524 A1	06-20-2002	Cyril J. Schweich Jr. et al.
		US-6,436,107 B1	08-20-2002	Yulun Wang et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 00/06027 A3	02-10-2000	Todd J. Mortier et al.	
		WO 00/06028 A1	02-10-2000	Todd J. Mortier et al.	
		WO 01/66018 A1	09-13-2001	Richard A. Gambale et al.	
		WO 01/095809 A1	12-20-2001	Anthony A. Nobles et al.	
		WO 03/059209 A2	07-24-2003	Robert M. Vidlund et al.	
		WO 03/059209 A3	07-24-2003	Robert M. Vidlund et al.	

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	11/813,695
				Filing Date	July 11, 2007
				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	4	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,443,922 B1	09-03-2002	Craig P. Roberts et al.
		US-6,451,054	09-17-2002	John H. Stevens
		US-6,461,366	10-08-2002	Jacques Seguin
		US-2002/0169359 A1	11-14-2002	Patrick M. McCarthy et al.
		US-2002/0173694 A1	11-21-2002	Todd J. Mortier et al.
		US-2002/0183766 A1	12-05-2002	Jacques Sequin
		US-6,508,777 B1	01-21-2003	John Macoviak et al.
		US-6,514,194 B2	02-04-2003	Cyril J. Schweich Jr. et al.
		US-2003/0032979 A1	02-13-2003	Todd J. Mortier et al.
		US-2003/0050529 A1	03-13-2003	Robert M. Vidlund et al.
		US-2003/0050693 A1	03-13-2003	Rodolfo C. Quijano et al.
		US-6,537,198 B1	03-25-2003	Robert M. Vidlund et al.
		US-6,537,314 B2	03-25-2003	Jonathan J. Langberg et al.
		US-6,551,331 B2	04-22-2003	Anthony A. Nobles et al.
		US-2003/0078600 A1	04-24-2003	Philip S. O'Quinn et al.
		US-6,558,416 B2	05-06-2003	Delos M. Cosgrove et al.
		US-6,562,052 B2	05-13-2003	Anthony A. Nobles et al.
		US-6,564,805 B2	05-20-2003	Michi E. Garrison et al.
		US-6,582,388 B1	06-24-2003	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 03/082157 A2	10-09-2003	Stefan Schreck	
		WO 03/082157 A3	10-09-2003	Stefan Schreck	
		WO 04/043265 A2	05-27-2004	Robert M. Vidlund et al.	
		WO 04/043265 A3	05-27-2004	Robert M. Vidlund et al.	
		WO 05/039428 A2	05-06-2005	Jan Lan	
		WO 05/039428 A3	05-06-2005	Jan Lan	

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	11/813,695
Filing Date	July 11, 2007
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher Templeton
Attorney Docket Number	630666.00074

Sheet	5	of	15

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,585,727 B1	07-01-2003	Christopher M. Cashman et al.
		US-6,589,160 B2	07-08-2003	Cyril J. Schweich Jr. et al.
		US-2003/0130731 A1	07-10-2003	Robert M. Vidlund et al.
		US-6,602,288 B1	08-05-2003	Deles M. Cosgrove et al.
		US-2003/0166992 A1	09-04-2003	Cyril J. Schweich Jr. et al.
		US-2003/0167071 A1	09-04-2003	Brian B. Martin et al.
		US-6,616,684 B1	09-09-2003	Robert M. Vidlund
		US-2003/0171641 A1	09-11-2003	Cyril J. Schweich Jr. et al.
		US-6,619,291 B2	09-16-2003	Edwin J. Hlavka et al.
		US-6,622,730 B2	09-23-2003	Craig A. Ekvall et al.
		US-2003/0181928 A1	09-25-2003	Robert M. Vidlund et al.
		US-6,626,930 B1	09-30-2003	William J. Allen et al.
		US-6,629,534 B1	10-07-2003	Frederick G. St. Goar et al.
		US-6,629,921 B1	10-07-2003	Cyril J. Schweich Jr. et al.
		US-2003/0199975 A1	10-23-2003	Shlomo Gabbay
		US-6,645,205 B2	11-11-2003	Richard S. Ginn
		US-2004/0003819 A1	01-08-2004	Frederick G. St. Goar et al.
		US-6,679,268 B2	01-20-2004	John H. Stevens et al.
		US-2004/0030382 A1	02-12-2004	Frederick G. St. Goar et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 05/094525 A2	10-13-2005	Richard M. Beane et al.	
		WO 06/032051 A2	03-23-2006	Avraham Zakay et al.	
		WO 06/032051 A3	03-23-2006	Avraham Zakay et al.	
		WO 06/065966 A2	06-22-2006	Richard M. Beane et al.	
		WO 06/065966 A3	06-22-2006	Richard M. Beane et al.	
		WO 06/078694 A2	07-27-2006	Giovanni Speziali	

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use as many sheets as necessary)

Complete if Known	
Application Number	11/813,695
Filing Date	July 11, 2007
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher Templeton
Attorney Docket Number	630666.00074

Sheet	6	of	14

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,695,866 B1	02-24-2004	Stephen T. Kuehn et al.
		US-2004/0039442 A1	02-26-2004	Federick G. St. Goar et al.
		US-2004/0044350 A1	03-04-2004	Brian B. Martin et al.
		US-2004/0049207 A1	03-11-2004	Eric A. Goldfarb et al.
		US-2004/0049552 A1	03-11-2004	Tetsuro Motoyama et al.
		US-6,709,456 B2	03-23-2004	Jonathan J. Langberg et al.
		US-6,718,985 B2	04-13-2004	Edwin J. Hlavka et al.
		US-6,723,038 B1	04-20-2004	Richard F. Schroeder et al.
		US-2004/0087975 A1	05-06-2004	Sylvester Lucatero et al.
		US-6,733,509 B2	05-11-2004	Anthony A. Nobles et al.
		US-2004/0092962 A1	05-13-2004	Troy L. Thornton et al.
		US-6,740,107 B2	05-25-2004	Marvin P. Loeb et al.
		US-6,746,471 B2	06-08-2004	Todd J. Mortier et al.
		US-6,752,813 B2	06-22-2004	Eric A. Goldfarb et al.
		US-2004/0122448 A1	06-24-2004	Robert A. Levine
		US-6,755,777 B2	06-29-2004	Cyril J. Schweich Jr. et al.
		US-2004/0127983 A1	07-01-2004	Todd J. Mortier et al.
		US-2004/0133063 A1	07-08-2004	Patrick m. McCarthy et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 06/078694 A3	07-27-2006	Giovanni Speziali	
		WO 06/116310 A2	11-02-2006	Robert M. Vidlund et al.	
		WO 06/116310 A3	11-02-2006	Robert M. Vidlund et al.	
		WO 06/127509 A2	11-30-2006	Giovanni Speziali et al.	
		WO 06/127509 A3	11-30-2006	Giovanni Speziali et al.	
		WO 07/002627 A1	01-04-2007	Patrick Perier et al.	
		WO 07/027451 A2	03-08-2007	Steven J. Weiss	

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	11/813,695
Filing Date	July 11, 2007
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher Templeton
Attorney Docket Number	630666.00074

Sheet	7	of	14

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,764,510 B2	07-20-2004	Robert M. Vidlund et al.
		US-6,770,083 B2	08-03-2004	Jacques Seguin
		US-6,770,084 B1	08-03-2004	Gregory H. Bain et al.
		US-2004/0167374 A1	08-26-2004	Cyril Schweich et al.
		US-2004/0167539 A1	08-26-2004	Stephen T. Kuehn et al.
		US-6,793,618 B2	09-21-2004	Cyril J. Schweich Jr. et al.
		US-6,802,860 B2	10-12-2004	Delos M. Cosgrove et al.
		US-6,808,488 B2	10-26-2004	Todd J. Mortier et al.
		US-6,810,882 B2	11-02-2004	Jonathan J. Langberg et al.
		US-2004/0225300 A1	11-11-2004	Eric A. Goldfarb et al.
		US-2004/0225304 A1	11-11-2004	Robert M. Vidlund et al.
		US-2004/0236354 A1	11-25-2004	Jacques Seguin
		US-2004/0243229 A1	12-02-2004	Robert M. Vidlund et al.
		US-2004/0267083 A1	12-30-2004	Patrick M. McCarthy et al.
		US-2005/0021056 A1	01-27-2005	Frederick G. St. Goar et al.
		US-2005/0021057 A1	01-27-2005	Frederick G. St. Goar et al.
		US-2005/0033446 A1	02-10-2005	Mark E. Deem et al.
		US-2005/0065396 A1	03-24-2005	Todd J. Mortier et al.
		US-6,875,224 B2	04-05-2005	Randall Y. Grimes

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 07/027451 A3	03-08-2007	Steven J. Weiss	
		WO 07/062128 A2	05-31-2007	Dean T. Crabtree	
		WO 07/062128 A3	05-31-2007	Dean T. Crabtree	
		WO 07/081418 A1	07-19-2007	Richard M. Beane et al.	
		WO 07/117612 A1	10-18-2007	Richard M. Beane et al.	
		WO 08/010738 A2	01-24-2008	Uros Babic	

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use as many sheets as necessary)

Complete if Known	
Application Number	11/813,695
Filing Date	July 11, 2007
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher Templeton
Attorney Docket Number	630666.00074

Sheet	8	of	14

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-2005/0075727 A1	04-07-2005	David J. Wheatley
		US-2005/0075723 A1	04-07-2005	Richard Schroeder et al.
		US-2005/0101975 A1	05-12-2005	John D. Nguyen et al.
		US-2005/0125011 A1	06-09-2005	Paul A. Spence et al.
		US-2005/0131277 A1	06-16-2005	06-16-2005
		US-2005/0131533 A1	06-16-2005	Ottavio Alfieri et al.
		US-6,908,424 B2	06-21-2005	Todd J. Mortier et al.
		US-2005/0143620 A1	06-30-2005	Todd J. Mortier et al.
		US-2005/0148815 A1	07-07-2005	Todd J. Mortier et al.
		US-2005/0149014 A1	07-07-2005	Wallace N. Hauck et al.
		US-6,918,917 B1	07-19-2005	John D. Nguyen et al.
		US-6,921,407 B2	07-26-2005	John D. Nguyen et al.
		US-2005/0171601 A1	08-04-2005	Delos M. Cosgrove et al.
		US-6,929,715 B2	08-16-2005	Gerdt Fladda et al.
		US-2005/0216039 A1	09-29-2005	Robert J. Lederman
		US-6,955,175 B2	10-18-2005	John H. Stevens et al.
		US-2005/0240202 A1	10-27-2005	Hani Shennib et al.
		US-6,962,605 B2	11-08-2005	Delos M. Cosgrove et al.
		US-2005/0251187 A1	11-10-2005	Richard M. Beane et al.
		US-6,978,176 B2	12-20-2005	Omar M. Lattouf

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 09/052528 A2	04-23-2009	John Zentgraf	
		WO 09/052528 A3	04-23-2009	John Zentgraf	

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	11/813,695
				Filing Date	July 11, 2007
				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	9	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,986,775 B2	01-17-2006	Rodolfo A. Morales et al.
		US-6,989,028 B2	01-24-2006	Randall T. Lashinski et al.
		US-2006/0020275 A1	01-26-2006	Eric A. Goldfarb et al.
		US-2006/0036317 A1	02-16-2006	Robert M. Vidlund et al.
		US-2006/0041306 A1	02-23-2006	Robert M. Vidlund et al.
		US-7,004,176 B2	02-28-2006	Jan Lau
		US-7,004,952 B2	02-28-2006	Anthony A. Nobles et al.
		US-2006/0052868 A1	03-09-2006	Todd J. Mortier et al.
		US-7,011,669 B2	03-14-2006	Per Ola Kimblad
		US-2006/0058871 A1	03-16-2006	Avraham Zakay et al.
		US-2006/0074485 A1	04-06-2006	Fidel Realyvasquez
		US-2006/0089671 A1	04-27-2006	Eric A. Goldfarb et al.
		US 2006/0100699 A1	05-11-2006	Robert M. Vidlund et al.
		US-2006/0241340 A1	10-26-2006	Robert M. Vidlund et al.
		US-7,044,905 B2	05-16-2006	Robert Vidlund et al.
		US-7,048,754 B2	05-23-2006	Brian B. Martin et al.
		US-2006/0127509 A1	06-15-2006	Christopher B. Eckman et al.
		US-2006/0135993 A1	06-22-2006	Jacques Seguin
		US-2006/0149123 A1	07-06-2006	Robert M. Vidlund et al.
		US-7,077,862 B2	07-18-2006	Robert M. Vidlund et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	11/813,695
				Filing Date	July 11, 2007
				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	10	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-2006/016040 A1	07-20-2006	Patrick M. McCarthy et al.
		US-2006/0161193 A1	07-20-2006	Richard M. Beane et al.
		US-7,083,628 B2	08-01-2006	Alan Bachman
		US-7,083,638 B2	08-01-2006	Seth A. Foerster
		US-7,090,686 B2	08-15-2006	Anthony A. Nobles et al.
		US-2006/0184203 A1	08-17-2006	Brian B. Martin et al.
		US-7,094,244 B2	08-22-2006	Stefan Schreck
		US-2006/0195012 A1	08-31-2006	Todd J. Mortier et al.
		US-2006/0195134 A1	08-31-2006	James F. Crittenden
		US-7,100,614 B2	09-05-2006	John H. Stevens et al.
		US-7,112,207 B2	09-26-2006	William J. Allen et al.
		US-7,112,219 B2	09-26-2006	Robert M. Vidlund et al.
		US-2006/0287657 A1	12-21-2006	Alan B. Bachman
		US-2007/0002627 A1	01-04-2007	Tae Un Youn
		US-2007/0027451 A1	02-01-2007	Kai Desinger et al.
		US-7,179,291 B2	02-20-2007	Jonathan M. Rourke et al.
		US-2007/0049952 A1	03-01-2007	Steven J. Weiss
		US-2007/0050022 A1	03-01-2007	Robert M. Vidlund et al.
		US-7,186,264 B2	03-06-2007	John R. Liddicoat et al.
		US-2007/0055303 A1	03-08-2007	Robert M. Vidlund et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	11/813,695
				Filing Date	July 11, 2007
				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	11	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-7,189,199 B2	03-13-2007	Patrick M. McCarthy et al.
		US-2007/0088375 A1	04-19-2007	Richard M. Beane et al.
		US-2007/0100356 A1	05-03-2007	Sylvester Lucatero et al.
		US-7,217,240 B2	05-15-2007	Edward Ramsey Snow
		US-2007/0112244 A1	05-17-2007	Patrick M. McCarthy et al.
		US-2007/0118154 A1	05-24-2007	Traves Dean Crabtree
		US-2007/0118155 A1	05-24-2007	Eric A. Goldfarb et al.
		US-7,226,467 B2	06-05-2007	Sylvester Lucatero et al.
		US-2007/0129737 A1	06-07-2007	Eric A. Goldfarb et al.
		US-7,247,134 B2	07-24-2007	Robert M. Vidlund et al.
		US-7,250,028 B2	07-31-2007	Christopher A. Julian et al.
		US-2007/0197858 A1	08-23-2007	Eric A. Goldfarb et al.
		US-2007/0203391 A1	08-30-2007	Eliot Bloom et al.
		US-2007/0239272 A1	10-11-2007	Jose Luis Navia et al.
		US-7,288,097 B2	10-30-2007	Jacques Séquin
		US-7,294,148 B2	11-13-2007	Patrick M. McCarthy
		US-2007/0265643 A1	11-15-2007	Richard M. Beane et al.
		US-2007/0299468 A1	12-27-2007	Frank J. Viola
		US-2008/0051703 A1	02-28-2008	Troy L. Thornton et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	11/813,695
				Filing Date	July 11, 2007
				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	12	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-2008/0065011 A1	03-13-2008	Philippe Marchand et al.
		US-2008/0065156 A1	03-13-2008	David L. Hauser et al.
		US-2008/0065205 A1	03-13-2008	Duy Nguyen et al.
		US-2008/0091059 A1	04-17-2008	Timothy R. Machold et al.
		US-2008/0091264 A1	04-17-2008	Timothy R. Machold et al.
		US-2008/0097489 A1	04-24-2008	Eric A. Goldfarb et al.
		US-2008/0167714 A1	07-10-2008	Federick G. St. Goar et al.
		US-2008/0183194 A1	07-31-2008	Eric A. Goldfarb et al.
		US-2008/0188873 A1	08-07-2008	Giovanni Speziali
		US-2008/0195200 A1	08-14-2008	Robert M. Vidlund et al.
		US-2008/0208006 A1	08-28-2008	Mina Farr
		US-2008/0228223 A1	09-18-2008	Yousef F. Alkhatib
		US-7,464,712 B2	12-16-2008	Mehmet C. Oz et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	11/813,695
Filing Date	July 11, 2007
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher Templeton
Attorney Docket Number	630666.00074

Sheet	13	of	14

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-2009/0105729 A1	04-23-2009	John Zentgraf
		US-2009/0105751 A1	04-23-2009	John Zentgraf
		US-2009/0131880 A1	05-21-2009	Giovanni Speziali et al.
		US-2009/0156995 A1	06-18-2009	Brian B. Martin et al.
		US-2009/0163934 A1	06-25-2009	Alfred H. Raschdorf Jr. et al.
		US-7,563,267 B2	07-21-2009	Eric A. Goldfarb et al.
		US-7,563,273 B2	07-21-2009	Eric A. Goldfarb et al.
		US-2009/0259304 A1	10-15-2009	Patricia O'Beirne et al.
		US-7,604,646 B2	10-20-2009	Eric A. Goldfarb et al.
		US-7,608,091 B2	10-27-2009	Eric A. Goldfarb et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use as many sheets as necessary)

Complete if Known	
Application Number	11/813,695
Filing Date	July 11, 2007
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher Templeton
Attorney Docket Number	630666.00074

Sheet	14	of	14

NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Port Access System For Mitral Valve Repair Proves Its Value In Study; MedGadget July 9, 2009; available at: http://www.medgadget.com/archives/2009/07/port_access_system_for_mitral_valve_repair_proves_its_value_in_study.html. (5 pages).	
		Interactive CardioVascular And Thoracic Surgery; Abstracts: Supplemental 3 to Vol. 7 (September 2008). 52 pages.	
		Image File Wrapper for U.S. Application No. 12/254,807 (filed October 20, 2008).	
		Image File Wrapper For U.S. Application No. 12/254,808 (filed October 20, 2008).	

EXAMINER SIGNATURE	/Christopher Templeton/	DATE CONSIDERED	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	"3807657".pn.	US-PGPUB; USPAT	ADJ	OFF	2010/04/08 08:39
L2	3	("20030078600" | "20040044365" | "5667472").PN.	US-PGPUB; USPAT	ADJ	OFF	2010/04/08 08:41
S1	1	("6156039").PN.	US-PGPUB; USPAT	ADJ	OFF	2010/04/06 17:08
S2	39	("20030078600" | "20040044365" | "3667474" | "3842840" | "4351345" | "4972874" | "5059201" | "5336229" | "5452733" | "5571215" | "5653716" | "5693091" | "5762613" | "5772672" | "5797960" | "5839639" | "5908428" | "5919128" | "5961440" | "5972030" | "5667472" | "6022360" | "6045497" | "6050936" | "6059715" | "6077214" | "6149660" | "6162168" | "6165119" | "6165120" | "6177144" | "6183411" | "6190357" | "6197052" | "6234995" | "6245079" | "6260552" | "6261222" | "6264602").PN.	US-PGPUB; USPAT	ADJ	OFF	2010/04/06 17:28
S3	77	606/139,144,145.ccls. and suture and needle and heart valve	US-PGPUB; USPAT	ADJ	OFF	2010/04/06 17:35
S4	16	606/139,144,145.ccls. and suture and needle and heart valve and heart wall	US-PGPUB; USPAT	ADJ	OFF	2010/04/06 18:11
S5	36	606/139,144,145.ccls. and needle and heart valve and (chordae or chorda)	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 08:04
S7	2	"623/11"."11,13"."11".ccls. and needle and heart valve and (chordae or chorda)	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 08:19
S8	33	("20030105519" | "20040106989" | "20040122513" | "20040138745" | "20050010287" | "20050107871" | "3130418" | "4960424" | "5415667" | "5554184" | "5662704" | "6074417" | "6143025" | "6312447" | "6332893" | "6338240" | "6350282" | "6358277" | "6409759" | "6726715" | "6764510" | "6797002").PN. OR ("6997950").URPN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2010/04/07 08:24

S9	80	("3130418" | "4021863" | "4106129" | "4164046" | "4261342" | "4275469" | "4339831" | "4340977" | "4489446" | "4602911" | "4655773" | "4917698" | "4960424" | "5061277" | "5104407" | "5163955" | "5171252" | "5201880" | "5306296" | "5332402" | "5360444" | "5397351" | "5415667" | "5449384" | "5450860" | "5545214" | "5549665" | "5554184" | "5554185" | "5662704" | "5674279" | "5709695" | "5716397" | "5733331" | "5824065" | "5824066" | "5824067" | "5855601" | "5888240" | "5908450" | "5931868" | "6332893").PN. OR ("6797002").URPN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2010/04/07 09:20
S10	66	128/898.ccls. and suture same leaflet $1	US-PGPUB; USPAT; USOCR	ADJ	OFF	2010/04/07 09:38
S11	82	128/898.ccls. and chordae	US-PGPUB; USPAT; USOCR	ADJ	OFF	2010/04/07 10:13
S12	1110	chordae	US-PGPUB; USPAT; USOCR	ADJ	OFF	2010/04/07 10:13
S13	494	chordae tendineae	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2010/04/07 10:14
S14	337	chordae tendineae and suture	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2010/04/07 10:16
S15	19	("20030078653" | "20030105519" | "20030105519" | "20040122512" | "20040122513" | "20040143323" | "20040210303" | "20050075727" | "20060195182" | "20060195183" | "20060259135").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2010/04/07 10:25
S16	18	("20050149093" | "20060100698" | "20060167541" | "20070112422" | "20090005863" | "6010531" | "6840246" | "6978176" | "7291168" | "7294148").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2010/04/07 12:13

S17	130	("20020107531" | "20020087148" | "20020107531" | "20020161378" | "20030065338" | "20030065388" | "20030105519" | "20040039442" | "20040167573" | "20040044353" | "20040167573" | "20040225300" | "20050021052" | "20050033323" | "20050149122" | "20060155307" | "20070265702" | "20080004597" | "20080188873" | "0207932" | "3995619" | "4972874" | "5613974" | "5665096" | "5797927" | "5984917" | "5080663" | "5330442" | "5383886" | "5450860" | "5540704" | "5571137" | "5618306" | "5725556" | "5741280" | "5797927" | "5797960" | "5843031" | "5885271" | "5928250" | "5961440" | "6074404" | "6136010" | "6206893" | "6840246" | "6875224" | "6978176" | "6997950" | "6019722" | "6022360" | "6063106" | "6099553" | "6269819" | "6346074" | "6575971" | "6629534" | "6746471" | "6770083" | "6911043" | "6945978" | "7083628" | "7118583" | "7232448" | "7264587" | "7011669" | "7048754" | "7083628" | "7094244" | "7112207" | "7288097").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	OFF	2010/04/07 13:05
S18	27	("20020042651" | "20020161378" | "20030078465" | "20030078653" | "20030083742" | "20030105519" | "20030167062" | "20030181940" | "20040003819" | "20040024414" | "20040024451" | "20040024452" | "20040034380" | "20040037813" | "20040044350" | "20040073301" | "5571215" | "6099547" | "6129758" | "6332893" | "6629534" | "6629921" | "6719786" | "6726715" | "7144363" | "7252632").PN. OR ("7431692").URPN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2010/04/07 14:34
S19	1	"6978176".pn.	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 14:39
S20	42	(US-20040225300-$ or US-20070112425-$ or US-20050021057-$ or US-20030105519-$ or US-20090088837-$ or US-20100042147-$ or US-20100023118-$ or US-20040143323-$ or US-20040210303-$ or US-20030078653-$ or US-20050075727-$ or US-20060167541-$ or US-20060100698-$ or US-20100030242-$ or US-20090198324-$ or US-20050021056-$ or US-20080243150-$ or US-20070049952-$ or US-20090043153-$).did. or (US-6997950-$ or US-6358277-$ or US-	US-PGPUB; USPAT; DERWENT	ADJ	OFF	2010/04/07 15:05

		4960424-$ or US-7513908-$ or US-6332893-$ or US-6074417-$ or US-6797002-$ or US-6840246-$ or US-6978176-$ or US-7563273-$ or US-7431692-$ or US-6746471-$ or US-7527647-$).did. or (US-20040143323-$ or US-20030105519-$ or WO-02102237-$ or WO-2006089236-$ or US-20040210303-$ or WO-03037227-$ or US-20020161378-$ or WO-03049619-$ or US-7635386-$ or WO-9829041-$). did.				
S21	2	S20 and cordae and (tension or tighten)	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 15:05
S22	19	("20010005787" | "20040002719" | "20060058817" | "20060058871" | "20060064115" | "20060064116" | "20060064118" | "5609598" | "6149660" | "6269819" | "6575971").PN.	US-PGPUB; USPAT; DERWENT	ADJ	OFF	2010/04/07 15:19
S23	2	"5908428".pn.	US-PGPUB; USPAT; DERWENT	ADJ	OFF	2010/04/07 15:28
S24	3	"2004044365"	US-PGPUB; USPAT; DERWENT	ADJ	OFF	2010/04/07 15:32
S25	0	"2004044365"	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 15:33
S26	2	"20040044365"	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 15:33
S27	1	"6149660".pn.	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 15:34
S28	39	("20030078600" | "20040044365" | "3667474" | "3842840" | "4351345" | "4972874" | "5059201" | "5336229" | "5452733" | "5571215" | "5653716" | "5693091" | "5762613" | "5772672" | "5797960" | "5839639" | "5908428" | "5919128" | "5961440" | "5972030" | "5667472" | "6022360" | "6045497" | "6050936" | "6059715" | "6077214" | "6149660" | "6162168" | "6165119" | "6165120" | "6177144" | "6183411" | "6190357" | "6197052" | "6234995" | "6245079" | "6260552" | "6261222" | "6264602").PN.	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 15:37
S29	7	S20 and purse	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 15:43
S30	3	S20 and purse-string	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 16:01
S31	93	purse-string and heart and leaflet	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 16:02

S32	69	purse-string and heart and leaflet and @ay<="2005"	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 16:02
S33	9	S20 and (tee or dopplar or ultrasound)	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 16:09
S34	1	"6997950".pn.	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 16:17
S35	110	606/145.ccls. and needle and suture	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 16:40
S36	0	606/145.ccls. and needle and suture and leaflet	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 16:41
S37	3	606/145.ccls. and needle and suture and heart valve	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 16:41
S38	0	"11813695" and in the heart	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 17:22
S39	0	"11813695" and in near heart	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 17:25
S40	0	"11813695" and in with heart	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 17:25
S41	1	"11813695"	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 18:00
S42	6	speziali, giovanni.in.	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 18:20
S43	231	623/2.11-2.35.ccls. and leaflet and heart valve and (chordae or chorda)	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 18:27
S44	199	623/2.11-2.35.ccls. and leaflet and heart valve and (chordae or chorda) and suture	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 18:27
S45	19	(("6269819") or ("20010016675") or ("6283993") or ("20010021872") or ("6312447") or ("6332863") or ("6332864") or ("6332893") or ("20020013571") or ("20020029080") or ("6355050") or ("20020049402") or ("6402679") or ("6402680") or ("6401720") or ("6402781") or ("6404420") or ("20020077524") or ("6436107")). PN.	US-PGPUB; USPAT	OR	OFF	2010/04/07 18:40
S46	19	(("6443922") or ("6451054") or ("6461366") or ("20020169359") or ("20020173694") or ("20020183766") or ("6508777") or ("6514194") or ("20030032979") or ("20030050529") or ("20030050693") or ("6537198") or ("6537314") or ("6551331") or ("20030078600") or ("6558416") or ("6562052") or ("6564805") or ("6582388")).PN.	US-PGPUB; USPAT	OR	OFF	2010/04/07 18:44

S47	19	(("6585727") or ("6589160") or ("20030130731") or ("6602288") or ("20030166992") or ("20030167071") or ("6616684") or ("20030171641") or ("6619291") or ("6622730") or ("20030181928") or ("6626930") or ("6629534") or ("6629921") or ("20030199975") or ("6645205") or ("20040003819") or ("6679268") or ("20040030382")).PN.	US-PGPUB; USPAT	OR	OFF	2010/04/07 18:47
S48	18	(("6695866") or ("20040039442") or ("20040044350") or ("20040049207") or ("20040049552") or ("6709456") or ("6718985") or ("6723038") or ("20040087975") or ("6733509") or ("20040092962") or ("6740107") or ("6746471") or ("6752813") or ("20040122448") or ("6755777") or ("20040127983") or ("20040133063")).PN.	US-PGPUB; USPAT	OR	OFF	2010/04/07 18:51
S49	19	(("6764510") or ("6770083") or ("6770084") or ("20040167374") or ("20040167539") or ("6793618") or ("6802860") or ("6808488") or ("6710882") or ("20040225300") or ("20040225304") or ("20040236354") or ("20040243229") or ("20040267083") or ("20050021056") or ("20050021057") or ("20050033446") or ("20050065396") or ("6875224")).PN.	US-PGPUB; USPAT	OR	OFF	2010/04/07 18:54
S50	20	(("20050075727") or ("20050075723") or ("20050101975") or ("20050125011") or ("20050131277") or ("20050131533") or ("6908424") or ("20050143620") or ("20050148815") or ("20050149014") or ("6918917") or ("6921407") or ("20050171601") or ("6929715") or ("20050216039") or ("6955175") or ("20050240202") or ("6962605") or ("20050251187") or ("6978176")).PN.	US-PGPUB; USPAT	OR	OFF	2010/04/07 18:59

S51	19	(("6986775") or ("6989028") or ("20060020275") or ("20060036317") or ("20060041306") or ("7004176") or ("7004952") or ("20060052868") or ("7011669") or ("20060058871") or ("20060074485") or ("20060089671") or ("20060241340") or ("7044905") or ("7048754") or ("20060127509") or ("20060135993") or ("20060149123") or ("7077862")).PN.	US-PGPUB; USPAT	OR	OFF	2010/04/07 19:03
S52	19	(("2006016040") or ("20060161193") or ("7083628") or ("7083638") or ("7090686") or ("20060184203") or ("7094244") or ("20060195012") or ("20060195134") or ("7100614") or ("7112207") or ("7112219") or ("20060287657") or ("20070027451") or ("20070002627") or ("7179291") or ("20070049952") or ("20070050022") or ("7186264") or ("20070055303")).PN.	US-PGPUB; USPAT	OR	OFF	2010/04/07 19:06
S53	17	(("7189199") or ("20070088375") or ("20070100356") or ("7217240") or ("20070112244") or ("20070118154") or ("20070118155") or ("7226467") or ("20070129737") or ("7247134") or ("7250028") or ("20070197858") or ("20070203391") or ("200702303391") or ("7288097") or ("20070265643") or ("20070299468") or ("20080051703")).PN.	US-PGPUB; USPAT	OR	OFF	2010/04/07 19:09
S54	9	("20030078465" | "20030105519" | "20040193191" | "20050070999" | "20050075727" | "20050125011" | "20050240202" | "20070118213" | "7144363").PN.	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 19:11
S55	12	(("20080065011") or ("20080065156") or ("20080065205") or ("20080091059") or ("20080091264") or ("20080167714") or ("20080183194") or ("20080188873") or ("20080195200") or ("20080208006") or ("20080228223") or ("7464712")).PN.	US-PGPUB; USPAT	OR	OFF	2010/04/07 19:22

S56	11	(("20090105729") or ("20080097489") or ("20090105751") or ("20090131880") or ("20090156995") or ("20090163934") or ("7563267") or ("7563273") or ("20090259304") or ("7604646") or ("7608091")).PN.	US-PGPUB; USPAT	OR	OFF	2010/04/07 19:25
S57	236	("20020035361" | "20020087048" | "20020087049" | "20020087166" | "20020087169" | "20020095167" | "20020095175" | "20020161378" | "20030018358" | "20030078465" | "20030105519" | "20030105520" | "20030233142" | "20040019378" | "20040024414" | "20040133192" | "20040152947" | "20050075723" | "20050197692" | "20050197693" | "20050197694" | "20060287661" | "20060287716" | "20070118154" | "3166072" | "3704711" | "4204283" | "4259959" | "4492229" | "4524771" | "4639252" | "4655773" | "4731075" | "4816339" | "4841888" | "4938760" | "5013316" | "5059201" | "5101592" | "5108420" | "5125926" | "5171252" | "5222508" | "5224946" | "5236445" | "5258016" | "5275162" | "5281218" | "5284488" | "5290300" | "5304184" | "5334217" | "5336252" | "5354298" | "5374275" | "5380334" | "5383897" | "5403329" | "5417699" | "5423856" | "5425744" | "5431666" | "5433727" | "5443446" | "5450860" | "5454807" | "5458609" | "5462560" | "5462561" | "5470338" | "5476470" | "5480403" | "5489298" | "5489498" | "5492119" | "5496336" | "5499991" | "5501691" | "5507811" | "5520700" | "5527321" | "5527322" | "5527342" | "5540704" | "5542917" | "5562686" | "5573540" | "5578045" | "5584859" | "5585616" | "5601558" | "5609598" | "5613974" | "5613975" | "5632752" | "5639276" | "5643317" | "5643320" | "5662654" | "5662663" | "5662683" | "5667513" | "5673695" | "5679005" | "5683402" | "5700273" | "5702421" | "5713903" | "5720753" | "5724978" | "5725521" | "5725552" | "5732707" | "5741297" | "5752963" | "5766234" | "5776189" | "5779719" | "5792152" | "5797960" | "5810847" | "5810849" | "5814070" | "5817110" |	US-PGPUB; USPAT	ADJ	OFF	2010/04/07 19:27

		"5823342" | "5823956" | "5824067" | "5827203" | "5827268" | "5829447" | "5830145" | "5836955" | "5846261" | "5855552" | "5855614" | "5860920" | "5860991" | "5861003" | "5868749" | "5868762" | "5888247" | "5895404" | "5910155" | "5928224" | "5944738" | "5944739" | "5947125" | "5947997" | "5948000" | "5948001" | "5954732" | "5957916" | "5968047" | "5972030" | "5989284" | "5993459" | "5997534" | "5997554" | "6004269" | "6010531" | "6012457" | "6013083" | "6014589" | "6019768" | "6036690" | "6056743" | "6068648" | "6074395" | "6077281" | "6077291" | "6079414" | "6086591" | "6086612" | "6096060" | "6113631" | "6120453" | "6126682" | "6146387" | "6149660" | "6152144" | "6152935" | "6159235" | "6161543" | "6165183" | "6167889" | "6174287" | "6187040" | "6206886" | "6231561" | "6245079" | "6269819" | "6270515" | "6280448" | "6283962" | "6283993" | "6290674" | "6290702" | "6306133" | "6311623" | "6319270" | "6332468" | "6332893" | "6334873" | "6344053" | "6346074" | "6346109" | "6355030" | "6355052" | "6363940" | "6368339" | "6409759" | "6440154" | "6451024" | "6472983" | "6547787" | "6592610" | "6599310" | "6616684" | "6619291" | "6626899" | "6629534" | "6669687" | "6695866" | "6702826" | "6718985" | "6719785" | "6740107" | "6743239" | "6746472" | "7087064" | "7101395" | "7186262" | "7189199" | "7217284" | "7562660" | "D404128").PN.			

4/8/2010 8:42:46 AM
C:\Documents and Settings\ctempleton\My Documents\EAST\Workspaces\11813695.wsp

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 6073

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/813,695	07/11/2007	606	3773	630666.00074

APPLICANTS

Giovanni Speziali, Pittsburgh, PA;

**** CONTINUING DATA ***************************

This application is a 371 of PCT/US06/01699 01/19/2006
which claims benefit of 60/645,677 01/21/2005

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **

Foreign Priority claimed	☐ Yes ☑ No	☐ Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
35 USC 119(a-d) conditions met	☐ Yes ☑ No					
Verified and Acknowledged	/CHRISTOPHER L TEMPLETON/ Examiner's Signature	Initials	PA	10	17	2

ADDRESS

QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI 53202-4497
UNITED STATES

TITLE

Thorascopic Heart Valve Repair Method and Apparatus

FILING FEE RECEIVED		
500	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

PTO/SB/08a (05-07)
Approved for use through 11/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11813695
Filing Date	2007-07-11
First Named Inventor	Giovanni Speziali
Art Unit	3731
Examiner Name	
Attorney Docket Number	630666.00074

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5908428		1999-06-01	Scirica et al.	
	2	6149660		2000-11-21	Laufer et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11813695
	Filing Date	2007-07-11
	First Named Inventor	Giovanni Speziali
	Art Unit	3731
	Examiner Name	
	Attorney Docket Number	630666.00074

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	PCT Search Report and Written Opinion for PCT/US06/01699.	☐

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	/Christopher Templeton/	Date Considered	04/08/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.T./

Docket Number 630666.00074

I hereby certify that this correspondence is being transmitted via the Electronic Filing System (EFS) of the U.S. Patent and Trademark Office.

Date: February 19, 2010

/Richard T. Roche/
Richard T. Roche, Reg. No. 38,599

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Giovanni Speziali

Serial No.: 11/813,695

Filed: July 11, 2007

Conf. No.: 6073

Art Unit: 3773

Examiner: Christopher L. Templeton

For: Thorascopic Heart Valve Repair Method and Apparatus

RESPONSE TO ELECTION/RESTRICTION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper is in response to the restriction and/or election requirement mailed January 26, 2010.

Amendments to the Claims begin on page 2.

Remarks begin on page 4.

CLAIMS

1. (Original) A method for repairing a heart valve, the steps comprising:

a) inserting an instrument through the subject's chest wall and into the chest cavity;

b) inserting the distal end of the instrument through a heart wall and entering a heart chamber;

c) grasping a leaflet on the heart valve with a movable device on the distal end of the instrument;

d) puncturing the leaflet with a needle disposed on the distal end of the instrument and drawing a suture through the puncture to connect the suture thereto;

e) anchoring the suture to another structure in the heart;

f) withdrawing the instrument from the heart chamber; and

g) withdrawing the instrument from the chest cavity.

2. (Original) The method as recited in claim 1 in which step e) includes withdrawing the suture with the instrument from the heart chamber as recited in step f) and anchoring the suture to the outer surface of the heart wall.

3. (Original) The method as recited in claim 2 in which the tension on the suture is adjusted before anchoring by observing the operation of the heart valve using a medical imaging system.

4. (Original) The method as recited in claim 1 which includes placing a purse-string suture in the heart wall around the location of the instrument insertion.

5. (Original) The method as recited in claim 1 in which the distal end of the instrument is inserted in step b) through the apex of the heart.

6. (Original) The method as recited in claim 5 in which step e) includes withdrawing the suture with the instrument from the heart chamber as recited in step f) and anchoring the suture to the outer surface of the heart wall near the apex of the heart.

7. (Cancelled).

8. (Cancelled).

9. (Cancelled).

10. (Cancelled).

11. (Cancelled).

12. (Cancelled).

13. (Cancelled).

14. (Cancelled).

15. (Cancelled).

16. (Cancelled).

17. (Cancelled).

REMARKS

Applicant hereby elects claims 1-6 of Group I.

With respect to the Examiner's requirement that the Applicant elect a species within Group I, Applicant elects Species A (Figures 8A-F) with traverse. It is submitted that the methods of claims 1-6 can be performed with any of the embodiments depicted in Figures 8A-F (Species A) and Figures 9A-10D (Species B). As such, Species A and Species B are generic to all of the claims in Group I.

Claims 7-17 have been cancelled. Applicant reserves the right to file a divisional application for the subject matter of claims 7-17.

Conclusion

No fees are believed to be due with this submission. If any fees are due please charge them to Deposit Account No. 17-0055.

Respectfully submitted,

Dated: February 19, 2010

/Richard T. Roche/

Richard T. Roche
Registration No. 38,599
Quarles and Brady LLP
411 East Wisconsin Ave.
Milwaukee, WI 53202
(414) 277-5805

9792665

Electronic Acknowledgement Receipt

EFS ID:	7049080
Application Number:	11813695
International Application Number:	
Confirmation Number:	6073
Title of Invention:	Thorascopic Heart Valve Repair Method and Apparatus
First Named Inventor/Applicant Name:	Giovanni Speziali
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	630666.00074
Receipt Date:	19-FEB-2010
Filing Date:	11-JUL-2007
Time Stamp:	15:50:42
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		mayo_74_response.pdf	50923 b4cde7d8ceee58e074af0936201e8708d249a959	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response to Election / Restriction Filed	1	1
	Claims	2	3
	Applicant Arguments/Remarks Made in an Amendment	4	4
Warnings:			
Information:			
	Total Files Size (in bytes):	50923	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/813,695	07/11/2007	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 02/19/2010	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 6	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/PATRICIA WARNER/

Docket Number: 630666.00074

I hereby certify that, on the date shown below, this correspondence is being transmitted via the U.S. Patent and Trademark Office's Patent Electronic Filing System (EFS).

Date: February 8, 2010 /Richard T. Roche/
Richard T. Roche, Reg. No. 38,599

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Giovanni Speziali
Serial No.:	11/813,695
Filed:	July 11, 2007
Conf. No.:	6073
Art Unit:	3773
Examiner:	Christopher L. Templeton
For:	Thorascopic Heart Valve Repair Method and Apparatus

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.97-1.98, Applicant is submitting herewith a listing of documents on a substitute for form 1449/PTO. For those documents that are not a U.S. patent/patent application publication document, a copy is also attached.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any rights to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Applicant respectfully requests that the listed documents be considered by the Examiner, be made of record in the present application and that an initialed copy of Form 1449/PTO be returned in accordance with MPEP § 609.

Respectfully submitted,
Giovanni Speziali

Date: February 8, 2010 /Richard T. Roche/
Richard T. Roche, Reg. No. 38,599
Attorney for Applicants
Quarles & Brady LLP
411 E. Wisconsin Ave.
Milwaukee, WI 53202
414-277-5805

QB\9713004.1

Substitute for form 1449/PTO				Complete if Known	
				Application Number	11/813,695
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	July 11, 2007
(Use as many sheets as necessary)				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	1	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-3,667,474	06-06-1972	Konstantin V. Lapkin et al.
		US-3,842,840	10-22-1974	Edward E. Schweizer
		US-4,351,345	09-28-1982	Andrew L. Carney
		US-4,972,874	11-27-1990	Harold E. Jackson
		US-5,059,201	10-22-1991	Stanely E. Asnis
		US-5,336,229	08-09-1994	Wayne A. Noda
		US-5,452,733	09-26-1995	Wesley D. Sterman et al.
		US-5,571,215	11-05-1996	Wesley D. Sterman et al.
		US-5,653,716	08-05-1997	Cheryne M. Malo et al.
		US-5,693,091	12-02-1997	Carl O. Larson Jr. et al.
		US-5,762,613	06-09-1998	Gregg S. Sutton et al.
		US-5,772,672	06-30-1998	Frederick K. Toy et al.
		US-5,797,960	08-25-1998	John H. Stevens et al.
		US-5,839,639	11-24-1998	Jude S. Sauer et al.
		US-5,919,128	07-06-1999	Joseph P. Fitch
		US-5,961,440	10-05-1999	Cyril J. Schweich Jr. et al.
		US-5,972,030	10-26-1999	Michi E. Garrison et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		EP 1 039 851 B1	07-20-2005	Todd J. Mortier et al.	
		EP 1 408 850 B1	09-23-2009	Eric A. Goldfarb et al.	
		EP 1 637 091 A2	03-22-2006	Todd J. Mortier et al.	
		EP 1 845 861 A2			
		EP 1 845 861 A4			
		WO 1999/00059	01-07-1999	Mehmet C. Oz	

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	11/813,695
				Filing Date	July 11, 2007
				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	2	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,022,360	02-08-2000	William J. Reimels et al.
		US-6,045,497	04-04-2000	Cyril J. Schweich Jr. et al.
		US-6,050,936	04-18-2000	Cyril J. Schweich Jr. et al.
		US-6,059,715	05-09-2000	Cyril J. Schweich Jr. et al.
		US-6,077,214	06-20-2000	Todd J. Mortier et al.
		US-6,117,144	09-12-2000	Anthony A. Nobles et al.
		US-6,162,168	12-19-2000	Cyril J. Schweich Jr. et al.
		US-6,165,119	12-26-2000	Cyril J. Schweich Jr. et al.
		US-6,165,120	12-26-2000	Cyril J. Schweich Jr. et al.
		US-6,165,183	12-26-2000	Stephen T. Kuehn et al.
		US-6,183,411	02-06-2001	Todd J. Mortier et al.
		US-6,190,357	02-20-2001	Richard M. Ferrari et al.
		US-6,197,052	03-06-2001	Delos M. Cosgrove et al.
		US-6,234,995	05-22-2001	James C. Peacock III
		US-6,245,079	06-12-2001	Anthony A. Nobles et al.
		US-6,260,552	07-17-2001	Todd J. Mortier et al.
		US-6,261,222	07-17-2001	Cyril J. Schweich Jr. et al.
		US-6,264,602	07-24-2001	Todd J. Mortier et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 99/30647	06-24-1999	Todd J. Mortier et al.	
		WO 00/16700	03-30-2000	Todd J. Mortier et al.	
		WO 00/06026 A2 (corrected version)	02-10-2000	Cyril J. Schweich et al.	
		WO 00/06026 A2	02-10-2000	Cyril J. Schweich et al.	
		WO 00/06026 A3	02-10-2000	Cyril Schweich et al.	
		WO 00/06027 A2 (corrected version)	02-10-2000	Todd J. Mortier et al.	
		WO 00/06027 A2	02-10-2000	Todd J. Mortier et al.	

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	11/813,695
				Filing Date	July 11, 2007
				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	3	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,269,819	08-07-2001	Mehmet C. Oz et al.
		US-2001/0016675	08-23-2001	Todd J. Mortier et al.
		US-6,283,993	09-04-2001	Delos M. Cosgrove et al.
		US-2001/0021872	09-13-2001	Steven R. Bailey et al.
		US-6,312,447	11-06-2001	Randall Y. Grimes
		US-6,332,863	12-25-2001	Cyril J. Schweich Jr. et al.
		US-6,332,864	12-25-2001	Cyril J. Schweich Jr. et al.
		US-6,332,893	12-25-2001	Todd J. Mortier et al.
		US-2002/0013571	01-31-2002	Eric A. Goldfarb et al.
		US-2002/0029080	03-07-2002	Todd J. Mortier et al.
		US-6,355,050	03-12-2002	Bernard H. Andreas et al.
		US-2002/0049402	04-25-2002	James C. Peacock III et al.
		US-6,402,679	06-11-2002	Todd J. Mortier et al.
		US-6,402,680	06-11-2002	Todd J. Mortier et al.
		US-6,401,720	06-11-2002	John H. Stevens et al.
		US-6,402,781	06-11-2002	Jonathan J. Langberg et al.
		US-6,406,420 B1	06-18-2002	Patrick M. McCarthy et al.
		US-2002/0077524 A1	06-20-2002	Cyril J. Schweich Jr. et al.
		US-6,436,107 B1	08-20-2002	Yulun Wang et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 00/06027 A3	02-10-2000	Todd J. Mortier et al.	
		WO 00/06028 A1	02-10-2000	Todd J. Mortier et al.	
		WO 01/66018 A1	09-13-2001	Richard A. Gambale et al.	
		WO 01/095809 A1	12-20-2001	Anthony A. Nobles et al.	
		WO 03/059209 A2	07-24-2003	Robert M. Vidlund et al.	
		WO 03/059209 A3	07-24-2003	Robert M. Vidlund et al.	

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
				Application Number	11/813,695
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	July 11, 2007
(Use as many sheets as necessary)				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	4	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,443,922 B1	09-03-2002	Craig P. Roberts et al.
		US-6,451,054	09-17-2002	John H. Stevens
		US-6,461,366	10-08-2002	Jacques Seguin
		US-2002/0169359 A1	11-14-2002	Patrick M. McCarthy et al.
		US-2002/0173694 A1	11-21-2002	Todd J. Mortier et al.
		US-2002/0183766 A1	12-05-2002	Jacques Sequin
		US-6,508,777 B1	01-21-2003	John Macoviak et al.
		US-6,514,194 B2	02-04-2003	Cyril J. Schweich Jr. et al.
		US-2003/0032979 A1	02-13-2003	Todd J. Mortier et al.
		US-2003/0050529 A1	03-13-2003	Robert M. Vidlund et al.
		US-2003/0050693 A1	03-13-2003	Rodolfo C. Quijano et al.
		US-6,537,198 B1	03-25-2003	Robert M. Vidlund et al.
		US-6,537,314 B2	03-25-2003	Jonathan J. Langberg et al.
		US-6,551,331 B2	04-22-2003	Anthony A. Nobles et al.
		US-2003/0078600 A1	04-24-2003	Philip S. O'Quinn et al.
		US-6,558,416 B2	05-06-2003	Delos M. Cosgrove et al.
		US-6,562,052 B2	05-13-2003	Anthony A. Nobles et al.
		US-6,564,805 B2	05-20-2003	Michi E. Garrison et al.
		US-6,582,388 B1	06-24-2003	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 03/082157 A2	10-09-2003	Stefan Schreck	
		WO 03/082157 A3	10-09-2003	Stefan Schreck	
		WO 04/043265 A2	05-27-2004	Robert M. Vidlund et al.	
		WO 04/043265 A3	05-27-2004	Robert M. Vidlund et al.	
		WO 05/039428 A2	05-06-2005	Jan Lan	
		WO 05/039428 A3	05-06-2005	Jan Lan	

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
				Application Number	11/813,695
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	July 11, 2007
(Use as many sheets as necessary)				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	5	of	15	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,585,727 B1	07-01-2003	Christopher M. Cashman et al.
		US-6,589,160 B2	07-08-2003	Cyril J. Schweich Jr. et al.
		US-2003/0130731 A1	07-10-2003	Robert M. Vidlund et al.
		US-6,602,288 B1	08-05-2003	Delos M. Cosgrove et al.
		US-2003/0166992 A1	09-04-2003	Cyril J. Schweich Jr. et al.
		US-2003/0167071 A1	09-04-2003	Brian B. Martin et al.
		US-6,616,684 B1	09-09-2003	Robert M. Vidlund
		US-2003/0171641 A1	09-11-2003	Cyril J. Schweich Jr. et al.
		US-6,619,291 B2	09-16-2003	Edwin J. Hlavka et al.
		US-6,622,730 B2	09-23-2003	Craig A. Ekvall et al.
		US-2003/0181928 A1	09-25-2003	Robert M. Vidlund et al.
		US-6,626,930 B1	09-30-2003	William J. Allen et al.
		US-6,629,534 B1	10-07-2003	Frederick G. St. Goar et al.
		US-6,629,921 B1	10-07-2003	Cyril J. Schweich Jr. et al.
		US-2003/0199975 A1	10-23-2003	Shlomo Gabbay
		US-6,645,205 B2	11-11-2003	Richard S. Ginn
		US-2004/0003819 A1	01-08-2004	Frederick G. St. Goar et al.
		US-6,679,268 B2	01-20-2004	John H. Stevens et al.
		US-2004/0030382 A1	02-12-2004	Frederick G. St. Goar et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 05/094525 A2	10-13-2005	Richard M. Beane et al.	
		WO 06/032051 A2	03-23-2006	Avraham Zakay et al.	
		WO 06/032051 A3	03-23-2006	Avraham Zakay et al.	
		WO 06/065966 A2	06-22-2006	Richard M. Beane et al.	
		WO 06/065966 A3	06-22-2006	Richard M. Beane et al.	
		WO 06/078694 A2	07-27-2006	Giovanni Speziali	

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	11/813,695
				Filing Date	July 11, 2007
				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	6	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,695,866 B1	02-24-2004	Stephen T. Kuehn et al.
		US-2004/0039442 A1	02-26-2004	Federick G. St. Goar et al.
		US-2004/0044350 A1	03-04-2004	Brian B. Martin et al.
		US-2004/0049207 A1	03-11-2004	Eric A. Goldfarb et al.
		US-2004/0049552 A1	03-11-2004	Tetsuro Motoyama et al.
		US-6,709,456 B2	03-23-2004	Jonathan J. Langberg et al.
		US-6,718,985 B2	04-13-2004	Edwin J. Hlavka et al.
		US-6,723,038 B1	04-20-2004	Richard F. Schroeder et al.
		US-2004/0087975 A1	05-06-2004	Sylvester Lucatero et al.
		US-6,733,509 B2	05-11-2004	Anthony A. Nobles et al.
		US-2004/0092962 A1	05-13-2004	Troy L. Thornton et al.
		US-6,740,107 B2	05-25-2004	Marvin P. Loeb et al.
		US-6,746,471 B2	06-08-2004	Todd J. Mortier et al.
		US-6,752,813 B2	06-22-2004	Eric A. Goldfarb et al.
		US-2004/0122448 A1	06-24-2004	Robert A. Levine
		US-6,755,777 B2	06-29-2004	Cyril J. Schweich Jr. et al.
		US-2004/0127983 A1	07-01-2004	Todd J. Mortier et al.
		US-2004/0133063 A1	07-08-2004	Patrick m. McCarthy et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 06/078694 A3	07-27-2006	Giovanni Speziali	
		WO 06/116310 A2	11-02-2006	Robert M. Vidlund et al.	
		WO 06/116310 A3	11-02-2006	Robert M. Vidlund et al.	
		WO 06/127509 A2	11-30-2006	Giovanni Speziali et al.	
		WO 06/127509 A3	11-30-2006	Giovanni Speziali et al.	
		WO 07/002627 A1	01-04-2007	Patrick Perier et al.	
		WO 07/027451 A2	03-08-2007	Steven J. Weiss	

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	11/813,695
				Filing Date	July 11, 2007
				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	7	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,764,510 B2	07-20-2004	Robert M. Vidlund et al.
		US-6,770,083 B2	08-03-2004	Jacques Seguin
		US-6,770,084 B1	08-03-2004	Gregory H. Bain et al.
		US-2004/0167374 A1	08-26-2004	Cyril Schweich et al.
		US-2004/0167539 A1	08-26-2004	Stephen T. Kuehn et al.
		US-6,793,618 B2	09-21-2004	Cyril J. Schweich Jr. et al.
		US-6,802,860 B2	10-12-2004	Delos M. Cosgrove et al.
		US-6,808,488 B2	10-26-2004	Todd J. Mortier et al.
		US-6,810,882 B2	11-02-2004	Jonathan J. Langberg et al.
		US-2004/0225300 A1	11-11-2004	Eric A. Goldfarb et al.
		US-2004/0225304 A1	11-11-2004	Robert M. Vidlund et al.
		US-2004/0236354 A1	11-25-2004	Jacques Seguin
		US-2004/0243229 A1	12-02-2004	Robert M. Vidlund et al.
		US-2004/0267083 A1	12-30-2004	Patrick M. McCarthy et al.
		US-2005/0021056 A1	01-27-2005	Frederick G. St. Goar et al.
		US-2005/0021057 A1	01-27-2005	Frederick G. St. Goar et al.
		US-2005/0033446 A1	02-10-2005	Mark E. Deem et al.
		US-2005/0065396 A1	03-24-2005	Todd J. Mortier et al.
		US-6,875,224 B2	04-05-2005	Randall Y. Grimes

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 07/027451 A3	03-08-2007	Steven J. Weiss	
		WO 07/062128 A2	05-31-2007	Dean T. Crabtree	
		WO 07/062128 A3	05-31-2007	Dean T. Crabtree	
		WO 07/081418 A1	07-19-2007	Richard M. Beane et al.	
		WO 07/117612 A1	10-18-2007	Richard M. Beane et al.	
		WO 08/010738 A2	01-24-2008	Uros Babic	

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
				Application Number	11/813,695
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	July 11, 2007
(Use as many sheets as necessary)				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	8	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-2005/0075727 A1	04-07-2005	David J. Wheatley
		US-2005/0075723 A1	04-07-2005	Richard Schroeder et al.
		US-2005/0101975 A1	05-12-2005	John D. Nguyen et al.
		US-2005/0125011 A1	06-09-2005	Paul A. Spence et al.
		US-2005/0131277 A1	06-16-2005	06-16-2005
		US-2005/0131533 A1	06-16-2005	Ottavio Alfieri et al.
		US-6,908,424 B2	06-21-2005	Todd J. Mortier et al.
		US-2005/0143620 A1	06-30-2005	Todd J. Mortier et al.
		US-2005/0148815 A1	07-07-2005	Todd J. Mortier et al.
		US-2005/0149014 A1	07-07-2005	Wallace N. Hauck et al.
		US-6,918,917 B1	07-19-2005	John D. Nguyen et al.
		US-6,921,407 B2	07-26-2005	John D. Nguyen et al.
		US-2005/0171601 A1	08-04-2005	Delos M. Cosgrove et al.
		US-6,929,715 B2	08-16-2005	Gerdt Fladda et al.
		US-2005/0216039 A1	09-29-2005	Robert J. Lederman
		US-6,955,175 B2	10-18-2005	John H. Stevens et al.
		US-2005/0240202 A1	10-27-2005	Hani Shennib et al.
		US-6,962,605 B2	11-08-2005	Delos M. Cosgrove et al.
		US-2005/0251187 A1	11-10-2005	Richard M. Beane et al.
		US-6,978,176 B2	12-20-2005	Omar M. Lattouf

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		WO 09/052528 A2	04-23-2009	John Zentgraf	
		WO 09/052528 A3	04-23-2009	John Zentgraf	

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449/PTO				Complete if Known	
				Application Number	11/813,695
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	July 11, 2007
(Use as many sheets as necessary)				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	9	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,986,775 B2	01-17-2006	Rodolfo A. Morales et al.
		US-6,989,028 B2	01-24-2006	Randall T. Lashinski et al.
		US-2006/0020275 A1	01-26-2006	Eric A. Goldfarb et al.
		US-2006/0036317 A1	02-16-2006	Robert M. Vidlund et al.
		US-2006/0041306 A1	02-23-2006	Robert M. Vidlund et al.
		US-7,004,176 B2	02-28-2006	Jan Lau
		US-7,004,952 B2	02-28-2006	Anthony A. Nobles et al.
		US-2006/0052868 A1	03-09-2006	Todd J. Mortier et al.
		US-7,011,669 B2	03-14-2006	Per Ola Kimblad
		US-2006/0058871 A1	03-16-2006	Avraham Zakay et al.
		US-2006/0074485 A1	04-06-2006	Fidel Realyvasquez
		US-2006/0089671 A1	04-27-2006	Eric A. Goldfarb et al.
		US 2006/0100699 A1	05-11-2006	Robert M. Vidlund et al.
		US-2006/0241340 A1	10-26-2006	Robert M. Vidlund et al.
		US-7,044,905 B2	05-16-2006	Robert Vidlund et al.
		US-7,048,754 B2	05-23-2006	Brian B. Martin et al.
		US-2006/0127509 A1	06-15-2006	Christopher B. Eckman et al.
		US-2006/0135993 A1	06-22-2006	Jacques Seguin
		US-2006/0149123 A1	07-06-2006	Robert M. Vidlund et al.
		US-7,077,862 B2	07-18-2006	Robert M. Vidlund et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
				Application Number	11/813,695
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	July 11, 2007
(Use as many sheets as necessary)				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	10	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-2006/016040 A1	07-20-2006	Patrick M. McCarthy et al.
		US-2006/0161193 A1	07-20-2006	Richard M. Beane et al.
		US-7,083,628 B2	08-01-2006	Alan Bachman
		US-7,083,638 B2	08-01-2006	Seth A. Foerster
		US-7,090,686 B2	08-15-2006	Anthony A. Nobles et al.
		US-2006/0184203 A1	08-17-2006	Brian B. Martin et al.
		US-7,094,244 B2	08-22-2006	Stefan Schreck
		US-2006/0195012 A1	08-31-2006	Todd J. Mortier et al.
		US-2006/0195134 A1	08-31-2006	James F. Crittenden
		US-7,100,614 B2	09-05-2006	John H. Stevens et al.
		US-7,112,207 B2	09-26-2006	William J. Allen et al.
		US-7,112,219 B2	09-26-2006	Robert M. Vidlund et al.
		US-2006/0287657 A1	12-21-2006	Alan B. Bachman
		US-2007/0002627 A1	01-04-2007	Tae Un Youn
		US-2007/0027451 A1	02-01-2007	Kai Desinger et al.
		US-7,179,291 B2	02-20-2007	Jonathan M. Rourke et al.
		US-2007/0049952 A1	03-01-2007	Steven J. Weiss
		US-2007/0050022 A1	03-01-2007	Robert M. Vidlund et al.
		US-7,186,264 B2	03-06-2007	John R. Liddicoat et al.
		US-2007/0055303 A1	03-08-2007	Robert M. Vidlund et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [3]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	11/813,695
				Filing Date	July 11, 2007
				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	11	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-7,189,199 B2	03-13-2007	Patrick M. McCarthy et al.
		US-2007/0088375 A1	04-19-2007	Richard M. Beane et al.
		US-2007/0100356 A1	05-03-2007	Sylvester Lucatero et al.
		US-7,217,240 B2	05-15-2007	Edward Ramsey Snow
		US-2007/0112244 A1	05-17-2007	Patrick M. McCarthy et al.
		US-2007/0118154 A1	05-24-2007	Traves Dean Crabtree
		US-2007/0118155 A1	05-24-2007	Eric A. Goldfarb et al.
		US-7,226,467 B2	06-05-2007	Sylvester Lucatero et al.
		US-2007/0129737 A1	06-07-2007	Eric A. Goldfarb et al.
		US-7,247,134 B2	07-24-2007	Robert M. Vidlund et al.
		US-7,250,028 B2	07-31-2007	Christopher A. Julian et al.
		US-2007/0197858 A1	08-23-2007	Eric A. Goldfarb et al.
		US-2007/0203391 A1	08-30-2007	Eliot Bloom et al.
		US-2007/0239272 A1	10-11-2007	Jose Luis Navia et al.
		US-7,288,097 B2	10-30-2007	Jacques Séquin
		US-7,294,148 B2	11-13-2007	Patrick M. McCarthy
		US-2007/0265643 A1	11-15-2007	Richard M. Beane et al.
		US-2007/0299468 A1	12-27-2007	Frank J. Viola
		US-2008/0051703 A1	02-28-2008	Troy L. Thornton et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
				Application Number	11/813,695
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	July 11, 2007
(Use as many sheets as necessary)				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	12	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-2008/0065011 A1	03-13-2008	Philippe Marchand et al.
		US-2008/0065156 A1	03-13-2008	David L. Hauser et al.
		US-2008/0065205 A1	03-13-2008	Duy Nguyen et al.
		US-2008/0091059 A1	04-17-2008	Timothy R. Machold et al.
		US-2008/0091264 A1	04-17-2008	Timothy R. Machold et al.
		US-2008/0097489 A1	04-24-2008	Eric A. Goldfarb et al.
		US-2008/0167714 A1	07-10-2008	Federick G. St. Goar et al.
		US-2008/0183194 A1	07-31-2008	Eric A. Goldfarb et al.
		US-2008/0188873 A1	08-07-2008	Giovanni Speziali
		US-2008/0195200 A1	08-14-2008	Robert M. Vidlund et al.
		US-2008/0208006 A1	08-28-2008	Mina Farr
		US-2008/0228223 A1	09-18-2008	Yousef F. Alkhatib
		US-7,464,712 B2	12-16-2008	Mehmet C. Oz et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

Substitute for form 1449/PTO				Complete if Known	
				Application Number	11/813,695
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	July 11, 2007
(Use as many sheets as necessary)				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	13	of	14	Attorney Docket Number	630666.00074

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-2009/0105729 A1	04-23-2009	John Zentgraf
		US-2009/0105751 A1	04-23-2009	John Zentgraf
		US-2009/0131880 A1	05-21-2009	Giovanni Speziali et al.
		US-2009/0156995 A1	06-18-2009	Brian B. Martin et al.
		US-2009/0163934 A1	06-25-2009	Alfred H. Raschdorf Jr. et al.
		US-7,563,267 B2	07-21-2009	Eric A. Goldfarb et al.
		US-7,563,273 B2	07-21-2009	Eric A. Goldfarb et al.
		US-2009/0259304 A1	10-15-2009	Patricia O'Beirne et al.
		US-7,604,646 B2	10-20-2009	Eric A. Goldfarb et al.
		US-7,608,091 B2	10-27-2009	Eric A. Goldfarb et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	11/813,695
				Filing Date	July 11, 2007
				First Named Inventor	Giovanni Speziali
				Art Unit	3773
				Examiner Name	Christopher Templeton
Sheet	14	of	14	Attorney Docket Number	630666.00074

NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Port Access System For Mitral Valve Repair Proves Its Value In Study; MedGadget July 9, 2009; available at: http://www.medgadget.com/archives/2009/07/port_access_system_for_mitral_valve_repair_proves_its_value_in_study.html. (5 pages).	
		Interactive CardioVascular And Thoracic Surgery; Abstracts: Supplemental 3 to Vol. 7 (September 2008). 52 pages.	
		Image File Wrapper for U.S. Application No. 12/254,807 (filed October 20, 2008).	
		Image File Wrapper For U.S. Application No. 12/254,808 (filed October 20, 2008).	

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 039 851 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
20.07.2005 Bulletin 2005/29

(21) Application number: **98965994.1**

(22) Date of filing: **16.12.1998**

(51) Int Cl.[7]: **A61F 2/24**

(86) International application number:
PCT/US1998/026667

(87) International publication number:
WO 1999/030647 (24.06.1999 Gazette 1999/25)

(54) **VALVE TO MYOCARDIUM TENSION MEMBERS DEVICE AND METHOD**

SPANNUNGS-VORRICHTUNG ZWISCHEN HERZKLAPPE UND MYOCARDIUM SOWIE ENTSPRECHENDES VERFAHREN

SYSTEME D'ELEMENTS TENDEURS ENTRE VALVULE ET MYOCARDE ET PROCEDE

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE

(30) Priority: **17.12.1997 US 992316**

(43) Date of publication of application:
04.10.2000 Bulletin 2000/40

(73) Proprietor: **Myocor, Inc.**
St. Paul, MN 55108 (US)

(72) Inventors:
- **MORTIER, Todd, J.**
  Minneapolis, MN 55408 (US)
- **SCHWEICH, Cyril, J., Jr.**
  St. Paul, MN 55116 (US)

(74) Representative: **Pedersen, Tenna Marian et al**
Zacco Denmark A/S
Hans Bekkevolds Allé 7
2900 Hellerup (DK)

(56) References cited:
WO-A-95/06447 **WO-A-96/04852**

EP 1 039 851 B1

Description

Backaround of the Invention

[0001] The present invention pertains generally to the field of heart valve repair. More specifically, the present invention pertains to a device for the reduction of myocardial wall tension and the repair of mitral valve insufficiency.

[0002] Dilated cardiomyopathy is often accompanied by mitral valve insufficiency. There are several reasons for the presence of mitral valve insufficiency associated with a dilated heart. First, chamber dilation and associated high wall stresses increase the diameter of the mitral valve annulus. Additionally, as the heart dilates, the positioning of the papillary muscles is altered. Papillary muscles and chordae in a dilated heart will have moved both radially away and down from the mitral valve. This rearrangement of the vascular apparatus and enlargement of the annulus prevent the valve from closing properly.

[0003] Currently mitral valve insufficiency is treated by either repairing or replacing the valve. Surgical procedures used to repair the valve including ring posterior annuloplasty which consists of sewing a C or D-shaped ring around the posterior leaflet of the mitral valve and drawing in the annulus, reducing its previously enlarged diameter. Another method is to approximate the anterior and posterior mitral leaflets (Alfieri repair) by placing one suture through the center of both leaflets. This gives the valve a figure 8-shaped appearance when the valve is opened. When the mitral valve is replaced, the original leaflets are removed and the chordae are cut. An artificial valve consists of mechanical or tissue leaflets suspended on struts attached to a metal stent, and is sutured into place on the mitral annulus.

[0004] It has been argued that valve repair is preferable to valve replacement if the leaflet-chordae-papillary connections can be maintained. Heart wall stress will increase if the chordae are cut during valve replacement. It has been shown that by severing the chordae there can be 30 percent (30%) reduction in chamber function. Mitral valve replacement has high morality in very sick, chronic heart failure patients.

[0005] Document WO-A-95/06447 discloses a device for repairing a heart valve.

Summary of the Invention

[0006] The present invention pertains to a device for mitral valve repair. The mitral valve is generally defined as its leaflets or cusps, but in reality, it actually consists of the entire left ventricle chamber. By creating an improved chamber geometry, both chamber and valve function will be improved. The device of the present invention and method for valve repair/replacement can include treatment for chronic heart failure by reducing left ventricular wall tension.

[0007] The valve repair device includes an elongate tension member having a first end and second end. The basal anchor is disposed at the first end and the secondary anchor is disposed at the second end.

[0008] The basal anchor could include a pad and annuloplasty ring or the like. Alternately an artificial heart valve could serve as the basal anchor.

[0009] Tension members can be substantially rigid or substantially flexible. The secondary anchor can include a hook-shaped papillary muscle tissue loop, screw-shaped tissue anchor or transmural anchor pad.

[0010] A method using the present invention providing a tension member having a first end and a second end. The tension member has a basal anchor at the first end and a secondary anchor at the second end. The basal anchor is anchored proximate to the valve such that the tension member is disposed in the chamber. The secondary anchor is anchored to a portion of the heart spaced from the basal anchor such that the tension member is under tension and the geometry of the chamber has been altered by placement of the tension member.

[0011] The basal anchor can include an artificial heart valve, annuloplasty ring or the like. The secondary anchor can be anchored to a papillary muscle or transmurally anchored.

[0012] More than one tension member can be used. Additionally, a transverse tension member can be placed across the chamber generally perpendicular to the other tension members to further alter the geometry of the heart, reducing wall stress and improving chamber performance. The invention is defined in claim 1. Any embodiment which is in contradiction to the subject-matter of claim 1 is not part of the invention.

Brief Description of the Drawings

[0013]

Figure 1 is a transverse cross section of the left ventricle of a human heart taken from Figure 2;

Figure 2 is a vertical cross section of the left ventricle of a human heart;

Figure 3 is a modified, transverse, cross section of the left ventricle of a human heart taken from Figure 4;

Figure 4 is modified, vertical cross section of a human heart, modified by a device in accordance with the present invention;

Figure 5 is a cross section of an insufficient mitral valve of a left ventricle of a human heart;

Figure 6 is a cross section of a repaired valve and device in accordance with the present invention;

Figure 7 is an embodiment of the device of the present invention;

Figure 8 is an alternate embodiment of a device in accordance with the present invention;

Figure 9 is yet another alternate embodiment of a

device in accordance with the present invention;
Figure 10 is yet another alternate embodiment of the device in accordance with the present invention;
Figure 11 is yet another alternate embodiment of a device in accordance with the present invention;
Figure 12 is a view of a basal anchor for the device of the present invention;
Figure 13 is a suture ring serving as a basal anchor for the device of the present invention;
Figure 14 is a replacement valve serving as a anchor for the device of the present invention;
Figure,15 is a top view of an alternate embodiment of a suture ring acting as an anchor for the device of the present invention;
Figure 16 is a side view of the suture ring of Figure 15;
Figure 17 is a view of an alternate embodiment of a suture ring which can act as basal anchor for the device of the present invention;
Figure 18 is a view of yet another alternate embodiment of a suture ring which can act as a basal anchor for the present invention;
Figure 19 is a embodiment of a secondary anchor for the device of the present invention;
Figure 20 is a view of an alternate embodiment of a secondary anchor for the device of the present invention; and
Figure 21 is yet another embodiment of a secondary anchor for the device of the present invention.

Detailed Description of the Invention

[0014] Referring now the drawings wherein like reference numerals refer to like elements throughout the several views, Figure 1 shows a transverse cross section of the left ventricle 10 of a failing heart taken from Figure 2. The papillary muscles 12 are shown in cross section. Figure 2 is a vertical cross section of human heart 10. A mitral valve is disposed near the top of left ventricle 10. Mitral valve 14 includes two leaflets or cusps 16. Chordae 18 extend between leaflets 16 and papillary muscles 12.

[0015] Figure 3 is a cross section of heart 10 modified from that shown in Figure 1 by placement of valve repair device 20 in accordance with the present invention as shown in Figure 4. Figure 4 is a vertical cross section of left ventricle 10 with geometry modified by device 20. In this embodiment of the invention, device 20 includes a basal anchor 22 such as an annuloplasty or suture ring sewn proximate the annulus of valve 14. Extending from basal anchor 22 are elongate tension members 24. Each have a first end connected to basal anchor 22 and a second end anchored to papillary muscles 12 or the heart wall.

[0016] As can be seen in Figures 3 and 4, both the transverse radius and vertical dimension of left ventricle 10 has been reduced in comparison to that of Figures 1 and 2 by drawing papillary muscles 12 toward valve 14 with tension members 24. This change in geometry reduces heart wall stress and consequently increasing chamber function. Valve function is also improved as explained in more detail by reference to Figures 5 and 6.

[0017] Figure 5 is a generally vertical cross section of an insufficient mitral valve of a heart suffering from chronic heart failure. In this case as the failing heart has dilated, papillary muscle 12 has been drawn away from mitral valve 14. The chordae connections between papillary muscles 12 and valve 14 in turn draws leaflets 16 apart such that during the normal cardiac cycle, leaflets 16 may not completely close. Thus, an opening 26 is left between leaflets 16 throughout the cardiac cycle. Opening 26 will allow blood to leak, reducing chamber efficiency.

[0018] Figure 6 is a view of the mitral valve 14 of Figure 5 which has been modified by placement of valve repair device 20 as shown. Suture ring 22 is sewn proximate the annulus of valve 14, as known to those skilled in the use of suture rings. The annulus of valve 14 can be decreased in size by drawing the annulus toward the suture ring by the sutures used to connect ring 22 to the valve. Drawing the annulus of valve 14 toward suture ring 22 will help to eliminate opening 26. Tension member 24 is then anchored to papillary muscle 12 such that papillary muscle 12 is drawn toward valve 14. Whether or not the suture ring alone is sufficient to eliminate opening 26, drawing papillary muscle 12 toward valve 14 will provide additional stress relief on leaflet 16 promoting complete closure of valve 14. Drawing papillary muscle 12 toward 14 also reduces heart wall stress and increases chamber efficiency as discussed previously.

[0019] Figure 7 is a highly simplified view of left ventricle 10 and valve repair device 20 as shown in Figure 4. It can be noted that tension members 24 extend from basal anchor 22 to an adjacent papillary muscle 12. In contrast, Figure 8 is a similar cross sectional view of left ventricle 10, but a valve repair device 120 is placed such that its tension members 124 extend between a basal anchor 122 and a papillary muscle 12 transversely opposite the point at which tension member 124 is connected to basal anchor 122. This arrangement, as opposed to that shown in Figure 7, can increase the transverse component of the tension force in tension members 124 relative to the vertical component of that tensile force.

[0020] Figure 9 shows yet another embodiment of the valve repair device in accordance with the present invention referred to by numeral 220. In this embodiment, device 220 is disposed in left ventricle 10 in a manner similar to that of device 20 shown in Figure 7 in that tension members 224 of device 220 extend from a basal anchor 222 to an adjacent secondary anchor point. The secondary anchor point is established by transverse extension of a tension member 225 across left ventricle 10. Tension member 225 is anchored transmurally to the heart wall at its opposite ends by pads 227. In turn, tension members 224 are anchored or connected to ten-

sion member 225.

[0021] Tension member 225 can be used to further alter the geometry of left ventricle 10 in a manner disclosed in U.S. Patent Application Serial No. 08/933,456, entitled "HEART WALL TENSION REDUCTION APPARATUS AND METHOD", which was filed on September 18, 1997.

[0022] Figure 10 shows yet another embodiment of a valve repair device in accordance with the present invention referred to by numeral 320. This embodiment includes a basal anchor 322 and tension members 324 and a transverse tension member 325 having anchor pads 327 similar to those of device 220. With respect to device 320, however, tension members 324 are crossed similar to those of device 120 of Figure 8 to increase the horizontal component relative to the vertical component of the tensile force in tension member 324.

[0023] Figure 11 is a yet another embodiment 420 of the valve repair device of the present method. Valve repair device 420 includes a basal anchor 422 and tension members 424. Tension members 424 are disposed in an arrangement similar to tension members 24 of device 20 shown in Figure 7 except that tension members 424 are anchored transmurally by pads 427 rather than into papillary muscles 12. The relatively greater thickness of tension members 424 shown in Figure 11, as compared to tension members 24 shown in Figure 7, merely illustrates that the tension members can be substantially rigid or in the case of tension members 24, substantially flexible. It should be understood, however, that in any of the embodiments shown herein, the tension members could be advantageously formed to be substantially flexible or substantially rigid.

[0024] Figure 12 is a top or posterior view of valve 14. In this embodiment, the basal anchor for the valve repair device is shown as discrete pads 28 which can be sewn to the posterior side of valve 14. Tension members 24 are shown extending from respective pads 28 into the left ventricle.

[0025] Figure 13 is the same view of valve 14 as Figure 12. In Figure 13, however, the basal anchor 22 is shown as a crescent-shaped suture ring. Tension members 24 extends from basal anchor 22 through valve 14 into the left ventricle.

[0026] Figure 14 is a side view of an artificial heart valve 30. If it is necessary to replace the valve rather than merely repair it, artificial valve 30 can be used as a basal anchor for tension members 24.

[0027] Figure 15 is a top view of an alternate embodiment of a suture ring basal anchor 32. Ring 32 has a crescent shape and a pylon 34 extending through the mitral valve. Figure 16 is a side view of suture ring 32 showing tension members 24 attached to pylon 34.

[0028] Tension members 24 preferably extend through the tissue of valve 14 rather than through the valve opening. It can be appreciated, however, that tension members 24 could be disposed through the valve opening. In the case of the embodiment of Figures 15 and 16, however, pylon 34 would be disposed through the valve opening. Tension members 24 associated with pylon 34 would be disposed on the opposite side of valve 14 from suture ring 32. Pylon 34 would preferably be disposed through the valve opening rather than the tissue forming valve 14.

[0029] Figures 17 and 18 are yet additional alternate embodiments of suture rings which can be used as basal anchors in accordance with the present invention. The shape of the rings is selected such that as they are sewn into place on valve 14, the sutures can be used to draw tissue toward the inside of the ring, thus reducing the transverse and/or vertical cross sectional area of the associated heart chamber. This will advantageously reduce heart wall stress which is of particular benefit if the patient has a failing heart.

[0030] It can be appreciated that tension members 24 can be fixably or releasably attached to the basal anchor. Preferably, the tension members are fixably attached to the basal anchor during the valve repair procedure.

[0031] Figures 19-21 show various configurations of anchoring devices shown at the second end of tension member 24. It can be appreciated that these anchoring devices could be used with each of the tension members described above. In Figure 19, the second end of tension member 24 includes a secondary anchor 40 formed as screw which is shown augured into papillary muscle 12. Figure 20 shows a secondary anchor 42 including a loop sewn through papillary muscle 12. Figure 21 shows a tension member 24 extending transmurally to an exterior pad 44 to which it is connected. Tension member 24 could be sewn to pad 44 or otherwise mechanically connected thereto.

[0032] It can be appreciated that various biocompatible materials can be advantageously used to form the various components of the device of the present invention. It is anticipated that the present device will usually be chronically implanted. Thus, when selecting materials to form each of the components consideration should be given to the consequences of long term exposure of the device to tissue and tissue to the device.

[0033] Numerous characteristics and advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of parts without exceeding the scope of the invention. The inventions's scope is, of course, defined in the language in which the appended claims are expressed.

Claims

1. A device for repairing an in situ mitral valve, the device comprising:

an elongate tension member having a first end and a second end;

a first anchor on the first end of the elongate tension member and adapted to be anchored proximate to the valve such that the elongate tension member can be disposed in the chamber and

a second anchor on the second end of the elongate tension member and adapted to be anchored to a portion of the heart spaced from the first anchor such that the elongate tension member is under tension and the geometry of the heart is altered by placement of the elongate tension member.

2. A device in accordance with claim 1, wherein the first anchor includes a pad.

3. A device in accordance with claim 1, wherein the first anchor includes a crescent shaped ring.

4. A device in accordance with claim 1, wherein the first anchor includes a ring, which is configured to be sewn to a valve.

5. A device in accordance with claim 1, wherein the first anchor includes a suture ring having a varying radius of curvature.

6. A device in accordance with claim 1, wherein the first anchor includes an annuloplasty ring.

7. A device in accordance with claim 1, wherein the at least one tension member includes a pair of tension members.

8. A device in accordance with claim 1, wherein the at least one tension member is substantially rigid.

9. A device in accordance with claim 1, wherein the at least one tension member is substantially flexible.

10. A device in accordance with claim 1, wherein the second anchor is screw-shaped.

11. A device in accordance with claim 1, wherein the second anchor includes a screw-shaped tissue anchor.

12. A device in accordance with claim 1, wherein the second anchor includes a hook-shaped papillary muscle tissue loop.

Patentansprüche

1. Vorrichtung zum Reparieren einer *in situ* Mitralklappe mit:

einem länglichen Spannelement mit einem ersten Ende und einem zweiten Ende;
einem ersten Anker an dem ersten Ende des länglichen Spannelements, der zur Verankerung benachbart der Klappe ausgebildet ist, so dass das längliche Spannelement in der Kammer angeordnet werden kann, und
einem zweiten Anker an dem zweiten Ende des länglichen Spannelements, der zur Verankerung an einem Abschnitt des Herzens beabstandet von dem ersten Anker ausgebildet ist, so dass das längliche Spannelement unter Spannung steht und die Geometrie des Herzens durch Einsetzen des länglichen Spannelements verändert ist.

2. Vorrichtung nach Anspruch 1, bei der der erste Anker eine Unterlage umfasst.

3. Vorrichtung nach Anspruch 1, bei der der erste Anker einen sichelförmigen Ring umfasst.

4. Vorrichtung nach Anspruch 1, bei der der erste Anker einen Ring umfasst, der zum Annähen an eine Klappe ausgebildet ist.

5. Vorrichtung nach Anspruch 1, bei der der erste Anker einen Nähring mit veränderlichem Krümmungsradius umfasst.

6. Vorrichtung nach Anspruch 1, bei der der erste Anker einen annuloplastischen Ring umfasst.

7. Vorrichtung nach Anspruch 1, bei der das mindestens eine Spannelement ein Paar Spannelemente umfasst.

8. Vorrichtung nach Anspruch 1, bei der das mindestens eine Spannelement im Wesentlichen starr ist.

9. Vorrichtung nach Anspruch 1, bei der das mindestens eine Spannelement im Wesentlichen elastisch ist.

10. Vorrichtung nach Anspruch 1, bei der der zweite Anker schraubenförmig ist.

11. Vorrichtung nach Anspruch 1, bei der der zweite Anker einen schraubenförmigen Gewebeanker umfasst.

12. Vorrichtung nach Anspruch 1, bei der der zweite Anker eine hakenförmige Papillarmuskel-Gewebe-

schlaufe umfasst.

Revendications

1. Dispositif destiné à réparer une valvule mitrale in situ, le dispositif comprenant :

   un élément tendeur allongé ayant une première extrémité et une seconde extrémité,
   un premier dispositif de fixation sur la première extrémité de l'élément tendeur allongé et conçu pour être fixé à proximité de la valvule de sorte que l'élément tendeur allongé puisse être disposé dans la chambre et
   un second dispositif de fixation sur la seconde extrémité de l'élément tendeur allongé et conçu pour être fixé à une partie du coeur espacée du premier dispositif de fixation de sorte que l'élément tendeur allongé soit sous tension et la géométrie du coeur est modifiée par le positionnement de l'élément tendeur allongé.

2. Dispositif selon la revendication 1, dans lequel le premier dispositif dé fixation comprend une patte.

3. Dispositif selon la revendication 1, dans lequel le premier dispositif de fixation comprend un anneau en forme de croissant.

4. Dispositif selon la revendication 1, dans lequel le premier dispositif de fixation comprend un anneau qui est configuré afin d'être cousu à la valvule.

5. Dispositif selon la revendication 1, dans lequel le premier dispositif de fixation comprend un anneau de suture dont le rayon de courbure varie.

6. Dispositif selon la revendication 1, dans lequel le premier dispositif de fixation comprend un anneau d'annuloplastie.

7. Dispositif selon la revendication 1, dans lequel l'au moins un élément tendeur comprend une paire d'éléments tendeurs.

8. Dispositif selon la revendication 1, dans lequel l'au moins un élément tendeur est sensiblement rigide.

9. Dispositif selon la revendication 1, dans lequel l'au moins un élément tendeur est sensiblement souple.

10. Dispositif selon la revendication 1, dans lequel le second dispositif de fixation est en forme de vis.

11. Dispositif selon la revendication 1, dans lequel le second dispositif de fixation comprend un dispositif de fixation au tissu en forme de vis.

12. Dispositif selon la revendication 1, dans lequel le second dispositif de fixation comprend une boucle pour tissu du muscle papillaire en forme de crochet.

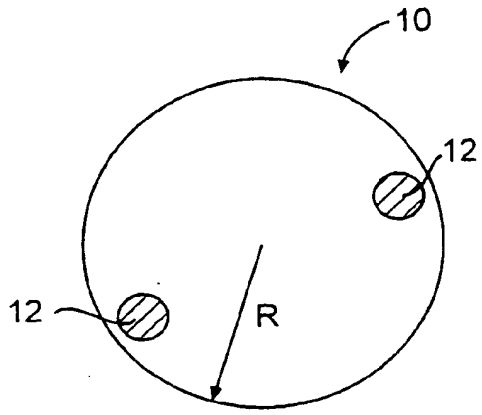


FIG. 1

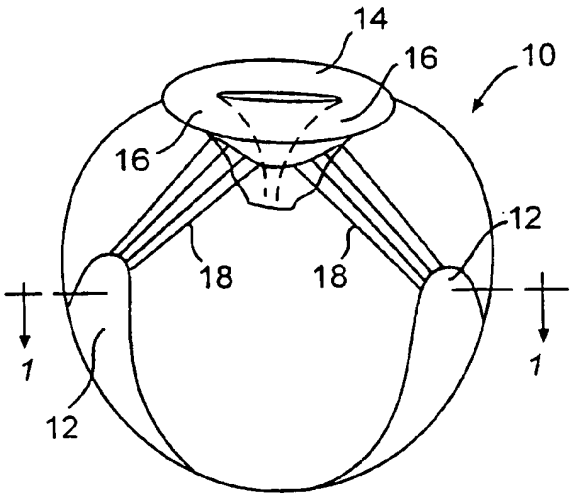


FIG. 2

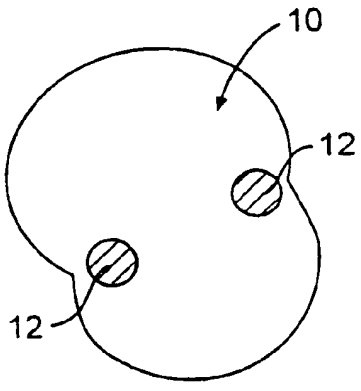


FIG. 3

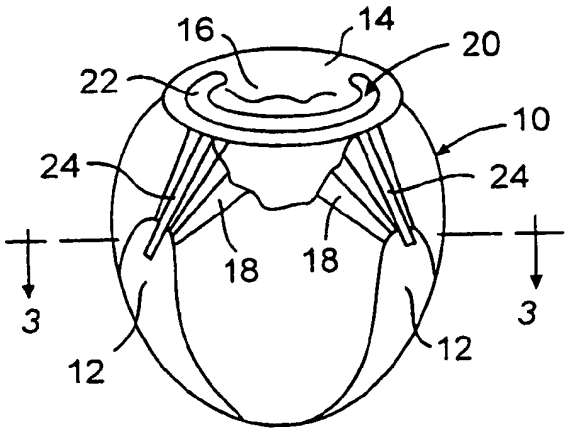


FIG. 4

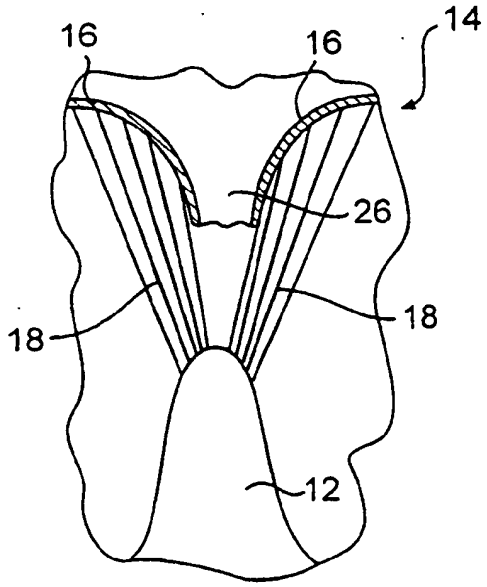


FIG. 5

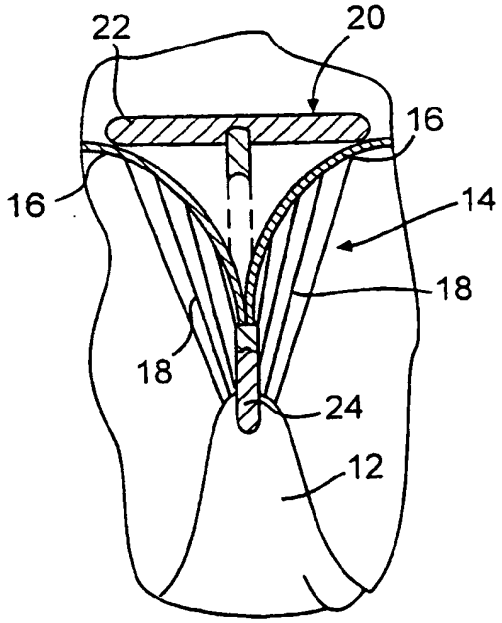


FIG. 6

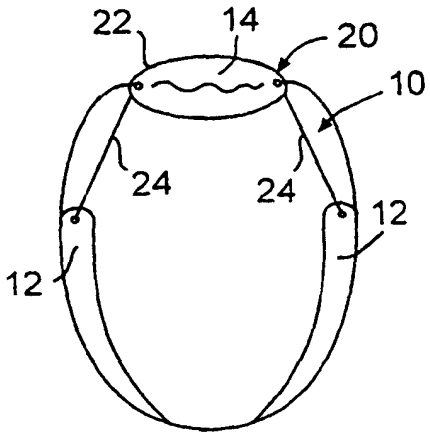


FIG. 7

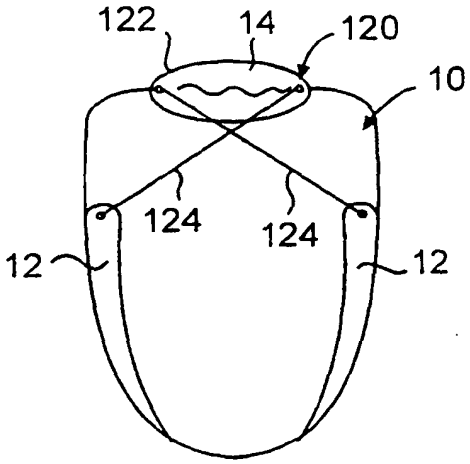


FIG. 8

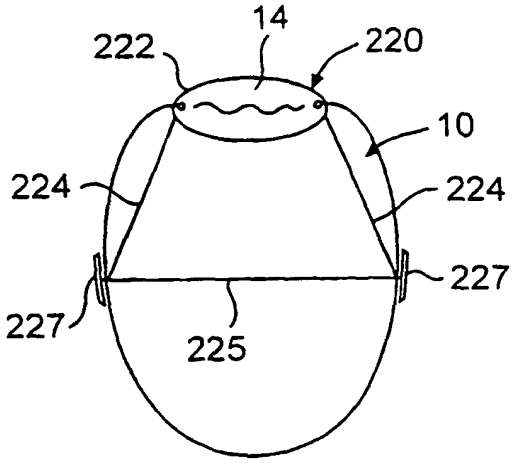


FIG. 9

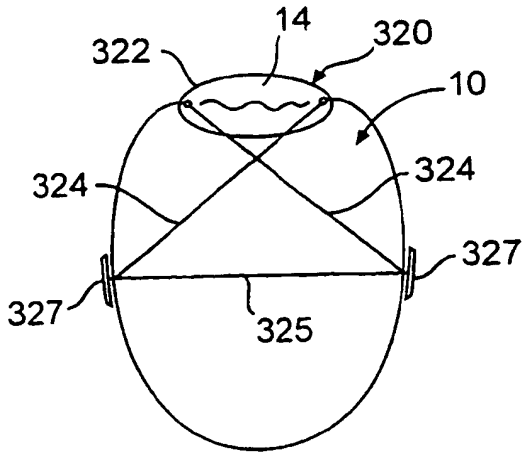


FIG. 10

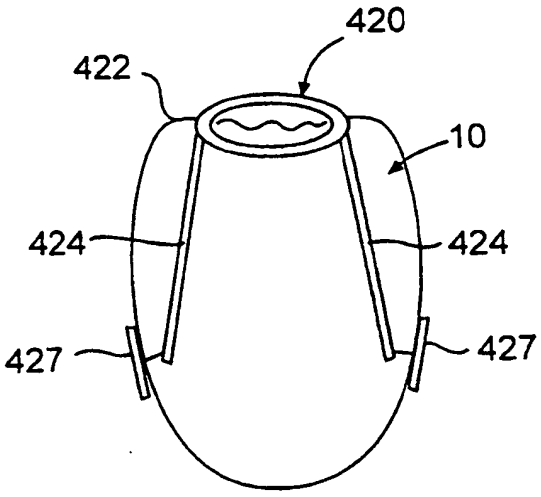


FIG. 11

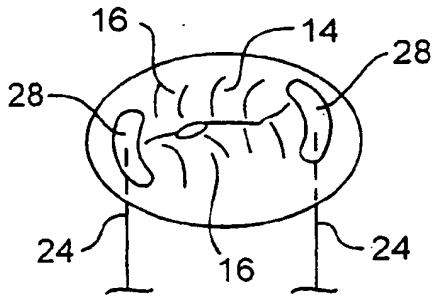


FIG. 12

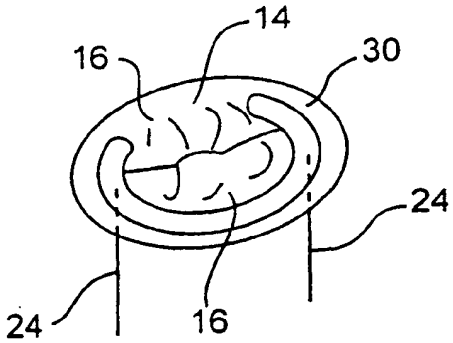


FIG. 13

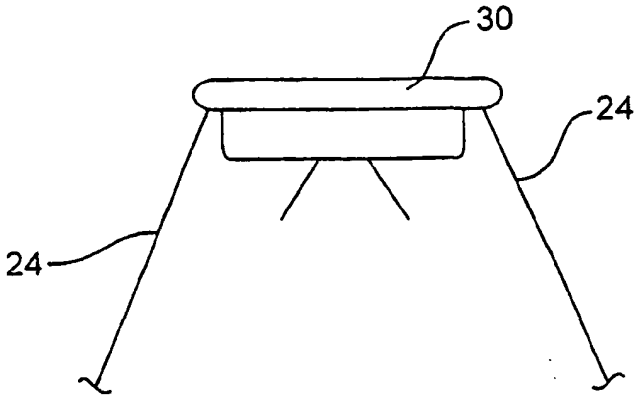


FIG. 14

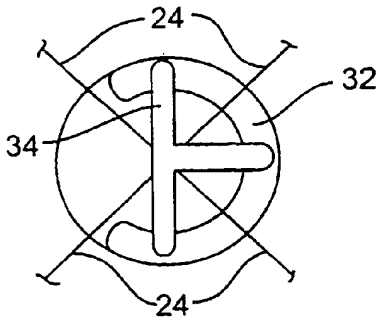


FIG. 15

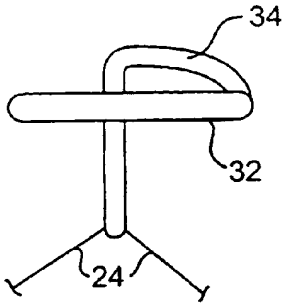


FIG. 16

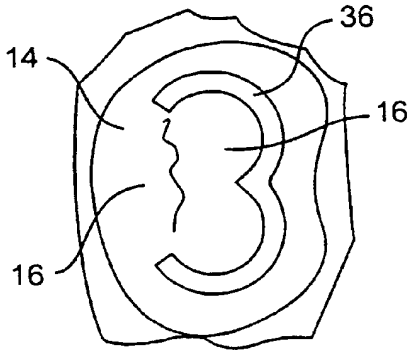


FIG. 17

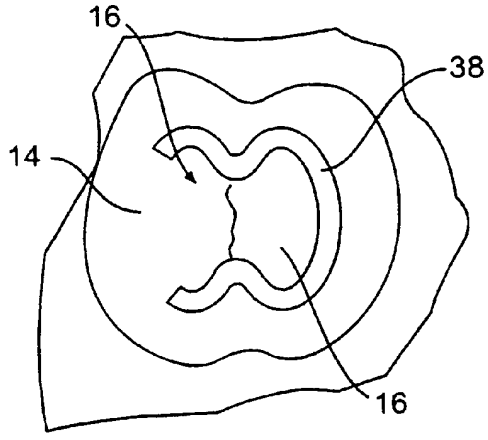


FIG. 18

FIG. 19

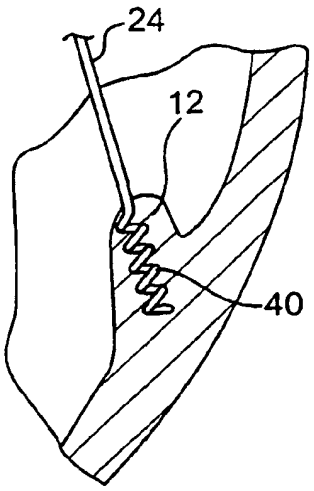


FIG. 20

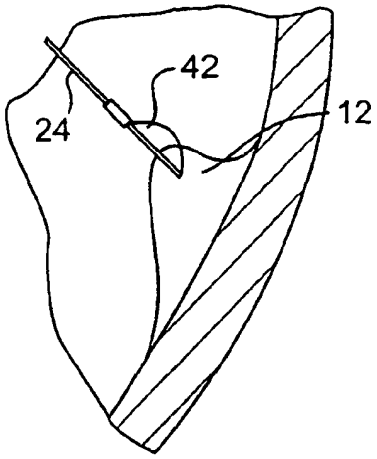
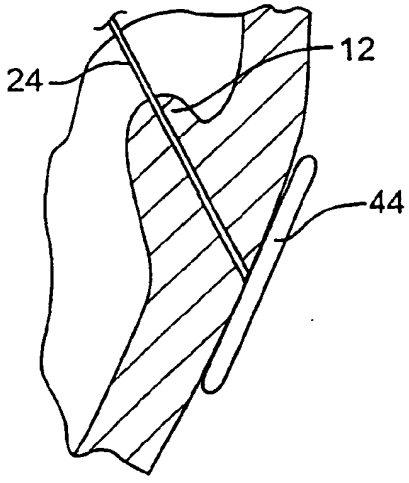


FIG. 21



(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 408 850 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
23.09.2009 Bulletin 2009/39

(21) Application number: **02746781.0**

(22) Date of filing: **27.06.2002**

(51) Int Cl.:
A61B 17/08 *(2006.01)*

(86) International application number:
PCT/US2002/020768

(87) International publication number:
WO 2003/001893 (09.01.2003 Gazette 2003/02)

(54) **DEVICES FOR CAPTURING AND FIXING LEAFLETS IN VALVE REPAIR**

VORRICHTUNGEN ZUM ERGREIFEN UND FESTLEGEN VON SEGELN BEI DER KLAPPENREPARATUR

DISPOSITIFS DE CAPTURE ET DE FIXATION DE FEUILLETS EN PLASTIE VALVULAIRE

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE TR

(30) Priority: **27.06.2001 US 894463**

(43) Date of publication of application:
21.04.2004 Bulletin 2004/17

(73) Proprietor: **Evalve, Inc.**
Menlo Park, CA 94025 (US)

(72) Inventors:
- **GOLDFARB, Eric, A.**
  San Francisco, CA 94110-5338 (US)
- **DELL, Kent, D.**
  Redwood City, CA 94061 (US)
- **FAN, Sylvia, Wen-Chin**
  San Francisco, CA 94114 (US)
- **MARTIN, Brian, B.**
  Boulder Creek, CA 95006 (US)
- **POWELL, Ferolyn, T.**
  San Francisco, CA 94114 (US)
- **RASCHDORF, Alfred, H.**
  San Francisco, CA 94114 (US)
- **THORNTON, Troy, L.**
  San Francisco, CA 94107 (US)

(74) Representative: **Kazi, Ilya et al**
Mathys & Squire LLP
120 Holborn
London
EC1N 2SQ (GB)

(56) References cited:
WO-A-00/03759
WO-A-01/28432
WO-A-98/32382
US-A- 5 554 185
US-A- 5 928 224
US-B1- 6 312 447

EP 1 408 850 B1

Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates generally to devices for the endovascular or minimally invasive surgical repair of the valves of the heart, particularly the mitral valve.

[0002] Mitral valve regurgitation is characterized by retrograde flow from the left ventricle of a heart through an incompetent mitral valve into the left atrium. During a normal cycle of heart contraction (systole), the mitral valve acts as a check valve to prevent flow of oxygenated blood back into the left atrium. In this way, the oxygenated blood is pumped into the aorta through the aortic valve. Regurgitation of the valve can significantly decrease the pumping efficiency of the heart, placing the patient at risk of severe, progressive heart failure.

[0003] Mitral valve regurgitation can result from a number of different mechanical defects in the mitral valve. The valve leaflets, the valve chordae which connect the leaflets to the papillary muscles, or the papillary muscles themselves may be damaged or otherwise dysfunctional. Commonly, the valve annulus may be damaged, dilated, or weakened limiting the ability of the mitral valve to close adequately against the high pressures of the left ventricle.

[0004] The most common treatments for mitral valve regurgitation rely on valve replacement or strengthening of the valve annulus by implanting a mechanical support ring or other structure. The latter is generally referred to as valve annuloplasty. A recent technique for mitral valve repair which relies on suturing adjacent segments of the opposed valve leaflets together is referred to as the "bow-tie" or "edge-to-edge" technique. While all these techniques can be very effective, they usually rely on open heart surgery where the patient's chest is opened, typically via a sternotomy, and the patient placed on cardiopulmonary bypass. The need to both open the chest and place the patient on bypass is traumatic and has associated morbidity.

[0005] For these reasons, it would be desirable to provide alternative and additional, devices, for performing the repair of mitral and other cardiac valves, particularly the tricuspid and aortic valves. Such devices should preferably not require open chest access and be capable of being performed either endovascularly, i.e., using devices which are advanced to the heart from a point in the patient's vasculature remote from the heart or by a minimally invasive approach. Still more preferably, the devices should not require that the heart be bypassed, although the devices should be useful with patients who are bypassed and/or whose heart may be temporarily stopped by drugs or other techniques. At least some of these objectives will be met by the inventions described hereinbelow.

2. Description of the Background Art

[0006] Minimally invasive and percutaneous techniques for coapting and modifying mitral valve leaflets to treat mitral valve regurgitation are described in WO 98/35638; WO 99/00059; WO 99/01377; and WO 00/03759.

[0007] Maisano et al. (1998) Eur. J. Cardiothorac. Surg. 13:240-246; Fucci et al. (1995) Eur. J. Cardiothorac. Surg. 9:621-627; and Umana et al. (1998) Ann. Thorac. Surg. 66:1640-1646, describe open surgical procedures for performing "edge-to-edge" or "bow-tie" mitral valve repair where edges of the opposed valve leaflets are sutured together to lessen regurgitation. Dec and Fuster (1994) N. Engl. J. Med. 331:1564-1575 and Alvarez et al. (1996) J. Thorac. Cardiovasc. Surg. 112: 238-247 are review articles discussing the nature of and treatments for dilated cardiomyopathy.

[0008] Mitral valve annuloplasty is described in the following publications. Bach and Bolling (1996) Am. J. Cardiol. 78:966-969; Kameda et al. (1996) Ann. Thorac. Surg. 61:1829-1832; Bach and Bolling (1995) Am. Heart J. 129:1165-1170; and Bolling et al. (1995) 109:676-683. Linear segmental annuloplasty for mitral valve repair is described in Ricchi et al. (1997) Ann. Thorac. Surg. 63: 1805-1806. Tricuspid valve annuloplasty is described in McCarthy and Cosgrove (1997) Ann. Thorac. Surg. 64: 267-268; Tager et al. (1998) Am. J. Cardiol. 81: 1013-1016; and Abe et al. (1989) Ann. Thorac. Surg. 48: 670-676.

[0009] Percutaneous transluminal cardiac repair procedures are described in Park et al. (1978) Circulation 58:600-608; Uchida et al. (1991) Am. Heart J. 121: 1221-1224; and Ali Khan et al. (1991) Cathet. Cardiovasc. Diagn. 23:257-262.

[0010] Endovascular cardiac valve replacement is described in U.S. Patent Nos. 5,840,081; 5,411,552; 5,554,185; 5,332,402; 4,994,077; and 4,056,854. See also U.S. Patent No. 3,671,979 which describes a catheter for temporary placement of an artificial heart valve.

[0011] Other percutaneous and endovascular cardiac repair procedures are described in U.S. Patent Nos. 4,917,089; 4,484,579; and 3,874,338; and WO 91/01689.

[0012] Thoracoscopic and other minimally invasive heart valve repair and replacement procedures are described in U.S. Patent Nos. 5,855,614; 5,829,447; 5,823,956; 5,797,960; 5,769,812; and 5,718,725.

[0013] WO 00/03759 discloses a device adapted for repairing a cardiac valve in a patient, the cardiac valve having leaflets. The device includes an interventional catheter that is configured to pass to a position within the heart adjacent to the cardiac valve. At the distal end of the catheter, a capture device is detachably provided and it has two extendable distal elements and two extendable proximal elements, each of which are moveable between a retracted position adjacent to the shaft and an extended position extending away from the shaft for capturing the

valve leaflets. A sheath is provided to hold the proximal and distal elements in their retracted positions and the elements are allowed to deploy into their expanded positions by retracting the sheath.

SUMMARY OF THE INVENTION

[0014] The present invention provides devices for the endovascular repair of cardiac valves, particularly the atrioventricular valves which inhibit back flow of blood from a heart ventricle during contraction (systole), most particularly the mitral valve between the left atrium and the left ventricle. By "endovascular," it is meant that the procedure(s) of the present invention are performed with interventional tools and supporting catheters and other equipment introduced to the heart chambers from the patient's arterial or venous vasculature remote from the heart. The interventional tools and other equipment may be introduced to the vasculature percutaneously, i.e., through an access sheath placed through the skin, or may be introduced via a surgical cut down, and then advanced from the remote access site through the vasculature to the heart. Thus, the procedures of the present invention will generally not require penetrations made directly through the exterior heart muscle, i.e., myocardium, although there may be some instances where penetrations will be made interior to the heart, e.g., through the interatrial septum to provide for a desired access route. While the procedures of the present invention will usually be percutaneous and intravascular, many of the tools will find use in minimally invasive and open surgical procedures as well. In particular, the tools for repositioning the valve leaflets prior to attachment can find use in virtually any type of procedure for modifying cardiac valve function.

[0015] Although the devices of the present invention may be used for the endovascular repair of any of the cardiac valves, the majority of the description will be in regards to the repair of atrioventricular valves. The atrioventricular valves are located at the junctions of the atria and their respective ventricles. The atrioventricular valve between the right atrium and the right ventricle has three valve leaflets (cusps) and is referred to as the tricuspid or right atrioventricular valve. The atrioventricular valve between the left atrium and the left ventricle is a bicuspid valve having only two leaflets (cusps) and is generally referred to as the mitral valve. In both cases, the valve leaflets are connected to the base of the atrial chamber in a region referred to as the valve annulus, and the valve leaflets extend generally downwardly from the annulus into the associated ventricle. In this way, the valve leaflets open during diastole when the heart atria fills with blood, allowing the blood to pass into the ventricle. During systole, however, the valve leaflets are pushed together and closed to prevent back flow of blood into the atria. Thus, the valve leaflets each have generally two planar surfaces, a surface facing the atrium which may be referred to as the atrial surface and a surface facing the ventricle which may be referred to as the ventricular surface. Such terminology may be used with cardiac valves which do not straddle an atrium and a ventricle. In these cases, it is understood that such terminology may be used to suitably describe the corresponding valve surfaces.

[0016] Alternatively, the surfaces of the valves may be described in relation to flow direction. For example, since valve leaflets each have two planar surfaces, a surface facing upstream may be referred to as the upstream surface and a surface facing downstream may be referred to as the downstream surface. In the case of the mitral valve, the atrial surface would be the upstream surface and the ventricular surface would be the downstream surface. In the case of the aortic valve, the ventricular surface would be the upstream surface and the surface facing the aorta would be the downstream surface. Such terminology may be most relevant when considering the natural shape of the leaflets since the shape is more related to direction of flow than orientation of the valve in the heart.

[0017] Interventions described herein are generally directed at the valve leaflets. It will be the general purpose of such interventions to modify the manner in which the valve leaflets coapt or close during systole so that back flow or regurgitation is minimized or prevented. While the procedures of the present invention will be most useful with the atrioventricular valves, at least some of the tools described hereinafter may be useful in the repair of other cardiac valves, particularly the aortic valve.

[0018] The methods of the present invention will usually include accessing a patient's vasculature at a location remote from the heart and advancing an interventional catheter having a capturing device through the vasculature to a location near a cardiac valve to be repaired. The methods may include applying an upward force against a downstream surface of at least one leaflet of the cardiac valve with the capturing device. Such application of force will reposition at least one leaflet so as to reduce leakage through the valve during ventricular systole. Typically, two or more leaflets are repositioned in this manner to achieve desired coaptation. The interventional tool may comprise an elongate shaft having a proximal end and a distal end wherein the capture device is disposed near the distal end. The capture device may comprise at least one distal element capable of protruding radially outward from the shaft. The above described application of force may be achieved by pressing a distal element of the capture device against the downstream surface of the leaflet

[0019] Methods are described in which the distal element may be adjusted prior to or after pressing the distal element against the surface of the leaflet Such adjustment may include adjusting the length of protrusion of the distal element from the shaft. This may be achieved by retracting or extending the distal element. This allows the capture device to be advanced to the valve in a low profile arrangement and the distal elements to be extended for use once the capture device has been positioned

in a desired orientation in relation to the valve. When adjustment of the length is performed after the distal element is in contact with the valve leaflet, such adjustment may serve to reposition the valve leaflet. In addition, adjustment may include adjusting the curvature of the distal element. Adjustment of the curvature may also be achieved by retracting or extending the distal element. Again, if this adjustment step is performed after the distal element is in contact with the leaflet, such adjustment in curvature may serve to reposition the valve leaflet. In some embodiments, the capture device may optionally comprise at least one proximal element capable of protruding radially outward from the shaft and the methods of the present invention may further include holding one or more leaflets between the proximal and distal elements. In this case, adjusting the length and/or curvature of the proximal or distal elements may serve to reposition the captured valve leaflets. Such adjustment of the proximal and distal elements may be achieved simultaneously. In an additional aspect, the proximal and distal elements may interlock for added grasping strength.

[0020] Methods are also described in which flow through the valve may be observed to determine if regurgitation has been inhibited by the leaflet repositioning. Such observation may be achieved by any suitable means. If the regurgitation has not been sufficiently inhibited, the application of upward force on at least one valve leaflet with the capturing device may be adjusted. This may be achieved with any of the adjustment steps previously described and/or by decreasing or removing any of the upward force against one or more valve leaflets. The observation and adjustment steps may be repeated any number of times until the regurgitation has been sufficiently inhibited.

[0021] Methods are also described in which the leaflets may optionally be fixed together. Fixing may include fastening, suturing, clipping, stapling, riveting, gluing, or fusing the leaflets together. Alternatively, the capturing tool may be detached from the interventional tool to serve as a fixation device. This involves activating a detachment or decoupling mechanism which allows the capture tool to separate from the interventional tool to be left behind as a permanent implant.

[0022] Methods are also described in which one or more valve leaflets may be atraumatically captured with the capturing device and the captured leaflets may be repositioned independently of each other. When the capture device comprises at least one distal element capable of protruding radially outward from the shaft, a leaflet may be atraumatically captured by pressing the distal element against the leaflet surface. The captured leaflets may be independently repositioned by independently adjusting the distal elements. Likewise, when the capture device comprises at least one proximal element and one distal element, each capable of protruding radially outward from the shaft, the atraumatically capturing step comprises holding the leaflet between the proximal and distal elements. The captured leaflets may be independently repositioned by simultaneously retracting or extending the proximal element and distal element disposed on opposite sides of the leaflet. Again, once the leaflets have been repositioned to a desired orientation, the leaflets may be fixed together by any suitable means including detaching the capture device from the interventional tool and leaving it behind.

[0023] Methods are also described in which the valve leaflets, each leaflet comprising a proximal side and a distal side, may be repaired with the use of sutures having attached anchors. To begin, a first leaflet may be penetrated from the proximal side to the distal side of the leaflet with a penetrating device. In this case, at least a portion of first anchor having a first attached suture is then deployed on the distal side of the first leaflet. A second leaflet is penetrated from the proximal side to the distal side with a penetrating device. Such a penetrating device may be the same penetrating device as penetrated the first leaflet or a separate penetrating device. At least a portion of a second anchor having a second attached suture is deployed on the distal side of the second leaflet. The first and second sutures are then secured together. By securing the sutures together, the valve is repaired by fixing the leaflets together in the desired coapted orientation. Typically, the anchors are disposed in or on the penetrating devices. For example, the anchors may be loaded within a lumen in the penetrating devices or mounted externally on a penetrating device. In any case, the deploying steps comprise releasing the anchors from the respective penetrating devices. In many cases, the anchors are expanded to provide anchoring support on the distal side of the leaflet to prevent the anchor from passing through the penetration and releasing the suture. The anchors may be self-expanding or the deploying steps may further comprise expanding the anchors.

[0024] As an alternative, anchors may be used simply to aid in the placement of sutures wherein the anchors are removed prior to securing the sutures together. In this case, again, a first leaflet is penetrated from the proximal side to the distal side of the leaflet with a penetrating device. And, at least a portion of a first anchor having a first attached future is deployed on the distal side of the first leaflet. The first leaflet is again penetrated from the proximal side to the distal side with a penetrating device, however, this time at a new location. At this new location, a snare is deployed on the distal side of the leaflet so that the snare captures at least part of the first anchor. The snare is then retracted so that the anchor is drawn through the penetration of the snare. By drawing the anchor through the penetration to the proximal side of the leaflet, the suture line effectively passes from the proximal side of the leaflet through a penetration to the distal side traversing a portion of the distal side of the leaflet and then passing through a separate penetration back to the proximal side of the leaflets. This may be repeated on a second leaflet in a similar manner. The four portions of suture on the proximal side of the leaflets may then be secured together. This method may be repeated at any

number of locations on the leaflet to create any number of suture lines on the proximal side of the leaflet for securing together. Additional suture lines may provide added fixation strength or possible repositioning of the leaflets. Likewise, the anchor and snare may be deployed on separate leaflets, respectively, so that a suture line may penetrate a first leaflet from the proximal side to the distal side traverse on the distal side of the leaflet to a second leaflet and then cross back through a penetration on the second leaflet to the proximal side. One or more sutures may be positioned in this manner and secured together as previously described. Also, it may be appreciated that such suture placement may be achieved on the opposite side of the leaflets so that the sutures are secured on the distal side of the leaflets.

[0025] The penetrating devices described above may be advanced through guide conduits on the interventional tool. Such guide conduits may be adjusted to direct the penetrating device toward the desired location on the valve leaflet. Adjustment may include extending or retracting the guide conduits or angularly adjusting the guide conduits in relation to the shaft. When the capture device comprises at least one loop which is protrudable radially outward from the shaft, the guide conduit may be positioned so that the conduit guides the penetration device through the loop when the penetration device is advanced. Once the penetrating device has penetrated the leaflet, the loops may be retracted to radially translate the penetration devices and the penetrated leaflets toward the shaft. This may serve to reposition the leaflets in a more desired coapted orientation.

[0026] According to a first aspect, the invention provides a device adapted for repairing a cardiac valve in a patient, the cardiac valve having leaflets, said device comprising an interventional catheter comprising a shaft having a proximal end, a distal end and a longitudinal axis therebetween, configured to pass to a position within the heart adjacent to the cardiac valve; and a capture device detachably connected to the catheter comprising at least two extendable distal elements and at least two extendable proximal elements, each of the proximal and distal elements being disposed near the distal portion of the shaft and being moveable between a retracted position adjacent the shaft and an extended position extending away from the shaft for capturing the valve leaflets; wherein the at least two distal elements and the at least two proximal elements are independently extendable, retractable and repositionable so that they can be extended or retracted by various amounts for protrusion of various distances from the shaft.

[0027] The distal elements of the capture devices may take a number of forms and these forms can take a number of shapes. In some embodiments, the distal elements have the form of loops. For clarity, loops include any shape wherein the form surrounds or nearly surrounds an opening. Loops may have circular, oval or petal shapes, or may include irregular shapes of any type, including pointed or angular edges and/or invaginations. The loops may have a petal shape so that when the loops are positioned on opposite sides of the shaft, the loops will form a "figure 8" shape when viewed from the top or bottom. This loop configuration is most suitable for use with valves having two leaflets. It may be appreciated that more than two loops may be present and arranged around the shaft having various distances between the loops. Thus, the looped distal elements may be configured for valves having three leaflets. In another embodiment, the distal element has the form of a block, rod or bar disposed perpendicularly to the shaft. The bar may pivot around a pivot point at the base of the shaft to manipulate the position of the bar. Such manipulation may be achieved with the use of a pullwire extending from the shaft to the bar. Retracting or pulling upwards on the pullwire may pivot the bar around the pivot point. Such pivoting orients the bar to a low profile position so that the interventional tool may more easily be passed through a guide catheter, and further between a set of valve leaflets so that the bar is disposed below the valve. The bar may then be pressed against the downstream surface of the leaflets to grasp and reposition the leaflets.

[0028] The distal elements are individually repositionable and adjustable and the elements may be extended or retracted by variable amounts for protrusion of various distances from the shaft. Such extension and retraction may also adjust the width of the exposed elements if the width varies radially from the shaft, such as with a petal shape. Further, the elements may have differing angles of curvature. This may be achieved by heat-shaping the elements to have different curvatures, or the curvatures may be adjusted by manipulation by the user. Individual manipulation of the elements allows individually protruding the elements prior to capturing the leaflets to ensure proper orientation and includes individually adjusting the elements after grasping the leaflets to reposition the leaflets. In addition, it may be appreciated that the elements may be extended and retracted simultaneously, if desired

[0029] The interventional tool comprises proximal elements which are capable of protruding radially outward from the shaft at a location which is proximal to the distal elements. The proximal elements may have any of the forms, shapes, material compositions, features or capabilities described in relation to the distal elements. Thus, the proximal elements may be extended, retracted or similarly adjusted to further orient the captured leaflets. The proximal elements may be deployed separately from the distal elements. For example, the proximal elements may be constrained within a shaft while the distal elements are extended radially outward. The proximal elements may then be released by retracting the shaft. Release of the proximal elements allows them to extend radially outward and downward to contact the valve leaflet. In this arrangement, the valve leaflets are held between the proximal and the distal elements. To assist in holding the leaflets the proximal and/or distal elements may include various friction accessories, such as prongs or windings around the elements such as bands or barbs.

Alternatively or in addition, the proximal elements and distal elements may interlock to prevent relative motion between the elements and more securely hold the leaflets.

[0030] In some embodiments, the proximal and distal elements are formed from a continuous structure. The continuous structure may be held in a low profile position under tension. When the continuous structure is released and allowed to relax, the reforming of the structure allows the structure to protrude outward at various points along the structure. Each protrusion is similar to an above-described proximal or distal element and functions in a similar manner.

[0031] The interventional catheter includes a capture device. The capture device functions as a fixation device when left in place. To this end, the capture device is detachable and can be left behind as a permanent or temporary implant. Detachment may be achieved by a variety of different mechanisms and design features.

[0032] In other embodiments, the fixation tools are used with the capture device either incorporated into the interventional tool or used in combination with the interventional tool. In many of these embodiments, the fixation tools are advanceable through guide conduits disposed near the distal end of the interventional tool. The guide conduits are used to guide the fixation tools to specific locations on the surfaces of the leaflets. The guide conduits are located proximal to the distal elements and are capable of extending and retracting axially and angularly outward from the shaft. Any angle may be used to target the leaflets at points which are approximately one to twelve millimeters inward or away from the free edge of each leaflet. Typically, the guide conduit is used to introduce a fixation tool comprising a penetrating device or needle. The needle may house a suture having an anchor disposed at the distal end of the suture. The needle is advanced toward a valve leaflet to penetrate the leaflet and emerge from the other side. The anchor may be deployed on the opposite side of the leaflet by passing the anchor through the needle and expanding or allowing it to self-expand after it has exited the needle. Alternatively, the anchor may be mounted on the outside of the needle and covered by a sheath. Retraction or removal of the sheath would allow expansion of the anchor. In any case, after anchor deployment, the needle is then retracted while maintaining the anchor on the distal side of the leaflet. A number of different types of anchors may be used during fixation of the leaflets. Typically the anchor is expandable from a compressed, low profile state, for delivery to the anchoring site, to an expanded state to provide a large enough surface for anchoring support. In addition, the fixation tools may include snares which are deployable on the distal side of the leaflet for capturing at least part of an anchor. The snare may then be retracted to move the anchor, such as to draw the anchor through a penetration in the leaflet. Once the suture is placed through the leaflets, either attached to anchors or free from anchors, the suture ends or lines may then be fixed together by conventional knot tying or any suitable method, including positioning suture fasteners.

[0033] The devices of the present invention may be provided in one or more kits for such use. The kits may include an interventional catheter configured to pass from the remote vasculature of a patient to a position within the heart adjacent to a cardiac valve to be repaired, wherein the catheter the above described capture device and instructions for use. The instructions for use may set forth any of the methods described above. Optionally, such kits may further include any of the other systems components described in relation to the present invention and any other materials or items relevant to the present invention.

[0034] Other objects and advantages of the present invention will become apparent from the detailed description to follow, together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0035]

Fig. 1 is a schematic illustration of the left ventricle of a heart showing blood flow during systole with arrows.

Fig. 2A shows normal closure of the leaflets, while Fig. 2B shows abnormal closure of the leaflets.

Fig. 3 is a perspective side view of the mitral valve showing an interventional tool approaching the valve leaflets from the atrial side.

Fig. 4 illustrates a short axis view if the mitral valve from the atrial side wherein elements of the interventional tool are shown in dashed outline as they are positioned on the ventricular side of the valve.

Fig. 5 illustrates the mitral valve as in Fig. 4 during diastole.

Fig. 5A illustrates the valve leaflets fixed together as in a surgical bow tie repair.

Figs. 6-7 show exemplary antegrade approaches to the mitral valve from the venous vasculature.

Figs. 8-9 show exemplary retrograde approaches to the mitral valve through the aortic valve and atrial vasculature.

Figs. 10A-10C show a number of embodiments of capture devices which may be disposed at the distal end of an interventional catheter.

Figs. 11A-11C and Fig. 12 show a number of embodiments of capture devices wherein an element is in the form of a block, rod, or bar.

Fig. 13 illustrates the extension of a first element independently of a second element.

Fig. 14 illustrates elements having differing angles of curvature.

Fig. 15 illustrates a capture device having extended elements pinched between the shaft and the cap.

Figs. 16A-16E illustrate an embodiment of the capture device wherein the distal elements are held in a retracted position under tension and are extendible

upon release.
Figs. 16F-16G illustrate an embodiment of the capture device wherein the distal elements extend and retract together.
Figs. 17A-17D show a number of embodiments of the interventional tool comprising proximal elements which are capable of protruding outward from the shaft at a location proximal to the distal elements.
Figs. 18A-18D show embodiments of the capture device wherein the valve leaflets are pinched between a superior loop and an inferior loop.
Figs. 19A-19B are perspective views of a capture device wherein the proximal elements and the distal elements are interlockable, and Fig. 19C illustrates a top view showing the interlocked elements.
Figs. 20A-20B illustrate an embodiment of the capture device wherein the proximal and distal elements are formed by a continuous structure.
Fig. 21A illustrates leaflets captured by a capture device detached from the shaft and left behind as a fixation device.
Figs. 21B-21H illustrates a variety of embodiments of detachment mechanisms.
Figs. 21I-21J illustrate the use of capture devices having a pledget for use as a fixation device.
Fig. 22 illustrates an embodiment of the interventional tool having distal elements and guide conduits disposed near its distal end.
Figs. 23A-23B illustrates the placement of a suture having an anchor with the use of a penetrating device advanced through a guide conduit.
Figs. 24, 25, 26A-26B, 27A-27T illustrate various embodiments of anchors.
Figs. 27U-27V illustrate anchors deployed from a doubled barreled delivery device.
Figs. 28 depicts a perspective view of an embodiment of the interventional tool having more than one guide conduit.
Fig. 29 depicts a top view of the interventional tool of Fig. 28 positioned between the valve leaflets.
Fig. 30 illustrates target points through which sutures may be placed and drawn together in the direction of the arrows.
Fig. 31 illustrates an anchor placed through a target point and a snare placed through an adjacent target point, wherein the snare captures the anchor.
Fig. 32 illustrates sutures placed by the method illustrated in Fig. 31, wherein the sutures are fastened together to repair the valve.
Fig. 33 illustrates the method of Fig. 31 performed on two adjacent valve leaflets.
Fig. 34 illustrates an embodiment of the interventional tool having more than one guide conduit including at least two slotted needles for use in deploying a suture line.
Fig. 35 illustrates a continuous suture line placed according to the methods illustrated in Fig. 34.
Fig. 36 illustrates an embodiment of the interventional tool having a guide conduit wherein a penetrating device is advanced through the guide conduit having a suture holding feature disposed near its distal end.
Fig. 37 illustrates a distal element of a capture device comprising a loop having a second loop comprised of suture.
Fig. 38 shows a cross-sectional view of the element shown in Fig. 37.
Figs. 39-41 illustrate methods of using the interventional tool illustrated in Figs. 36-38.
Figs. 42-51 illustrate a first device embodiment according to the aspects of the present invention and methods of use.
Fig. 52-58 illustrate a second device embodiment according to the aspects of the present invention and methods of use.
Fig. 59 illustrates a kit.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

I. CARDIAC PHYSIOLOGY

[0036] The left ventricle LV of a normal heart H in systole is illustrated in Fig. 1. The left ventricle LV is contracting and blood flows outwardly through the tricuspid (aortic) valve AV in the direction of the arrow. Back flow of blood or "regurgitation" through the mitral valve MV is prevented since the mitral valve is configured as a "check valve" which prevents back flow when pressure in the left ventricle is higher than that in the left atrium LA. The mitral valve MV comprises a pair of leaflets having free edges FE which meet evenly to close, as illustrated in Fig. 1. The opposite ends of the leaflets LF are attached to the surrounding heart structure along an annular region referred to as the annulus AN. The free edges FE of the leaflets LF are secured to the lower portions of the left ventricle LV through chordae tendineae CT (referred to hereinafter as the chordae) which include plurality of branching tendons secured over the lower surfaces of each of the valve leaflets LF. The chordae CT in turn, are attached to the papillary muscles PM which extend upwardly from the lower portions of the left ventricle and interventricular septum IVS.

[0037] A number of structural defects in the heart can cause mitral valve regurgitation. Regurgitation occurs when the valve leaflets do not close properly allowing leakage from the ventricle into the atrium. As shown in Fig. 2A, the free edges of the anterior and posterior leaflets normally meet along a line of coaptation C. An example of a defect causing regurgitation is shown in Fig. 2B. Here an enlargement of the heart causes the mitral annulus to become enlarged, making it impossible for the free edges FE to meet during systole. This results in a gap G which allows blood to leak through the valve during ventricular systole. Ruptured chordae can also cause a valve leaflet to prolapse since inadequate tension is transmitted to the leaflet via the chordae. While the other leaflet maintains a normal profile, the two valve

leaflets do not properly meet and leakage from the left ventricle into the left atrium will occur. Such regurgitation can also occur in patients who have suffered ischemic heart disease where papillary muscles do not contract sufficiently to effect proper closure.

II. GENERAL OVERVIEW

[0038] The present invention provides devices for grasping, and optional repositioning and fixation of the valve leaflets to treat cardiac valve regurgitation, particularly mitral valve regurgitation. Such grasping will typically be atraumatic providing a number of benefits. For example, atraumatic grasping may allow repositioning of the devices relative to the leaflets and repositioning of the leaflets themselves without damage to the leaflets. However, in some cases it may be necessary or desired to include grasping which pierces or otherwise permanently affects the leaflets. In some of these cases, the grasping step includes fixation. Although a number of embodiments are provided to achieve these results, a general overview of the basic features will be presented herein. Such features are not intended to limit the scope of the invention and are presented with the aim of providing a basis for descriptions of individual embodiments presented later in the application.

[0039] Generally, the valve leaflets are grasped and repositioned by pressing a capture device against the ventricular surface of the leaflets. The ventricular surface is the generally planar surface of the valve that faces the ventricle. Access to the ventricular surface will be described in the following section, however it is basically assumed that the ventricular surface is accessible by a retrograde approach through the ventricle or by an antegrade approach through the atrium and then passing through the valve to the ventricle. For illustration purposes, an antegrade approach will be described.

[0040] Referring to Fig. 3, a interventional tool 100, having a shaft 104 and a capture devices 105 comprising two elements 106 protruding radially outward from the distal end 102 of the shaft 104, is shown approaching the mitral valve MV from the atrial side. The mitral valve MV is shown in a perspective side view wherein the valve leaflets LF open through the valve annulus AN during diastole. In such a position, the chordae CT are can be seen attached along the free edge FE of the leaflet LF and the ventricular surface VS is visible. [Short-axis echocardiography may be used to visualize the interventional tool 100 and orient the elements 106 so that they are positioned substantially perpendicular to the line of coaptation C. The tool 100 may be moved roughly along the line of coaptation to the location of regurgitation. Under long-axis echo guidance, the elements 106 are then advanced through the valve, between the leaflets LF in the direction of the arrow 108, so that the elements 106 emerge beyond the valve. In this perpendicular position, the tool 100 is then retracted, pressing the elements 106 against the ventricular surface of the leaflets LF. This grasps the leaflets LF and pulls the leaflets up close to the annular plane so that the grasped free edges are coapted. This is illustrated in Fig. 4, a short-axis view of the mitral valve MV from the atrial side. Here the elements 106 are shown in dashed outline as the elements 106 are positioned on the ventricular side of the valve.

[0041] The interventional tool 100 is dimensioned at its waist 110 to fit between adjacent chordae where the chordae attach to the free edge. The elements 106 may be dimensioned to have a width 112 which is greater than the distance between the adjacent chordae, effectively trapping the chordae, however this is not necessary. In addition, the opposing tensioning force of the chordae on the free edge FE of the leaflets helps secure the leaflets LF on the elements 106. Such dimensioning and positioning prevents displacement of the leaflets LF from the interventional tool 100 due to the diastolic pressure gradient on the leaflets LF and relative movement of the annulus to the elements 106. This is shown in Fig. 5, a short-axis view of the mitral valve MV from the atrial side during diastole wherein the leaflets LF remain in position against the elements 106 surrounded by openings 114 which result from the diastolic pressure gradient. This simulates the double orifice geometry of a standard surgical bow-tie repair. Color Doppler echo will show if the regurgitation of the valve has been reduced. If the resulting mitral flow pattern is satisfactory, the leaflets may be fixed together in this orientation with a suture 115 or fixation device, as shown in Fig. 5A. If the resulting color Doppler image shows insufficient improvement in mitral regurgitation, the interventional tool 100 may be repositioned. This may be repeated until an optimal result is produced wherein the leaflets LF may then be fixed.

[0042] As will be discussed later, the interventional tool 100 may take a number of forms and may be comprised of a variety of materials, each design choice providing variations to the above described devices. Further, the tool 100 may include provisions for fixing the leaflets together after repositioning.

III. ACCESS TO THE MITRAL VALVE

[0043] Access to the mitral valve or other cardiac valve will preferably be accomplished through the patient's vasculature in a "percutaneous" manner. By "percutaneous" it is meant that a location of the vasculature remote from the heart is accessed through the skin, such as using needle access through, for example, the Seldinger technique. However, it may also include using a surgical cut down procedure or a minimally invasive procedure. The ability to percutaneously access the remote vasculature is well-known and described in the patent and medical literature. Further, access may be achieved directly through the chest and the heart wall, wherein the heart is either beating or stopped. Depending on the type and point of access, the approach to the mitral valve may be antegrade or retrograde. Entry to the left atrium, for example, may be achieved via the pulmonary vein or by

crossing the interatrial septum for an antegrade approach to the mitral valve. Alternatively, approach to the mitral valve can be retrograde, for example, where the left ventricle is entered through the aortic valve. Once access is achieved, the interventional tools and supporting catheter(s) may be advanced to the heart intravascularly where they may be positioned adjacent the target cardiac valve in a variety of manners, as described elsewhere herein. While the methods will be described as percutaneous and intravascular, many of the tools and catheters described herein will, of course, also be useful for performing surgical techniques where the heart is beating or stopped and the heart valve accessed through the myocardial tissue, either in an open heart or closed heart procedure. Many of the devices will also find use in minimally invasive procedures where access is achieved thorascopically and where the heart will usually be stopped but in some instances could remain beating.

[0044] A typical antegrade approach to the mitral valve is depicted in Fig. 6. The mitral valve MV may be accessed by a standard approach from the inferior vena cava IVC or superior vena cava SVC, through the right atrium RA, across the interatrial septum IAS and into the left atrium LA above the mitral valve MV. As shown, a catheter 120 having a needle 122 may be advanced from the inferior vena cava IVC into the right atrium RA. Once the catheter 120 reaches the interatrial septum IAS, the needle 122 may be advanced so that it penetrates through the septum at the fossa ovalis FO or the foramen ovale into the left atrium LA. At this point, a guidewire may be advanced out of the needle 122 and the catheter 120 withdrawn. As shown in Fig. 7, access through the interatrial septum IAS will usually be maintained by the placement of a guide catheter 125, typically over a guidewire 124 which has been placed as described above. The guide catheter 125 affords subsequent access to permit introduction of the tool(s) which will be used for performing the valve or tissue modification, as described in more detail below.

[0045] A typical retrograde approach to the mitral valve is depicted in Fig. 8. Here the mitral valve MV may be accessed by an approach from the aortic arch AA, across the aortic valve AV, and into the left ventricle below the mitral valve MV. The aortic arch AA may be accessed through a conventional femoral artery access route, as well as through more direct approaches via the brachial artery, axillary artery, or a radial or carotid artery. As shown in Fig. 9, such access may be achieved with the use of a guidewire 128. Once in place, a guide catheter 126 may be tracked over the guidewire 128. The guide catheter 126 affords subsequent access to permit introduction of the tool(s) which will be used for performing the valve modification, as described in more detail below.

[0046] In some cases, access routes to the mitral valve may be established in both antegrade and retrograde approach directions. This may be useful when, for instance, grasping is performed with the use of specific devices introduced through one route and fixation is achieved with the use of separate devices introduced through another route. In one possible situation, the leaflets may be grasped and repositioned by pressing a interventional tool against the ventricular surface of the valve via a retrograde approach. While the interventional tool is in place, a fixation tool may be introduced via an antegrade approach to fix the leaflets in place. Thus, a variety of access routes may be used individually or in combination with the devices of the present invention.

IV. LEAFLET CAPTURE DEVICE

[0047] Once the valve is accessed and the guidecatheter is positioned in place, the interventional catheter is introduced through the guidecatheter for use in capturing or holding the valve leaflets. The interventional catheter typically comprises a shaft, having a proximal end and a distal end, and an interventional tool disposed near its distal end. The interventional tool may take a number of forms. Fundamentally, the interventional tool comprises a capture device comprising at least one distal element capable of protruding radially outward from the shaft. Typically, the tool will have two distal elements, one element to press upwardly against each leaflet of the two leaflet that are to be fixed together. However, the tool may have any number of such elements, including multiple elements pressing against each of the leaflets or one element pressing against one leaflet and no element pressing against an adjacent leaflet. Any of these combinations may effectively coapt a pair of leaflets. Further, multiple elements may be present to reposition and coapt three leaflets, such as for use with the aortic valve.

[0048] Figs. 10A-10C show a number of embodiments of capture devices 204 that may be disposed at the distal end 202 of an interventional catheter 200. As described, each device 204 will typically have two distal elements 208 which are protrudable radially outward from the shaft 210. In many embodiments, the elements 208 extend from opposite sides of the shaft 210 so the elements 208 are approximately 180 degrees apart. However, it may be appreciated that the elements 208 may be spaced any distance apart and may be symmetrically or asymmetrically arranged.

[0049] In addition, the distal elements 208 may take a number of forms, including bars, rods, flaps, sheets, blocks or loops to name a few. These forms can in turn take a number of shapes, such as rectangular, circular, oblong, elliptical and petal. Thus, for clarity, loops include any shape wherein the form surrounds or nearly surrounds an opening 209. Loops may have circular, oval or petal shapes, as generally illustrated in Figs. 10A-10B, or may include irregular shapes of any type, including pointed or angular edges and/or invaginations. Further, these forms may be comprised of a number of materials, including wire, ribbon, filaments or fibers which are made from stainless steel, metals, nitinol, shape-memory alloy, polymers, silk, polyester or nylon, to name a few. Such materials may also be radiopaque to aid in visualization.

Likewise, the elements may be comprised of a combination of such forms and/or materials. As an example, Fig. 10A illustrates elements 208 in the form of loops 212 having a petal shape. Here, the loops are positioned on opposite sides of the shaft 210 so as to form a "figure-8" shape in a top view or a bottom view. These loops 212 are preferably made from nitinol or shape-memory wire, however other materials may be suitable. The loops 212 may protrude from the shaft 210 by a means of a number of designs. For example, as illustrated in Fig. 10A, the loops may protrude from a space between the shaft 210 and a cap 238 located at its tip. Alternatively, the loops 212 may protrude through the shaft 210, as shown in Fig. 10B, or through the cap 238. This may lend support to the loops 212 during use. As will be discussed later, such loops 212 may be combined with a second set of loops comprised of suture that are detachable from these loops 212 for leaflet fixation. Fig. 10C illustrates elements 208 in the form of flaps or sheets 214 which are essentially rectangular such as made from ribbon or other flat materials. These sheet 214 are also preferably made from nitinol or shape-memory wire, however other materials may be suitable.

[0050] Fig. 11A illustrates a element 208 in the form of a block, rod or bar 216 disposed perpendicularly to the shaft 210. The bar 216 may be comprised of any number of materials, including metals, alloys, polymers or fibers, to name a few. When such a bar 216 forms one continuous element 208 which extends beyond the diameter of the shaft, as shown, the bar 216 may pivot (indicated by arrows) around a pivot point 218 at the base of the shaft 210 to manipulate the position of the bar 216. As shown in Fig. 11B, the bar 216 may further comprise a pull-wire 219 which extends from the shaft 210 to the bar 216 and loops through the bar 216 to connect with each end of the bar 216. By retracting or pulling upwards on the pull-wire 219 the bar 216 will pivot around a pivot point 218 at the base of the shaft 210. This orients the bar 216 to a low profile position so that the interventional tool may more easily be passed through a guidecatheter and further between a set of valve leaflets LF, as shown. Once the element 208 is advanced and disposed below the valve, as shown in Fig. 11C, the element 208 is then pressed against the ventricular surface 217 of the leaflets LF to grasp and reposition the leaflets. Since the bar 216 is pivotable around a center pivot point 218, the bar 216 may slightly pivot during grasping based on the anatomy of the valve. This may allow a more desirable application of force to the valve leaflets, as a less rigid leaflet may receive a larger force to draw the leaflet up to a coapted position. In a similar design, each element 208 may pivot independently of the other around a pivot point at the base of the shaft. This is possible when such a bar or rod forms two elements 208 extending 180 degrees apart outwardly from the shaft 210. This may provide an even higher degree of flexibility during grasping.

[0051] Referring to Fig. 12, the element 208 may be comprised of a combination of forms and materials. Here, the element has the form of a block 220 having cutouts 222 surrounded by wire loops 224. Such loops 224 may increase the area in which the element 208 may contact the leaflet LF. In addition, such loops 224 may be adjustable to aid in manipulation and repositioning of the leaflets. Further, the block 220 may be pivotable around a center pivot point 218 at the base of the shaft 210 to manipulate the position of the block 220 as in the manner described and shown in Figs. 11B-11C.

[0052] In many embodiments, the distal elements are individually extendable, retractable and repositionable. Fig. 13 illustrates the extension of a first element 230 independently of the second element 232. Such elements 230, 232 may be utilized in this arrangement or the second element 232 may be extended at any point during the procedure. Likewise, the elements 230, 232 may be extended or retracted by variable amounts for protrusion of various distances from the shaft 210. Such extension and retraction may also adjust the width 231 of the exposed elements 230, 232 if the width of the element 230, 232 varies radially from the shaft, such as with a petal shape. In addition, the elements 230, 232 may be individually rotatable around the shaft 210 to vary the distance between the elements 230, 232. Further, as shown in Fig. 14, the elements 230, 232 may have differing angles of curvature. Here, the first element 230 has a first radius of curvature 234 which is larger than a second radius of curvature 236 of the second element 232. This may be achieved by heat shaping the elements 230, 232 to have different curvatures, or the curvatures may be adjusted by manipulation by the user at the proximal end of the interventional catheter 200. Consequently, each element 230, 232 will provide a different repositioning effect when pressed against a leaflet.

[0053] In some embodiments, the capture device 204 has a cap 238 located at its tip. Such a cap 238 has been shown in embodiments presented in Figs. 10A, 10C, 13, and 14 and may provide a variety of functions. For example, the cap 238 may serve as a blunt tip to assist in atraumatic passing of the device 204 through the valve, between valve leaflets, during placement of the device 204. The cap 238 may also be moveable to close a gap 240 between the cap 238 and the shaft 210 where the distal elements 230, 232 emerge. When the elements 230, 232 are retracted, movement of the cap 238 to close the gap minimizes the profile of the tool 204 and reduces the possibility of the elements 230, 232 or portions of the device 204 interfering with tissue or entangling with chordae. As shown in Fig. 15, when the elements 230, 232 are extended, movement of the cap 238 to close the gap 240 may increase rigidity of the elements 230, 232 by providing support for the elements 230, 232 or it may adjust the curvature of the elements 230, 232 by flexing a portion of the elements 230, 232 near the shaft 210. Further, when the elements 230, 232 are pressed against the ventricular surface of the valve leaflets, the leaflets may extend into the gap 240 between the cap 238 and the shaft 210. When the cap 238 is moved to close the

gap 240, the leaflets may be pinched between the shaft 210 and the elements 230, 232 and cap 238. This may assist grasping of the leaflets for later fixation. It may be appreciated that although these elements have been illustrated as curving upwardly, away from the distal end, the elements may alternatively be uncurved, curve downwardly, include compound curvatures or more than one curvature along each element, or any other combination of curvatures.

[0054] In some embodiments, the distal elements are held in a retracted position under tension and are extendable upon release. For example, Figs. 16A-16C illustrate one embodiment of the interventional tool 204 in various states of deployment. The elements 230, 232 are disposed near a distal end 231 of an inner shaft 233 within the shaft 210. Fig. 16A shows the elements 230, 232 in a retracted position as they are held under tension by loops 221, each loop 221 threaded through an element 230, 232 and pulled upwardly within the shaft 210 as shown. The loops 221 may be comprised of any suitable material, including suture, wire or polymer strands. It may be appreciated that the tool 204 may be introduced in this state or the inner shaft 233 and elements 230, 232 may be retracted within the shaft 210 and later deployed to this state when near the valve. Fig. 16B shows the elements 230, 232 in an extended state of deployment. Here, the upward force on the loops 221 have been relaxed and the tension released. Consequently, the elements 230, 232 extend outwardly as shown and the relaxed loops 221 hang at any location. As shown in Fig. 16C, the loops 221 may then be slid to toward the inner shaft 233 so that the elements 230, 232 may more easily engage the valve leaflets LF.

[0055] Figs. 16D-16E illustrate another embodiment wherein the distal elements are held in a retracted position under tension and are extendable upon release. Here, the elements 230, 232 are disposed near the distal end the shaft 210. Fig. 16D shows the elements 230, 232 in a retracted position as they are held downward against the shaft 210 under tension by loops 221, each loop 221 threaded through an element 230, 232 and pulled upwardly within the shaft 210 as shown. The loops 221 may be comprised of any suitable material, including suture, wire or polymer strands. Fig. 16E shows the elements 230, 232 in an extended state of deployment. Here, the upward force on the loops 221 have been relaxed and the tension released. Consequently, the elements 230, 232 extend upwardly and outwardly as shown and the relaxed loops 221 are drawn upward to hang from the extended elements 230, 232.

[0056] In some embodiments, the distal elements extend and retract together, an example of which is illustrated in Figs. 16F-16G. Referring to Fig. 16A, the elements 230, 232 are disposed at the distal end 231 of the inner shaft 233 within the shaft 210. The elements 230, 232 pass through the shaft 210 wall and outside the shaft 210 at locations 235, 237 desired for element protrusion. Upon retracting the inner shaft 233, as shown in Fig. 16B, the elements 230, 232 together are guided radially outward through the shaft 210 at the locations 235,237. It may be appreciated that although the elements 230, 232 in Figs. 16A-16G have been illustrated as curving downwardly, towards the distal end, the elements may alternatively be uncurved, curve upwardly, include compound curvatures or more than one curvature along each element, or any other combination of curvatures.

[0057] In a number of embodiments, an example of which is shown in Figs. 17A-17D, the interventional tool 204 also comprises proximal elements 240, 242 which are capable of protruding radially outward from the shaft at a location which is proximal to the elements 230, 232 previously described. The proximal elements 240, 242 may have any of the forms, shapes, material compositions, features, or capabilities described in relation to the distal elements 230, 232. In Fig. 17A, such proximal elements 240, 242 are shown as loops. Such proximal elements 240, 242 would most commonly be used in embodiments of capture devices 204 designed for an antegrade approach to the valve wherein the device 204 crosses the valve to access the ventricular surface of the leaflets. Typically, once the distal elements 230, 232 are extended and positioned against the ventricular surface of the leaflets, the proximal elements 240, 242 are then extended and positioned against the artrial surface of the leaflets. As shown in Fig. 17B, the leaflets LF are thus secured between the proximal elements 240,242 and distal elements 230, 232. The proximal elements 240, 242 and/or distal elements 230, 232 may then be extended, retracted or similarly adjusted to further orient the leaflets. In addition, the cap 238 may optionally be retracted toward the shaft 210 to further pinch the leaflets between the elements.

[0058] Referring to Fig. 17C, the proximal elements 240, 242 may be separately deployable from the distal elements 230, 232. Here, the elements 240, 242, 230, 232 are disposed near the distal end 231 of the inner shaft 233 within shaft 210. The proximal elements 240, 242 are constrained within the shaft 210 while the distal elements 230,232 are extended radially outward. In this state, the distal elements 230, 232 may be positioned against the ventricular surface of the valve leaflets LF. The proximal elements 240, 242 may then be released by retracting the shaft 210. As shown in Fig. 17D, release of the proximal elements 240, 242 allows them to extend radially outward and downward, as illustrated by arrows. Depending on the curvature of the proximal elements 240, 242, they may remain proximal to, move to within the same plane of, or move beyond the plane of the distal elements 230, 232. In addition, the proximal elements may include various friction accessories 227, such as prongs, to assist in holding the valve leaflets LF. Other friction accessories 227 include windings around the elements, such as metal, polymer or suture windings, cuffs, bands, or barbs. Further, such accessories 227 may additionally or alternatively be included on the distal elements 230, 232. Likewise, such accessories 227 may be

included on the elements of the capture devices in any of the embodiments of the interventional tool. In an additional embodiment, depicted in Figs. 18A-18D, the valve leaflets LF may be pinched between a proximal element or superior loop 720 and a distal element or inferior loop 721. In a preferred embodiment, the capture device or grasper is comprised of a nitinol flat ribbon heat set in the shape of double loops 720, 721. The ribbon may be mounted on a series of three coaxial shafts, an interior shaft 725, a central shaft 726 and an exterior shaft 727. The distal end of the ribbon may be attached to the distal end 730 of the interior shaft 725, a midportion of the ribbon may be attached to the distal end 731 of the central shaft 726, and the proximal end of the ribbon may be attached to the distal end 732 of the exterior shaft 727. One or more ribbons may be mounted on the coaxial shafts; in this example, two ribbons are shown 180 degrees apart. When extended, as shown in Fig. 18A, the grasper may be pulled flat against the shafts 725, 726 , 727 for ease of insertion through a guide catheter or tool and into a desired position between the valve leaflets LF. When the central shaft 726 is retracted or the exterior shaft 727 advanced, as shown in Fig. 18B, the superior loops 720 may extend radially from the shafts. The superior loops 720 may rest on the superior surface of the valve leaflets LF in the atrium, as shown in Fig. 18D. In this position, the superior loops 720 may aid in orientation assessment, as the superior loops may be echo or fluorogenic and may be easily visible in relation to the cardiac structures or other devices or components. When positioned in a desired location, the interior shaft 725 may then be retracted, as shown in Fig. 18C, to extend the inferior loops 721 radially from the shafts. The inferior loops 721 may be in contact with the inferior surface of the valves leaflets LF in the ventricle. Thus, the valve leaflets LF may be pinched between the inferior loop 721 and superior loop 720. It may also be appreciated that the inferior loops 721 may be deployed prior to the superior loops 720.

[0059] Further, the proximal elements 240, 242 and distal elements 230, 232 may interlock to prevent relative motion between the elements and more securely hold the leaflets LF. Referring to Fig. 19A, a distal element 230 is shown protruding radially outwardly from the shaft 210. In this example, the distal element 230 is shaped having a raised upwardly pointing tip portion 243 and two side portions 245. The proximal element 240 is shown protruding radially outwardly from the shaft 210 at a location proximal to the distal element 230. Here, the proximal element 240 is shaped having two downwardly pointing tip portions 247, 249. When the elements 230, 240 are drawn together, as shown in Fig. 19B, the raised upwardly pointing tip portion 243 fits between the two downwardly pointing tip portions 247, 249 locking the elements 230, 240 together. This may be more easily visualized in a top view of the interlocked elements 230, 240 shown in Fig. 19C. It may be appreciated that, in use, the distal element 230 is extended and positioned against a ventricular surface of a leaflet, the proximal element 240 is extended and positioned against an atrial surface of the leaflet. Thus, the leaflet is thus secured between the elements 230, 240 in the interlocked orientation.

[0060] In some embodiments, the proximal and distal elements are formed by a continuous structure. Referring to Fig. 20A, the continuous structure 260 is shown in a low profile position wrapped around the end portion 262 of the shaft 210 of the interventional catheter 200 under tension. In this profile position, the catheter 202 is advanced with an atrial approach through the valve, between the leaflets LF, so that the distal end 202 extends beyond the valve into the ventricle. Referring to Fig. 20B, the continuous structure 260 is then released and allowed to relax. Prior heat forming allows the structure 260 protrude radially outward at various points along the structure 260. Each protrusion is similar to an above described proximal or distal element and functions in a similar manner. The embodiment shown in Figs. 20A-20B includes protrusions similar to both proximal elements 240, 242 and distal elements 230, 232 as shown. These elements may protrude various distances and at various angles from the shaft, as previously described.

[0061] Many features of the distal elements 230, 232 and proximal elements 240, 242 have been described and illustrated with embodiments comprising wire loops. It may be appreciated that the described features are applicable to any of the above described embodiments, such as blocks, rods, ribbons, etc.

IV. LEAFLET FIXATION TOOL

[0062] With the valve leaflets grasped in a desired orientation using an embodiment of the capture device described above, the leaflets may be fixed together to maintain this orientation. This may be achieved by leaving the capture device in place to function as a fixation device. To this end, the capture device may be detachable from the interventional tool to be left behind as a permanent or temporary implant. Fig. 21A illustrates a capture device comprising distal elements 230, 232 and proximal elements 240, 242 wherein the leaflets LF are captured therebetween. As shown, the capture device may be detached from the shaft 210 and left behind as a fixation device. Detachment may be achieved by a variety of different mechanism and design features. Figs. 21B-21H illustrate embodiments of such detachment mechanisms. Fig. 21B shows an upper shaft 312 and a detachable lower shaft 313 which are interlocked at a joining line 314. The joining line 314 may have any shape or curvature which will allow or facilitate interlocking and later detachment. A snuggly fitting outer sheath 315 is positioned over the shafts 312, 313 to cover the joining line 314 as shown. Fig. 21C illustrates detachment of the lower shaft 313 from the upper shaft 312. This is achieved by retracting the outer sheath 315, so that the joining line 314 is exposed, which allows the shafts 312, 313 to separate. Similarly, Fig. 21D illustrates a tubular upper shaft

316 and a detachable tubular lower shaft 317 which are interlocked at a joining line 314. Again, the joining line 314 may have any shape or curvature which will allow or facilitate interlocking and later detachment. A snuggly fitting rod 318 is inserted through the tubular shafts 316, 317 to bridge the joining line 314 as shown. Fig. 21E illustrates detachment of the lower shaft 317 from the upper shaft 316. This is achieved by retracting the rod 318 to a position above the joining line 314 which in turn allows the shafts 316, 317 to separate.

[0063] Figs. 21F-21H illustrate another embodiment of a detachment mechanism. Referring to Fig. 21F, an upper shaft 900 is shown attached to a detachable lower shaft 902. An outer tube 910 surrounds the upper shaft 900 and contacts the lower shaft 902 as shown. The upper shaft 900 is held in attachment to the lower shaft 902 by the presence of a ball 904 or similar device which is disposed in recess 906, shaped to receive a portion of the ball 904, in the lower shaft 902. The ball 904 is held in the recess 906 by an angular cutout 908 in the upper shaft 900. Referring to Fig. 21G, the upper shaft. 900 may be retracted. This may be achieved by pulling the upper shaft 900 upwards within the outer tube 910 while the outer tube 910 applies force on the lower shaft 902 to aid separation. As the upper shaft 900 is retracted, the angular cutout 908 allows the ball 904 to move from the recess 906 to a position within the upper shaft 900. Referring to Fig. 21H, upper shaft 900 and ball 904 may retracted into the outer tube 910, completing the detachment from the lower shaft 902. It may be appreciated that this detachment mechanism concept may be used with other shaped shafts, recesses, and balls or similar devices and may function without the use of the outer tube.

[0064] In some cases, use of the capture device as a fixation device may create one or more small gaps between the leaflets LF at the coaptation line. If this is likely to occur, or as an added precaution, a block, disk or pledget 321 of material may be positioned such that it blocks possible flow through such a gap. As shown in Fig. 21I, the pledget 321 may be positioned between the proximal elements 240, 242 and distal elements 230, 232. When the leaflets LF are captured between the proximal elements 240, 242 and distal elements 230, 232, as shown in a top view in Fig. 21J, the pledget 321 is positioned between the leaflet LF edges to block flow therethrough.

[0065] Alternatively, fixation may be accomplished with the use of separate devices used in combination with an interventional tool having a capture device. And, many embodiments of the present invention incorporate a fixation tool into the interventional tool for such use. The fixation tools described herein below may be used with any of the capture devices previously described. A few examples will be presented to illustrate possible embodiments.

[0066] In many embodiments, such as illustrated in Fig. 22, the interventional tool 100 has distal elements 302 and guide conduits 304 disposed near its distal end 306. Guide conduits 304 such as these may be used to guide a number of tools or devices to specific locations near the distal end 306. For example, in this case, the guide conduits 304 are used to guide fixation tools to specific locations on the surfaces of the leaflets. In addition, as will be described in a later section, the conduits 304 may be attached to the proximal loops. In addition to other benefits described later, the conduits 304 may provide added support or rigidity to the interventional tool which may aid in the fixation process.

[0067] As shown in Fig. 22, the guide conduits 304 are located proximal to the distal elements 302 and are capable of extending angularly outward from the shaft 308. It may be appreciated that the conduits 304 may be located at any point along the shaft 308 and may be capable of extending at any angle 310. Typically, such an angle 310 ranges from approximately 90 degrees, perpendicular to the shaft, to around zero degrees, essentially parallel to the shaft. Any angle 310 may be used to target the leaflets LF at points which are approximately 1-12 mm, preferably 3-5 mm, inward from the free edge FE of each leaflet LF. In a particular embodiment of the interventional tool 100, the guide conduit 304 is used for fixation. Here, the guide conduit 304 is used to introduce a fixation tool 305 comprising a penetrating device or needle 320 housing a suture 322 having an anchor 324 disposed at the distal end of the suture 322. The needle 320 is advanced toward a valve leaflet, either by extension of the guide conduit 304 or the needle 320 itself. In either case, the needle 320 is then advanced to penetrate the leaflet and emerge from the other side or the distal side of the leaflet. The needle 320 may be rigid, possibly made from a metallic material, or flexible, made from a flexible polymer, for example. As shown in Fig. 23A, an atrial approach would involve the needle 320 penetrating the atrial surface 326 of the leaflet LF, passing through the leaflet LF and emerging on the ventricular surface 327 of the leaflet LF. Once emerged, the anchor 324 is deployed as shown. The anchor 324 may be deployed by passing the anchor 324 through the needle 320 and expanding or allowing it to self-expand after it has exited the needle 320. Alternatively, the anchor 324 may be mounted on the outside of the needle 320 and covered by a sheath. Retraction or removal of the sheath would allow expansion of the anchor 324. In any case, after anchor deployment, the needle 320 is then retracted while maintaining the anchor 324 on the distal side of the leaflet LF. Consequently, the attached suture 322 remains in place, passing through the leaflet penetration. Once each fixation tool 305 has deployed its anchor 324 on the distal side of a leaflet LF, individually or simultaneously, the guide conduit 304 and interventional tool 204 are retracted. As shown in Fig. 23B, the ends of the sutures 322 may then be fixed together by conventional knot tying or any suitable method, including positioning fasteners. This may be achieved with the use of additional tools which are part of the interventional catheter 200, or this may be achieved by other methods after withdrawal

and removal of the interventional catheter 200.

[0068] A number of different types of anchors 324 may be used during fixation of the leaflets. Typically, the anchor 324 is expandable from a compressed low profile state, for delivery to the anchoring site, to an expanded state to provide a large enough surface for anchoring support. One embodiment of the anchor 324, shown in Fig. 24, is comprised of a wire 360 curved into a ring shape. The wire 360 may be stainless steel, nitinol or other shape memory wire, polymer or similar material. Suture 322 is attached to the center 366 of the ring by a bonding material. The wire 360 has a first end 362 and a second end 364 wherein the first end 362 is disposed on top of the ring and the second end 364 is disposed underneath the ring as shown. This configuration provides support for the ring when the anchor 324 is pulled snuggly against a valve leaflet surface by the suture 322. In addition, the first end 362 and second end 364 may have radiopaque markers 365 disposed thereon. Referring to Fig. 25, this embodiment of the anchor 324 is shown in possible use for fixation of valve leaflets. As described previously, an atrial approach would involve the needle 320 penetrating the atrial surface 326 of the leaflet LF, passing through the leaflet LF and emerging on the ventricular surface 327 of the leaflet LF. When the anchor wire 360 is comprised of flexible materials, the anchor 324 is collapsible for loading within the needle 320. Once the needle 320 has emerged on the ventricular surface 327, the anchor 324 is deployed as shown. The needle 320 is then retracted while maintaining the anchor 324 on the distal side of the leaflet LF. Consequently, the attached suture 322 remains in place, passing through the leaflet penetration. Once each fixation tool 305 has deployed its anchor 324 on the distal side of a leaflet LF, individually or simultaneously, the guide conduit 304 and interventional tool 204 are retracted. The sutures 322 may be pulled tight so that the anchors 324 are disposed against the leaflets LF and the ends of the sutures 322 may then be fixed together by conventional knot tying or any suitable method, including positioning fasteners.

[0069] Another embodiment of the anchor 324, shown in Figs. 26A-26B, involves two parts which are disposed on opposite sides of a valve leaflet. Referring to Fig. 26A, the anchor 324 is comprised of a first part 370 and a second part 372 wherein the suture 322 is fixedly attached to the first part 370, slidably attached to the second part 372, and continues to a free end 373 proximal to the second part 372. In addition, the first part 370 may have spikes 374 or other protrusions which interlock with receptacles 376 in the second part 372. It may be appreciated that such spikes 374 may be located on the second part 372 to interlock with receptacles 376 on the first part 370 or such spikes 374 and receptacles 376 may be located on both parts 370, 372. The anchor 324 may be comprised of flexible materials so that the anchor 324 is collapsible for loading within the needle 320. In this case, as previously described, the needle may penetrate the atrial surface 326 of the leaflet LF, pass through the leaflet LF and emerge on the ventricular surface 327 of the leaflet LF. Here the first part 370 of the anchor 324 is deployed, as shown in Fig. 26A. The needle 320 is then retracted while maintaining the first part 370 on the distal side of the leaflet LF. Consequently, the attached suture 322 remains in place, passing through the leaflet. Once the needle 320 is disengaged from the leaflet LF, the second part 372 of the anchor is deployed so the second part 372 is disposed on the atrial surface 326 as shown. Referring to Fig. 26B, the parts 370, 372 may then be drawn together so the spikes 374 pass through the leaflet LF and are received in the receptacles 376 locking the anchor in place. One or more sutures 322 with anchors 324 may be placed in other locations on the same or other leaflets LF. The ends of the sutures 322 may then be fixed together by conventional knot tying or any suitable method, including positioning fasteners.

[0070] Another embodiment of the anchor 324, shown in Figs. 27A-27B, involves a single structure having flanges which are disposed on opposite sides of a valve leaflet. Referring to Fig. 27A, the anchor 324 is comprised of a structure 381 having a first flange 380, a second flange 382 and a cylindrical portion 383 therebetween. The suture 322 is fixedly attached to the structure 381 as shown. In addition, the structure 381 may optionally include a compressible layer 384 on a surface of either the first flange 380, the second flange 382 or both facing the cylindrical portion 383. The anchor 324 may be comprised of flexible materials so that the anchor 324 is collapsible for loading within the needle 320. In this case, as previously described, the needle may penetrate the atrial surface 326 of the leaflet LF, pass through the leaflet LF and emerge on the ventricular surface 327 of the leaflet LF. Here the structure 381 is partially deployed so that the first flange 380 emerges and is positionable against the ventricular surface 327. The needle 320 is then retracted while maintaining the first flange 380 on the distal side of the leaflet LF. Consequently, cylindrical portion 383 emerges and is positioned through the leaflet. As the needle 320 is disengages from the leaflet LF, the second flange 382 is deployed so the second flange 382 is disposed on the atrial surface 326 as shown in Fig. 27B. One or more sutures 322 with anchors 324 may be placed in other locations on the same or other leaflets LF. The ends of the sutures 322 may then be fixed together by conventional knot tying or any suitable method, including positioning fasteners.

[0071] Another embodiment of the anchor 324, shown in Figs. 27C-27D, involves a single tubular structure 800 having longitudinal slits 802 attached to the end of the suture 322. As shown in Fig. 27C, the structure 800 may be compressed to a low profile position so that it can be loaded within or on the outside of a catheter, needle or other delivery device. Upon delivery, as shown in Fig. 27D, the structure 800 may expand so that side-arms 804 project radially outward. This provides a broad surface to rest against the leaflets. A similar embodiment, shown in Figs. 27E-27F, comprises a tubular structure

810 having a central bar 812 to which the suture 322 is attached. As shown in Fig. 27F, the structure 810 may be compressed to a low profile position. Upon delivery, as shown in Fig. 27G, the structure 810 may expand so that side-arms 814 project radially outward. Such positioning of the suture 322 may provide allow the anchor 324 to be positioned more flush to the leaflets.

[0072] Another embodiment of the anchor 324, shown in Figs. 27G-27H, involves a tubular structure 820 attached to the end of the suture 322. As shown in Fig. 27G, the structure 820 may be mounted on the outside of a needle or introductory device 822 in a low profile position. Upon delivery, as shown in Fig. 27H, the structure 820 may expand radially outward. To achieve this, the structure 820 may be self expanding, wherein the structure 820 is released by retracting a sheath or similar restraining support. Or, the structure 820 may be mechanically expanded by action of a balloon or similar device mounted on the introductory device. In any case, introductory device 822 may then be removed.

[0073] Another embodiment of the anchor 324, shown in Figs. 27I-27J, involves a longitudinal structure 830 having a horizontal beam 832 attached to the end of the suture 322. As shown in Fig. 27I, the structure 830 may be compressed to a low profile position so that it can be loaded within a catheter, needle or other delivery device. Upon delivery, as shown in Fig. 27J, the structure 830 may expand so that side-arms 834 project radially outward. This may be achieved by expanding the horizontal beam 832 which in turn pushes the side-arms outward. Alternatively, this may be achieved by the side-arms 834 self-expanding which in turn expands the horizontal beam 832.

[0074] Another embodiment of the anchor 324, shown in Figs. 27K-27L, involves a thin disk 840 attached to the end of the suture 322. As shown in Fig. 27K, the disk 840 may be rolled to a cylinder shape, for either mounting on the outside of or for insertion through a lumen in a needle, catheter or other introductory device. Upon delivery, as shown in Fig. 27L, the disk 840 may then be flattened to provide a large surface area to rest against the leaflets.

[0075] Another embodiment of the anchor 324, shown in Figs. 27M-27N, involves a single tubular structure 850, having longitudinal slits 852 from one end to approximately midsection, attached to the end of the suture 322. As shown in Fig. 27M, the structure 850 may be compressed to a low profile position so that it can be loaded within or on the outside of a catheter, needle or other delivery device. Upon delivery, as shown in Fig. 27N, the slit structure portions 854 may curl or bend outwardly and/or downwardly. This provides a broad surface to rest against the leaflets.

[0076] Another embodiment of the anchor 324, shown in Figs. 27P-27Q, involves a tubular structure 860 attached to the end of the suture 322. As shown in Fig. 27P, the structure 860 may be mounted on the outside of a needle or introductory device 862 in a low profile position. Upon delivery, as shown in Fig. 27Q, the structure 860 may compress longitudinally, as in an accordion-type fashion. In doing so, the structure 860 additionally expands radially to provide added surface area to rest against the leaflets.

[0077] Another embodiment of the anchor 324, shown in Figs. 27R-27T, involves a bar 870 attached to the end of the suture 322. As shown in Fig. 27R, the suture 322 may rest flush against the bar 870 in a low profile position for loading within a needle, catheter or similar delivery device. Upon delivery, as shown in Fig. 27T, the bar 870 may reposition such that it is perpendicular to the suture line 322. In this way, the bar may rest against the leaflet in an anchoring fashion. Referring to Figs. 27U-27V, similar bars may be deployed from a double-barreled delivery device 880. As shown in Fig. 27U, a first bar 884 and a second bar 886 are loaded in parallel barrels separated by a partition 882. As shown in Fig. 17V, the first bar 884 may be deployed through the single lumen tip 888 of the delivery device 882. The device 882 may then be repositioned at another location where the second bar 886 may be deployed in a similar fashion.

[0078] In an additional embodiment of the interventional tool 100, more than one guide conduit 304 is present and directed at each leaflet for leaflet fixation. An example of such a tool 100 is shown in Fig. 28. Here the guide conduits 304 are shown attached to proximal elements 400 in a radially protruded position. Interconnection of the proximal elements 400 with the guide conduits 304 may allow one to deploy the other. For example, deployment and advancement of the guide conduits 304 angularly outward may draw the proximal elements 400 out from the shaft 402 effecting their deployment. Alternatively, the proximal elements 400 may be comprised of a material that is sufficiently rigid so that deployment of the proximal elements 400 draws the guide conduits 304 downward and outward from the shaft 402 effecting their deployment. The proximal elements 400 may also serve to position the guide conduits 304 in a desired location. Distal elements 404 are also illustrated in a radially protruded position near the distal end 406 of the tool 100.

[0079] In use, the tool 100 is positioned between the valve leaflets LF, as shown in a top view in Fig. 29, so that the proximal elements 400 are disposed against the atrial surface (in an atrial approach) of the valve. The distal elements 404 are disposed against the ventricular surface of the valve and thus are out of view. Such placement of the proximal elements 400 provides four target points 406 on the valve leaflet LF, two target points 406 per leaflet LF. Advancement of one or more fixation tools through the guide conduits 304 allows placement of sutures and optionally anchors 324 through the leaflets LF at the target points 406 by the fixation tools. Once sutures and optionally anchors 324 are placed through each of the target points 406, the sutures may be pulled together, cinched and fastened in place. Fig: 30 illustrates such action as the target points 406 will be drawn together in the direction of the arrows. This may provide a more sturdy and effective fixation of the leaflets and therefore re-

pair of the valve.

[0080] Sutures 233 may be placed through each of the target points 406 by a number of methods using a variety of fixation tools and devices. For example, Fig. 31 shows the placement of suture 233 through two adjacent target points 406 on one leaflet LF. Such illustrations assume an atrial approach with a top view of the atrial surface of the leaflet LF as depicted by shading. A first guide conduit 420 and a second guide conduit 422 protruding from the shaft 402 of an interventional tool 100 are shown directed toward the target points 406. Through the first guide conduit 420 a needle 423 or other device may be used to penetrate the leaflet LF and deploy a snare 424 on the ventricular side of the leaflet LF. Such a snare 424 may be comprised of any suitable material. Through the second guide conduit 422, a needle 423 or other device may be used to penetrate the leaflet LF and deploy an anchor 426 through the snare 424 on the ventricular side of the leaflet LF. Attached to the anchor 426 is a suture line 233 which passes through the penetration at the target point 406 and continues up through the second guide conduit 422. The snare 424 is then retracted back through the needle 423 pulling the anchor 426 and attached suture line 233 with it. Thus, the anchor 426 is drawn up through the first guide conduit 422 creating a continuous suture line 233 through the second guide conduit 422, across the ventricular surface of the leaflet LF and up through the first guide conduit 420. As shown in Fig. 32, this may be repeated on an adjacent leaflet LF and the suture lines 233 may be fixed together by conventional knot tying or any suitable method, including positioning fasteners. Although such fixation is shown with the sutures in a relaxed position for clarity, such fixation will typically involve cinching the leaflets together so that the target points 406 are adjacent to one another.

[0081] It may be appreciated that the methods shown in relation to Fig. 31 may be similarly performed across two adjacent leaflets LF, as illustrated in Fig. 33. Here, a needle 423 or other device may be used to penetrate a leaflet LF and deploy a snare 424 on the ventricular side of the leaflet LF. Such a snare 424 may be comprised of any suitable material. Through the second guide conduit 422, a needle 423 or other device may be used to penetrate the adjacent leaflet LF and deploy an anchor 426 through the snare 424 on the ventricular side of the leaflet LF. Again, the anchor 426 is drawn up through the first guide conduit 422 creating a continuous suture line 233 through the second guide conduit 422, across the line of coaptation C of the leaflet LF and up through the first guide conduit 420. This may be repeated on two or more additional target points 406 in a similar manner and the suture lines 233 may be fixed together by conventional knot tying or any suitable method, including positioning fasteners.

[0082] Fig. 34 illustrates a similar embodiment of an interventional tool 100 having more than one guide conduit present and directed at each leaflet for leaflet fixation. This embodiment is used to place suture through target points in a method similar to that described above in relation to Figs. 31-33. However, this embodiment includes at least two slotted needles 440 or similar devices having slots 442 or openings which continue longitudinally from the needle 440 tip toward the shaft 443 for a desired distance. As shown, the tool 100 comprises a first, second, third and fourth guide conduit 451, 452, 453, 454 respectively. Through the first and fourth guide conduits 451, 454 needles 461 or other devices are introduced to penetrate the adjacent leaflets LF and deploy snares 456 on the ventricular side of the leaflets LF. Through the second and third guide conduit 452, 453 slotted needles 440 or other device are introduced to penetrate the leaflets LF and deploy anchors 458 through the snares 456 on the ventricular side of the leaflets LF. Attached to the anchors 458 is a continuous line of suture 459 which runs between the anchors 458. The suture line 459 passes through the penetrations at the target points 406, continues up through the slotted needles 440, out of the slots 442, into a lumen or compartment within the catheter shaft 443 where it forms a loop. Such a suture line 459 is illustrated in Fig. 34. Thus, a continuous line of suture 459 runs from one anchor 458 to another anchor 458 between adjacent leaflets LF. The anchors 458 are then drawn up through the first and fourth guide conduits 451, 454 by retracting the snares 456. As shown in Fig. 35, this results in a continuous suture line 459 across the line of coaptation C on the atrial surface, between adjacent target points 406 on the ventricular side surface of each leaflet LF and again across the line of coaptation C on the atrial surface where the free ends are fixed together by conventional knot tying or any suitable method, including positioning fasteners. It may be appreciated that the above described method and device may be adapted to fix the leaflets together using target points 406 in a variety of locations.

[0083] In another embodiment of the interventional tool 100, each guide conduit 304 comprises a penetrating device or needle 340 having a suture holding feature 341, in this example notch, disposed near its distal end, as shown in Fig. 36. This type of fixation tool 305 is used in combination with a interventional tool 204 having a specific type of distal element 302. This element 302 is similar to the loop 212 previously shown in Fig. 10A. As stated, these loops 212 are preferably made from nitinol or shape-memory wire, however other materials may be suitable. However, in this case, the loops 212 are combined with a second set of loops comprised of suture 342. The suture loops 342 are removably attached to the inside surface of the loops 212. Such attachment may be provided by a number device features. For example, as shown in Fig. 37, the suture loops 342 may be attached and held in place by heatshrink tubing 344 over the loops 212. The heatshrink tubing 344 has perforations 345 along the inside surface of the loop 212 to assist in release of the suture loop 342 when desired. Alternatively, the suture loop 342 may be held in place with a thin layer of material, such as polyurethane, which is applied by

dipping or spraying. The suture loop 342 may also be attached by a combination of heatshrink tubing 344 and liquid polyurethane droplets in isolated sections. Further, as shown in cross-section in Fig. 38, the loops 212 themselves may be extruded with a cavity 346 to house the suture 342. The suture 342 may be held in place by the cavity 346 or by heatshrink tubing 344 and/or a layer of material such as polyurethane.

[0084] In any case, the interventional catheter 200 has fixation tools 305, comprising a needle 340 having a suture holding feature 341, and distal elements 302, comprising loops 212 combined with suture loops 342, as described above. The guide conduits 304 are located proximal to the distal elements 302 and are capable of extending angularly outward from the shaft 308 to protrude through the loops 212 and suture loops 342. Fig. 39 illustrates an atrial approach to the mitral valve. The interventional catheter 200 is positioned so that the distal element 302 is deployed beyond the valve leaflet LF and one of the loops 212 is pressed against the ventricular surface of the leaflet LF (shading illustrates its planar surface demarked by a leaflet edge 350). It may be appreciated that although the catheter 200 is illustrated to suture one leaflet, the catheter 200 will typically comprise a duplicate arrangement symmetrically positioned on the opposite side of the shaft 308 to additionally suture the other leaflet. Only one leaflet LF is shown for clarity. The needle 340 is advanced toward the leaflet LF either by extension of the guide conduit 304 or the needle 340 itself. In either case, the needle 340 is then advanced to penetrate the leaflet LF and emerge from the other side or the distal side of the leaflet. The penetration hole 352 illustrates the point of entry through the leaflet LF. The needle 340 is further advanced so that the suture holding feature 341 is disposed in the same plane as the suture loop 342. As shown in Fig. 40, the suture loop 342 is then retracted so that it is released from the heatshrink tubing 344 and is disposed within the suture holding feature 341. The needle 340 is then retracted, as shown in Fig. 41, pulling the suture loop 342 through the penetration hole 352 to the atrial side of the valve. To aid in maintaining the suture loop 342 within the suture holding feature 341, a sheath or tubing may be slid over the suture holding feature 341 to hold the suture loop 342 in place. The other leaflet LF of the mitral valve is pierced in the same manner wherein the suture loop is threaded to the atrial side of the valve. The suture loops are then fixed together by conventional knot tying or any suitable method, including positioning suture fasteners.

V. DEVICE EMBODIMENTS

[0085] The following device embodiments depict complete device designs utilizing a variety of the specific features described above. In addition, new features are also introduced which provide additional device capabilities. The embodiments shown are designed for treatment of the mitral valve with an atrial approach. However, it may be appreciated that the design features may be adapted for other valves and other approaches.

[0086] The embodiments of the interventional catheter 500 will be described in conjunction with its method of use for repairing a regurgitive mitral valve. However, the device will be illustrated independently of the valve anatomy to more clearly illustrate the workings of the device. The relationship of the device to the valve anatomy throughout the steps of the method may be easily visualized based on description.

[0087] In the first embodiment, referring to Fig. 42, the interventional catheter 500 comprises an elongate shaft 502 having at least one capture device 504 and guide conduit 506 disposed near its distal end 508. The capture device 504 comprises distal loops 510 which are located near the tip 512 of the catheter. Two distal loops 510 are shown, one on each side of the catheter 500, for the capturing of two valve leaflets. The distal loops 510 are retracted for introduction of the catheter 500 through a previously placed guidecatheter. Proximal loops 514 and guide conduits 506 are also shown. Since both the proximal loops 514 and the guide conduits 506 are located proximal to the distal loops and approach the atrial surface of the leaflets, they may be interconnected at the guide conduit cuff 516 as shown. In addition, such interconnectivity may provide advantages which have been presented earlier in relation to embodiments having similar interconnectivity. It may be appreciated, however, that these features may be independent in other embodiments. Similar to the distal loops 510, the proximal loops 514 and guide conduits 506 are retracted for introduction of the catheter 500 through the previously placed guidecatheter. In addition, portions of the catheter 500 may have an integral spring or flexible section 516 which may assist in passing the device through any curves in the guidecatheter during introduction.

[0088] After introduction, the catheter 500 is advanced so that the tip 512 of the catheter is positioned within the atrium, above the mitral valve. Referring to Fig. 43, the distal loops 510 are then deployed so that they protrude radially outward from the shaft 502. The device is then oriented so that the distal loops 510 are positioned substantially perpendicular to the line of coaptation between the two valve leaflets. This may be accomplished with the use of short-axis echocardiography. The tip 512 may be moved roughly along the line of coaptation to the location of regurgitation. After alignment, the tip 512 and distal loops 510 are advanced through the valve, between the leaflets, so that the loops 510 emerge beyond the valve. Perpendicular alignment is then reconfirmed using echocardiography. At this point, the distal end 508 is retracted so that the distal loops 510 move upward, toward the atrium, and press against the ventricular surface of the leaflets. This grasps the leaflets and holds the leaflets in place throughout the cardiac cycle. During diastole, a double orifice geometry may be visualized using short-axis echocardiography, as previously shown in Fig. 5.

[0089] Referring to Fig. 44, the proximal loops 514 and guide conduits 506 are co-deployed and advanced toward the atrial surface of the leaflets. As previously described, interconnection of the proximal loops 514 with the guide conduits 506 may allow one to deploy the other. For example, deployment and advancement of the guide conduits 506 angularly outward may draw the proximal loops 514 out from the shaft 502 effecting their deployment. Alternatively, the proximal loops 514 may be comprised of a material that is of sufficient rigidity so that deployment of the proximal loops 514 draws the guide conduits 506 downward and outward from the shaft 502 effecting their deployment. The proximal loops 514 may also serve to position the guide conduit cuffs 516 within the distal loop 510 as shown.

[0090] In any case, as shown in Fig. 45 in a side-view, the proximal loops 514 and guide conduits 506 are deployed to near or below the plane of the distal loops 510 so that they are in contact with the atrial surface of the leaflets. Although not illustrated, the valve leaflets would reside between the proximal loops 514 and the distal loops 510. In some cases, such as in severe prolapsing valves, the proximal loops 514 may be deployed prior to grasping the leaflets with the distal loops 510. In these cases, the proximal loops 514 may act to limit the extent of prolapse and to assist in trapping the leaflet between the proximal and distal loops.

[0091] Once the leaflets are securely grasped between the proximal and distal loops, the double orifice geometry is confirmed during diastole using short-axis echocardiography. If the positioning of the leaflets appears as desired, piercing devices or needles 520 are advanced from the guide conduit cuffs 516 to puncture and penetrate the valve leaflets. As shown in Fig. 46, the needles 520 are advanced through the distal loops 510 so that the distal loops 510 may support the leaflet during penetration. As shown in Fig. 47, the distal loops 510 are then retracted, pulling the needles 520 radially toward the shaft 502. Since each needle 520 is pierced through a leaflet, the radially inward movement of the needles 520 draws the leaflets together at the points of penetration. This simulates the methods of performing a standard surgical bow-tie repair. At this point, the proximal loops 514 may be removed from the valve surface and the mitral regurgitation may be evaluated to determine if the two pierced points are suitable for fixing the leaflets together. Color Doppler echo will show if the regurgitation of the valve has been reduced. If the resulting mitral flow pattern is satisfactory, the leaflets may be fixed together in this orientation. If the pattern is unsatisfactory, the above steps may be repeated until a satisfactory flow pattern is obtained.

[0092] Referring to Fig. 48, fixation may be achieved with the use of fixation pledgets or anchors 522 which are deployable from the needles 520. Push rods (not shown) may be advanced within the needles 520 to deploy the anchors 522 from the needles 520. Attached to each anchor 522 is a line of suture 524 which is captured within each needle 520, as shown. The needles 520 are then retracted back through the leaflet penetrations, leaving the anchors 522 on the ventricular side of the valve leaflets while threading the suture 524 through the penetrations. Simultaneously or subsequently, the tip 512 and/or distal end 508 is advanced distally to position the distal loops 510 slightly below the anchors 522. In this way, the distal loops 510 may be retracted inwardly without trapping the lines of suture 524 in the loops 510. The distal loops 510 are thus retracted to a low profile position and the proximal loops 514 and guide conduits 506 are also retracted to their original low profile position. As shown in Fig. 49, the distal end 508 is then withdrawn from the valve, leaving the anchors 522 disposed on the ventricular side of the leaflets LF and the lines of suture 524 threaded through the penetrations 526, continuing up through the guide conduits 506.

[0093] Referring to Fig. 50, a holding tube 530 containing the free ends of both sutures 524 is separated from the shaft 502 and advanced toward the atrial surface of the leaflets LF. This holds tension on the anchors 522 to maintain the position of the anchors 522 against the ventricular surface of the leaflets LF and to maintain the coaptation of the leaflets LF along the line of coaptation C. A suture fixation device deployment catheter (not shown) is then inserted through, over or replacing the holding tube 530 to tie the sutures together with a knot or to deploy a fixation device 532 to hold the sutures 524 in place, as shown in Fig. 51. A suture cutter (not shown) is integral with the deployment catheter and is used to cut the suture lines 524 proximal to the fixation device 532. The deployment catheter is then removed leaving the fixed leaflets in a repaired condition.

[0094] In the second embodiment, referring to Fig. 52; the interventional catheter 1050 comprises an elongate shaft 1052 and a detachable capture device 1054. The capture device 1054 comprises, among others, proximal elements 1056 and distal elements 1058. Such a capture device 1054 is similar to that presented in Figs. 17C-17D. Again, the proximal elements 1056 may be separately deployable from the distal elements 1058. As shown, the distal elements 1058 are deployed so that they are extended radially outward from the shaft 1052. The proximal elements 1056 may be held against the shaft by sutures 1060 which are drawn up within the shaft 1052. In this orientation, the catheter 1050 may be manipulated between the leaflets so that the distal elements 1058 are positioned against the ventricular surface of the valve leaflets LF.

[0095] preferring to Fig. 53, the proximal elements 1056 may then be released by slacking the sutures 1060. This allows the preformed elements 1056 to extend radially outward and downward, as illustrated. Depending on the curvature of the proximal elements 1056, they may remain proximal to, move to within the same plane of, or move beyond the plane of the distal elements 1058. Here, the proximal elements 1056 are shown slightly beyond the plane of the distal elements 1058. Thus, the leaflets

LF would be grasped and held in place between the elements 1056, 1058. In addition, the proximal elements 1056 include prongs 1057 to provide friction and assist in holding the leaflets LF.

[0096] The leaflets LF may then be repositioned by manipulating the elements 1056, 1058 while the leaflets LF are grasped therebetween. Referring to Fig. 54, the elements 1056, 1058 may be drawn inward by rotation of a torque shaft 1064, such rotation indicated by an arrow. Rotation of the torque shaft 1064 drives a screw 1065 in the capture device 1054 which translates a nut 1066 downward within the capture device 1054. The translating nut 1066 draws the elements 1056, 1058 inward to assist in coaptation of the leaflets LF.

[0097] Fig. 55 more closely illustrates the workings of the capture device 1054. The nut 1066 is positioned on the screw 1065 between a top structure 1068 and a bottom structure 1069. The proximal and distal elements 1056, 1058 are fixedly attached in holes 1076 in the nut 1066 and pass through holes 1074 in the top structure 1068. The screw 1065 has a screw top 1070 which extends into a torque driver 1072. The inner diameter of the driver 1072 is square to receive the square screw top 1070. The torque shaft 1064 is attached to the driver 1072 so that rotation of the shaft 1064 rotates the screw 1065. This in turn translates the nut 1066 downward, drawing the elements 1056,1058 inward through the holes 1074. Since the nut 1066 has flat sides, the nut 1066 will not rotate within an outer casing 1076 (shown in Fig. 54) which fits against the nut 1066.

[0098] During repositioning of the leaflets LF, imaging is used to verify that coaptation and mitral regurgitation reduction is suitable. Once the leaflets LF are suitably positioned, the capture device 1054 is ready for detachment. Figs. 56-57 illustrate an embodiment of the detachment mechanism which is similar in design and function to that previously described in relation to Figs. 21D-21E.. Fig. 56 illustrates a tubular upper shaft 1080 and a detachable lower shaft 1082 which are interlocked at a joining line 1084. Again, the joining line 1084 may have any shape or curvature which will allow or facilitate interlocking and later detachment. The torque driver 1072 bridges the joining line 1084 as shown. Such placement of the driver 1072 prevents twisting and translation of the upper and lower shafts 1080, 1082. Fig. 57 illustrates detachment of the lower shaft 1082 from the upper shaft 1080. This is achieved by retracting the driver 1072 to a position above the joining line 1084 which in turn allows the shafts 1080, 1082 to separate. Consequently, the capture device 1054 is detached from the shaft 1052 of the interventional catheter 1050, as shown in Fig. 58, and left behind as an implant to hold the leaflets LF in the desired coapted position.

[0099] Kits 1000 comprise any number of items related to the devices described above. As shown in Fig. 59, such kits 1000 typically include at least one interventional catheter 1002 having a capture device 1004. Optionally, the capture device 1004 may be detachable and, in such a case, a number of capture devices 1004 (or fixation devices) may be included in the kit 1000. The kits 1000 also include instructions for use IFU setting forth any of the methods. Optionally, the kits 900 may further include any of the other system components described above, such as one or more guidecatheters 1006, guide wires 1008, dilators 1009, penetration devices 1010, sutures 1012, anchors 1014 optionally having sutures 1012 attached, snares 1016 optionally having sutures 1012 attached, and fasteners 1018 to fix sutures together, to name a few. Some or all kit components will usually be packaged together in a pouch 1020 or other conventional medical device packaging. Usually, those kit components which will be used in performing the procedure on the patient will be sterilized and maintained within the kit Optionally, separate pouches, bags, trays or other packaging may be provided within a larger package, where the smaller packs may be opened separately to separately maintain the components in a sterile fashion.

Claims

1. A device adapted for repairing a cardiac valve in a patient, the cardiac valve having leaflets, said device comprising:

   an interventional catheter (200) comprising a shaft (210) having a proximal end, a distal end and a longitudinal axis therebetween, configured to pass to a position within the heart adjacent to the cardiac valve; and
   a capture device (204) detachably connected to the catheter (200) comprising at least two extendable distal elements (230, 232) and at least two extendable proximal elements (240, 242), each of the proximal and distal elements being disposed near the distal portion of the shaft (210) and being moveable between a retracted position adjacent the shaft (210) and an extended position extending away from the shaft (210) for capturing the valve leaflets; **characterized in that** the at least two distal elements (230, 232) and the at least two proximal elements (240, 242) are independently extendable, retractable and repositionable so that they are adapted to be extended or retracted by various amounts for protrusion of various distances from the shaft.

2. A device as in claim 1, wherein the length of protrusion of the distal elements (230, 232) is adjustable.

3. A device as in claim 1, wherein each of the at least two distal elements (230, 232) have a radius of curvature that is adjustable.

4. A device according to claim 1, wherein each of the distal elements (230, 232) and each of the proximal

elements (240, 242) is independently extendable, retractable and repositionable.

5. A device as in claim 1, wherein each of the at least two distal elements (230, 232) is configured to capture one of the leaflets and reposition the captured leaflets independently of each other.

6. A device as in claim 1, wherein the at least two distal elements (230, 232) are disposed on opposite sides of the shaft.

7. A device as in claim 1, wherein the at least two proximal or the at least two distal elements are made from a material comprising stainless steel, metals, nitinol, Cobalt-Chromium-Nickel alloy, shape-memory alloy, polymer, silk, polyester, nylon or a combination of these.

8. A device as in claim 1, wherein the at least two proximal elements (240, 242,) are interlockable with the at least two distal elements (230, 232).

9. A device as in claim 1, wherein the interventional catheter (200) further comprises at least one fixation tool for fixing the valve leaflets together.

10. A device as in claim 9, wherein the fixation tool is adapted for fastening, suturing, clipping, stapling, riveting, gluing, or fusing the leaflets together.

11. A capture device (204) for repairing a cardiac valve having valve leaflets, the capture device comprising:

a shaft (313) having a proximal end and a distal end;
a coupling mechanism disposed near the proximal end of the shaft (313) for coupling with an interventional catheter (200);
and at least two extendable distal elements (230, 232) and at least two extendable proximal elements (240, 242), the proximal and distal elements being disposed near the distal portion of the shaft and being moveable between a retracted position adjacent the shaft (313) and an extended position extending away from the shaft (313) for capturing the valve leaflets; **characterized in that** the at least two distal elements (230, 232) and the at least two proximal elements (240, 242) are independently extendable, retractable and repositionable so that they are adapted to be extended or retracted by various amounts for protrusion of various distances from the shaft.

12. A capture device as in claim 11, wherein the length of protrusion of the distal elements (230, 232) and/or proximal elements (240, 242) is adjustable.

13. A capture device as in claim 11, wherein each of the at least two distal elements (230, 232) has a radius of curvature that is adjustable.

14. A capture device as in claim 11, wherein the at least two distal elements (230, 232) are disposed on opposite sides of the shaft.

15. A capture device as in claim 11, wherein the at least two proximal elements (240, 242) are disposed on opposite sides of the shaft.

16. A capture device as in claim 11, wherein the at least two proximal or distal elements are made from a material comprising stainless steel, metals, nitinol, Cobalt-Chromium-Nickel alloy, shape-memory alloy, polymer, silk, polyester, nylon or a combination of these.

17. A capture device as in claim 11, wherein the at least two proximal elements (240, 242) are interlockable with at the at least two distal elements (230, 232).

18. A capture device as in claim 11, wherein the at least two proximal or distal elements have at least one friction accessory (227).

19. A capture device as in claim 18, wherein the at least one friction accessory comprises prongs, windings, bands or barbs.

Patentansprüche

1. Vorrichtung, die zur Reparatur einer Herzklappe bei einem Patienten geeignet ist, wobei die Herzklappe Segel aufweist, wobei die Vorrichtung folgendes umfasst:

einen Interventionskatheter (200), der eine Welle (210) mit einem proximalen Ende, einem distalen Ende und einer dazwischen angeordneten Längsachse umfasst, der so gestaltet ist, dass er in eine Position im Herz in der Nähe der Herzklappe gelangt; und
eine Greifvorrichtung (204), die lösbar mit dem Katheter (200) verbunden ist und mindestens zwei erweiterbare distale Elemente (230, 232) und mindestens zwei erweiterbare proximale Elemente (240, 242) aufweist, wobei jedes der proximalen und distalen Elemente in der Nähe des distalen Bereiches der Welle angeordnet ist und zwischen einer eingezogenen Position in der Nähe der Welle (210) und einer erweiterten Position, die sich von der Welle (210) weg erstreckt, bewegbar ist, um die Klappensegel zu ergreifen; **dadurch gekennzeichnet, dass** die mindestens zwei distalen Elemente (230, 232)

und die mindestens zwei proximalen Elemente (240, 242) unabhängig voneinander erweiterbar, einziehbar und repositionierbar sind, so dass sie dazu geeignet sind, um verschiedene Beträge erweitert oder eingezogen zu werden, so dass sich Vorsprünge mit verschiedenen Abständen von der Welle ergeben.

2. Vorrichtung nach Anspruch 1, wobei die Länge des Vorsprungs der distalen Elemente (230, 232) einstellbar ist.

3. Vorrichtung nach Anspruch 1, wobei jedes der mindestens zwei distalen Elemente (230, 232) einen Krümmungsradius aufweist, der einstellbar ist.

4. Vorrichtung nach Anspruch 1, wobei jedes der distalen Elemente (230, 232) und jedes der proximalen Elemente (240, 242) unabhängig voneinander erweiterbar, einziehbar und repositionierbar ist.

5. Vorrichtung nach Anspruch 1, wobei jedes der mindestens zwei distalen Elemente (230, 232) so gestaltet ist, dass es eines der Segel ergreift und die ergriffenen Segel unabhängig voneinander repositioniert.

6. Vorrichtung nach Anspruch 1, wobei die mindestens zwei distalen Elemente (230, 232) an gegenüberliegenden Seiten der Welle angeordnet sind.

7. Vorrichtung nach Anspruch 1, wobei die mindestens zwei proximalen oder die mindestens zwei distalen Elemente aus einem Material gefertigt sind, das rostfreien Stahl, Metalle, Nitinol, eine Kobalt-Chrom-Nikkel-Legierung, eine Formgedächtnis-Legierung, Polymere, Seide, Polyester, Nylon oder eine Kombination davon umfasst.

8. Vorrichtung nach Anspruch 1, wobei die mindestens zwei proximalen Elemente (240, 242) mit den mindestens zwei distalen Elementen (230, 232) in Eingriff gelangen können.

9. Vorrichtung nach Anspruch 1, wobei der Interventionskatheter (200) ferner mindestens ein Befestigungswerkzeug umfasst, um die Ventilsegel aneinander zu befestigen.

10. Vorrichtung nach Anspruch 9, wobei das Befestigungswerkzeug dazu geeignet ist, die Segel durch Festschnallen, Nähen, Klammern, Stapeln, Nieten, Kleben oder Fusionieren aneinander zu befestigen.

11. Greifvorrichtung (204) zum Reparieren einer Herzklappe mit Klappensegeln, wobei die Greifvorrichtung folgendes umfasst:

eine Welle (313) mit einem proximalen Ende und einem distalen Ende;
einen in der Nähe des proximalen Endes der Welle (313) angeordneten Kupplungsmechanismus zur Kupplung an einen Interventionskatheter (200);
und mindestens zwei erweiterbare distale Elemente (230, 232) und mindestens zwei erweiterbare proximale Elemente (240, 242), wobei die proximalen und distalen Elemente in der Nähe des distalen Bereiches der Welle angeordnet sind und zwischen einer eingezogenen Position neben der Welle (213) und einer erweiterten Position, die sich weg von der Welle (313) erstreckt, bewegbar sind, um die Ventilsegel zu ergreifen, **dadurch gekennzeichnet, dass** die mindestens zwei distalen Elemente (230, 232) und die mindestens zwei proximalen Elemente (240, 242) unabhängig voneinander erweiterbar, einziehbar und repositionierbar sind, so dass sie dazu geeignet sind, um verschiedene Beträge erweitert oder eingezogen zu werden, so dass sich Vorsprünge mit verschiedenen Abständen von der Welle ergeben.

12. Greifvorrichtung nach Anspruch 11, wobei die Länge des Vorsprungs der distalen Elemente (230, 232) und/oder der proximalen Elemente (240, 242) einstellbar ist.

13. Greifvorrichtung nach Anspruch 11, wobei jedes der mindestens zwei distalen Elemente (230, 232) einen Krümmungsradius aufweist, der einstellbar ist.

14. Greifvorrichtung nach Anspruch 11, wobei die mindestens zwei distalen Elemente (230, 232) an gegenüberliegenden Seiten der Welle angeordnet sind.

15. Greifvorrichtung nach Anspruch 11, wobei die mindestens zwei proximalen Elemente (240, 242) an gegenüberliegenden Seiten der Welle angeordnet sind.

16. Greifvorrichtung nach Anspruch 11, wobei die mindestens zwei proximalen oder distalen Elemente aus einem Material gefertigt sind, das rostfreien Stahl, Metalle, Nitinol, eine Kobalt-Chrom-Nickel-Legierung, eine Formgedächtnis-Legierung, Polymere, Seide, Polyester, Nylon oder eine Kombination davon umfasst.

17. Greifvorrichtung nach Anspruch 11, wobei die mindestens zwei proximalen Elemente (240, 242) mit den mindestens zwei distalen Elementen (230, 232) in Eingriff gelangen können.

18. Greifvorrichtung nach Anspruch 11, wobei die min-

destens zwei proximalen oder distalen Elemente mindestens eine Friktionszubehörvorrichtung (227) aufweisen.

19. Greifvorrichtung nach Anspruch 18, wobei die mindestens eine Friktionszubehörvorrichtung Zinken, Biegungen, Bänder oder Widerhaken umfasst.

Revendications

1. Dispositif adapté pour réparer une valvule cardiaque chez un patient, la valvule cardiaque ayant des feuillets valvulaires, ledit dispositif comprenant :

un cathéter interventionnel (200) comprenant une gaine (210) ayant une extrémité proximale, une extrémité distale et un axe longitudinal entre les deux, configuré pour passer à une position dans le coeur adjacente à la valvule cardiaque ; et
un dispositif de capture (204) relié de manière détachable au cathéter (200) comprenant au moins deux éléments distaux extensibles (230, 232) et au moins deux éléments proximaux extensibles (240, 242), chacun des éléments proximaux et distaux étant disposés à proximité de la partie distale de la gaine (210) et étant déplaçable entre une position rétractée adjacente à la gaine (210) et une position étendue s'étendant en s'éloignant de la gaine (210) pour capturer les feuillets valvulaires ; **caractérisé en ce que** les au moins deux éléments distaux (230, 232) et les au moins deux éléments proximaux (240, 242) sont indépendamment extensibles, rétractables et repositionnables de sorte qu'ils sont adaptés pour être étendus ou rétractés à différents degrés en saillie à différentes distances de la gaine.

2. Dispositif selon la revendication 1, dans lequel la longueur de saillie des éléments distaux (230, 232) est ajustable.

3. Dispositif selon la revendication 1, dans lequel chacun des au moins deux éléments distaux (230, 232) présente un rayon de courbure qui est ajustable.

4. Dispositif selon la revendication 1, dans lequel chacun des éléments distaux (230, 232) et chacun des éléments proximaux (240, 242) est indépendamment extensible, rétractable et repositionnable.

5. Dispositif selon la revendication 1, dans lequel chacun des au moins deux éléments distaux (230, 232) est configuré pour capturer l'un des feuillets valvulaires et repositionner les feuillets valvulaires capturés indépendamment l'un de l'autre.

6. Dispositif selon la revendication 1, dans lequel les au moins deux éléments distaux (230, 232) sont disposés sur des côtés opposés de la gaine.

7. Dispositif selon la revendication 1, dans lequel les au moins deux éléments proximaux ou les au moins deux éléments distaux sont faits d'un matériau comprenant de l'acier inoxydable, des métaux, du nitinol, un alliage de cobalt chrome nickel, un alliage à mémoire de forme, un polymère, de la soie, du polyester, du nylon ou une combinaison de ceux-ci.

8. Dispositif selon la revendication 1, dans lequel les au moins deux éléments proximaux (240, 242) sont verrouillables mutuellement avec les au moins deux éléments distaux (230, 232).

9. Dispositif selon la revendication 1, dans lequel le cathéter interventionnel (200) comprend en outre au moins un outil de fixation pour fixer les feuillets valvulaires ensemble.

10. Dispositif selon la revendication 9, dans lequel l'outil de fixation est adapté pour attacher, suturer, poinçonner, agrafer, river, coller, ou fusionner les feuillets valvulaires ensemble.

11. Dispositif de capture (204) pour réparer une valvule cardiaque ayant des feuillets valvulaires, le dispositif de capture comprenant :

une gaine (313) ayant une extrémité proximale et une extrémité distale ;
un mécanisme de couplage disposé à proximité de l'extrémité proximale de la gaine (313) pour un couplage avec un cathéter interventionnel (200) ;
et au moins deux éléments distaux extensibles (230, 232) et au moins deux éléments proximaux extensibles (240, 242), les éléments proximaux et distaux étant disposés à proximité de la partie distale de la gaine et étant déplaçable entre une position rétractée adjacente à la gaine (313) et une position étendue s'étendant en s'éloignant de la gaine (313) pour capturer les feuillets valvulaires ; **caractérisé en ce que** les au moins deux éléments distaux (230, 232) et les au moins deux éléments proximaux (240, 242) sont indépendamment extensibles, rétractables et repositionnables de sorte qu'ils sont adaptés pour être étendus ou rétractés à différents degrés en saillie à différentes distances de la gaine.

12. Dispositif de capture selon la revendication 11, dans lequel la longueur de saillie des éléments distaux (230, 232) et/ou des éléments proximaux (240, 242) est ajustable.

13. Dispositif de capture selon la revendication 11, dans lequel chacun des au moins deux éléments distaux (230, 232) présente une rayon de courbure qui est ajustable.

14. Dispositif de capture selon la revendication 11, dans lequel les au moins deux éléments distaux (230, 232) sont disposés sur des côtés opposés de la gaine.

15. Dispositif de capture selon la revendication 11, dans lequel les au moins deux éléments proximaux (240, 242) sont disposés sur des côtés opposés de la gaine.

16. Dispositif de capture selon la revendication 11, dans lequel les au moins deux éléments proximaux ou éléments distaux sont faits d'un matériau comprenant de l'acier inoxydable, des métaux, du nitinol, un alliage de cobalt chrome nickel, un alliage à mémoire de forme, un polymère, de la soie, du polyester, du nylon ou une combinaison de ceux-ci.

17. Dispositif de capture selon la revendication 11, dans lequel les au moins deux éléments proximaux (240, 242) sont verrouillables mutuellement avec les au moins deux éléments distaux (230, 232).

18. Dispositif de capture selon la revendication 11, dans lequel les au moins deux éléments proximaux ou distaux possèdent au moins un accessoire de friction (227).

19. Dispositif de capture selon la revendication 18, dans lequel l'au moins un accessoire de friction comprend des pattes, des enroulements, des bandelettes ou des ardillons.

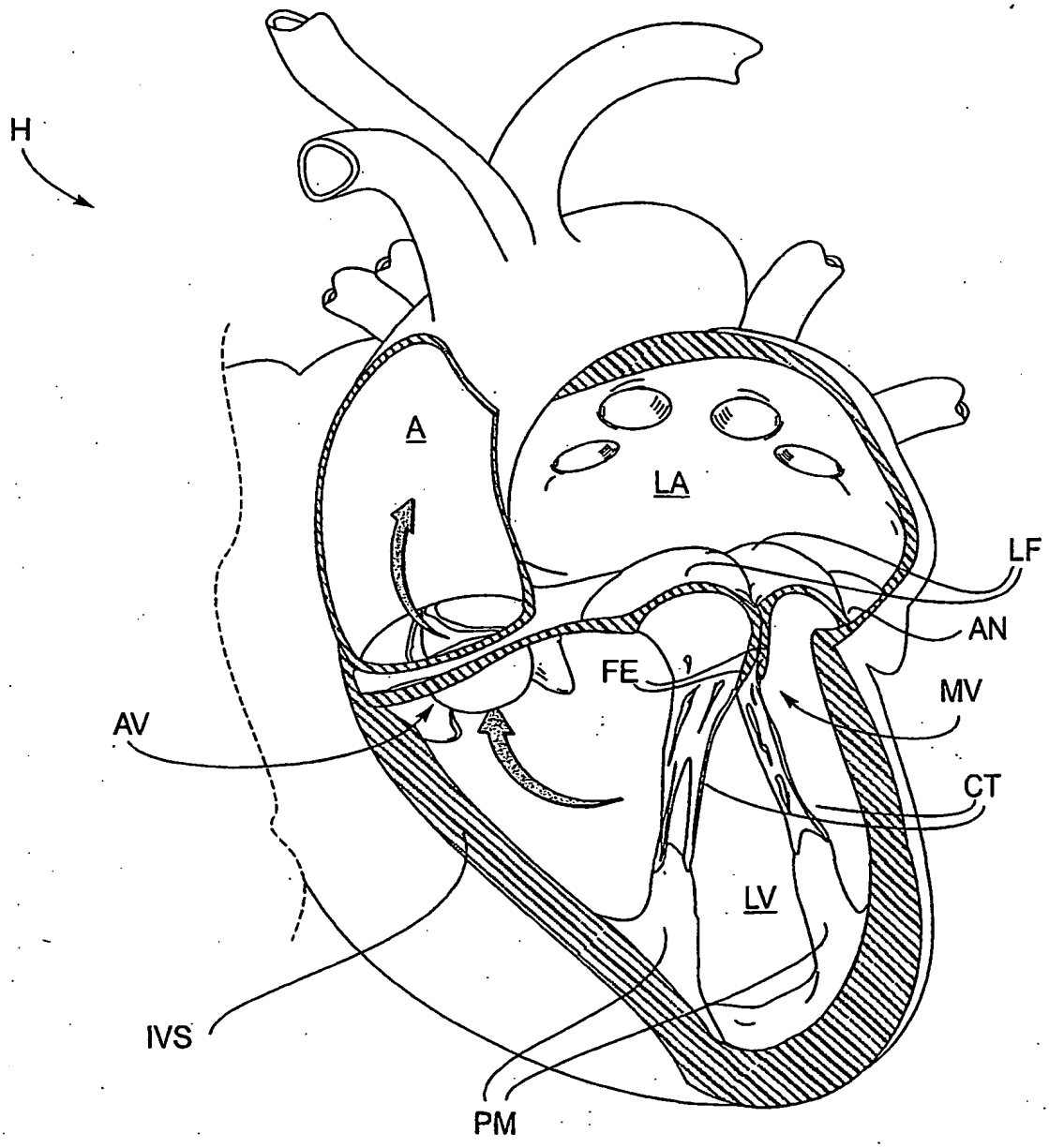


Fig. 1

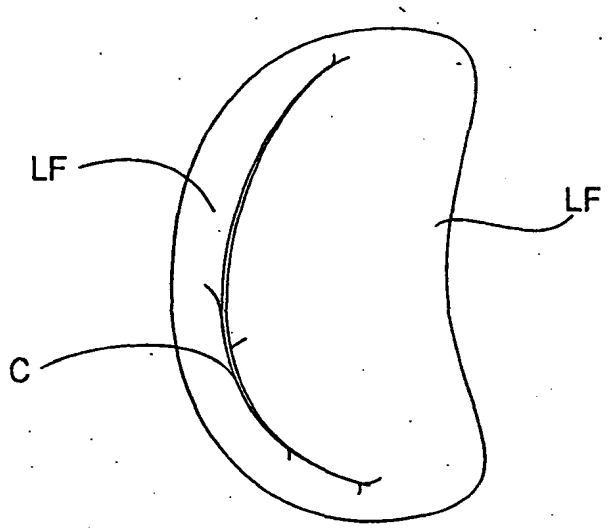


Fig. 2A

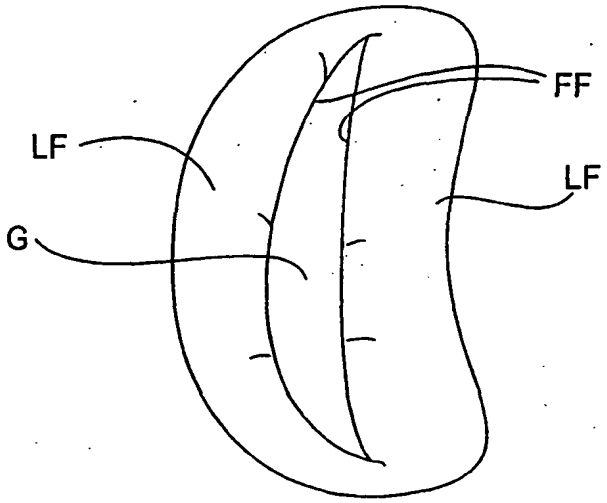


Fig. 2B

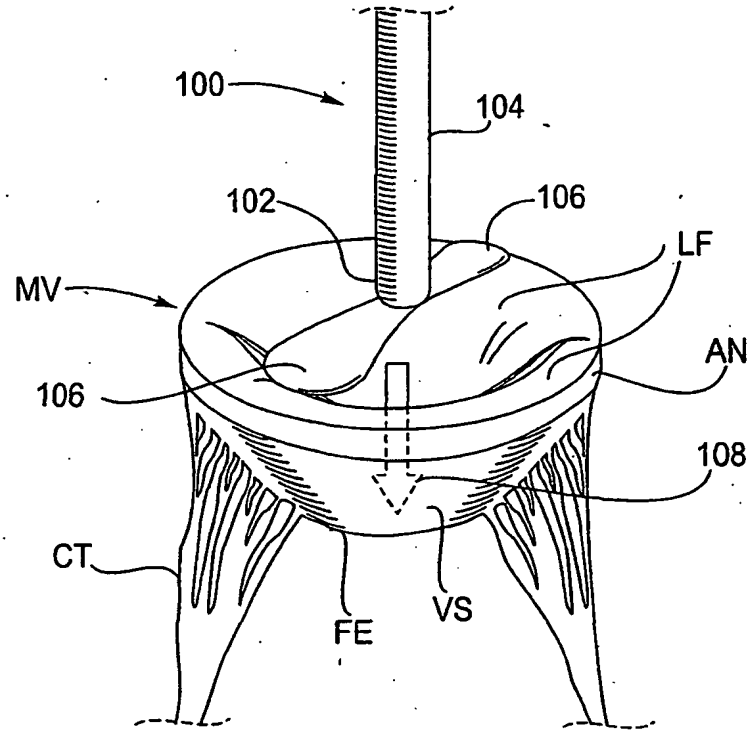


Fig. 3

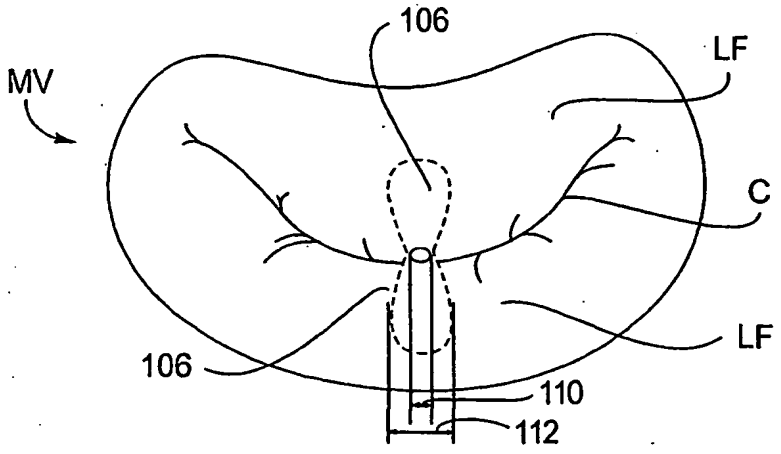


Fig. 4

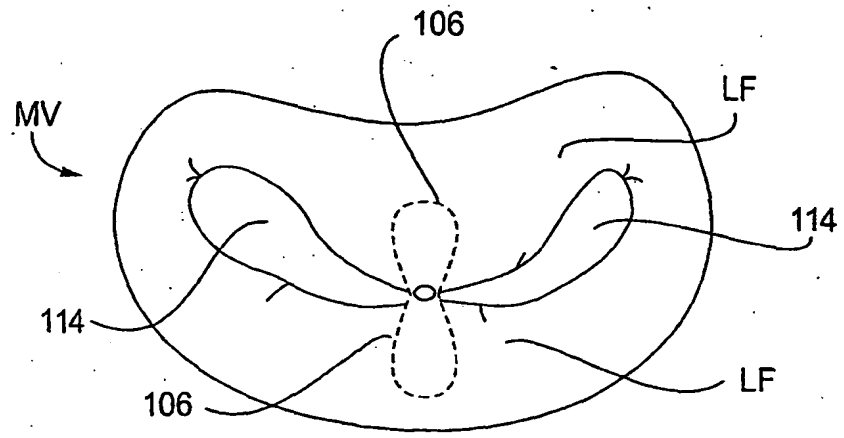


Fig. 5

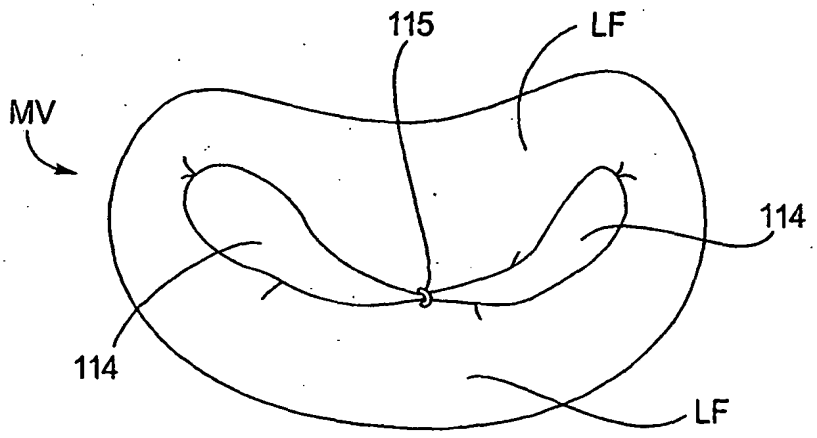


Fig. 5A

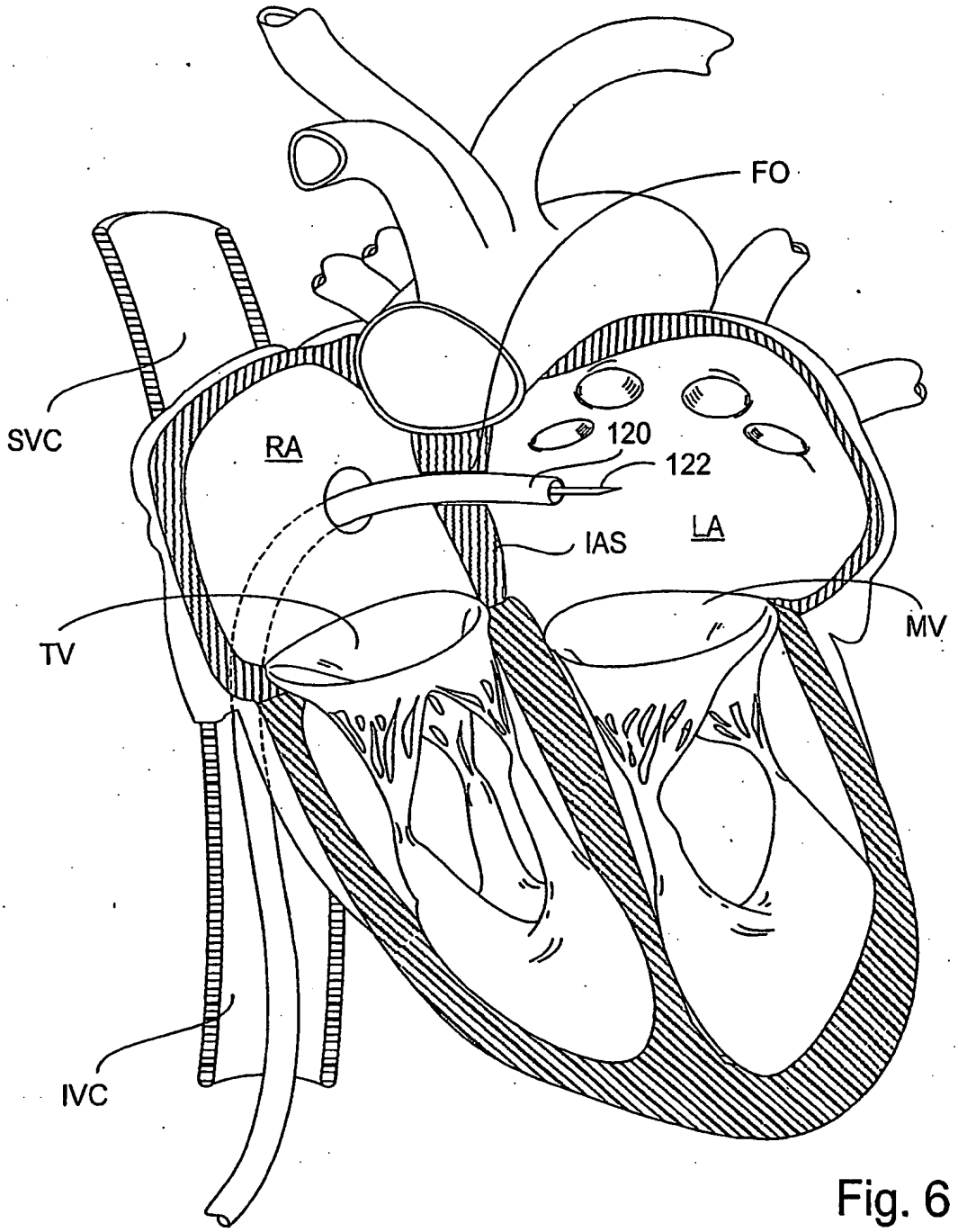


Fig. 6

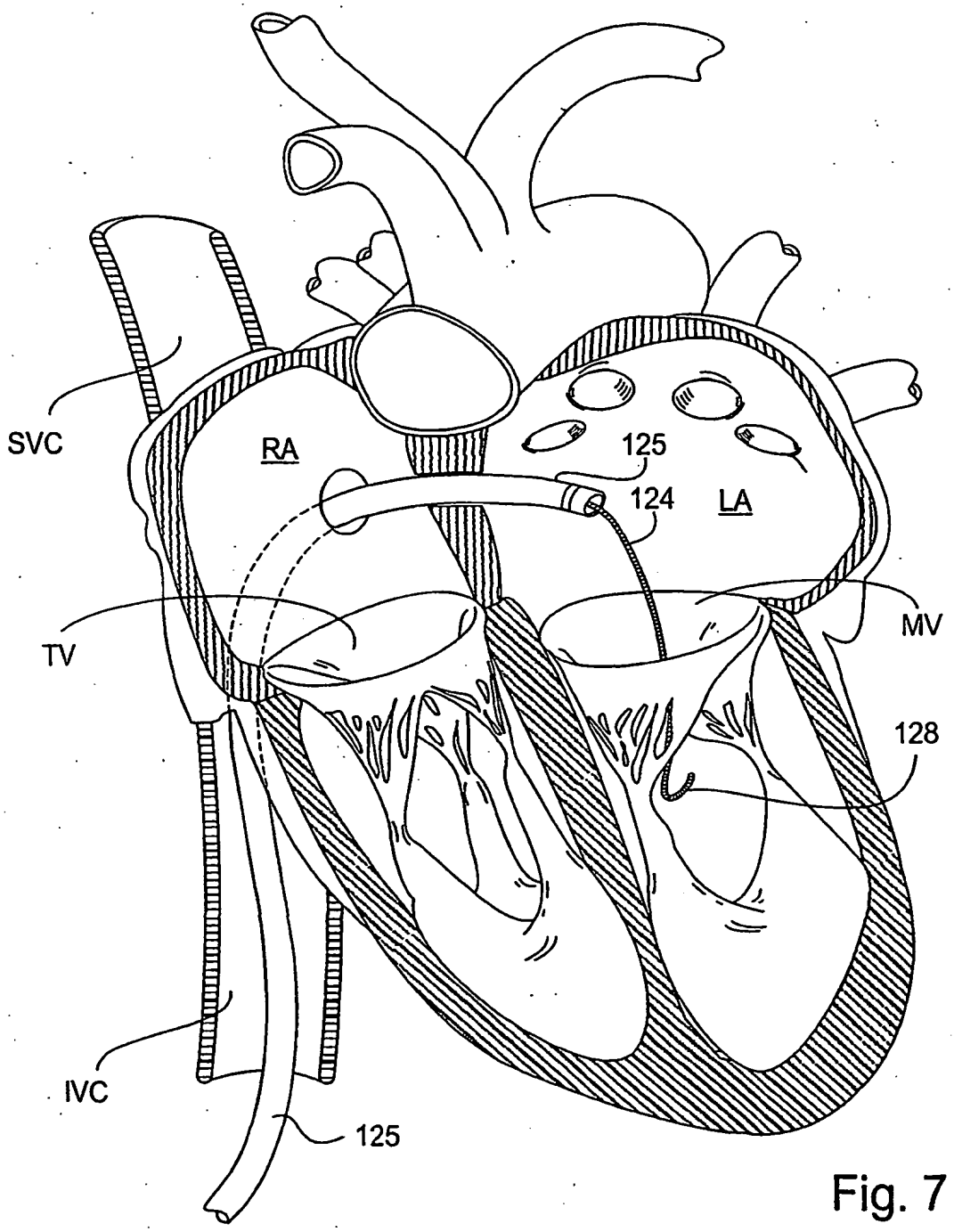


Fig. 7

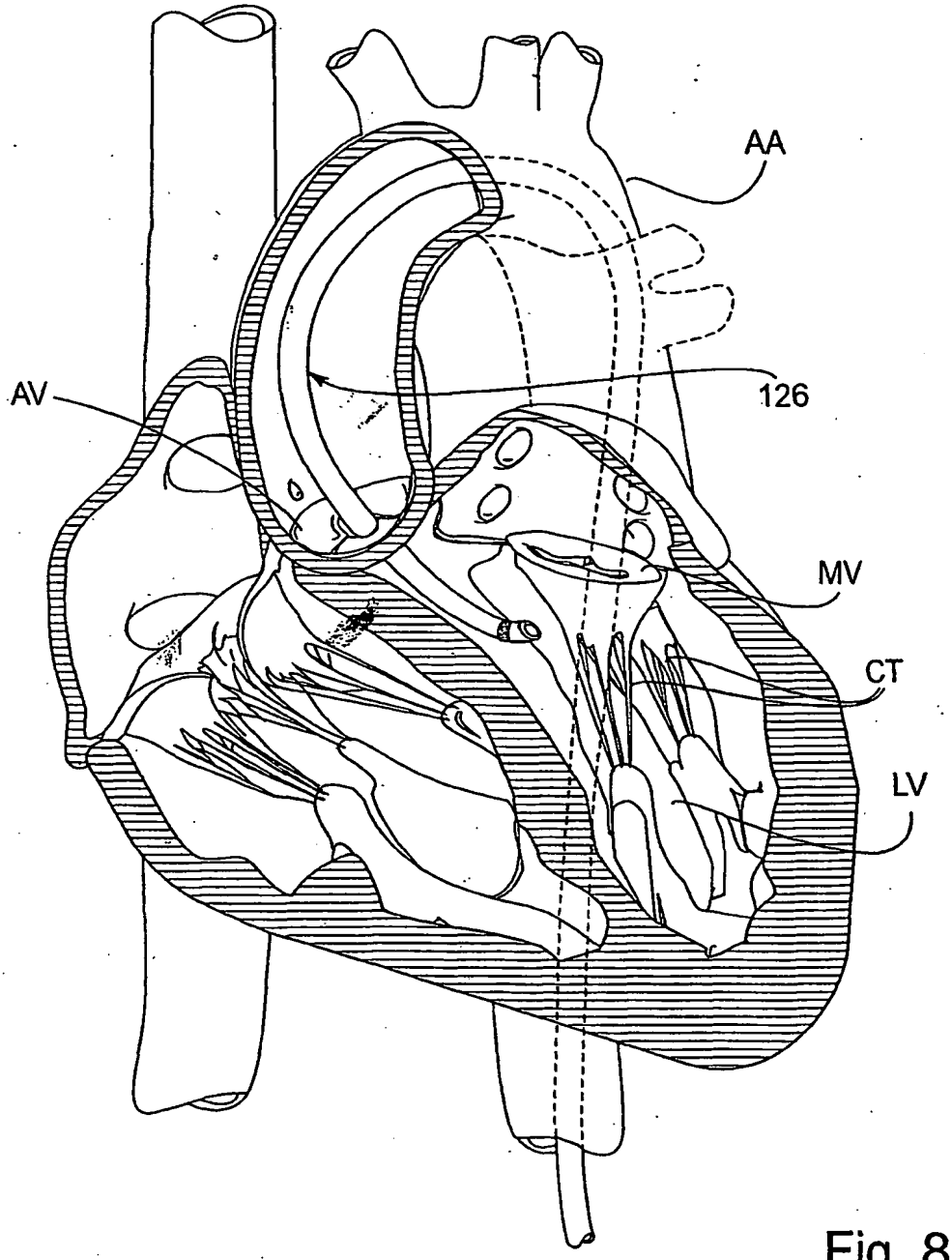


Fig. 8

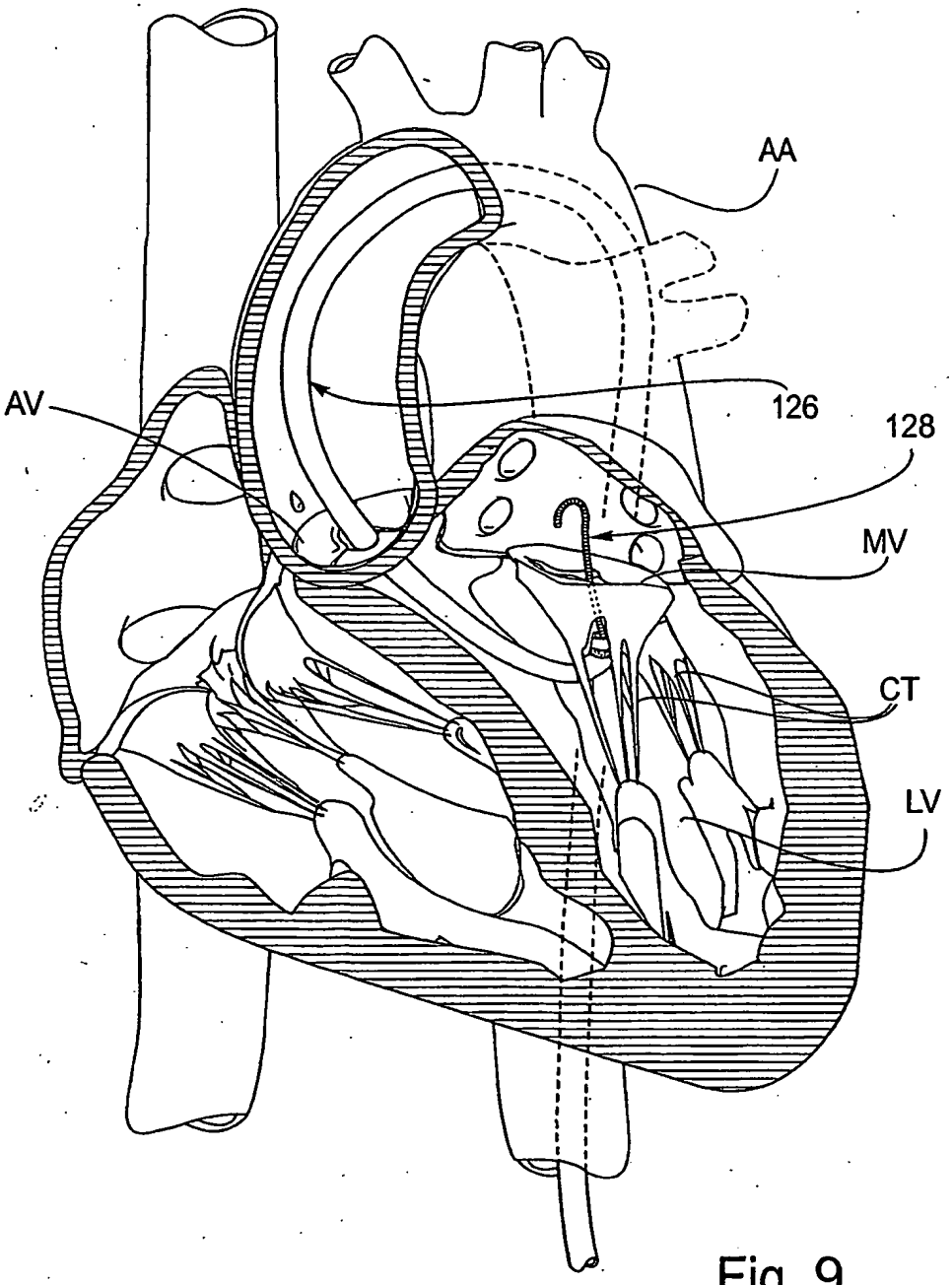


Fig. 9

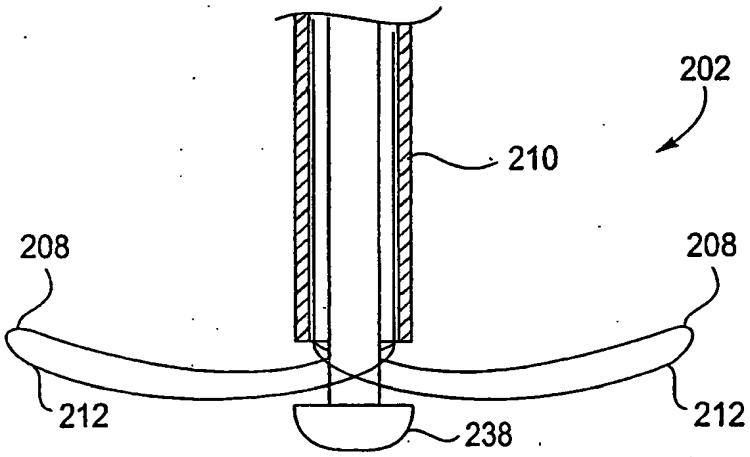


Fig. 10A

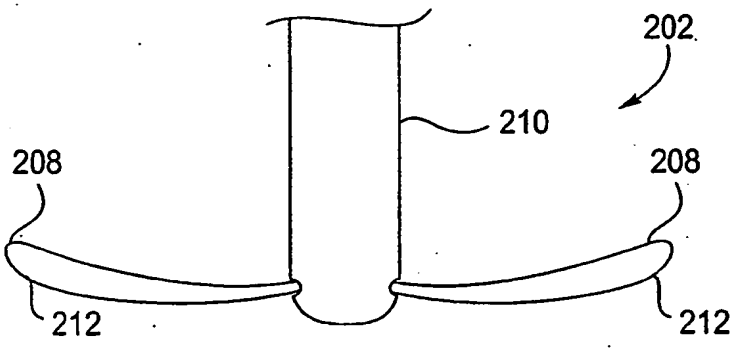


Fig. 10B

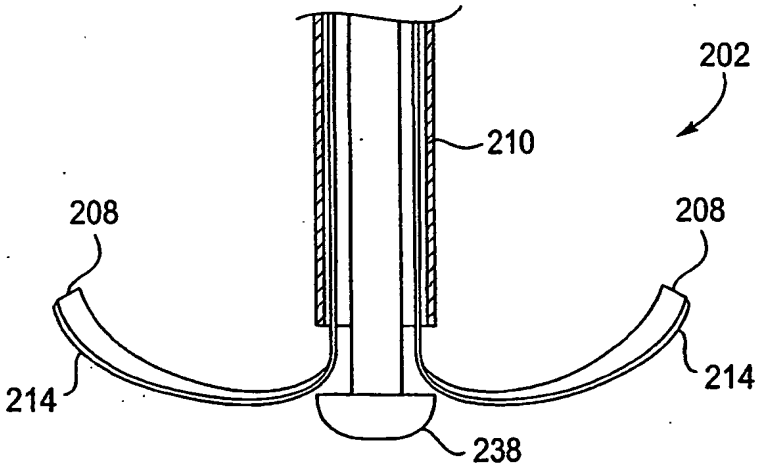


Fig. 10C

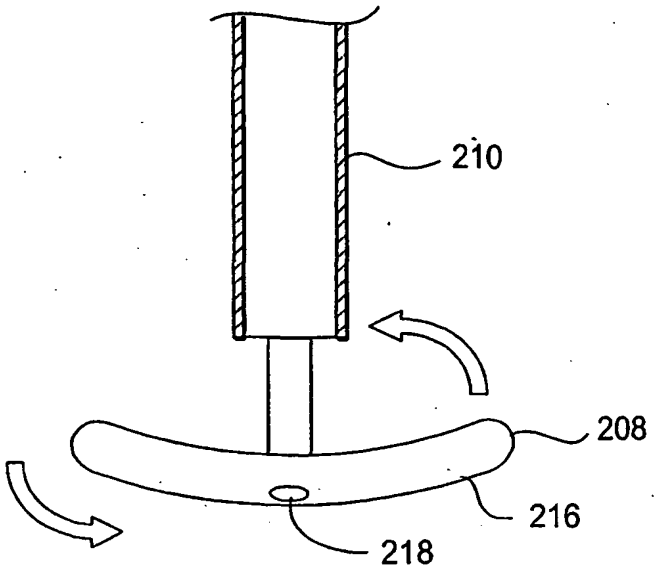


Fig. 11A

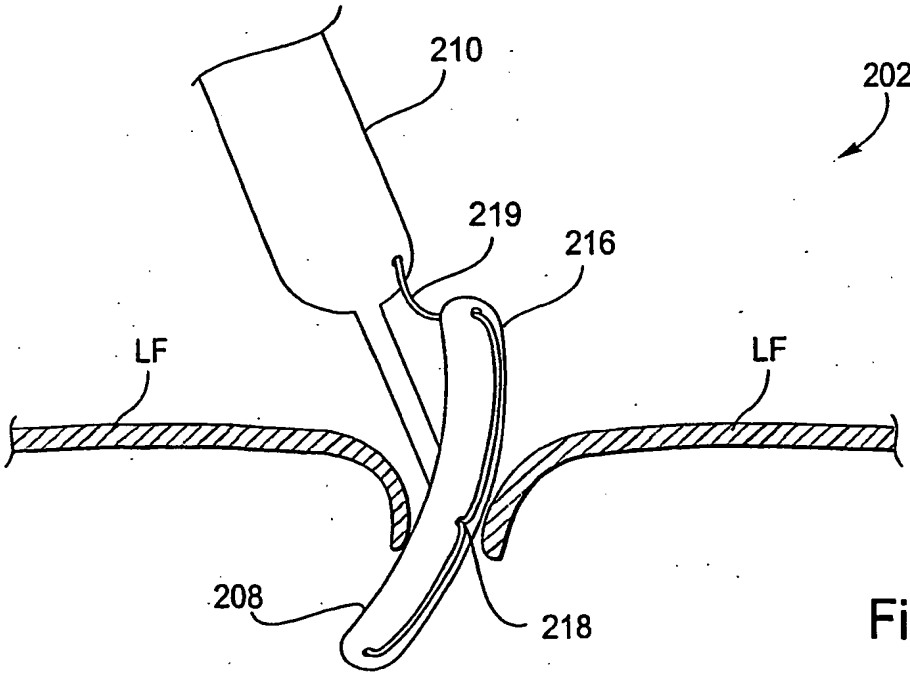


Fig. 11B

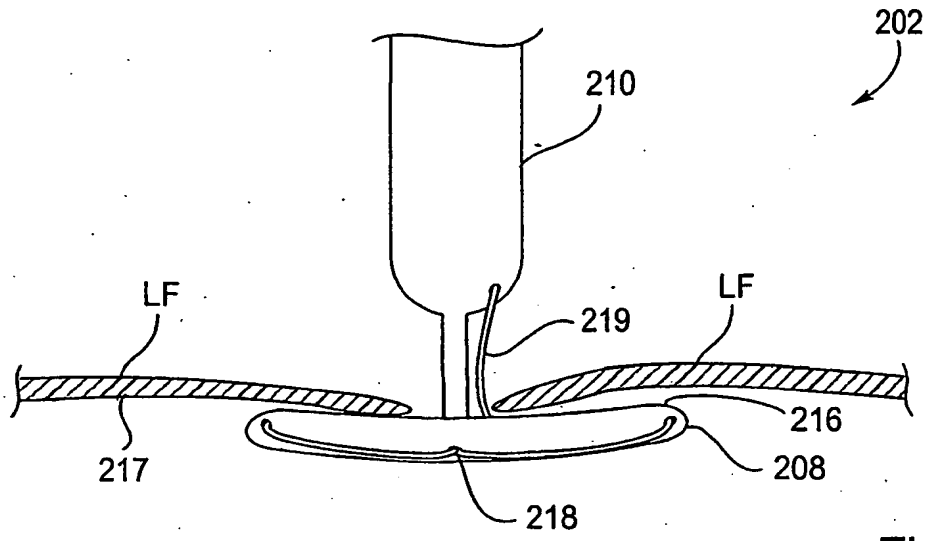


Fig. 11C

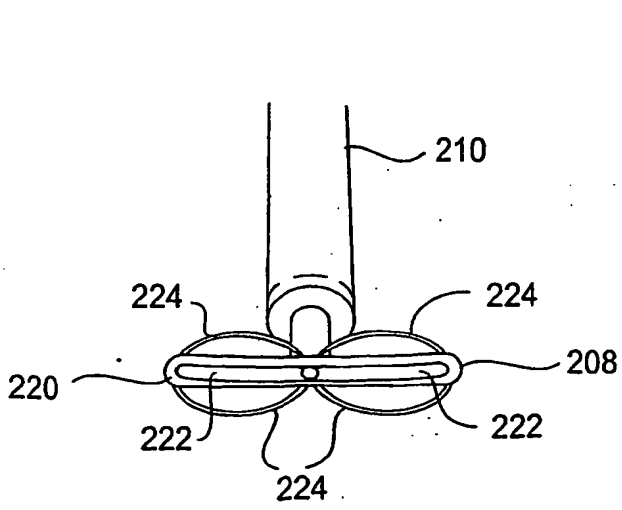


Fig. 12

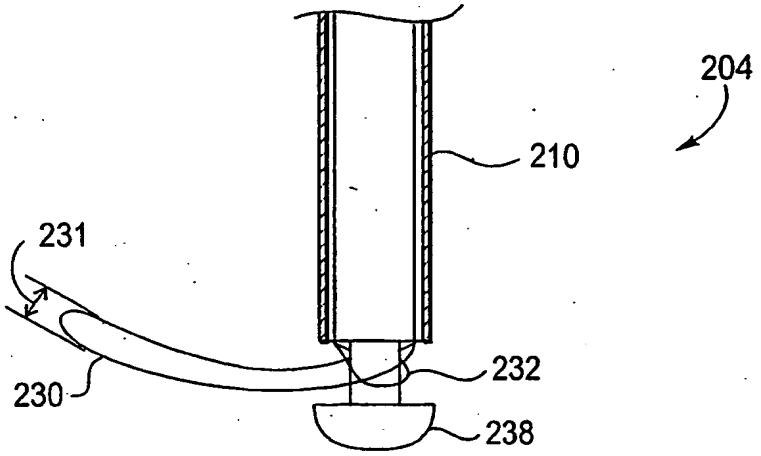


Fig. 13

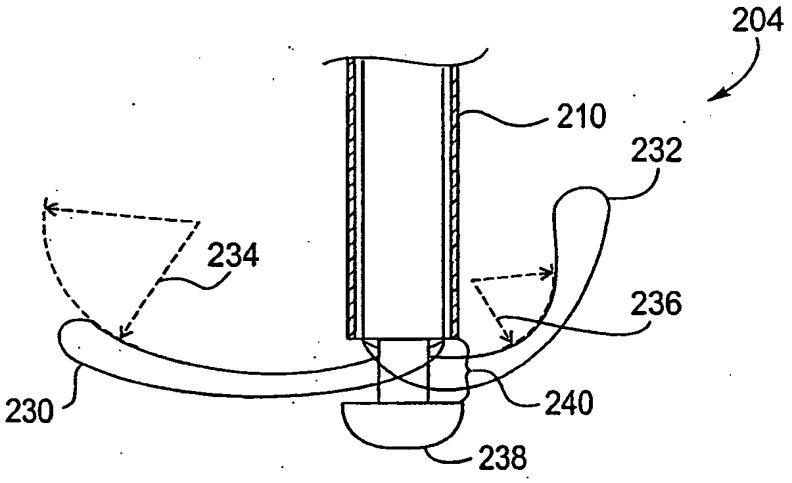


Fig. 14

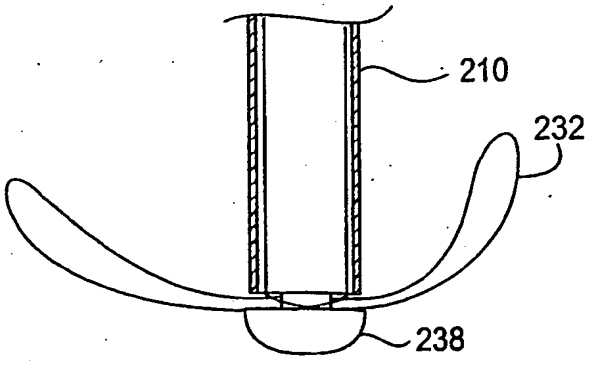


Fig. 15

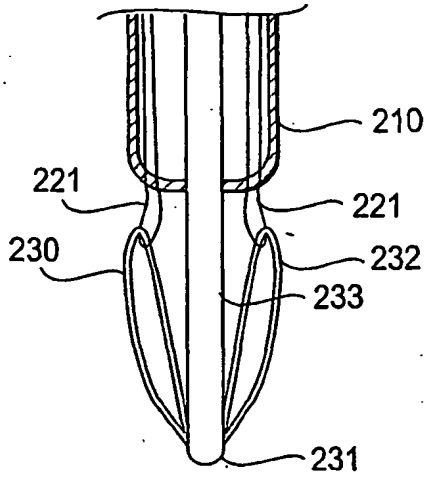


Fig. 16A

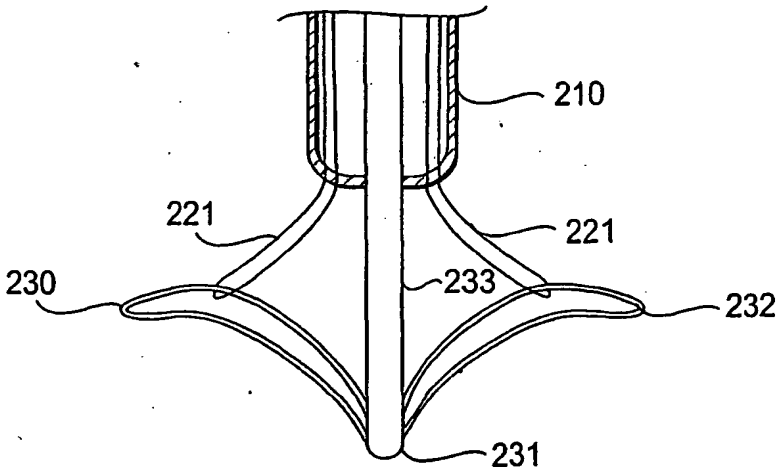


Fig. 16B

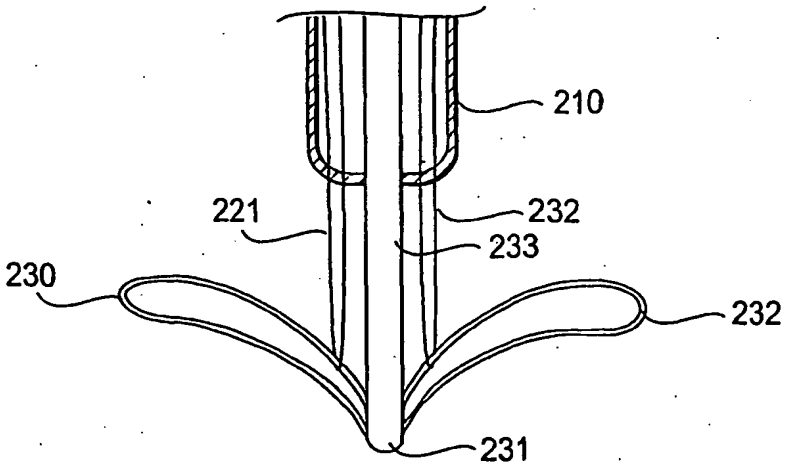


Fig. 16C

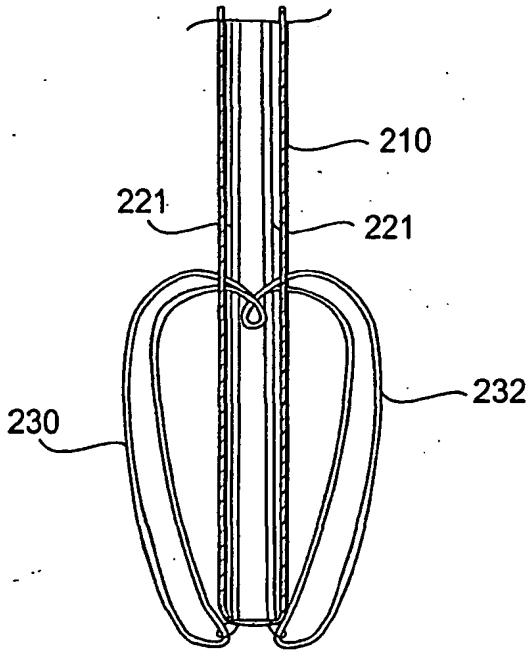


Fig. 16D

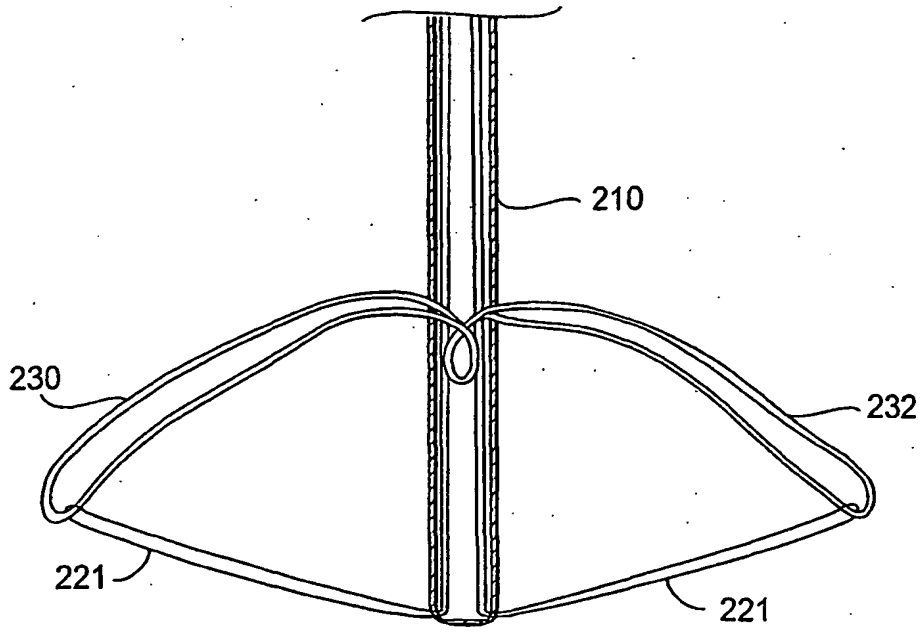


Fig. 16E

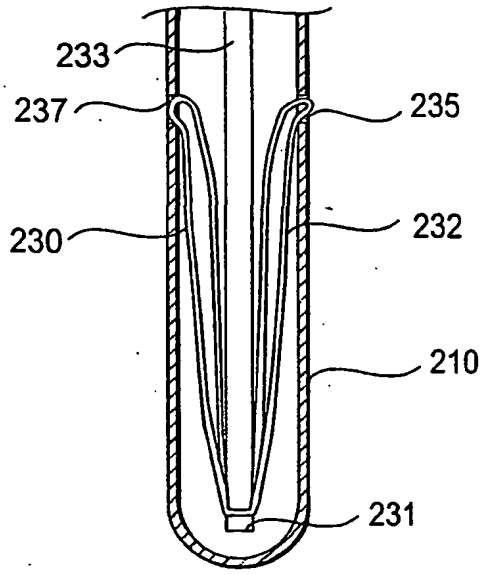


Fig. 16F

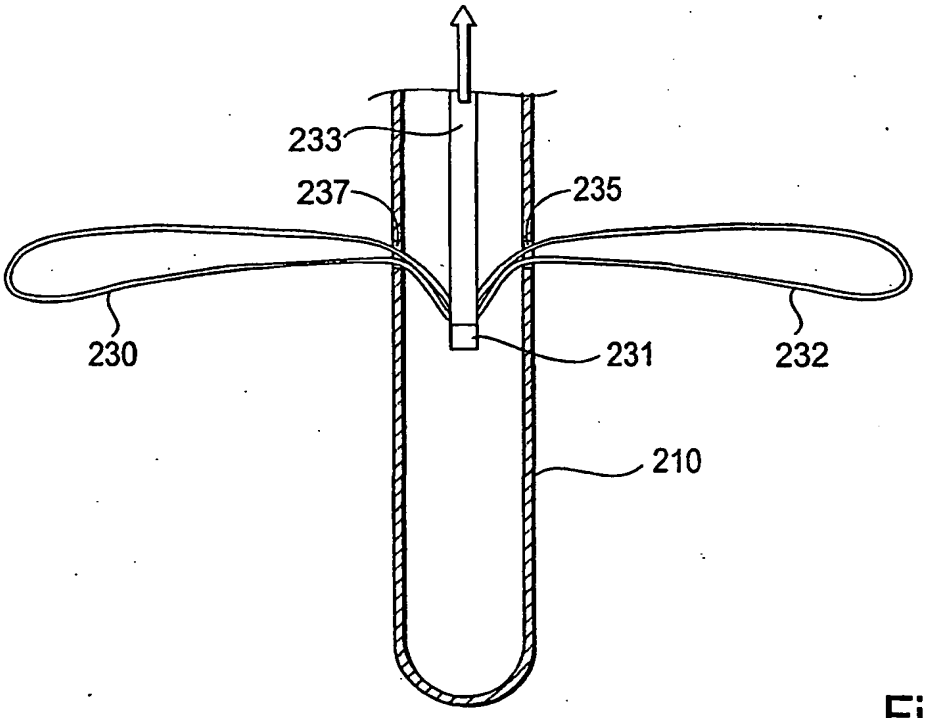


Fig. 16G

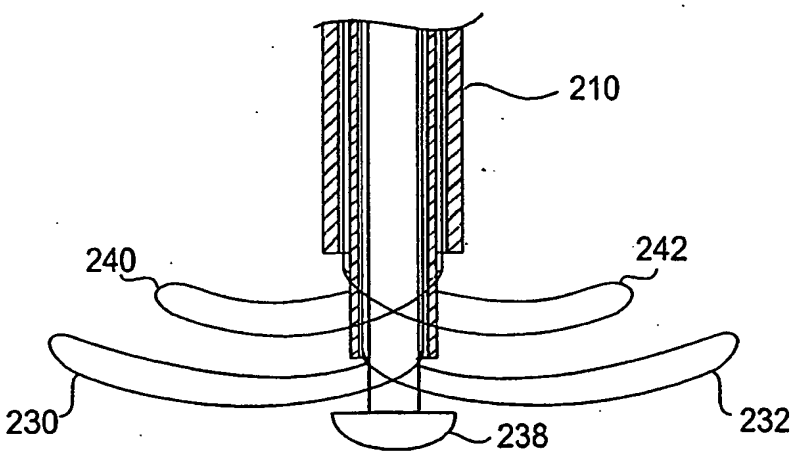


Fig. 17A

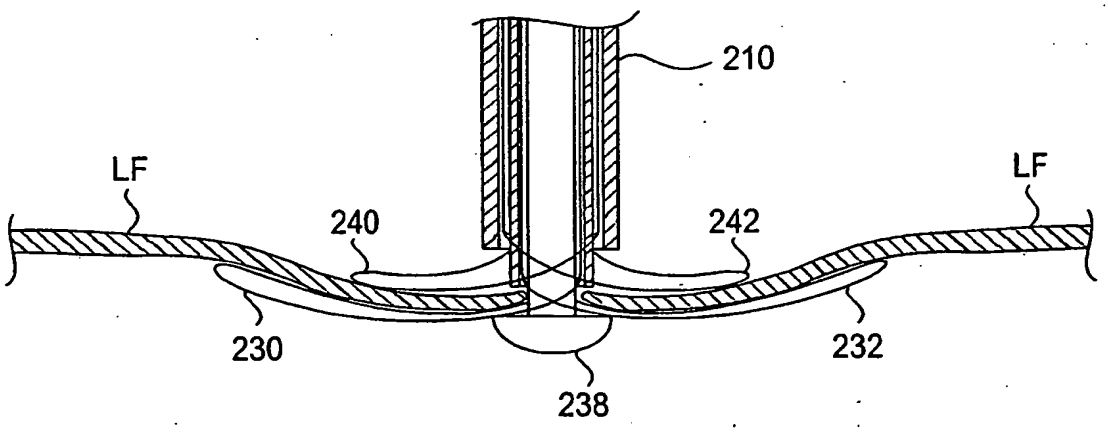


Fig. 17B

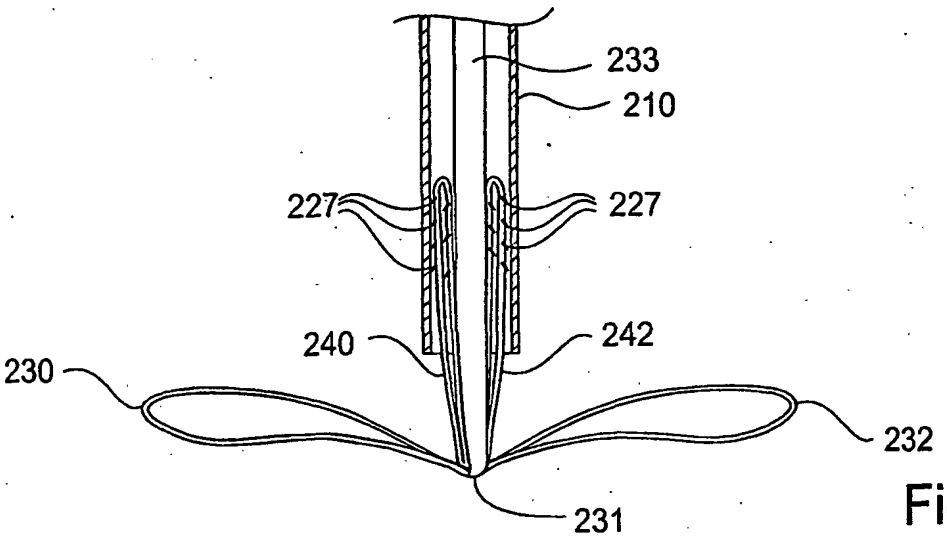


Fig. 17C

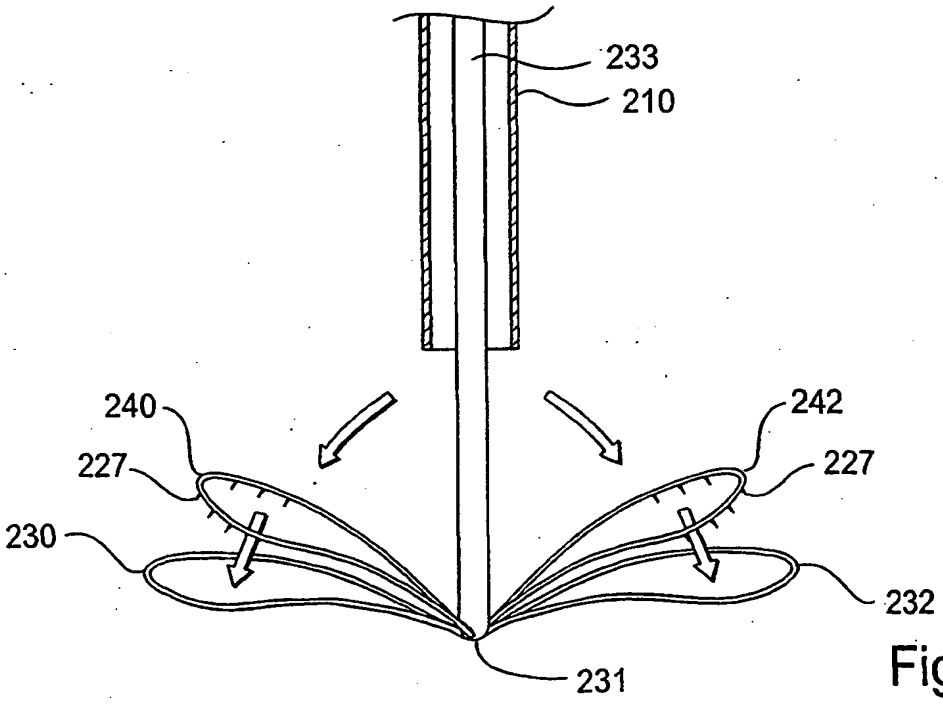


Fig. 17D

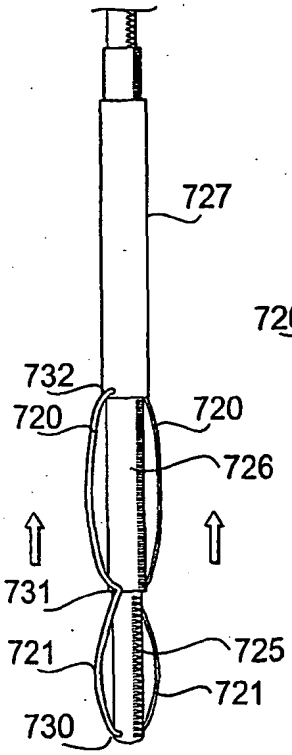


Fig. 18A

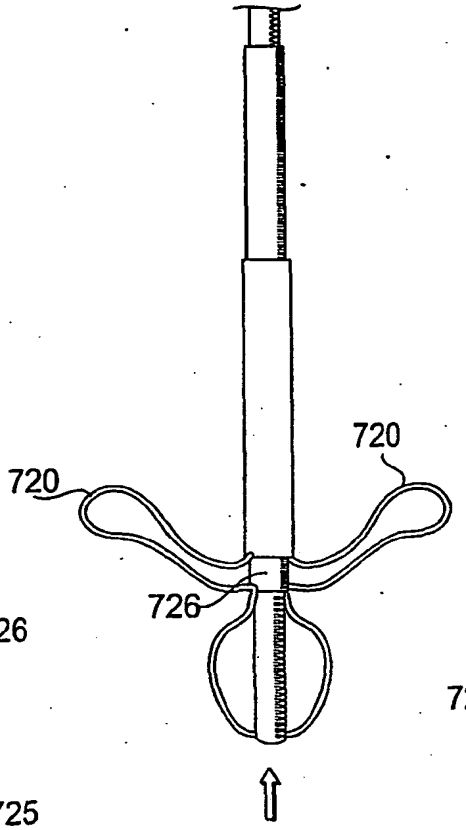


Fig. 18B

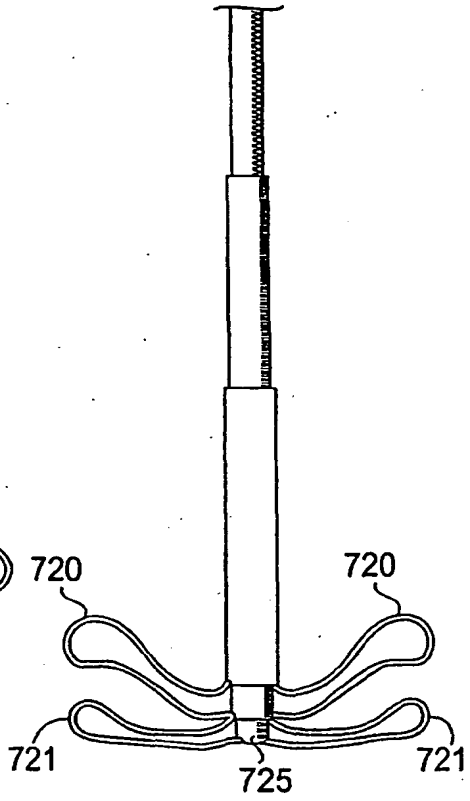


Fig. 18C

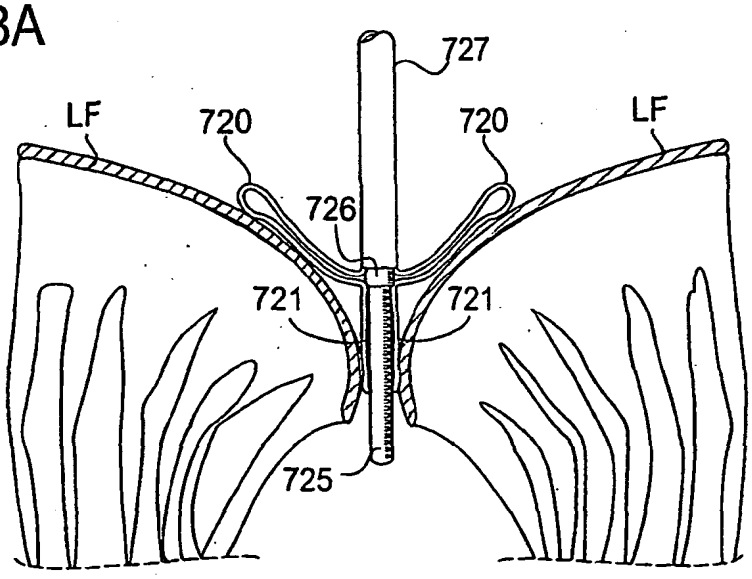


Fig. 18D

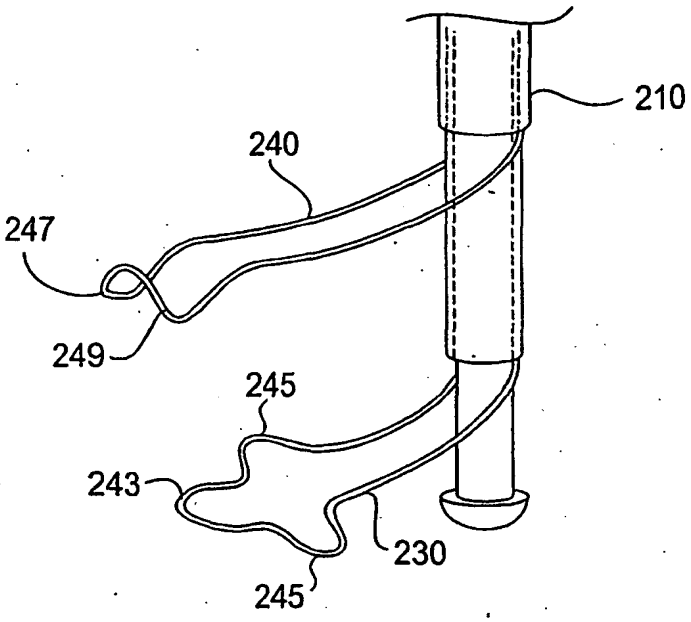


Fig. 19A

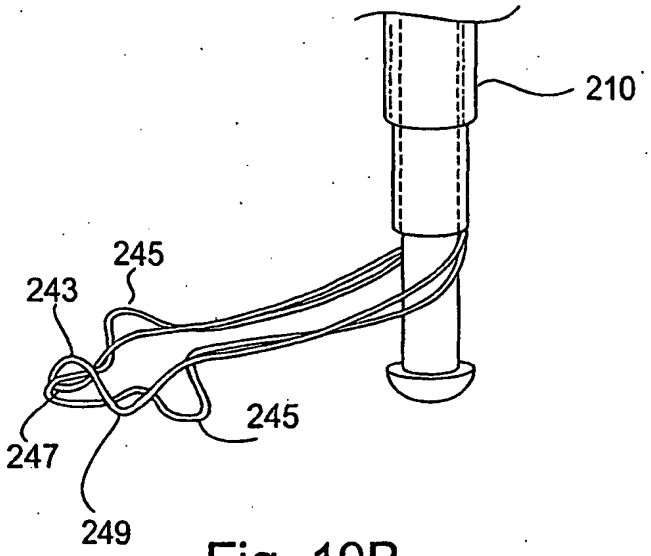


Fig. 19B

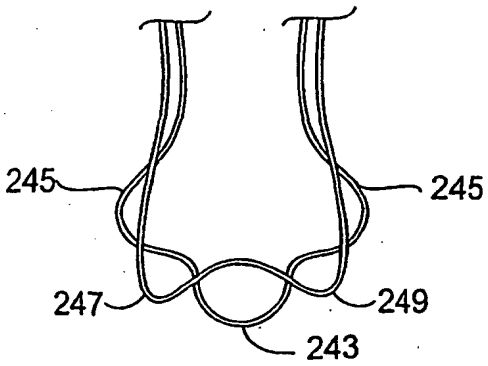


Fig. 19C

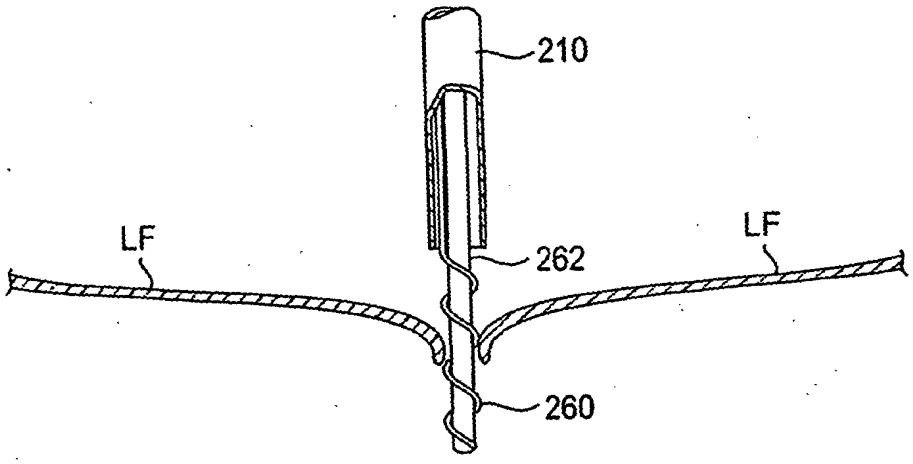


Fig. 20A

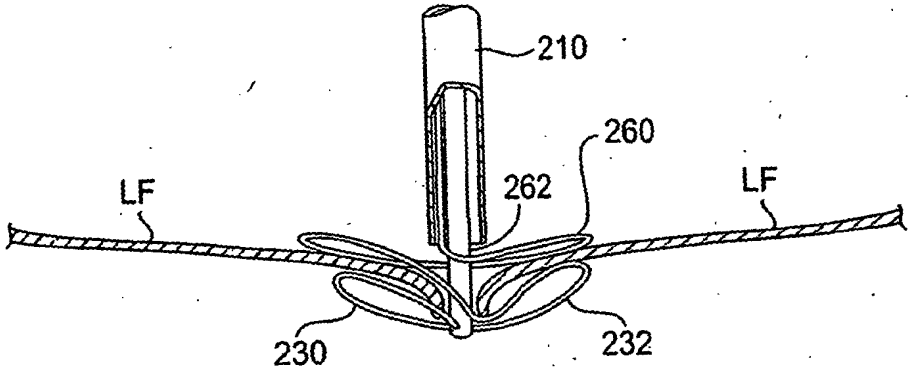


Fig. 20B

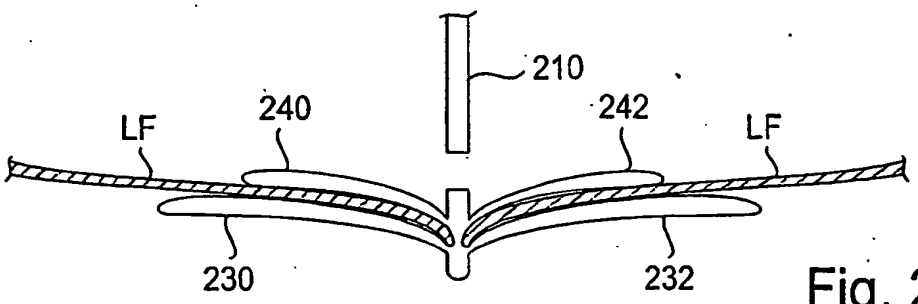


Fig. 21A

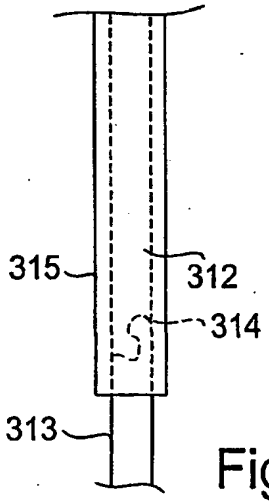


Fig. 21B

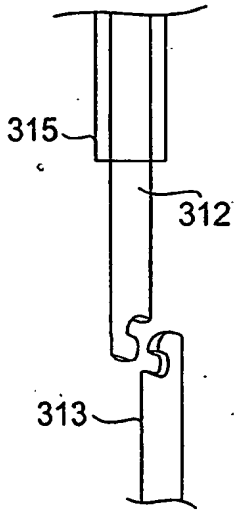


Fig. 21C

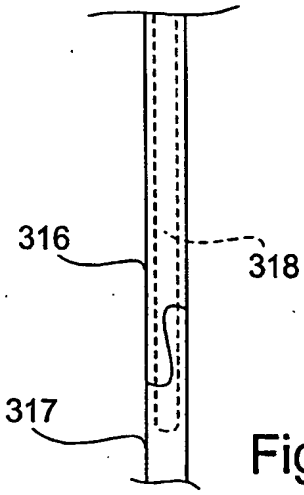


Fig. 21D

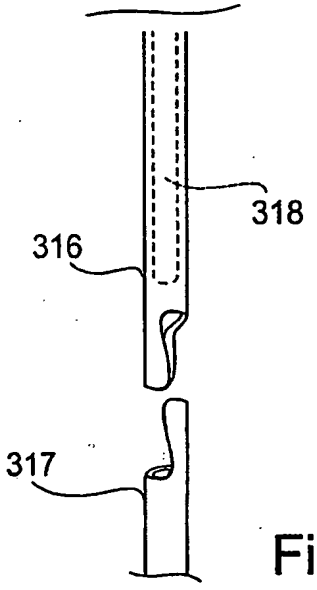


Fig. 21E

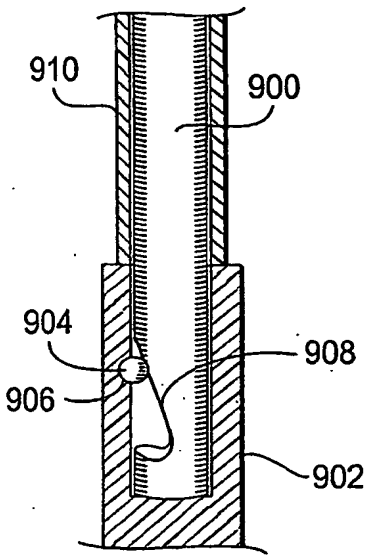


Fig. 21F

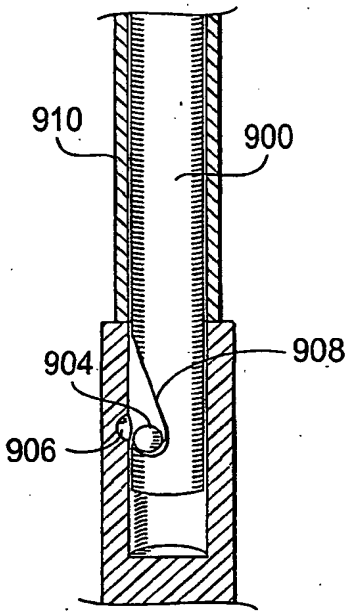


Fig. 21G

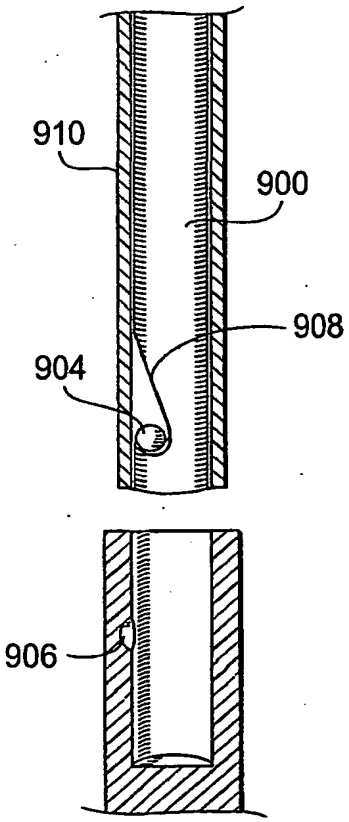


Fig. 21H

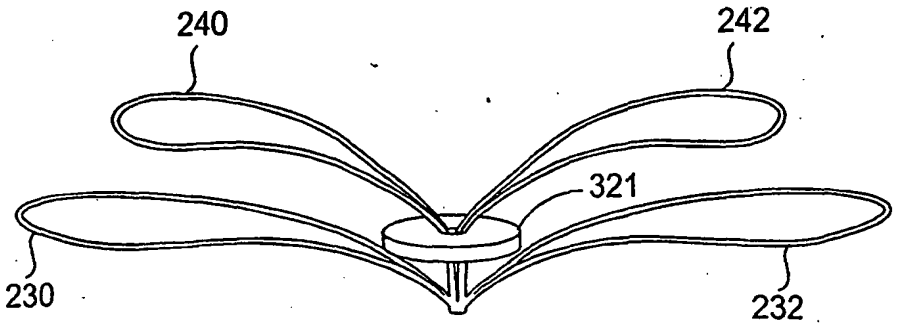


Fig. 21I

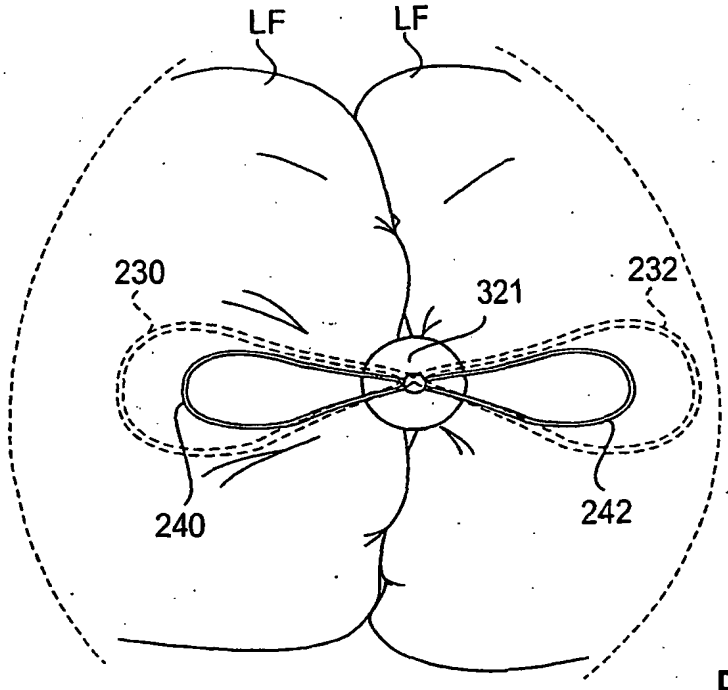


Fig. 21J

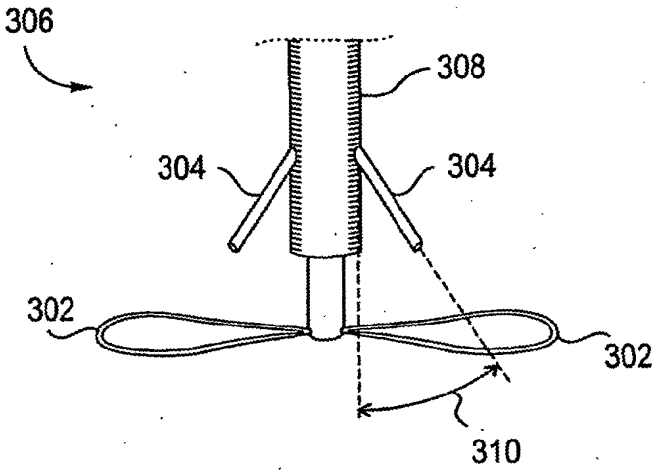


Fig. 22

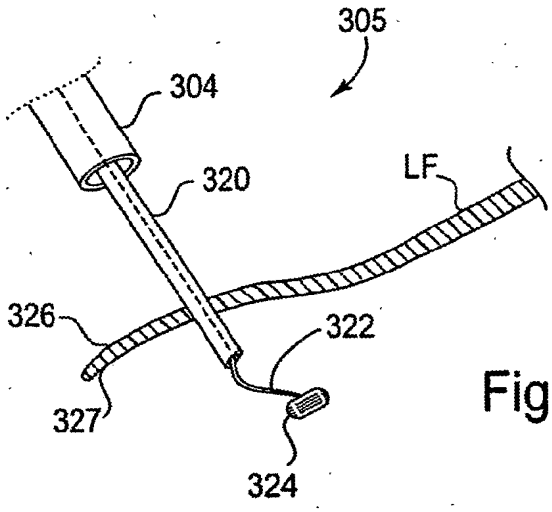


Fig. 23A

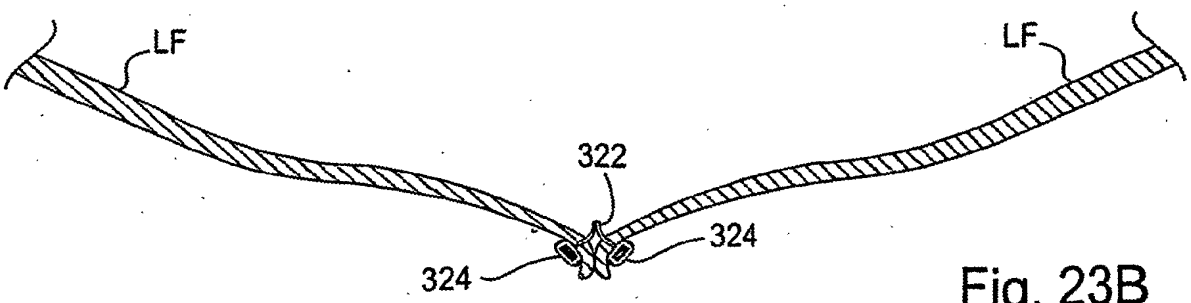


Fig. 23B

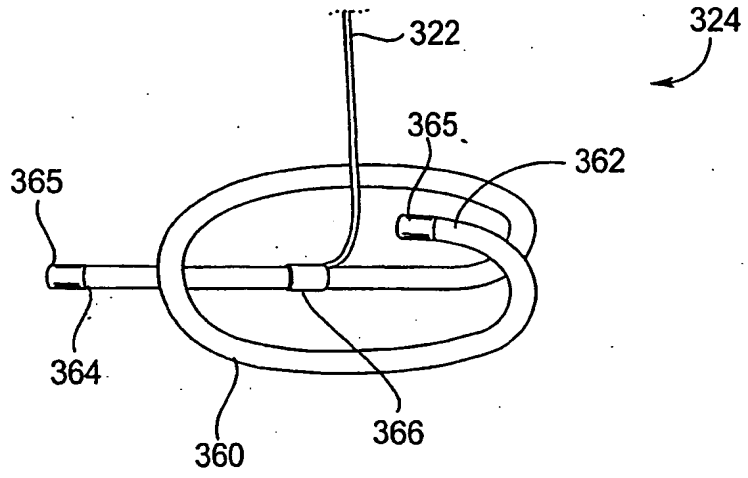


Fig. 24

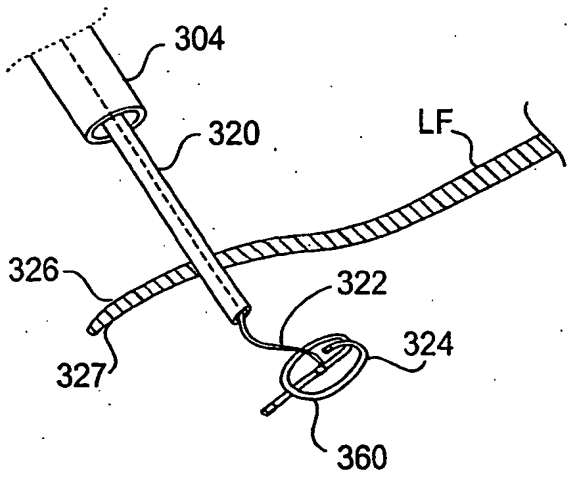


Fig. 25

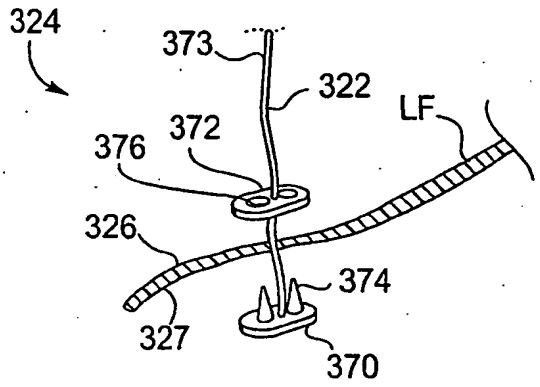


Fig. 26A

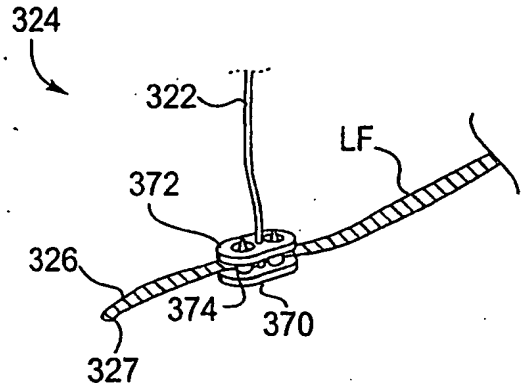


Fig. 26B

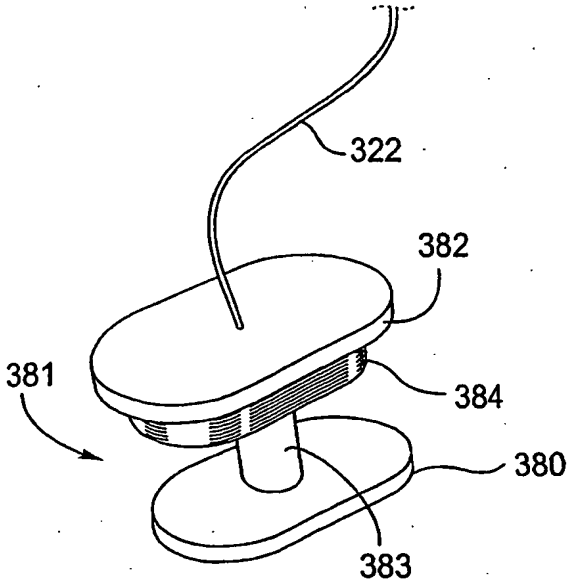


Fig. 27A

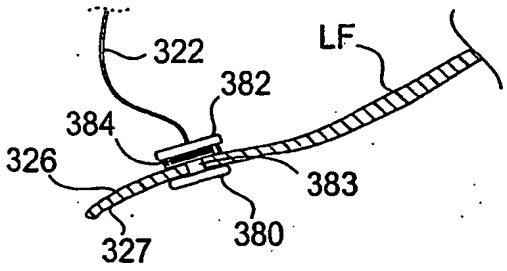


Fig. 27B

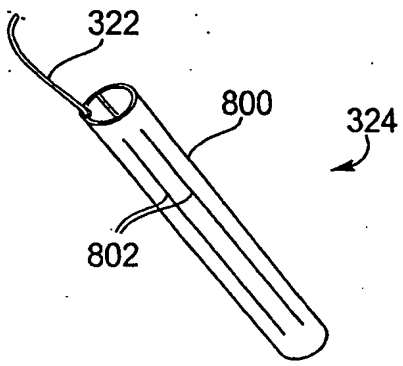


Fig. 27C

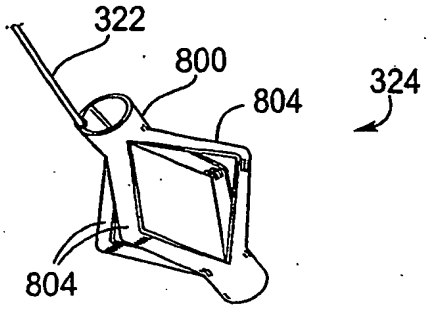


Fig. 27D

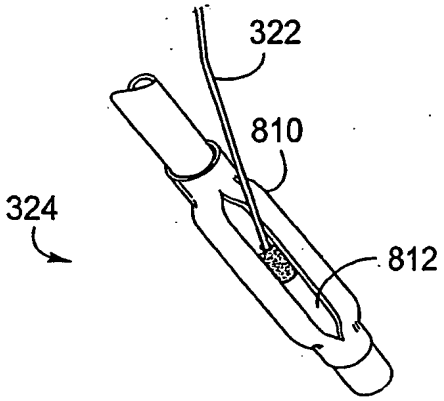


Fig. 27E

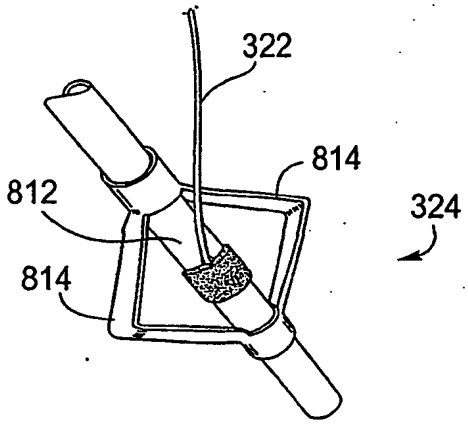


Fig. 27F

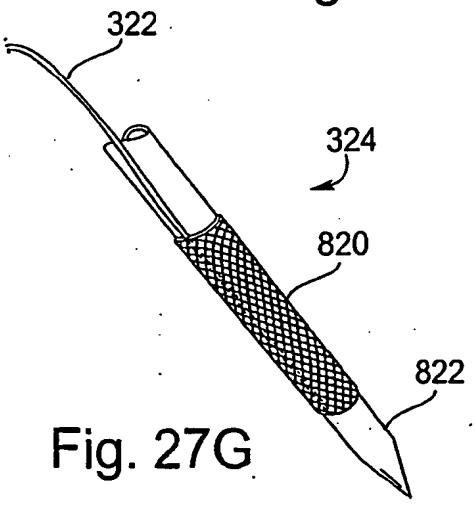


Fig. 27G

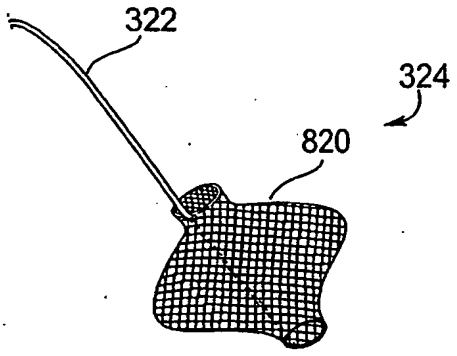


Fig. 27H

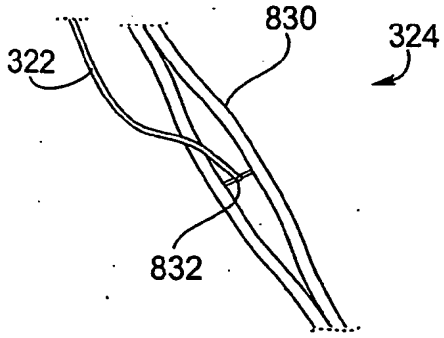


Fig. 27I

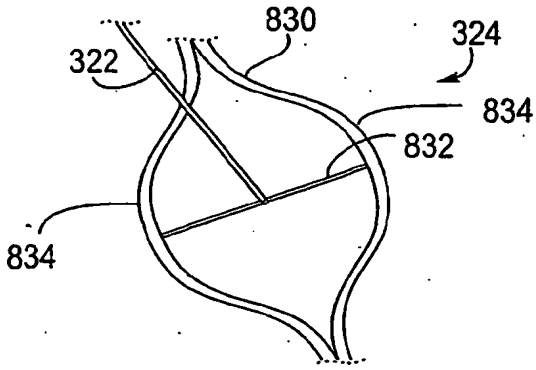


Fig. 27J

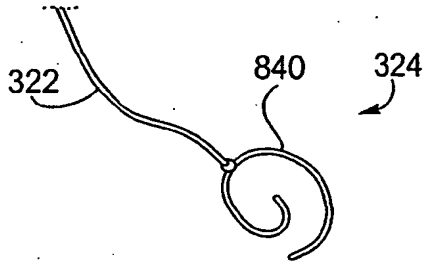


Fig. 27K

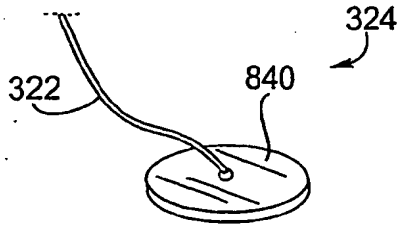


Fig. 27L

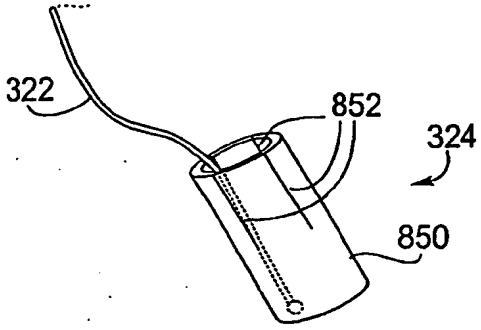


Fig. 27M

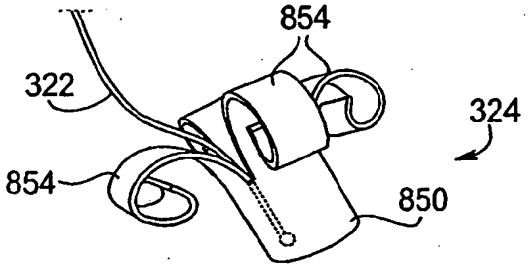


Fig. 27N

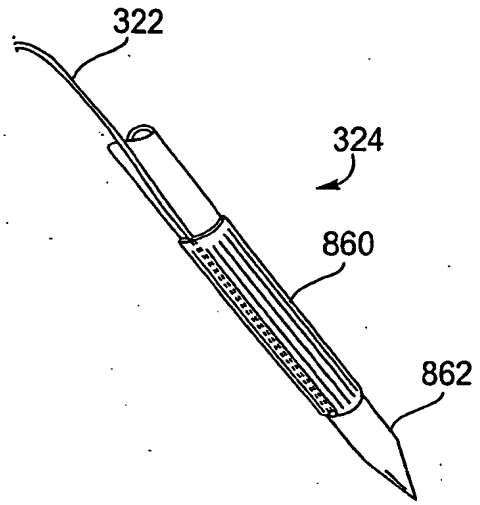


Fig. 27P

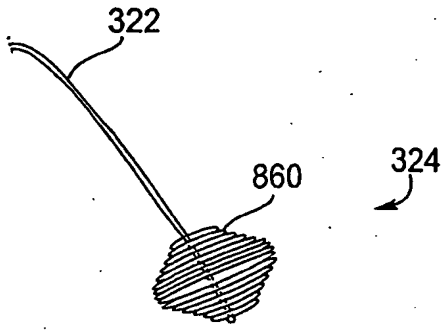


Fig. 27Q

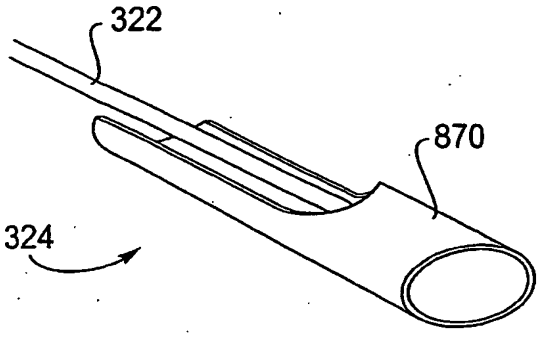


Fig. 27R

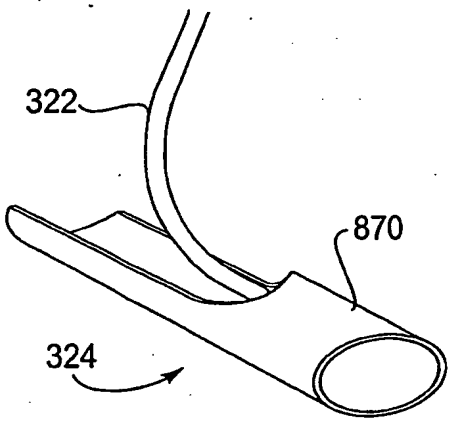


Fig. 27T

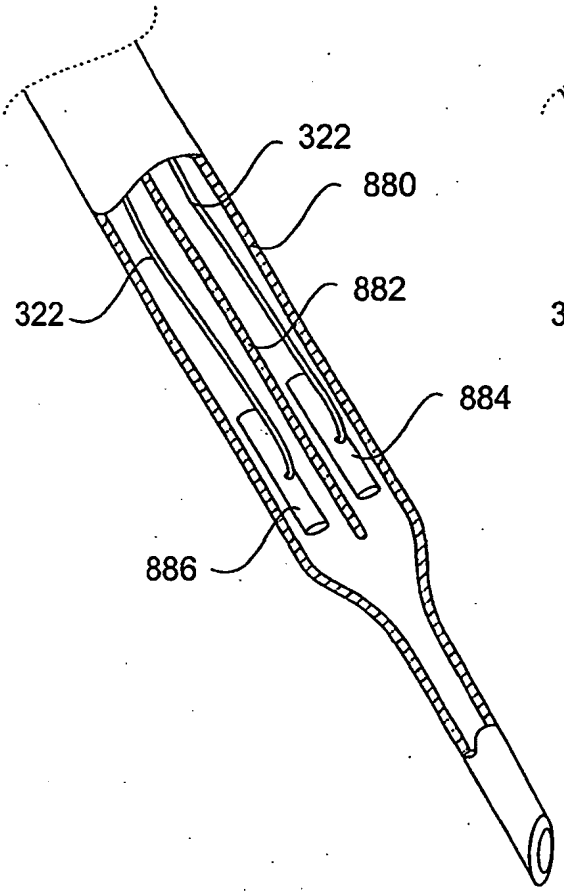


Fig. 27U

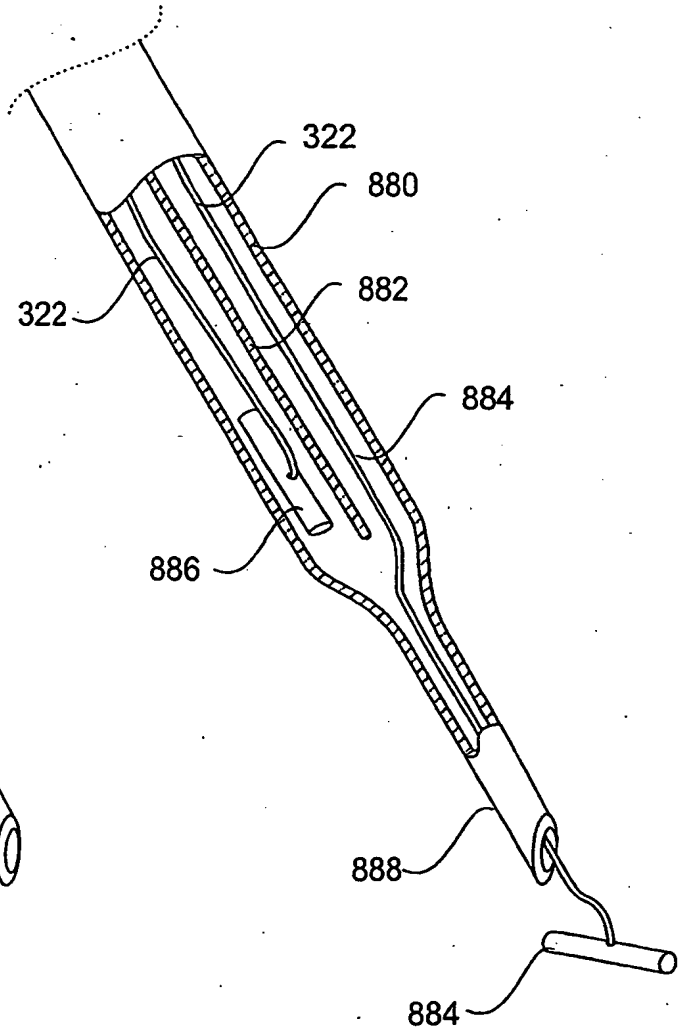


Fig. 27V

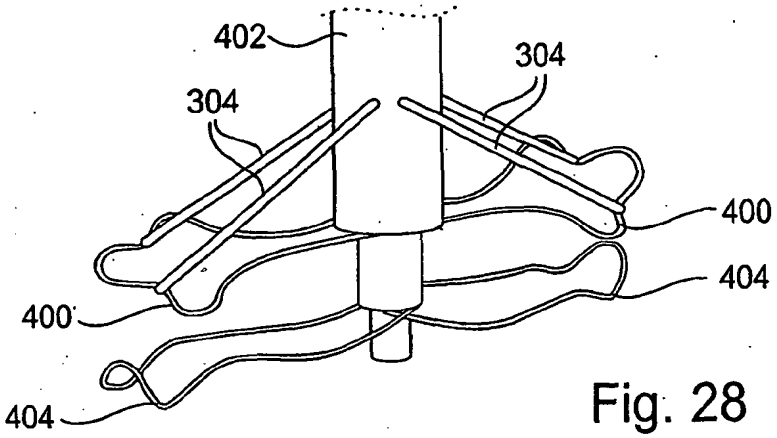


Fig. 28

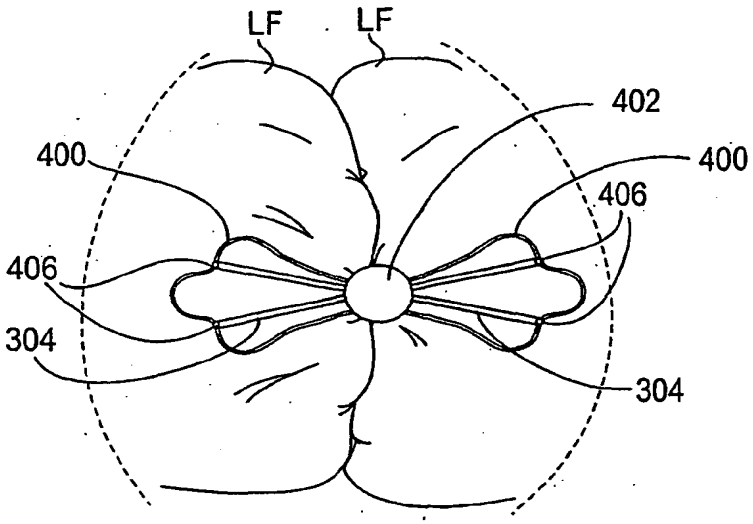


Fig. 29

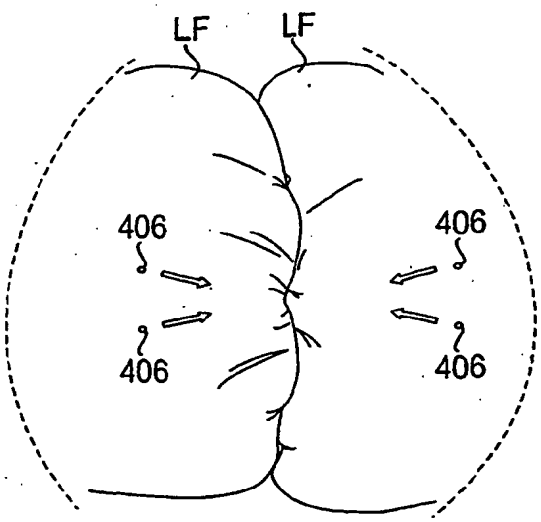


Fig. 30

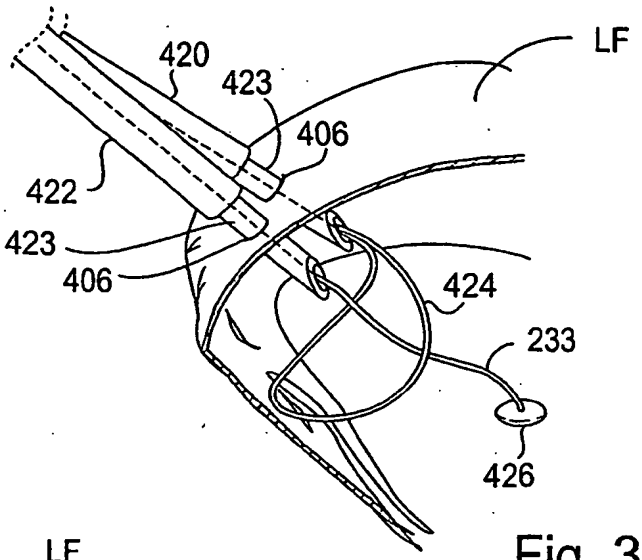


Fig. 31

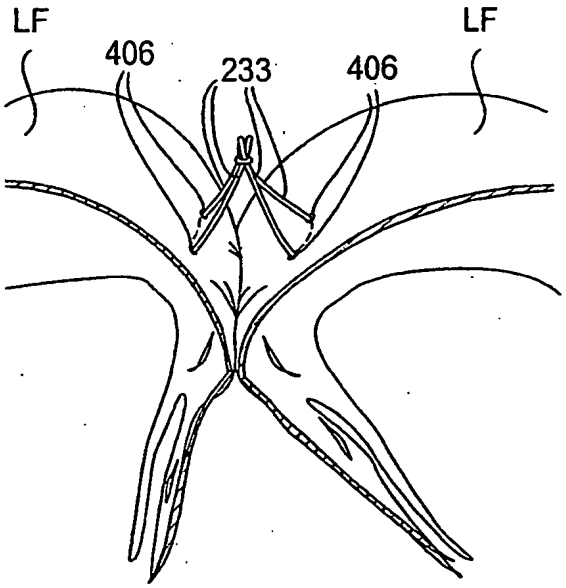


Fig. 32

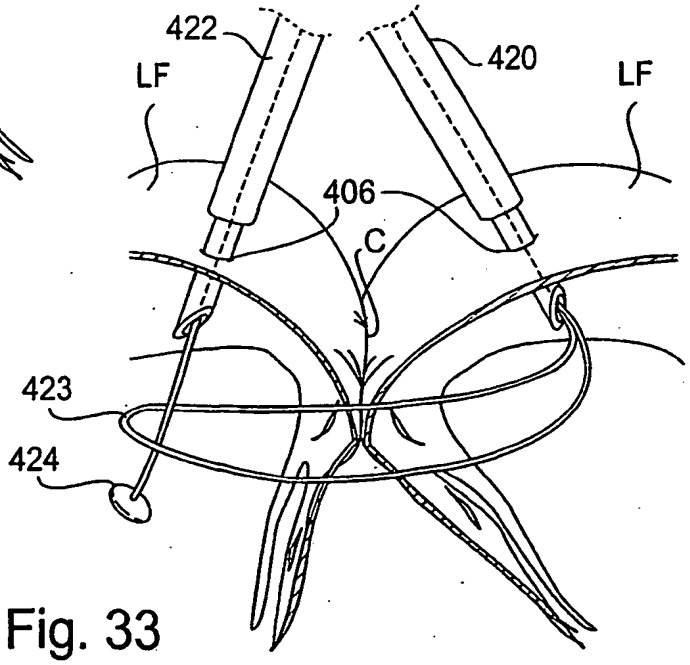


Fig. 33

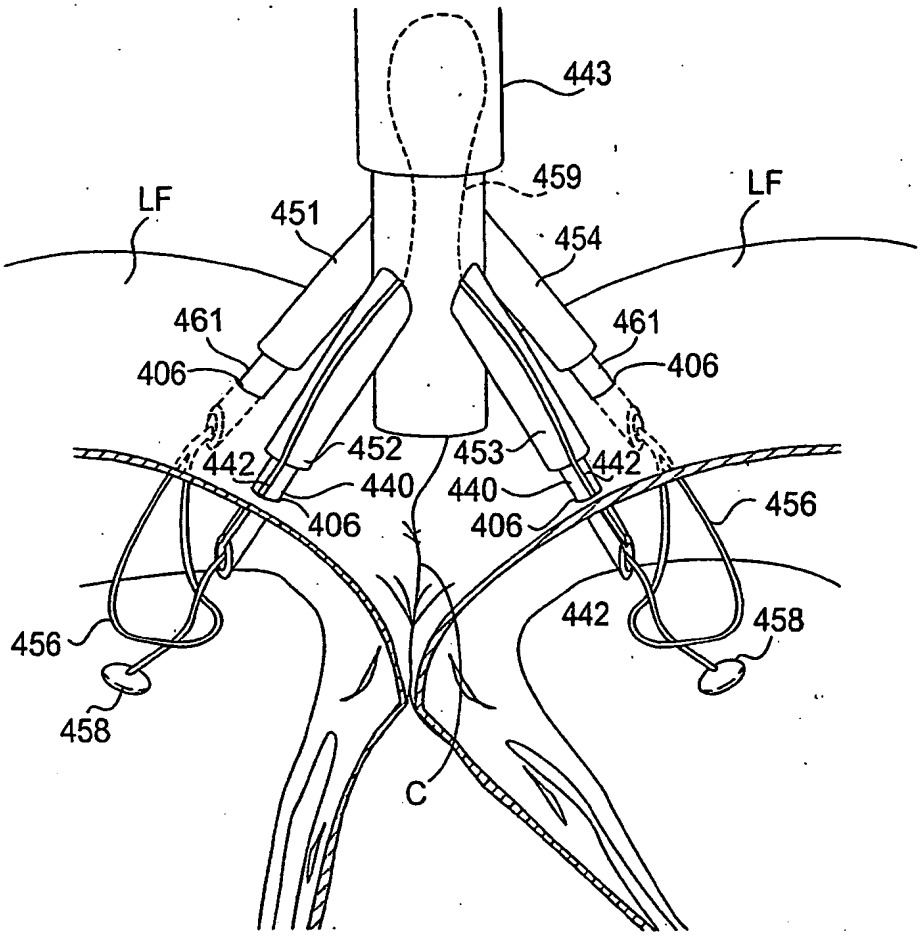


Fig. 34

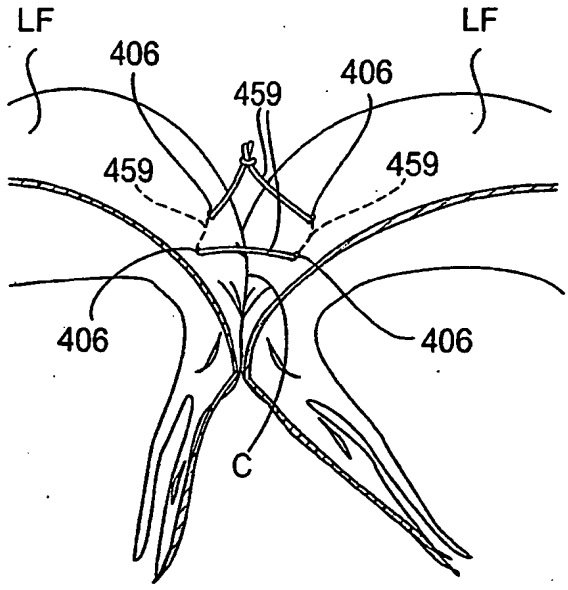


Fig. 35

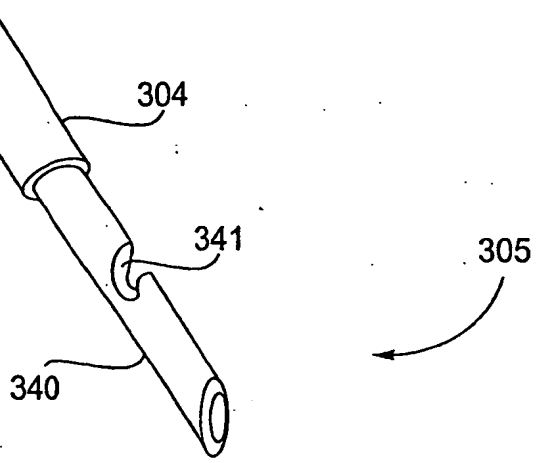


Fig. 36

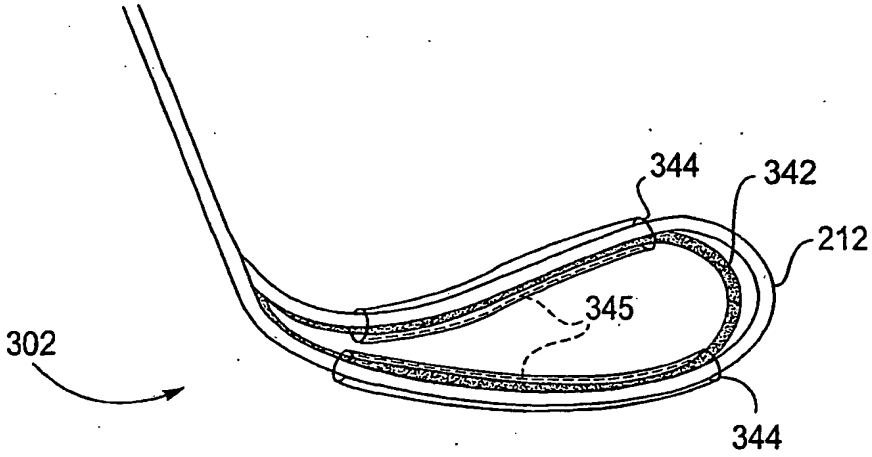


Fig. 37

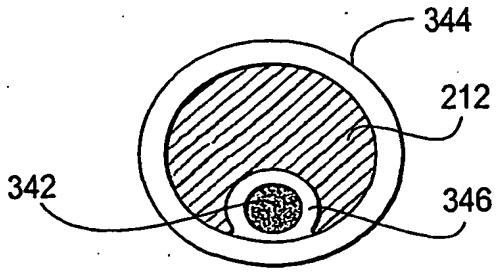


Fig. 38

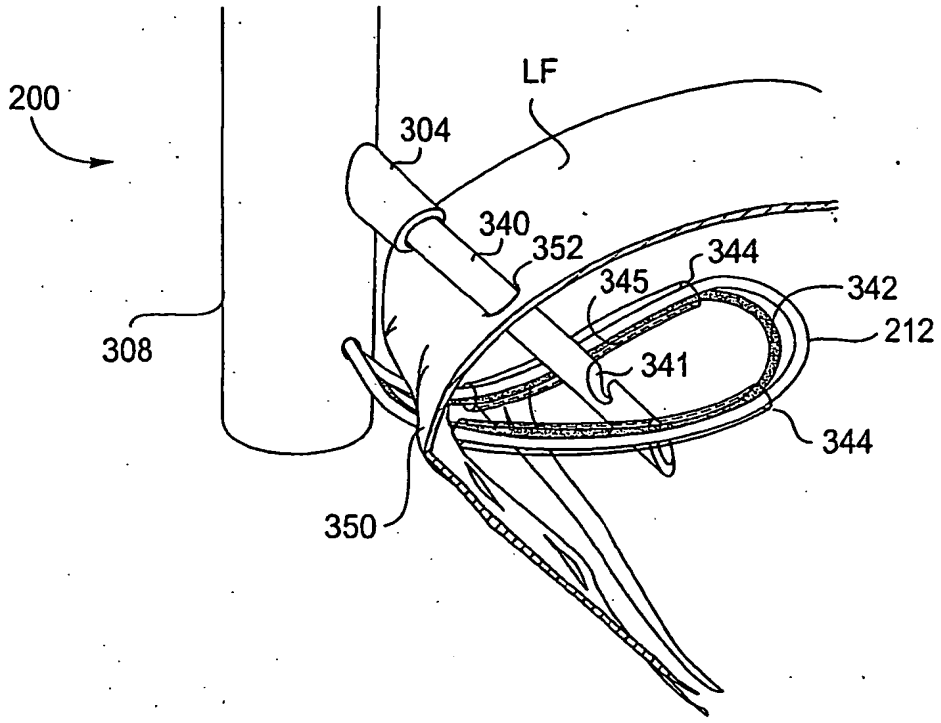


Fig. 39

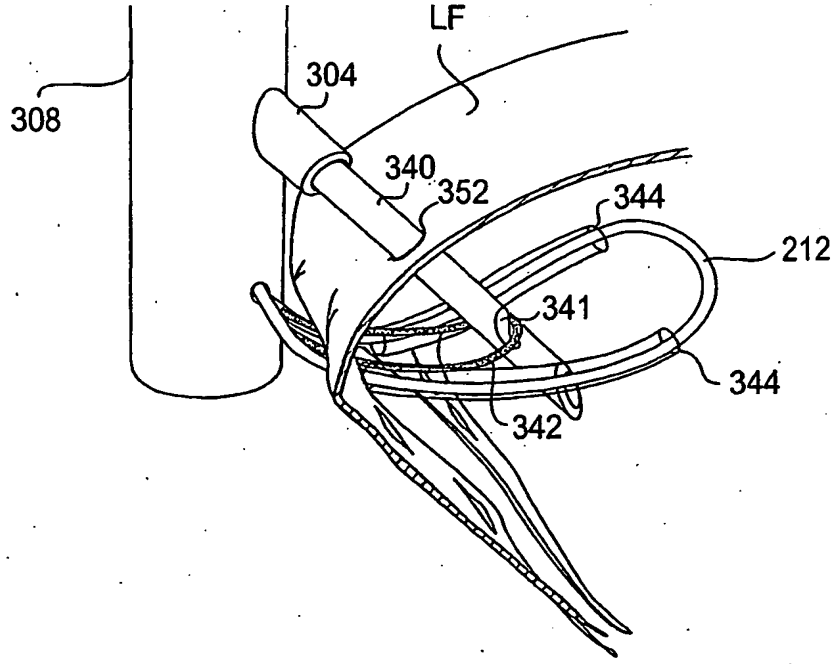


Fig. 40

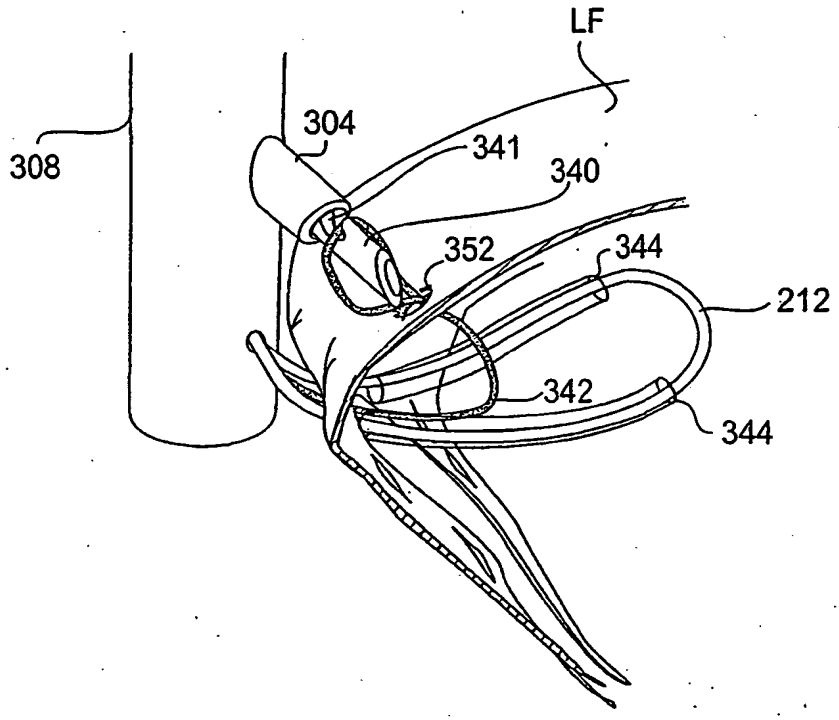


Fig. 41

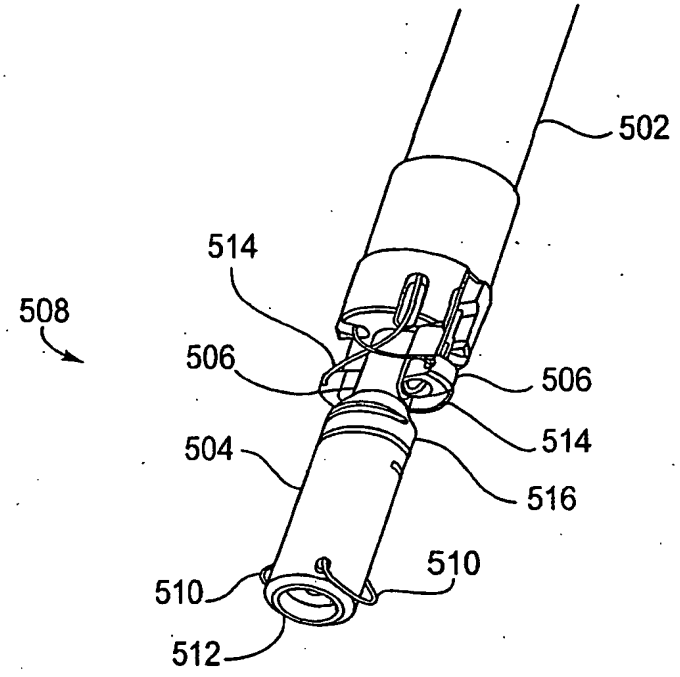


Fig. 42

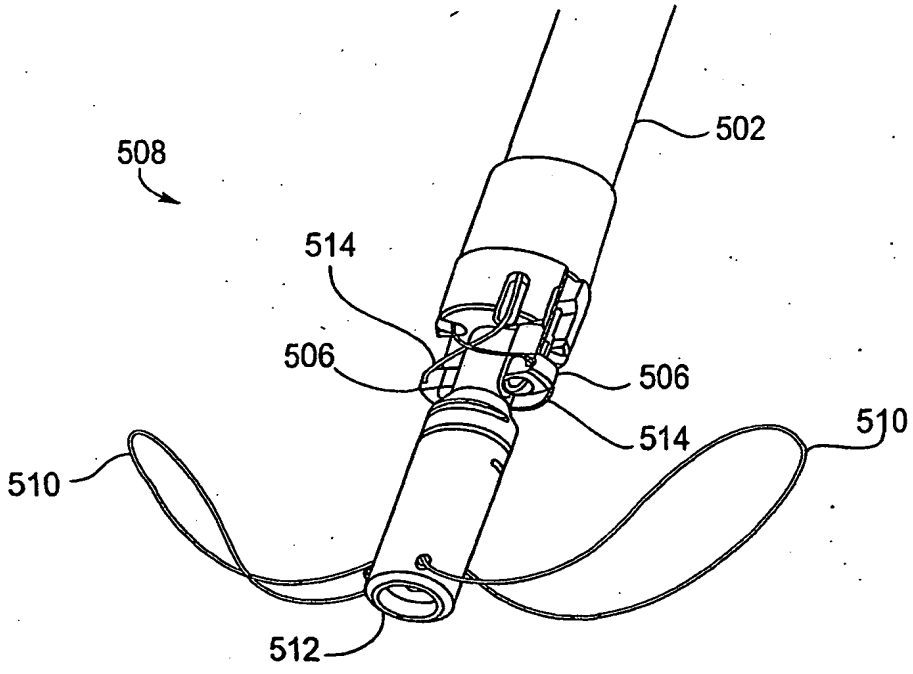


Fig. 43

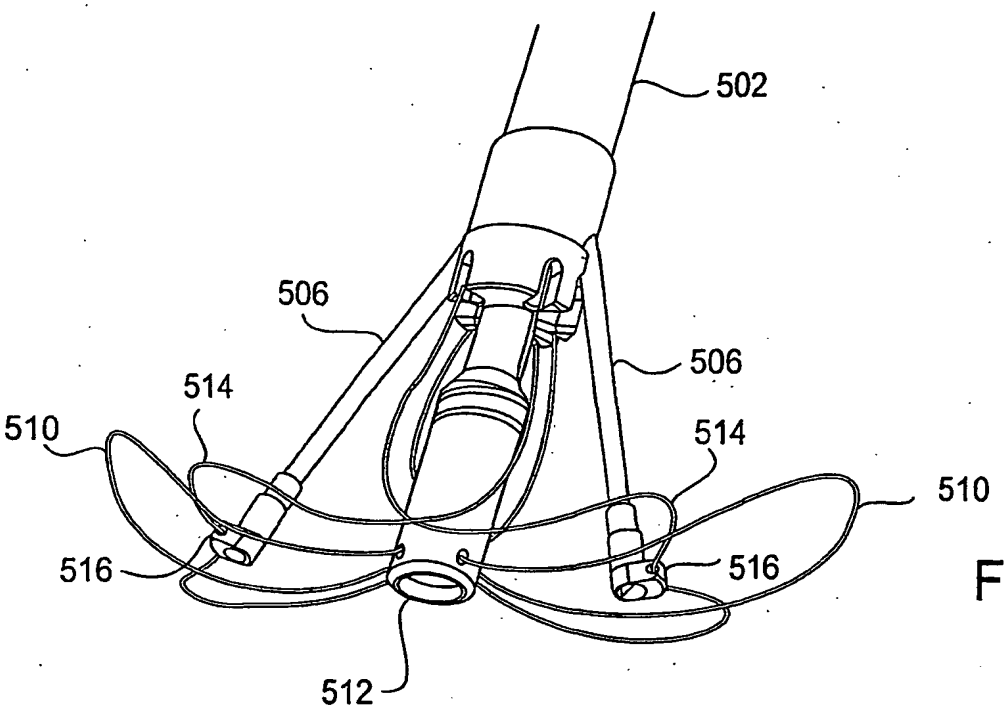


Fig. 44

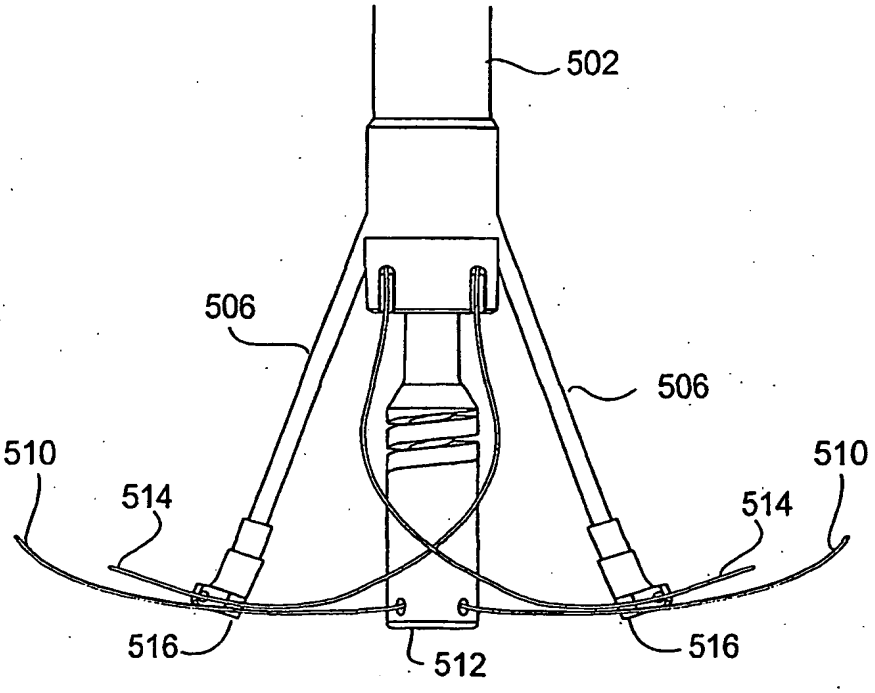


Fig. 45

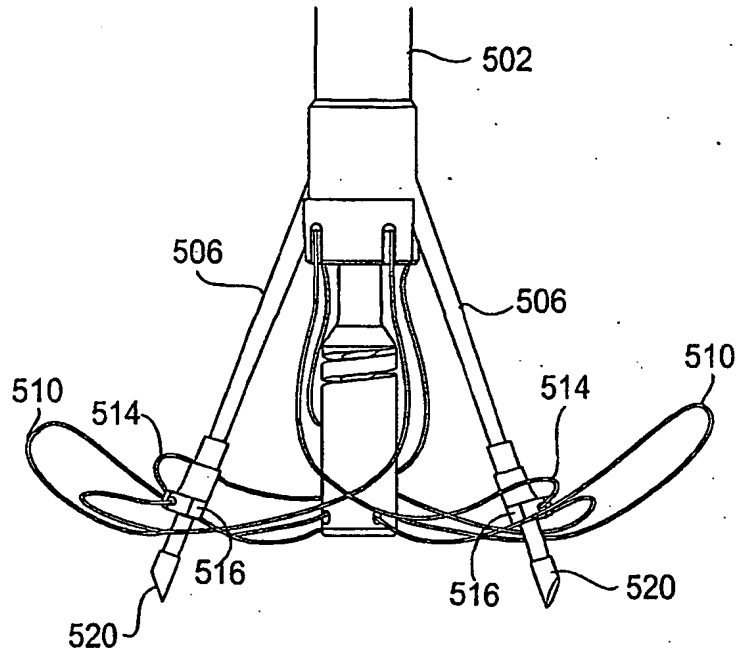


Fig. 46

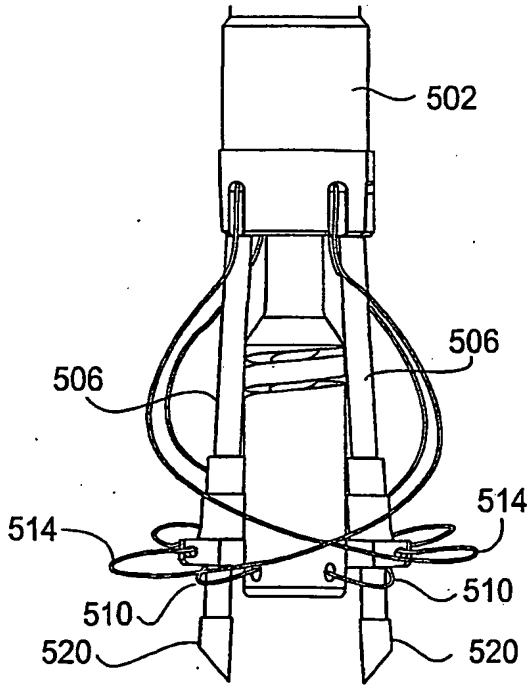


Fig. 47

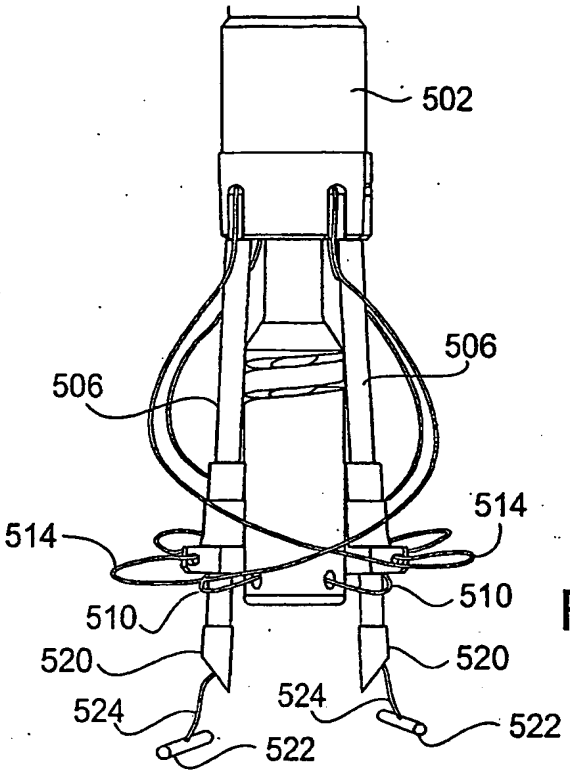


Fig. 48

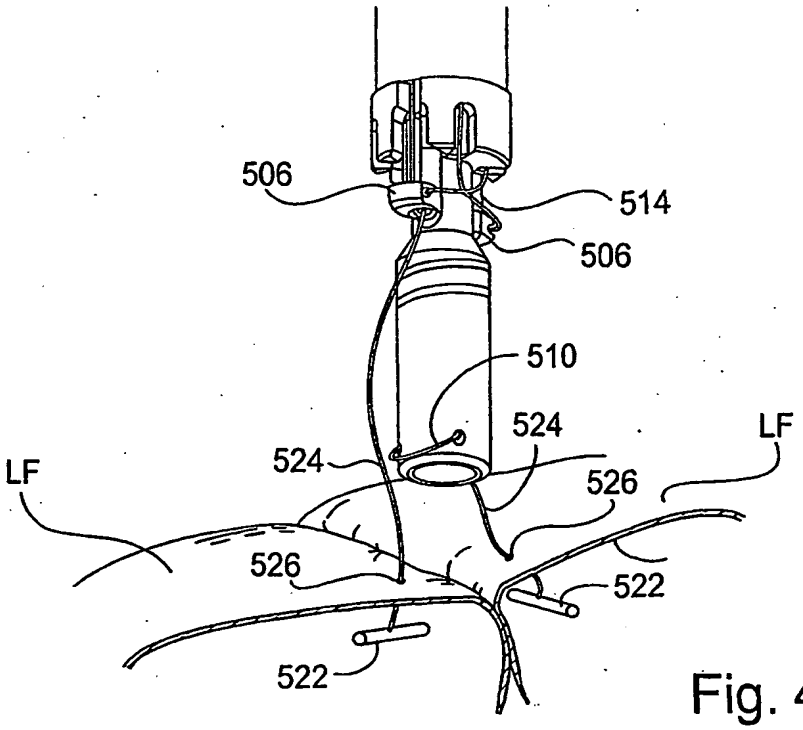


Fig. 49

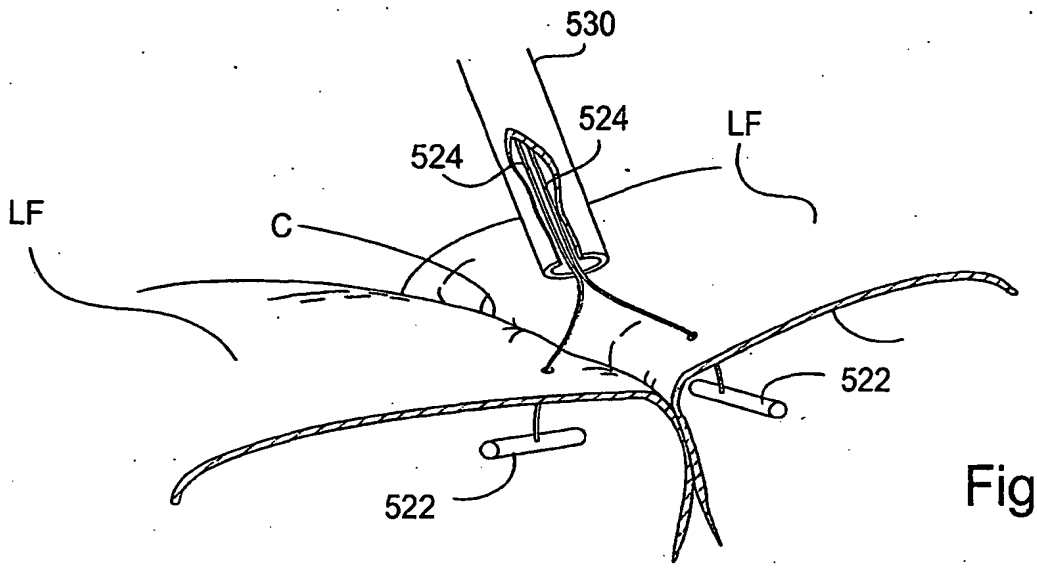


Fig. 50

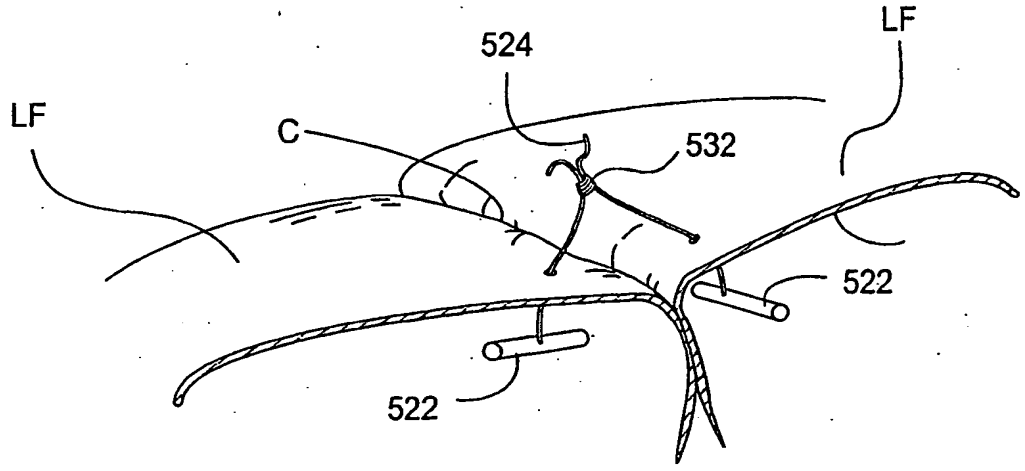


Fig. 51

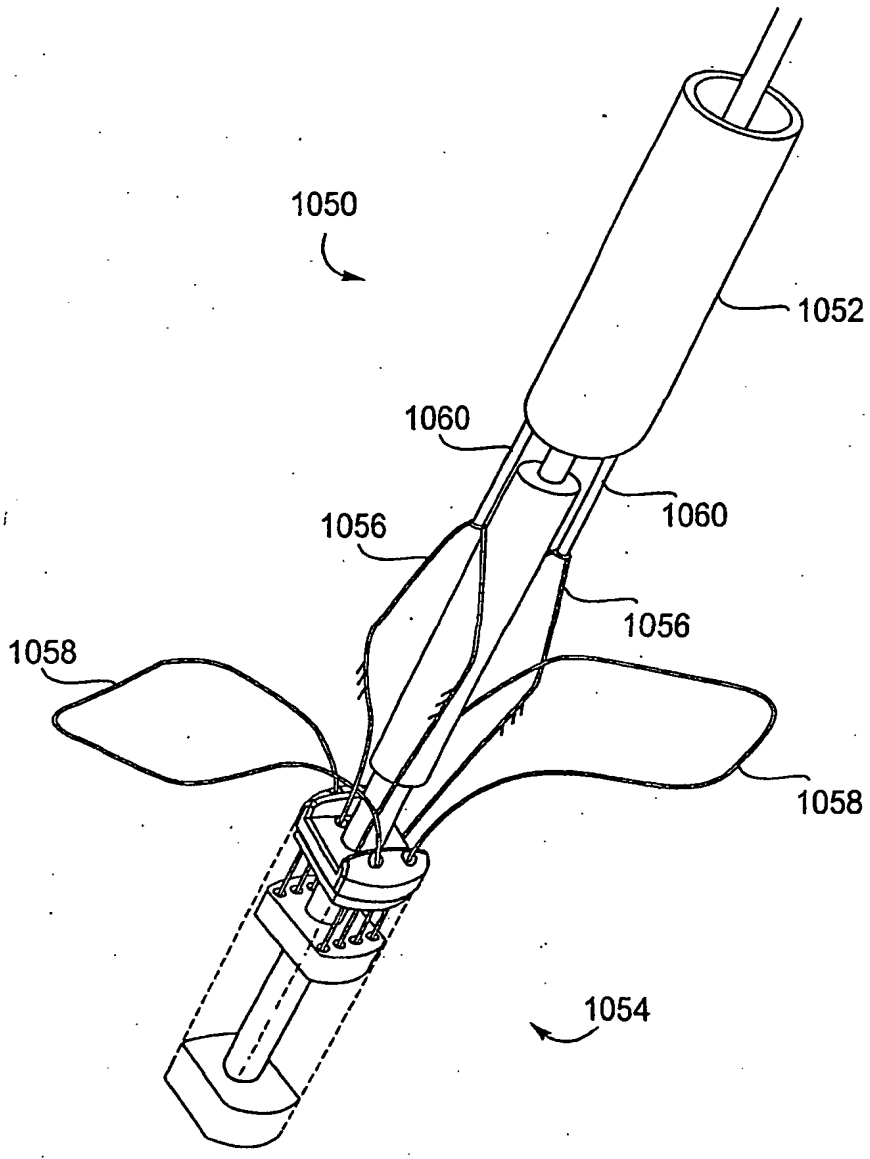


Fig. 52

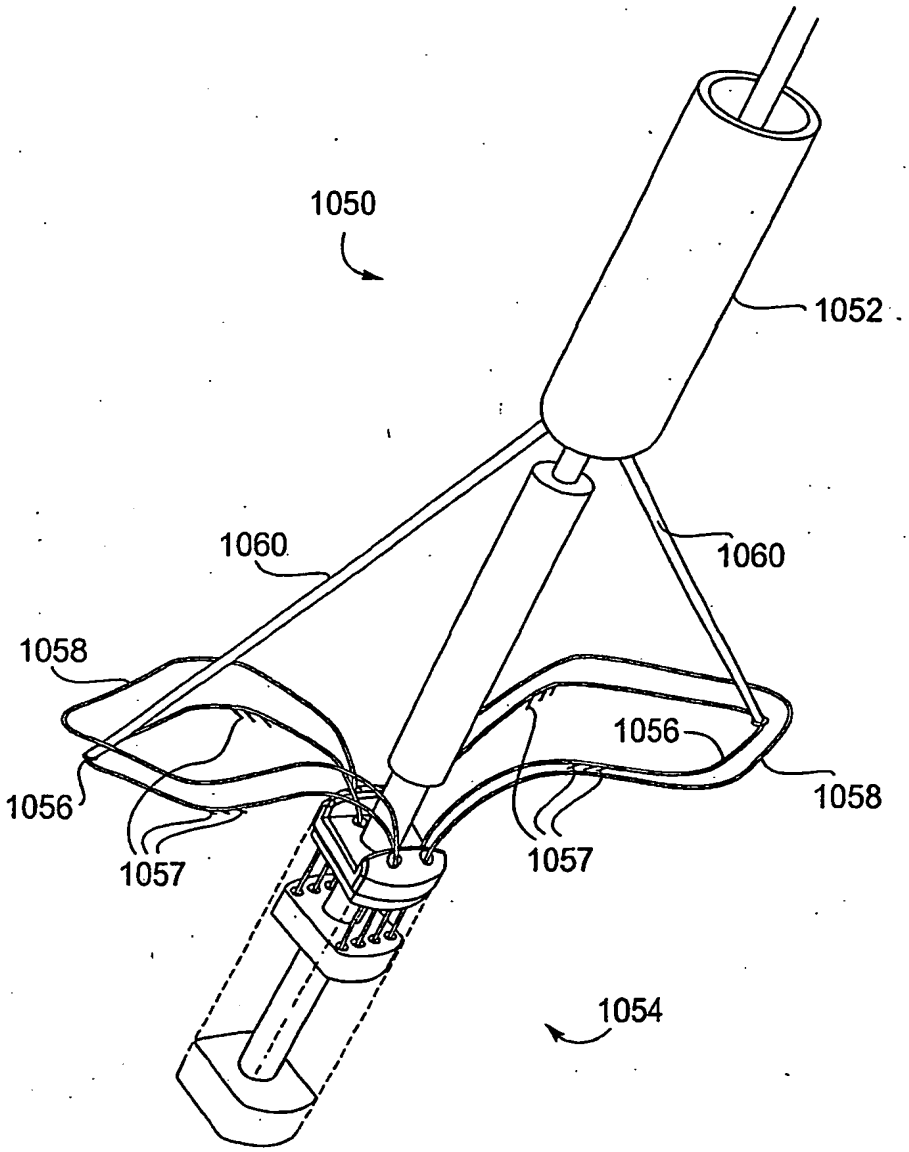


Fig. 53

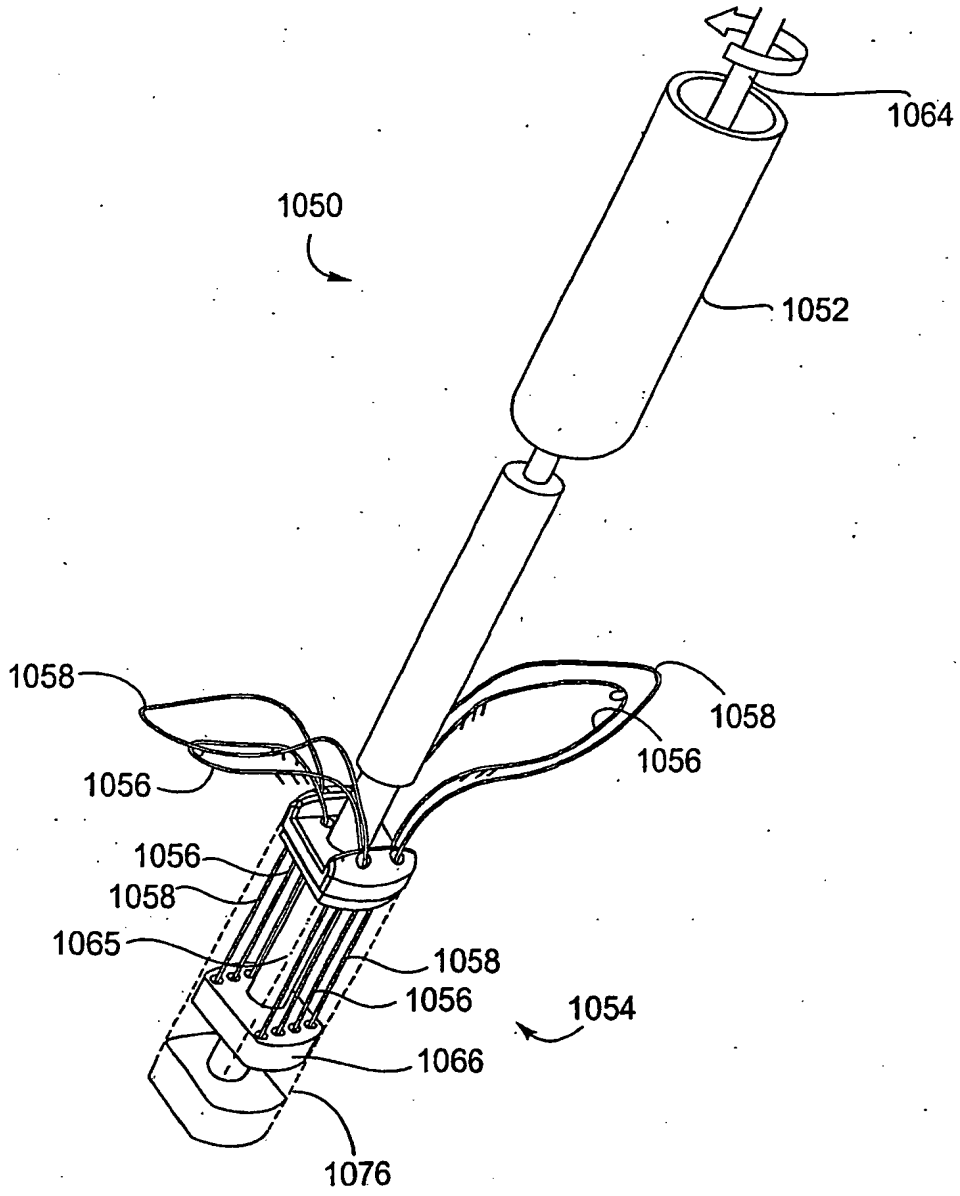


Fig. 54

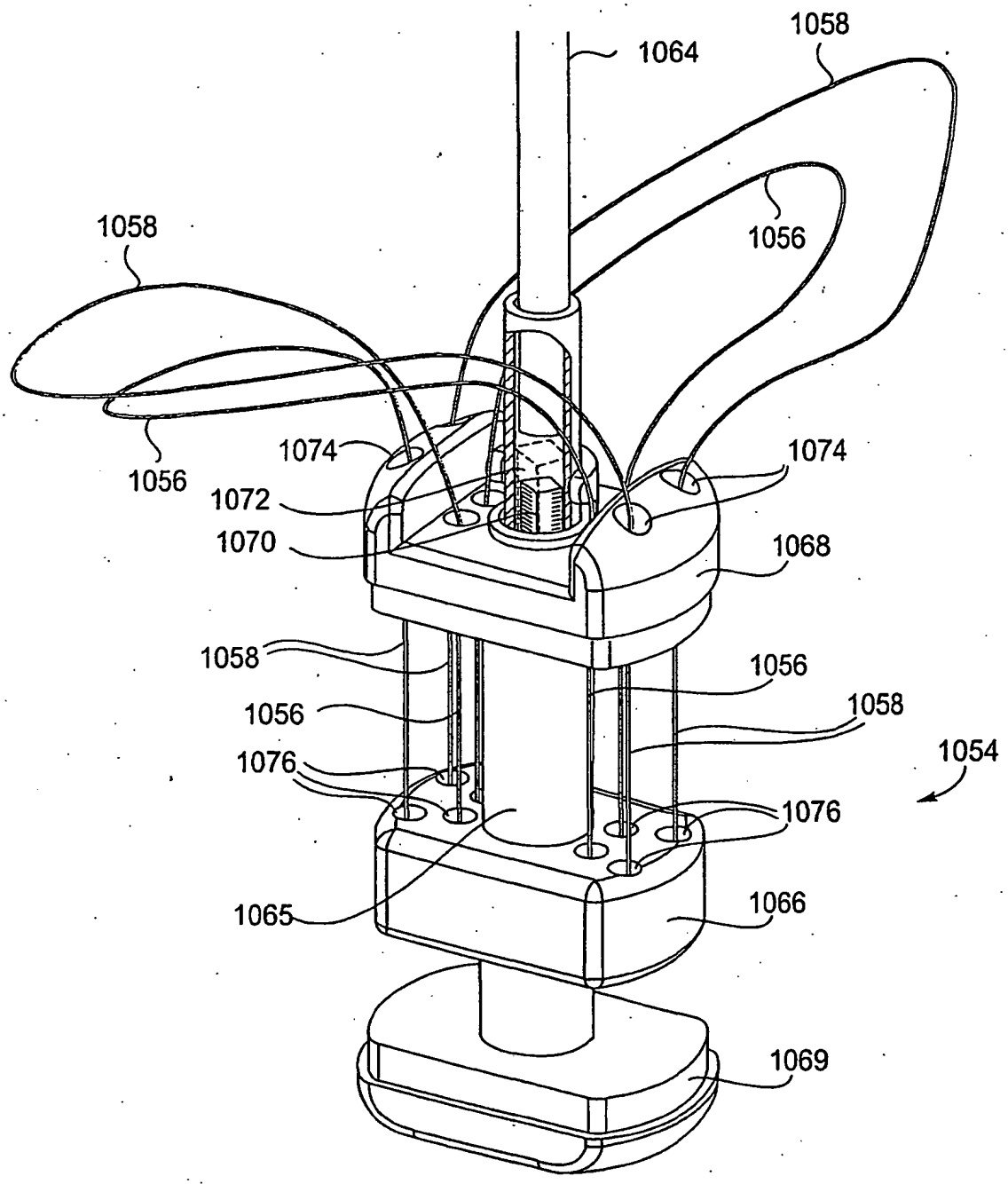


Fig. 55

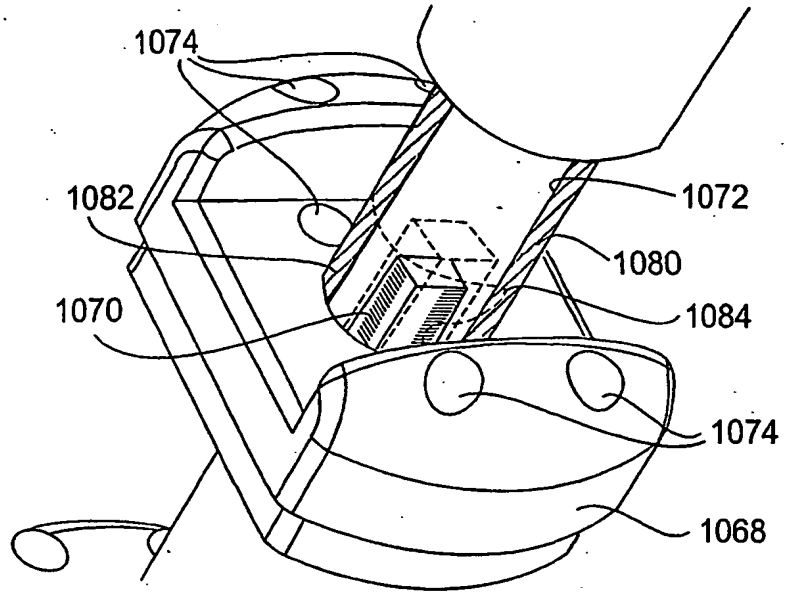


Fig. 56

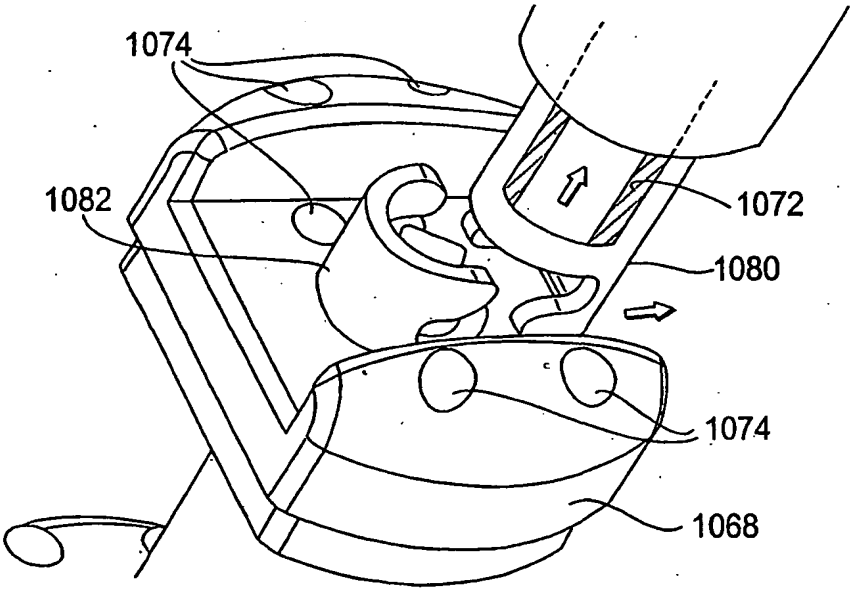


Fig. 57

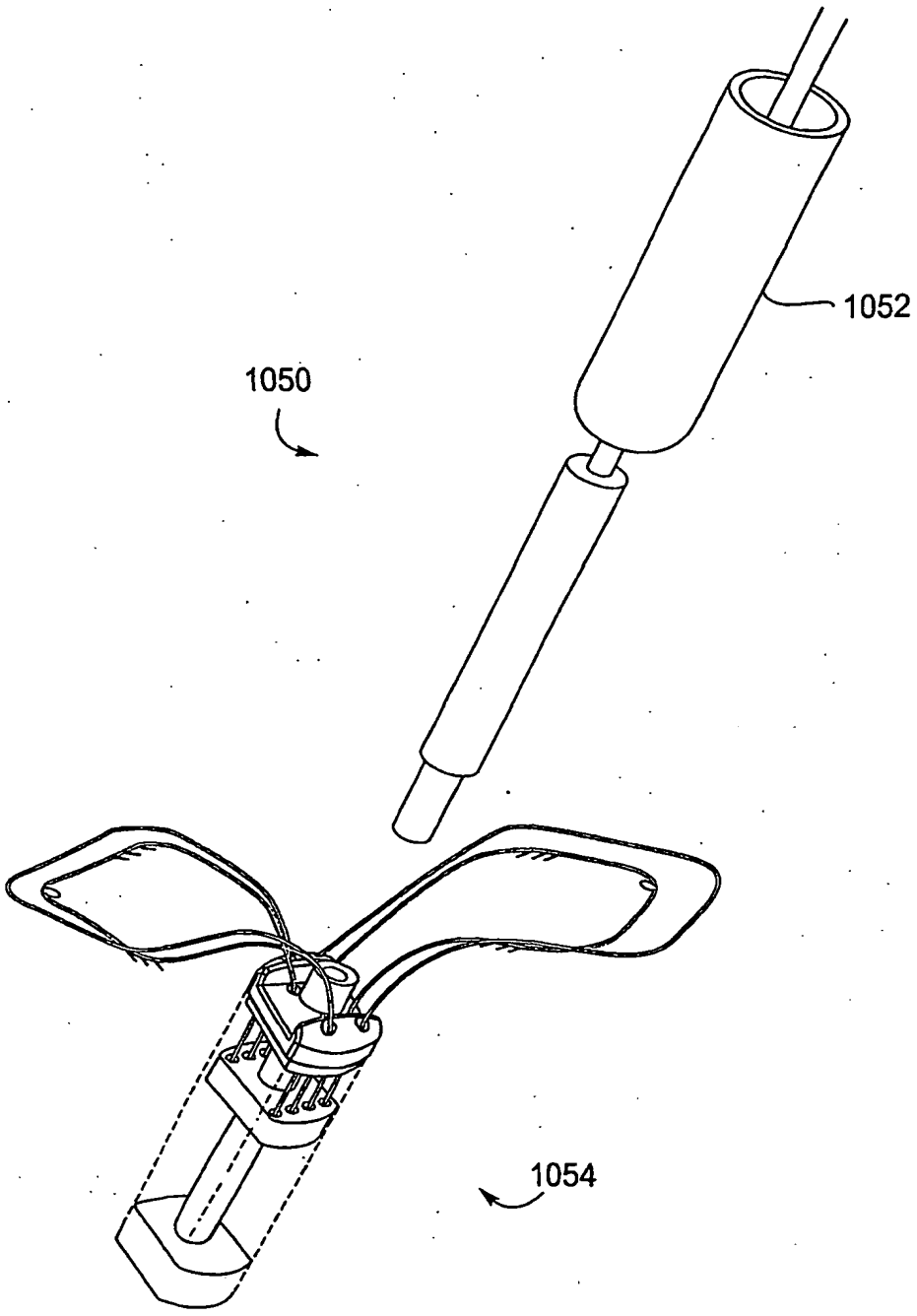


Fig. 58

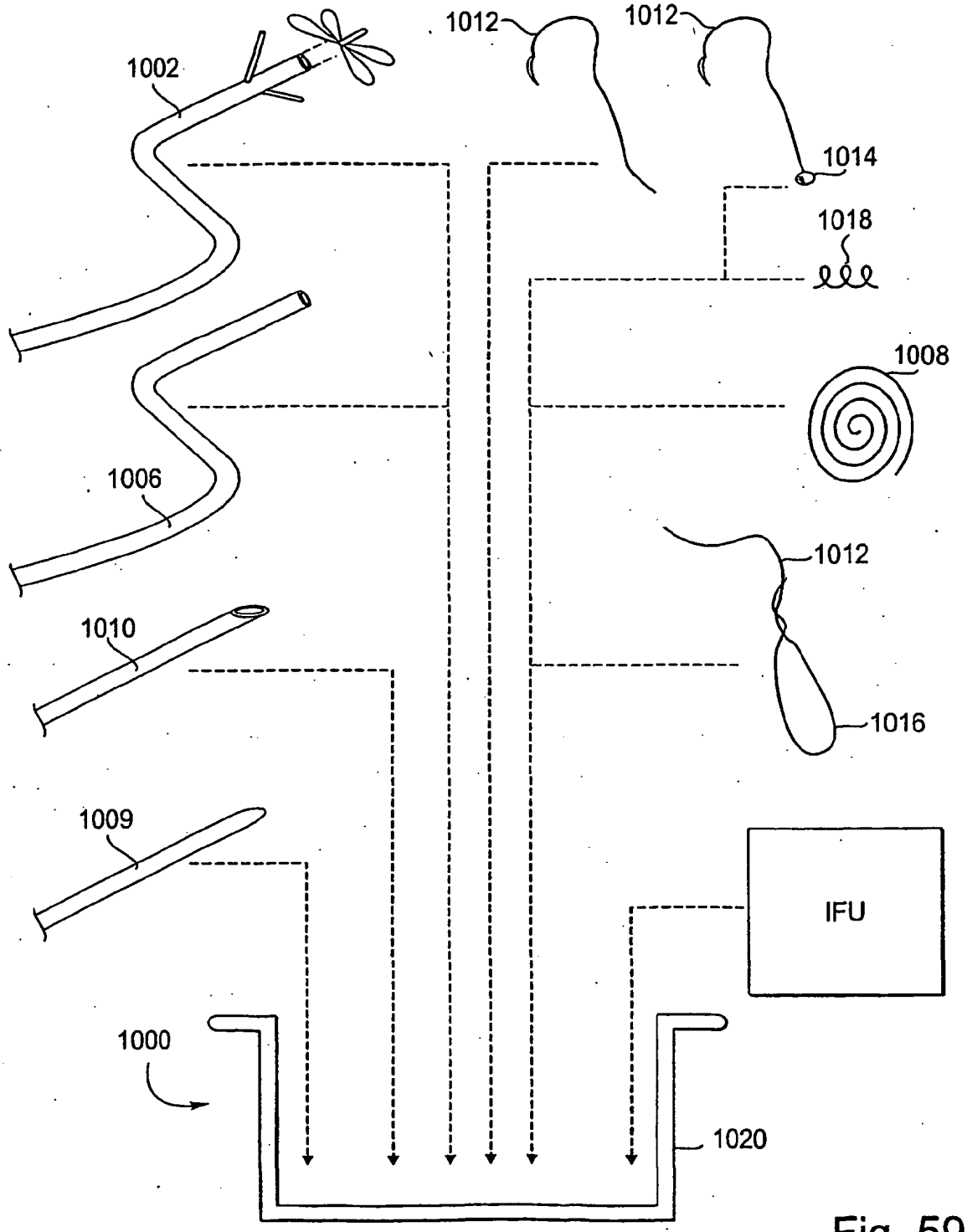


Fig. 59

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- WO 9835638 A **[0006]**
- WO 9900059 A **[0006]**
- WO 9901377 A **[0006]**
- WO 0003759 A **[0006] [0013]**
- US 5840081 A **[0010]**
- US 5411552 A **[0010]**
- US 5554185 A **[0010]**
- US 5332402 A **[0010]**
- US 4994077 A **[0010]**
- US 4056854 A **[0010]**
- US 3671979 A **[0010]**
- US 4917089 A **[0011]**
- US 4484579 A **[0011]**
- US 3874338 A **[0011]**
- WO 9101689 A **[0011]**
- US 5855614 A **[0012]**
- US 5829447 A **[0012]**
- US 5823956 A **[0012]**
- US 5797960 A **[0012]**
- US 5769812 A **[0012]**
- US 5718725 A **[0012]**

Non-patent literature cited in the description

- **Maisano et al.** *Eur. J. Cardiothorac. Surg.,* 1998, vol. 13, 240-246 **[0007]**
- **Fucci et al.** *Eur. J. Cardiothorac. Surg.,* 1995, vol. 9, 621-627 **[0007]**
- **Umana et al.** *Ann. Thorac. Surg.,* 1998, vol. 66, 1640-1646 **[0007]**
- **Dec ; Fuster.** *N. Engl. J. Med.,* 1994, vol. 331, 1564-1575 **[0007]**
- **Alvarez et al.** *J. Thorac. Cardiovasc. Surg.,* 1996, vol. 112, 238-247 **[0007]**
- **Bolling.** *Am. J. Cardiol.,* 1996, vol. 78, 966-969 **[0008]**
- **Kameda et al.** *Ann. Thorac. Surg.,* 1996, vol. 61, 1829-1832 **[0008]**
- **Bach ; Bolling.** *Am. Heart J.,* 1995, vol. 129, 1165-1170 **[0008]**
- **Bolling et al.** *Am. Heart J.,* 1995, vol. 109, 676-683 **[0008]**
- **Ricchi et al.** *Ann. Thorac. Surg.,* 1997, vol. 63, 1805-1806 **[0008]**
- **McCarthy ; Cosgrove.** *Ann. Thorac. Surg.,* 1997, vol. 64, 267-268 **[0008]**
- **Tager et al.** *Am. J. Cardiol.,* 1998, vol. 81, 1013-1016 **[0008]**
- **Abe et al.** *Ann. Thorac. Surg.,* 1989, vol. 48, 670-676 **[0008]**
- **Park et al.** *Circulation,* 1978, vol. 58, 600-608 **[0009]**
- **Uchida et al.** *Am. Heart J.,* 1991, vol. 121, 1221-1224 **[0009]**
- **Ali Khan et al.** *Cathet. Cardiovasc. Diagn.,* 1991, vol. 23, 257-262 **[0009]**

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 637 091 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
22.03.2006 Bulletin 2006/12

(51) Int Cl.:
A61F 2/00 *(2006.01)*

(21) Application number: **05076541.1**

(22) Date of filing: **16.12.1998**

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **17.12.1997 US 992316**

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
98965994.1 / 1 039 851

(71) Applicant: **Myocor, Inc.**
St. Paul, MN 55108 (US)

(72) Inventors:
- **Mortier, Todd J.**
Minneapolis, MN 55408 (US)
- **Schweich, Cyril J., Jr.**
St. Paul, MN 55116 (US)

(74) Representative: **Sundien, Thomas**
Zacco Denmark A/S,
Hans Bekkevolds Allé 7
2900 Hellerup (DK)

Remarks:
This application was filed on 07 -2005 as a divisional application to the application mentioned under INID code 62.

(54) Valve to myocardium tension members device and method

(57) A device for heart valve repair including at least one tension member having a first end and second end. A basal anchor is disposed at the first end of the tension member and a secondary anchor at the second end. The method includes the steps of anchoring the basal anchor proximate a heart valve and anchoring the secondary anchor at a location spaced from the valve such that the chamber geometry is altered to reduce heart wall tension and/or stress on the valve leaflets.

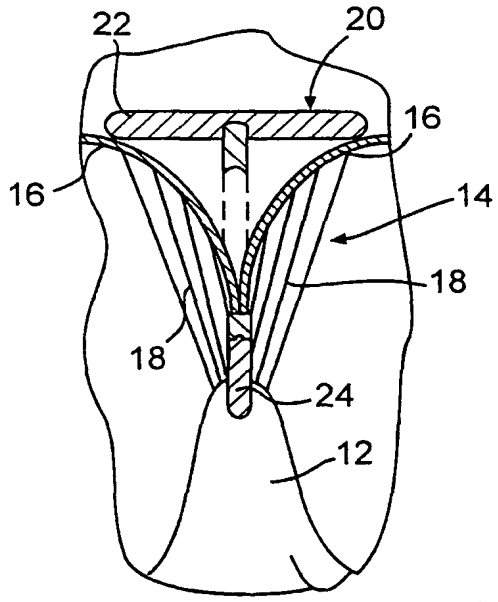


FIG. 6

EP 1 637 091 A2

Description

Background of the Invention

[0001] The present invention pertains generally to the field of heart valve repair. More specifically, the present invention pertains to a device and method for the reduction of myocardial wall tension and the repair of mitral valve insufficiency.

[0002] Dilated cardiomyopathy is often accompanied by mitral valve insufficiency. There are several reasons for the presence of mitral valve insufficiency associated with a dilated heart. First, chamber dilation and associated high wall stresses increase the diameter of the mitral valve annulus. Additionally, as the heart dilates, the positioning of the papillary muscles is altered. Papillary muscles and chordae in a dilated heart will have moved both radially away and down from the mitral valve. This rearrangement of the vascular apparatus and enlargement of the annulus prevent the valve from closing properly.

[0003] Currently mitral valve insufficiency is treated by either repairing or replacing the valve. Surgical procedures used to repair the valve including ring posterior annuloplasty which consists of sewing a C or D-shaped ring around the posterior leaflet of the mitral valve and drawing in the annulus, reducing its previously enlarged diameter. Another method is to approximate the anterior and posterior mitral leaflets (Alfieri repair) by placing one suture through the center of both leaflets. This gives the valve a figure 8-shaped appearance when the valve is opened. When the mitral valve is replaced, the original leaflets are removed and the chordae are cut. An artificial valve consists of mechanical or tissue leaflets suspended on struts attached to a metal stent, and is sutured into place on the mitral annulus.

[0004] It has been argued that valve repair is preferable to valve replacement if the leaflet-chordae-papillary connections can be maintained. Heart wall stress will increase if the chordae are cut during valve replacement. It has been shown that by severing the chordae there can be 30 percent (30%) reduction in chamber function. Mitral valve replacement has high morality in very sick, chronic heart failure patients.

Summary of the Invention

[0005] The present invention pertains to a device and method for mitral valve repair. The mitral valve is generally defined as its leaflets or cusps, but in reality, it actually consists of the entire left ventricle chamber. By creating an improved chamber geometry, both chamber and valve function will be improved. The device of the present invention and method for valve repair/replacement can include treatment for chronic heart failure by reducing left ventricular wall tension.

[0006] In one embodiment of the present invention, the valve repair device includes an elongate tension member having a first end and second end. The basal anchor is disposed at the first end and the secondary anchor is disposed at the second end.

[0007] The basal anchor could include a pad and annuloplasty ring or the like. Alternately an artificial heart valve could serve as the basal anchor.

[0008] Tension members can be substantially rigid or substantially flexible. The secondary anchor can include a hook-shaped papillary muscle tissue loop, screw-shaped tissue anchor or transmural anchor pad.

[0009] The method of the present invention providing a tension member having a first end and a second end. The tension member has a basal anchor at the first end and a secondary anchor at the second end. The basal anchor is anchored proximate to the valve such that the tension member is disposed in the chamber. The secondary anchor is anchored to a portion of the heart spaced from the basal anchor such that the tension member is under tension and the geometry of the chamber has been altered by placement of the tension member.

[0010] The basal anchor can include an artificial heart valve, annuloplasty ring or the like. The secondary anchor can be anchored to a papillary muscle or transmurally anchored.

[0011] More than one tension member can be used. Additionally, a transverse tension member can be placed across the chamber generally perpendicular to the other tension members to further alter the geometry of the heart, reducing wall stress and improving chamber performance.

Brief Description of the Drawings

[0012]

Figure 1 is a transverse cross section of the left ventricle of a human heart taken from Figure 2;
Figure 2 is a vertical cross section of the left ventricle of a human heart;
Figure 3 is a modified, transverse, cross section of the left ventricle of a human heart taken from Figure 4;
Figure 4 is modified, vertical cross section of a human heart, modified by a device in accordance with the present invention;
Figure 5 is a cross section of an insufficient mitral valve of a left ventricle of a human heart;
Figure 6 is a cross section of a repaired valve and device in accordance with the present invention;
Figure 7 is an embodiment of the device of the present invention;
Figure 8 is an alternate embodiment of a device in accordance with the present invention;
Figure 9 is yet another alternate embodiment of a device in accordance with the present invention;
Figure 10 is yet another alternate embodiment of the device in accordance with the present invention;
Figure 11 is yet another alternate embodiment of a

device in accordance with the present invention;
Figure 12 is a view of a basal anchor for the device of the present invention;
Figure 13 is a suture ring serving as a basal anchor for the device of the present invention;
Figure 14 is a replacement valve serving as a anchor for the device of the present invention;
Figure,15 is a top view of an alternate embodiment of a suture ring acting as an anchor for the device of the present invention;
Figure 16 is a side view of the suture ring of Figure 15;
Figure 17 is a view of an alternate embodiment of a suture ring which can act as basal anchor for the device of the present invention;
Figure 18 is a view of yet another alternate embodiment of a suture ring which can act as a basal anchor for the present invention;
Figure 19 is a embodiment of a secondary anchor for the device of the present invention;
Figure 20 is a view of an alternate embodiment of a secondary anchor for the device of the present invention; and
Figure 21 is yet another embodiment of a secondary anchor for the device of the present invention.

Detailed Description of the Invention

[0013] Referring now the drawings wherein like reference numerals refer to like elements throughout the several views, Figure 1 shows a transverse cross section of the left ventricle 10 of a failing heart taken from Figure 2. The papillary muscles 12 are shown in cross section. Figure 2 is a vertical cross section of human heart 10. A mitral valve is disposed near the top of left ventricle 10. Mitral valve 14 includes two leaflets or cusps 16. Chordae 18 extend between leaflets 16 and papillary muscles 12.

[0014] Figure 3 is a cross section of heart 10 modified from that shown in Figure 1 by placement of valve repair device 20 in accordance with the present invention as shown in Figure 4. Figure 4 is a vertical cross section of left ventricle 10 with geometry modified by device 20. In this embodiment of the invention, device 20 includes a basal anchor 22 such as an annuloplasty or suture ring sewn proximate the annulus of valve 14. Extending from basal anchor 22 are elongate tension members 24. Each have a first end connected to basal anchor 22 and a second end anchored to papillary muscles 12 or the heart wall.

[0015] As can be seen in Figures 3 and 4, both the transverse radius and vertical dimension of left ventricle 10 has been reduced in comparison to that of Figures 1 and 2 by drawing papillary muscles 12 toward valve 14 with tension members 24. This change in geometry reduces heart wall stress and consequently increasing chamber function. Valve function is also improved as explained in more detail by reference to Figures 5 and 6.

[0016] Figure 5 is a generally vertical cross section of an insufficient mitral valve of a heart suffering from chronic heart failure. In this case as the failing heart has dilated, papillary muscle 12 has been drawn away from mitral valve 14. The chordae connections between papillary muscles 12 and valve 14 in turn draws leaflets 16 apart such that during the normal cardiac cycle, leaflets 16 may not completely close. Thus, an opening 26 is left between leaflets 16 throughout the cardiac cycle. Opening 26 will allow blood to leak, reducing chamber efficiency.

[0017] Figure 6 is a view of the mitral valve 14 of Figure 5 which has been modified by placement of valve repair device 20 as shown. Suture ring 22 is sewn proximate the annulus of valve 14, as known to those skilled in the use of suture rings. The annulus of valve 14 can be decreased in size by drawing the annulus toward the suture ring by the sutures used to connect ring 22 to the valve. Drawing the annulus of valve 14 toward suture ring 22 will help to eliminate opening 26. Tension member 24 is then anchored to papillary muscle 12 such that papillary muscle 12 is drawn toward valve 14. Whether or not the suture ring alone is sufficient to eliminate opening 26, drawing papillary muscle 12 toward valve 14 will provide additional stress relief on leaflet 16 promoting complete closure of valve 14. Drawing papillary muscle 12 toward 14 also reduces heart wall stress and increases chamber efficiency as discussed previously.

[0018] Figure 7 is a highly simplified view of left ventricle 10 and valve repair device 20 as shown in Figure 4. It can be noted that tension members 24 extend from basal anchor 22 to an adjacent papillary muscle 12. In contrast, Figure 8 is a similar cross sectional view of left ventricle 10, but a valve repair device 120 is placed such that its tension members 124 extend between a basal anchor 122 and a papillary muscle 12 transversely opposite the point at which tension member 124 is connected to basal anchor 122. This arrangement, as opposed to that shown in Figure 7, can increase the transverse component of the tension force in tension members 124 relative to the vertical component of that tensile force.

[0019] Figure 9 shows yet another embodiment of the valve repair device in accordance with the present invention referred to by numeral 220. In this embodiment, device 220 is disposed in left ventricle 10 in a manner similar to that of device 20 shown in Figure 7 in that tension members 224 of device 220 extend from a basal anchor 222 to an adjacent secondary anchor point. The secondary anchor point is established by transverse extension of a tension member 225 across left ventricle 10. Tension member 225 is anchored transmurally to the heart wall at its opposite ends by pads 227. In turn, tension members 224 are anchored or connected to tension member 225.

[0020] Tension member 225 can be used to further alter the geometry of left ventricle 10 in a manner disclosed in U.S. Patent Application Serial No. 08/933,456, entitled "HEART WALL TENSION REDUCTION APPARATUS AND METHOD", which was filed on September 18, 1997 and is incorporated herein by reference.

[0021] Figure 10 shows yet another embodiment of a

valve repair device in accordance with the present invention referred to by numeral 320. This embodiment includes a basal anchor 322 and tension members 324 and a transverse tension member 325 having anchor pads 327 similar to those of device 220. With respect to device 320, however, tension members 324 are crossed similar to those of device 120 of Figure 8 to increase the horizontal component relative to the vertical component of the tensile force in tension member 324.

[0022] Figure 11 is a yet another embodiment 420 of the valve repair device of the present method. Valve repair device 420 includes a basal anchor 422 and tension members 424. Tension members 424 are disposed in an arrangement similar to tension members 24 of device 20 shown in Figure 7 except_that tension members 424 are anchored transmurally by pads 427 rather than into papillary muscles 12. The relatively greater thickness of tension members 424 shown in Figure 11, as compared to tension members 24 shown in Figure 7, merely illustrates that the tension members can be substantially rigid or in the case of tension members 24, substantially flexible. It should be understood, however, that in any of the embodiments shown herein, the tension members could be advantageously formed to be substantially flexible or substantially rigid.

[0023] Figure 12 is a top or posterior view of valve 14. In this embodiment, the basal anchor for the valve repair device is shown as discrete pads 28 which can be sewn to the posterior side of valve 14. Tension members 24 are shown extending from respective pads 28 into the left ventricle.

[0024] Figure 13 is the same view of valve 14 as Figure 12. In Figure 13, however, the basal anchor 22 is shown as a crescent-shaped suture ring. Tension members 24 extends from basal anchor 22 through valve 14 into the left ventricle.

[0025] Figure 14 is a side view of an artificial heart valve 30. If it is necessary to replace the valve rather than merely repair it, artificial valve 30 can be used as a basal anchor for tension members 24.

[0026] Figure 15 is a top view of an alternate embodiment of a suture ring basal anchor 32. Ring 32 has a crescent shape and a pylon 34 extending through the mitral valve. Figure 16 is a side view of suture ring 32 showing tension members 24 attached to pylon 34.

[0027] Tension members 24 preferably extend through the tissue of valve 14 rather than through the valve opening. It can be appreciated, however, that tension members 24 could be disposed through the valve opening. In the case of the embodiment of Figures 15 and 16, however, pylon 34 would be disposed through the valve opening. Tension members 24 associated with pylon 34 would be disposed on the opposite side of valve 14 from suture ring 32. Pylon 34 would preferably be disposed through the valve opening rather than the tissue forming valve 14.

[0028] Figures 17 and 18 are yet additional alternate embodiments of suture rings which can be used as basal anchors in accordance with the present invention. The shape of the rings is selected such that as they are sewn into place on valve 14, the sutures can be used to draw tissue toward the inside of the ring, thus reducing the transverse and/or vertical cross sectional area of the associated heart chamber. This will advantageously reduce heart wall stress which is of particular benefit if the patient has a failing heart.

[0029] It can be appreciated that tension members 24 can be fixably or releasably attached to the basal anchor. Preferably, the tension members are fixably attached to the basal anchor during the valve repair procedure.

[0030] Figures 19-21 show various configurations of anchoring devices shown at the second end of tension member 24. It can be appreciated that these anchoring devices could be used with each of the tension members described above. In Figure 19, the second end of tension member 24 includes a secondary anchor 40 formed as screw which is shown augured into papillary muscle 12. Figure 20 shows a secondary anchor 42 including a loop sewn through papillary muscle 12. Figure 21 shows a tension member 24 extending transmurally to an exterior pad 44 to which it is connected. Tension member 24 could be sewn to pad 44 or otherwise mechanically connected thereto.

[0031] It can be appreciated that various biocompatible materials can be advantageously used to form the various components of the device of the present invention. It is anticipated that the present device will usually be chronically implanted. Thus, when selecting materials to form each of the components consideration should be given to the consequences of long term exposure of the device to tissue and tissue to the device.

[0032] Numerous characteristics and advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of parts without exceeding the scope of the invention. The inventions's scope is, of course, defined in the language in which the appended claims are expressed.

Claims

1. A device for treating an in situ valve of a heart, the device comprising:

   at least one curved member configured to be disposed proximate an annulus of an in situ valve so as to extend along at least a portion of the annulus; and

   at least one elongate member having a first portion configured to be secured to the curved member and a second portion configured to be secured to a portion of one of a wall of the heart and a papillary muscle,

   wherein the device is configured to draw togeth-

er leaflets of the valve during at least a portion of the cardiac cycle.

2. The device of claim 1, wherein the device is configured to alter a shape of an annulus of the valve.

3. The device of claim 2, wherein the device is configured to reduce a radius of curvature of at least part of the annulus of the valve.

4. The device of claim 1, wherein the device is configured to alter at least one of a transverse radius and a vertical dimension of the heart chamber.

5. The device of claim 1, wherein the device is configured to alter the position of at least one papillary muscle associated with the valve.

6. The device of claim 1, wherein the curved member includes an annuloplasty ring.

7. The device of claim 1, further comprising at least one suture configured to connect the curved member to at least the portion of the valve annulus.

8. The device of claim 1, wherein the elongate member is a tension member.

9. The device of claim 1, further comprising an anchor assembly configured to be secured to the second portion of the elongate member and configured to secure the second portion of the elongate member to one of the portion of the heart wall and the papillary muscle.

10. The device of claim 9, wherein the anchor assembly is configured to be fixedly secured to the second portion.

11. The device of claim 9, wherein the anchor assembly is mechanically coupled to the second portion.

12. The device of claim 9, wherein the anchor assembly includes an anchor pad configured to be disposed on an external surface of the heart.

13. The device of claim 1, further comprising a plurality of elongate members, each of the elongate members having a first portion configured to be secured to the curved member and a second portion configured to be secured to a respective portion of one of a wall of the heart and a papillary muscle.

14. The device of claim 13, further comprising an anchor assembly configured to be secured to the second portion of each of the elongate members and configured to secure the second portion of each of the elongate members to the respective portion of one of a wall of the heart and a papillary muscle.

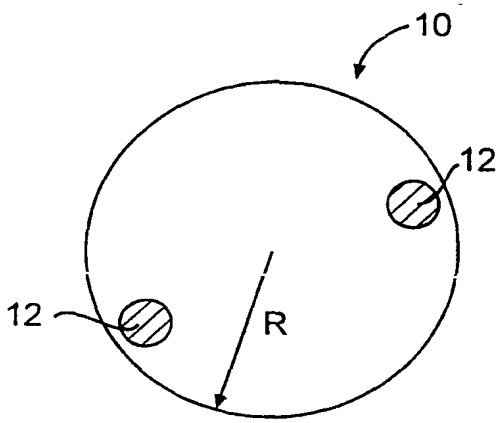


FIG. 1

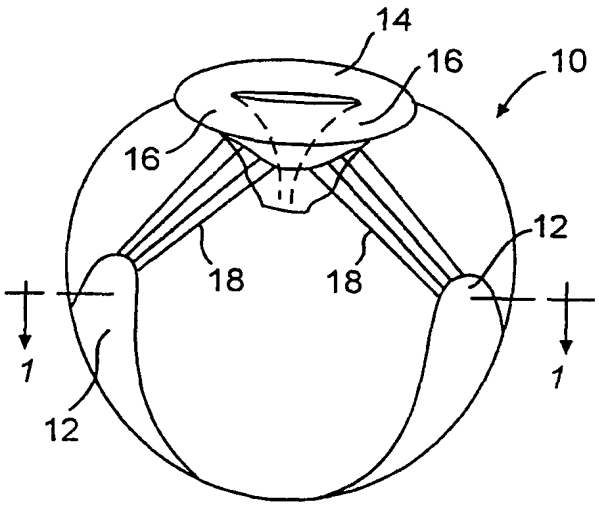


FIG. 2

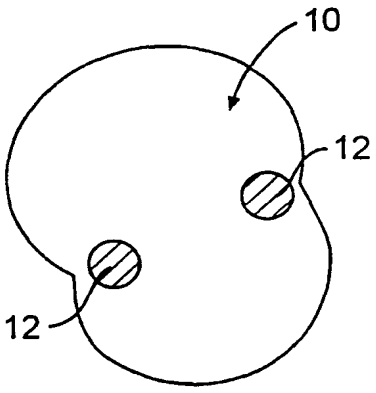


FIG. 3

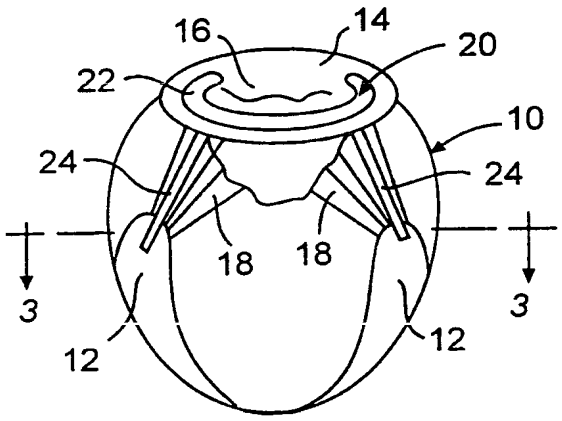


FIG. 4

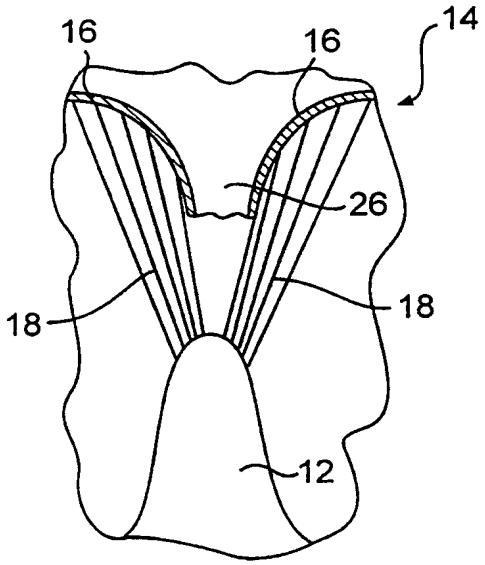


FIG. 5

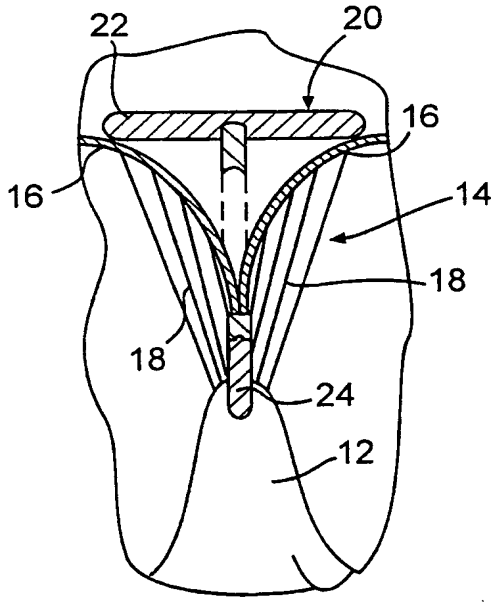


FIG. 6

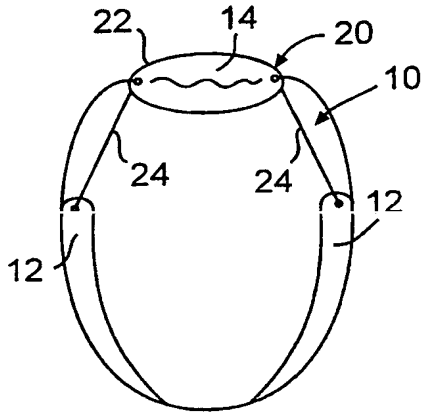


FIG. 7

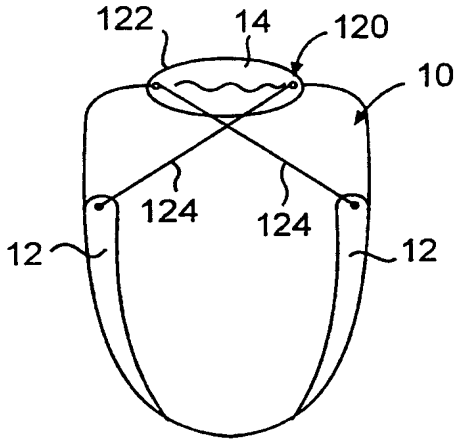


FIG. 8

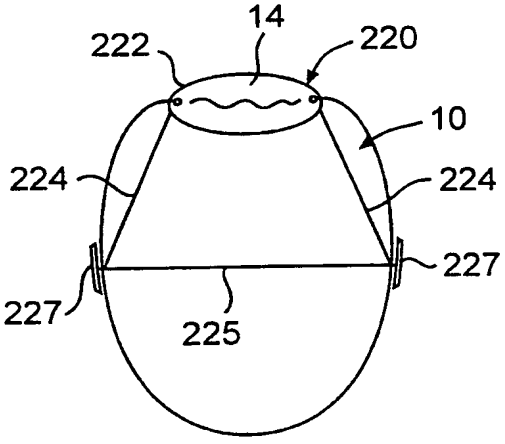


FIG. 9

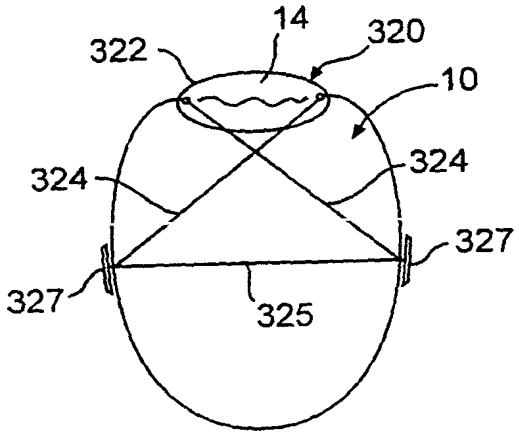


FIG. 10

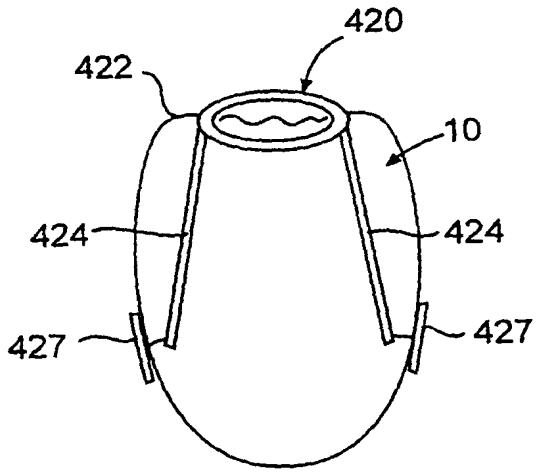


FIG. 11

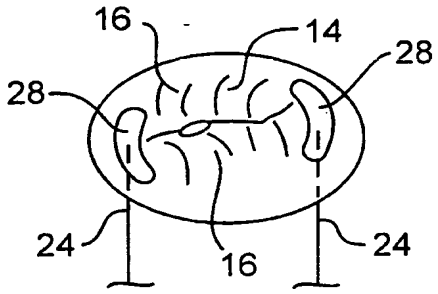


FIG. 12

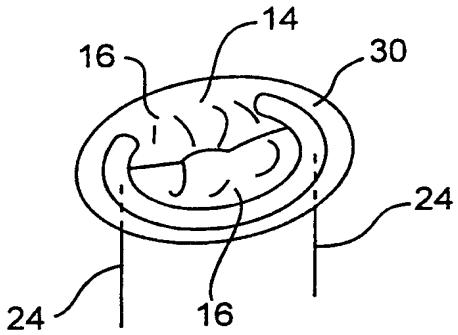


FIG. 13

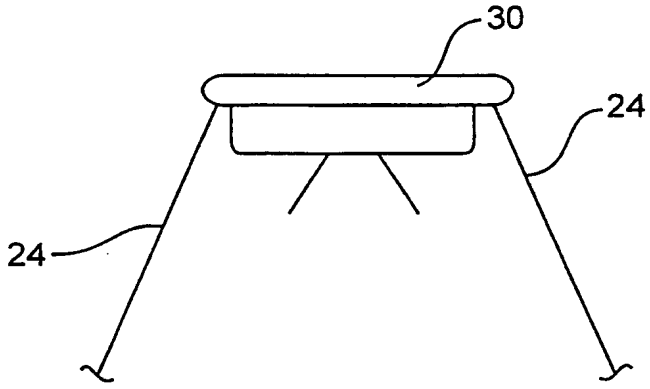


FIG. 14

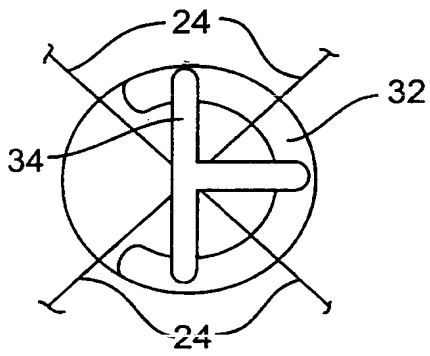


FIG. 15

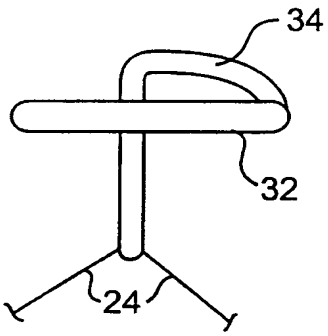


FIG. 16

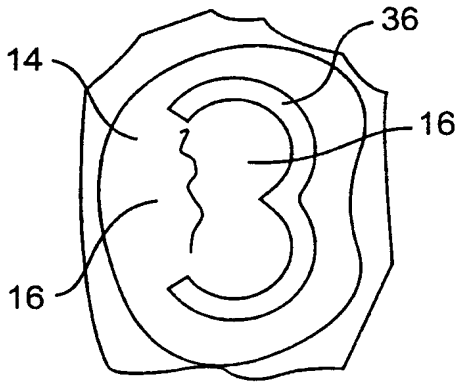


FIG. 17

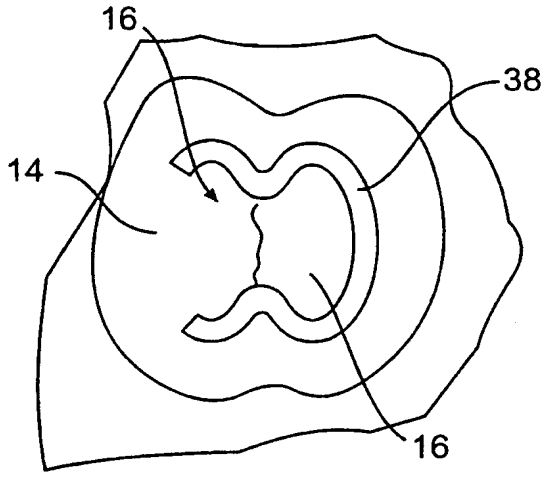


FIG. 18

FIG. 19

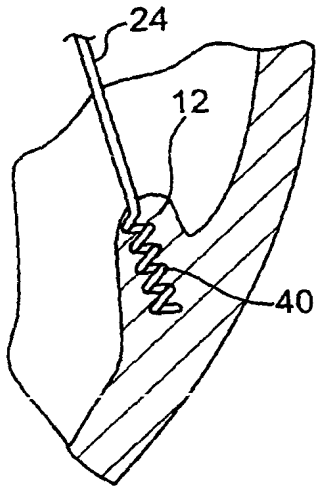


FIG. 20

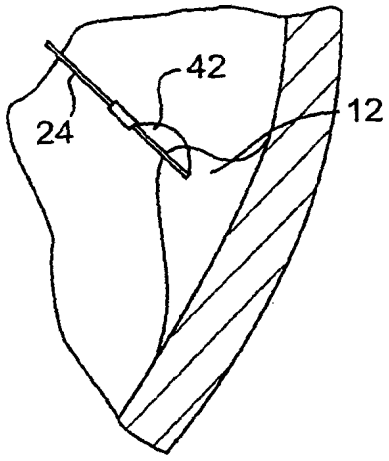
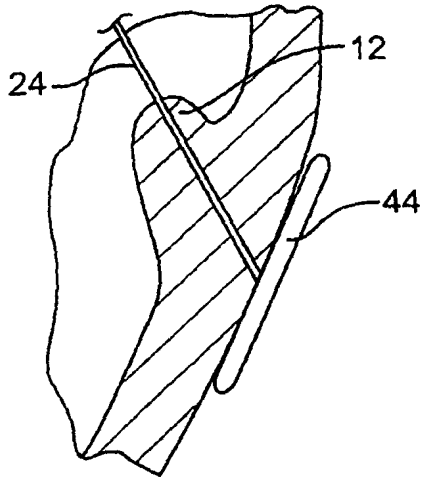


FIG. 21



(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Veröffentlichungsnummer:
(11) Publication number: **EP 1 845 861 A0**
(11) Numéro de publication:

Internationale Anmeldung veröffentlicht durch die Weltorganisation für geistiges Eigentum unter der Nummer:

WO 2006/078694 (art. 158 des EPÜ).

International application published by the World Intellectual Property Organisation under number:

WO 2006/078694 (art. 158 of the EPC).

Demande internationale publiée par l'Organisation Mondiale de la Propriété sous le numéro:

WO 2006/078694 (art. 158 de la CBE).

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
A61B 17/10

A1

(11) International Publication Number: **WO 99/00059**

(43) International Publication Date: 7 January 1999 (07.01.99)

(21) International Application Number: PCT/US98/13240

(22) International Filing Date: 25 June 1998 (25.06.98)

(30) Priority Data:
60/051,078 27 June 1997 (27.06.97) US

(71) Applicant *(for all designated States except US)*: THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK [US/US]; West 116th Street and Broadway, New York, 10027 (US).

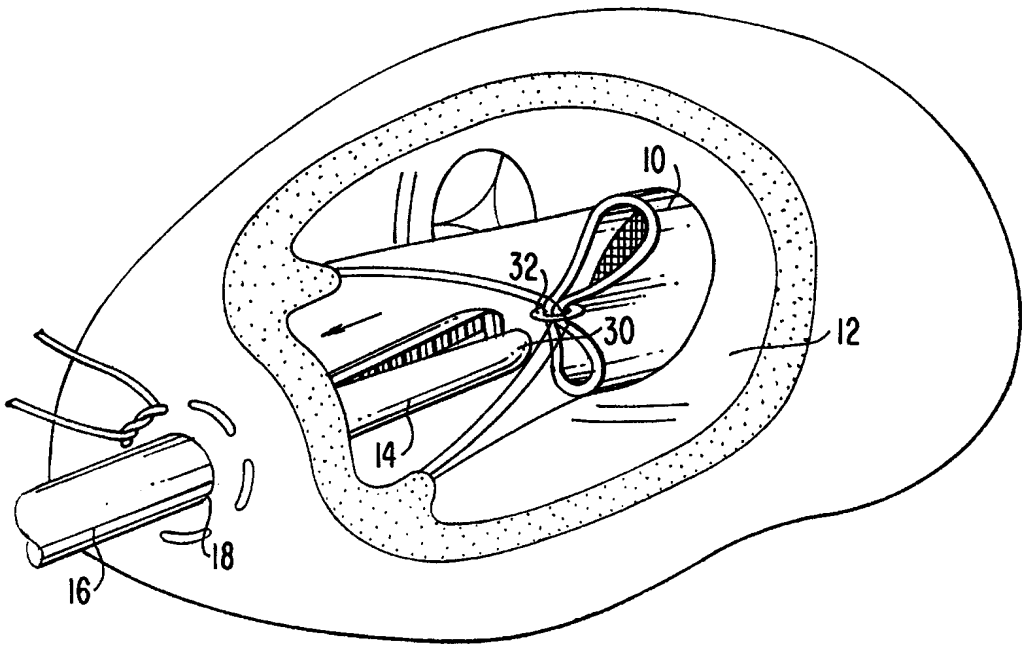
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: OZ, Mehmet, C. [US/US]; Villa G, 100 Winston Drive, Cliffside Park, NJ 07010 (US). LEMOLE, Gerald, M. [US/US]; 404 Tomlinson Road, Huntingdon Valley, PA 19006 (US). LOTVIN, Alan [US/US]; 7 Lilline Lane, Upper Saddle River, NJ 07458 (US). UMANA, Juan, P. [CO/US]; c/o Oz, Mehmet, C., Milstein Pavilion 7–435, 177 Fort Washington Avenue, New York, NY 10032 (US). LEVIN, Howard, P. [CO/US]; 406 Pomander Walk, Teaneck, NJ 07666 (US). ALLEN, William [US/US]; 30 Cut Spring Road, Stratford, CT 06614 (US).

(74) Agents: DIPPERT, William, H. et al.; Cowan, Liebowitz & Latman, P.C., 1133 Avenue of the Americas, New York, NY 10036–6799 (US).

(81) Designated States: AU, CA, IL, JP, MX, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: METHOD AND APPARATUS FOR CIRCULATORY VALVE REPAIR



(57) Abstract

An apparatus (16) for the repair of a cardiovascular valve having leaflets comprises a grasper (16) capable of grabbing, and co–apt the leaflets of the valve. Preferably the grasper (16) has jaws (30) that grasp, immobilize the leaflets, and then a fastener (32) is inserted to co–apt the leaflets. The apparatus (16) is particularly useful for repairing mitral valves to cure mitral regurgitation.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

METHOD AND APPARATUS FOR CIRCULATORY VALVE REPAIR

FIELD OF THE INVENTION

The present invention relates generally to the field of circulatory valve repair. More particularly, the present invention relates to the field of the repair of heart valves and specifically for the repair of mitral heart valves, for patients suffering from mitral regurgitation.

BACKGROUND OF THE INVENTION

There are four valves in the heart that serve to direct the flow of blood through the two sides of the heart in a forward direction. On the left side, the mitral and aortic valves direct oxygenated blood coming from the lungs, through the left side of the heart, into the aorta for distribution to the body. On the right side, the tricuspid valve, located between the right atrium and the right ventricle, and the pulmonary valve, located between the right ventricle and the pulmonary artery, direct de-oxygenated blood coming from the body, through the right side of the heart, into the pulmonary artery for distribution to the lungs. The anatomy of the heart and the structure and terminology of heart valves are described and illustrated in detail in numerous reference works on anatomy and cardiac surgery, including standard texts such as *Surgery of the Chest* (Sabiston and Spencer, eds., Saunders Publ., Philadelphia) and *Cardiac Surgery* by Kirklin and Barrett-Boyes, Pathology and Abnormalities of Heart Valves, incorporated herein by reference.

All four heart valves are passive structures in that they do not themselves expend any energy and do not perform any active contractile function. They consist of moveable "leaflets" that are designed simply to open and close in response to differential pressures on either side of the

valve. The mitral valve has two leaflets and the triscupid valve has three. The aortic and pulmonary valves are referred to as "semilunar valves" because of the unique appearance of their leaflets, which are most aptly termed "cusps" and are shaped somewhat like a half-moon. The components of the mitral valve assembly include the mitral valve annulus; the anterior leaflet; the posterior leaflet; two papillary muscles which are attached at their bases to the interior surface of the left ventricular wall; and multiple chordae tendineae, which couple the mitral valve leaflets to the papillary muscles.

. The problems that can develop with valves can be classified into two categories: (1) stenosis, in which a valve does not open properly, or (2) insufficiency, or regurgitation, in which a valve does not close properly.

Mitral regurgitation ("MR") is caused by dysfunction of the mitral subvalvular apparatus or direct injury to the valve leaflets. Multiple etiologies can lead to mitral regurgitation, with myxomatous degeneration of the valve and ischemic heart disease accounting for close to 60% of cases. Repair of the diseased valve requires major surgery on cardiopulmonary bypass to allow access to the valve. Consequently, some patients in the early or late stages of the disease are not considered appropriate candidates due to the high risk associated with the operation. Multiple studies have demonstrated that prosthetic replacement of the mitral valve can lead to significant postoperative left ventricular dysfunction and often requires lifelong treatment with anticoagulants. Mitral valve repair, using a posterior annuloplasty ring, has demonstrated improved results with better ventricular recovery. Nevertheless, recent studies performed by the inventors (Umana et al., Surg Forum 1997) have revealed that posterior ring annuloplasty causes changes

in ventricular geometry that lead to paradoxical movement of the normal papillary muscles, further deteriorating ventricular performance. In contrast, the "bow-tie" repair in which the anterior and posterior leaflets of the mitral valve are fixed in opposition appears to enhance annular contractility while preserving ventricular architecture. This has resulted in improved postoperative ventricular function almost uniformly.

The present invention addresses the needs of all patients with mitral regurgitation without mitral stenosis, including those who heretofore may have been excluded due to having only moderate MR or being too sick to be candidates for major surgery.

The present invention finds utility not only for the repair of mitral valves but for all valves of the circulatory system, including aortic valves, tricuspid valves, and venous valves.

Techniques for improving the efficacy of corporeal valves are known. For example, Laufer et al., U.S. Patent No. 5,609,598 describes a valving system for treatment of chronic venous insufficiency. The system has inherent limitations in terms of its effectiveness for the procedure described and its applicability, if any, to other valves, especially cardiac valves.

SUMMARY OF THE INVENTION

The present invention is directed to a method and apparatus for use in heart valve repair involving the use of an inserted device or grasper for grabbing and clasping together the anterior and posterior leaflets of the valve, by insertion into the left ventricle through the right chest via a thorascope, through the jugular vein, or through the

femoral artery. The grasper will grab both leaflets, preferably after the heart has been stopped or slowed pharmacologically. The correctness of the initial grasp is assessed by, for example, intraoperative echocardiography, to ensure, for example, in the case of the mitral valve, that the mitral regurgitation is resolved. If not, the grasper will be able to "adjust" the leaflets to allow better coaptation or, if needed, re-grab the leaflets in a different location.

Either inherent to the grasper, as an integrally attached component or as a separate device, a fastening device is introduced and a fastener is deployed to securely hold the leaflets in place after the grasper has been released. The remaining portion of the device, or optionally any separate device, is then removed.

Accessory devices needed for the procedure include instruments for thoracoscopic or percutaneous approaches. While the preferred method and apparatus described hereinbelow is discussed with reference to its use in connection with mitral valve repair, it is contemplated that the same or substantially similar apparatus and methodology would also be useful in repairing other valves found in the human circulatory systems, particularly other heart valves, such as, for example, venous valves, aortic valves and tricuspid valves, amongst others.

OBJECTS OF THE INVENTION

It is an object of the invention to provide a method for the repair of heart valves to increase their efficiency.

It is a further object of the invention to provide for a method for the repair of mitral valves to reduce mitral regurgitation.

It is also an object of the invention to provide for a method for the repair of the mitral valves which eliminates the need for cardiopulmonary bypass surgery.

It is a further object of the invention to provide for an apparatus for percutaneous insertion into the heart to effect the repair of a heart valve.

It is a yet further object of the invention to provide for the repair of a mitral valve by percutaneous insertion of a grasping and fastening device into the heart to repair a mitral valve and reduce or eliminate mitral regurgitation.

These and other objects of the invention will become apparent to one skilled in the art from the more detailed description given below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1 to 4 are each a schematic representation of a portion of the human heart showing the mitral valve, the left ventricle and an apparatus of the invention in operation;

FIG. 5 is a schematic representation of an embodiment of the distal portion of an apparatus of the invention useful for grasping a mitral valve;

FIG. 6 is a schematic representation of an embodiment of a distal portion of an apparatus of the invention showing a configuration of a fastener holder and a fastener clip in the open position;

FIG. 7 is a schematic representation of an embodiment of FIG. 6 showing the release and closure of the fastener clip;

FIG. 8 is a detailed, partly cross-sectional schematic representation of the distal end of a preferred embodiment of a grasper device according to the invention in the open position;

FIG. 9 is a detailed, partly cross-sectional schematic representation of the preferred embodiment of a grasper device according to the invention shown in FIG. 8 in a closed position depicting the translocated adjustable grasper and fastener anvil within the jaws;

FIG. 10 is a cross-sectional representation across line 10-10 of the adjustable grasper shown in FIG. 9;

FIG. 11 is a detailed schematic representation of a preferred embodiment of the grasper device of the apparatus of the invention in the closed position with the integral closure means shown;

FIG. 12 is a detailed schematic representation of the preferred embodiment depicted in FIG. 9 showing the closure means piercing the leaflets of the valve;

FIG. 13 is a detailed, partly cross-sectional schematic representation of yet another preferred embodiment of the distal end of a grasper device according to the invention showing the use of a coil closure means;

FIGS. 14, 15, and 16 are partly cross-sectional schematic representations of another embodiment of the invention, wherein a self-closing closure is used;

FIG. 17 is a schematic representation of the self-sealing closure;

FIGS. 18 and 19 are schematic representations of an embodiment of the invention with a three-piece closure;

FIG. 20 is a schematic representation of an embodiment of the invention with a three-piece closure;

FIGS. 21 and 22 are oblique, schematic representations of a valve leaflet closure useful according to the invention;

FIG. 23 is a partial cross-sectional view of the closure

shown in FIGS. 21 and 22;

FIG. 24 is an oblique, schematic representation of another valve leaflet closure useful according to the invention;

FIG. 25 is a partial cross-sectional view of the closure in FIG. 24 in position;

FIGS. 26 to 28 are each an oblique, schematic representation of a spiral coil valve leaflet closure useful according to the invention;

FIG. 29 is an oblique schematic representation of a U-shaped valve leaflet closure useful according to the invention; and

FIG. 30 is a partly cross-sectional view of the closure shown in FIG. 29.

DETAILED DESCRIPTION OF THE INVENTION

The invention can perhaps be better appreciated by making reference to the drawings. In FIG. 1 a portion of the human heart is depicted showing a mitral valve 10, a left ventricle 12 and the distal end 14 of a grasper apparatus of the invention 16, which has been inserted through an incision 18 in left ventricle 12. Incision 18 is loosely sutured with sutures 20 to loosely hold distal end 18 and to prevent bleeding.

Mitral valve 10 comprises anterior leaflet or cusp 22 and posterior leaflet or cusp 24, as well as two commissural cusps (not shown). The primary intent of the invention herein is to secure the distal sections 26 and 28 of cusps 22 and 24, respectively, together or substantially adjacent.

As can be seen in FIG. 2, the jaws 30 of distal end 14 are separated and positioned exterior to cusps 22 and 24.

Then, as shown in FIG. 3, jaws 30 are clamped together to cause cusp distal sections 26 and 28 to come together. Once a closure is embedded, such as the loop closure 32 in FIG. 4, jaws 30 are opened slightly so that distal section 14 can be withdrawn.

The distal ends of the grasper means can vary greatly. It is contemplated that a variety of grasper means may be employed having differing grasper configurations and elements. For example, it is contemplated that the grasper means could be of the type wherein one side of the grasper is stationary and the other side movable. Alternatively, the grasper means might be of the type wherein both sides are movable in concert. Another alternative arrangement comprises a grasper means having multiple grasper elements to enable one to grasp and hold the leaflets of the valve in multiple locations. It is also contemplated that the grasper elements themselves might comprise one or more suction elements to secure and hold the valve leaflets in place. Preferably the grasper will have the capacity to adjust the leaflets of, for example, a mitral valve to obtain optimal coaptation.

In addition it is contemplated that the grasper may comprise additional technology to facilitate the operation of the grasper. For example, the grasper may have echo doppler probe or a similar visualization technology that would allow even better localization of the leaflets and confirmation of ideal coaptation.

FIG. 5 depicts the grasper end 36 of a percutaneous apparatus 38 with jaws 40 in the open position. Jaws 40 of grasper end 36 are movably engaged about joint 42 such that the jaws may be easily and freely opened or closed by the operator of the percutaneous apparatus.

Depicted in FIG. 6 is an embodiment of the invention showing one possible configuration of a fastener holder 44 with a fastener clip 46 in place held in the open position for placement over the grasped leaflets of a mitral valve. The fastener holder 44 and fastener clip 46 may be integral with a grasper end as shown in FIG. 5 or separate from it, in which case it will be necessary to also provide a secondary percutaneous means for use in delivering and manipulating the fastener holder 44 and releasing and fixing the fastener clip 46 in the proper position about the leaves of a mitral valve, once they have been properly grasped by jaws 40 of grasper end 36.

FIG. 7 is a more detailed schematic representation of the fastener holder 44 with its jaws 48 in their open position and fastener clip 46 in place in the open position (dotted line). Also shown is fastener clip 46 in its released, closed position. Fastener clip 46, which may have a closed diameter of from about 3 to 7 mm, preferably about 5 mm, will be comprised of a suitable material such as stainless steel, nitinol, or titanium.

FIG. 8 depicts a detailed, partly cross-sectional schematic representation of a preferred embodiment of the grasper device of the present invention, comprising grasper end 50, movable jaws 52 which are movably engaged about joint 54, in the open position, in proximity to valve leaflets 56. Each jaw 52 has a protruding grasping surface 58. However, the grasping surface 58 of one jaw 52 is operatively and slidably connected to a control member 60 to enable one to properly align valve leaflets 56, prior to fastening.

In FIG. 9 the grasper device of the apparatus of the invention shown in FIG. 8 is in a closed position. Moveable jaws 52 have protruding grasper surfaces 58, which engage valve leaflets 56. Leaflets 56 are translocated to a more

optimum position for fastening by the action of control member 60 on one of protruding grasping surfaces 58, as shown in FIG. 11. Also, stapler action rod 68 is now operatively connected to stapler control member 70.

FIG. 10 is a schematic representation of a cross section of the adjustable grasper depicted in FIG. 9. The jaws comprise grasper surfaces 58, an upper anvil 62 with recess 71, and a lower anvil 64 within which is located a staple type fastener 66 to effect the fastening of valve leaflets.

As shown in FIGS. 9, 11, and 12, lower anvil 64 has at least one slanted surface member 72. When stapler action rod 68 is forced distally against slanted surface member 72, stapler fastener 66 is forced through leaflets 56 into upper anvil 62 to close stapler fastener 66.

In another embodiment of the invention shown in FIG. 13, a grasper 80 comprises jaws 82,84. Jaw 82 is movably connected to rod 86 at pivot point 87, and jaw 84 is movably connected at pivot point 88 to rod 90. Rod 92 is movably connected to jaw 84 at pivot 94. Operation of rods 90 and 92 causes jaws 82 and 84 to open and close on valve leaflets 96. Axial to grasper 80 is a sheath 98 containing a drive mechanism 100 for rotating coil fastener 102. Coil fastener 102 advances in a spiral mode piercing leaflets 96 in multiple locations as coil 102 is advanced into its final position.

Rods 86, 90, and 92 are each operatively connected to one or more control mechanisms (not shown). Also, distal section jaws 82,84 may be slidable within grasper sheath 81.

Another device 110 of the invention is shown in FIGS. 14 to 16, where jaws 112 are operatively connected to a handle mechanism (not shown). Device 110 comprises a movable sheath 114 that contains a straightened closure fastener 116 that is

capable of resuming or forming a circular shape to coapt valve leaflets (not shown). Device 110 has a slidably extruding grasping surface 118 that is operatively connected to the handle mechanism.

Once jaws 112 are closed, the distal tip of sheath 114 is advanced distally to be adjacent grasping surface 118 and its cooperating grasping surface 122. A pusher 124 coerces fastener 116 to advance out of the distal end 126 of sheath 114 to form a circular shape. Fastener 116 in this shape will coapt valve leaflets 120, as can be seen in FIG. 17.

The device 130 of the invention shown in FIGS. 18 and 19 is intended to form a three-piece closure device. Jaws 132 each removably hold a closure member 134 having a grasping surface 136. Located axially with device 130 is a closure crimper 138 that is removably fastened at the distal end 140 of a device rod 142. When jaws 132 grasp valve leaflets 144, closure crimper 138 is advanced distally by device rod 142 to fit over the proximal ends of closure members 134. The closure formed is shown in FIG. 20.

While a typical grasper means configuration would normally require the use of at least one control wire to actuate the grasper element(s), it is contemplated that multiple separate control wires could also be effectively employed and manipulated from the proximal end of the system to allow for the precise control of the individual grasper elements.

With regard to the fastening means employed, as noted above it is contemplated that the fastening means may be constituted as a single apparatus operating in concert with the grasper means. Alternatively, the fastening means may be constituted as an entirely separate device which is totally independent of the grasper means. More preferably the

fastening means will be a separate device which will function using a monorail type system, wherein the fastening means will operate independently of the grasper means, but will ride via a loop over the same guidewire/catheter which houses and guides the grasper means.

While the preferred fastener depicted is in the form of a clip or staple, it is also contemplated that the fasteners employed to secure the leaflets of the valve may be of a variety of different configurations, each of which would function with greater or lesser effectiveness depending upon the operative conditions which prevail. In addition to clips or staples it is also contemplated that the following types of fasteners may also be effectively employed: coils, sutures, dual button fasteners, cufflink-like fasteners, and the like.

Suitable suture fasteners would include those which might require an appropriate mechanism to automatically suture tissue. Coil fasteners would generally be provided with sharpened ends to allow one to screw these fasteners into place by threading the sharpened end through the tissue of the valve leaflet.

With reference to FIGS. 21 to 23 which depict a sequential representation of the closure of valve leaflets using one preferred closure means, shown in FIG. 22 is a clip type closure 150 being inserted through valve leaflets 152. FIG. 22 shows the clip type closure 150 in the fastened position. FIG. 23 is a cross-sectional view of the clip type closure 150 depicted in FIG. 23. Each closure 150 as shown in FIG. 21 would have a thickness of from about 0.5 to 1.8 mm, preferably about 1 mm, a width of from about 0.3 to 0.7 cm, preferably about 0.5 cm, and a length of from about 0.6 to 1.4 cm, preferably about 1 cm.

FIGS. 24 and 25 are each a schematic representation of the insertion of another preferred closure means of the invention. A staple-type closure 156 is inserted through valve leaflets 158, and then closed, as shown in FIG. 26. Closure 156 would preferably have an overall length (including sides) of from about 1 to 4 cm, preferably about 3 cm, an effective diameter of from about 0.1 to 0.5 mm, preferably about 0.3 mm, and an opening of from about 0.5 to 1.3 cm, preferably about 1 cm.

FIGS. 26 to 28 are each a schematic representation of the insertion of yet another preferred closure. A spiral coil closure 160 can be inserted across valve leaflets 162 in longitudinal, latitudinal, or transverse fashion, by use of, for example, the device shown in FIG. 13. Coils 160 will preferably have pointed ends and will have external dimensions comprising a length of from about 3 to 7 cm, preferably about 5 cm, and a diameter of from about 1 to 3 mm, preferably about 2 mm.

The overall diameter and/or the differential turns of coil 160 may be uniform or they may vary. For example, the diameter at each end of coil 160 could be the same as, greater than, or less than the diameter of the middle portion of the coil. Similarly, the ratio of the turns of the coil to the length, i.e., the pitch, could be consistent or the pitch could be greater or less at each end of the coil. The diameter of the coil wire will preferably be consistent.

Each coil 160 would have a length of from about 3 to 7 cm, preferably about 5 cm, with a diameter of from about 1 to 3 mm, preferably about 2 mm, and a coil wire diameter of from about 0.2 to 0.4 mm. The winding of coil 160 should be from about 5 to 10 turns/cm in an unstressed condition.

In FIGS. 29 and 30 a U-shaped barbed clip-type closure

164 is applied to leaflet 166.

The device and fasteners used according to the invention must be comprised of biocompatible, nonimmunogenic materials. The grasper is preferably comprised of rigid materials such as titanium, nitinol, stainless steel, or rigid polymeric material such as polyethylene or polyurethane. The clips, staples, coils, etc., are preferably comprised of titanium, nitinol, or stainless steel. In some instances fasteners comprised of molded polymeric material may also be useful.

There are four different approaches which one might take to effect a repair of the mitral heart valve according to the invention:

Such a procedure might be undertaken while the patient is on by-pass with an open-chest, either transapically or transatrially. A median sternotomy is performed and the patient is placed on cardiopulmonary bypass by cannulating the ascending aorta and the right atrium. A purse-string suture is then placed on the apex of the left ventricle and a stab incision performed to insert the instrument which will grasp and attach the mitral valve leaflets. Once adequate repair of the valve is attained, the instrument is removed and the air evacuated from the left ventricle through the apical incision. The ventricle is then repaired using conventional wound closure techniques.

Alternatively, the grasper can be introduced through a similar stab incision performed over the roof of the left atrium. The grasper will cross the valve and then be manipulated to revert to grasp the leaflets from the atrial side and place the suturing device, just as postulated from the transventricular approach. Once adequacy of repair is confirmed, the device is extracted and the atriotomy closed using conventional wound closure techniques.

This procedure can alternatively be performed with the patient off bypass, through either a left or right thoracotomy or a sternotomy incision. The technique would be similar to that outlined for repair of mitral regurgitation on cardiopulmonary bypass. After opening the chest, the patient is placed on medication (beta-blocker) to slow the heart rate to approximately 40 beats per minute. This allows adequate echocardiographic visualization of the leaflets in order to grasp and attach them.

Third, such a procedure can be undertaken thorascopically. The patient is intubated selectively in order to collapse the left lung, and percutaneous ports are inserted in to the left chest allowing visualization of the apex of the heart or left atrium. Through a separate port, the device is introduced into the thoracic cavity and subsequently into the left ventricle through the apex. Previously, a purse-string or triangular suture had been placed around the tip of the ventricle to control bleeding around the ventricular entry site. Subsequent steps of the repair are identical to those described for patients with an open chest, off bypass.

Should the operation require the patient to be placed on bypass, this can be attained percutaneously from the groin by cannulating the femoral artery and vein. This technique could prove particularly useful in the early stages of development of the technique, since the surgeon would be able to operate on a decompressed heart and slow or cease the heart rate as needed, without hemodynamic compromise.

Lastly, a percutaneous approach to repair of the mitral valve would be possible with this invention by inserting the device either through the femoral artery or jugular vein. When using the former, the left ventricle is reached by placing the device across the aortic valve. The leaflets

will be grasped by turning the tip of the instrument approximately 160° from the entry angle. As previously stated, the grasper's tips are adjusted to obtain optimal apposition and the suturing device delivered. If a transvenous approach is employed, the left atrium is entered through the interatrial septum and the leaflets are handled as described for the transatrial technique.

To determine the relative efficacy of the method of the invention in effecting the repair of heart valves such as mitral valves a number of procedures were performed on both animal and human test subjects as follows:

Animal Testing

Six adult sheep underwent ligation of OM2 and OM3 through a left thoracotomy to induce chronic ischemic MR. After 8 weeks, animals were placed on cardiopulmonary bypass. Using a posterior approach to the left atrium, a bow-tie repair was performed. A posterior suture annuloplasty (DeVega) served as control. Snares were placed on both repairs to allow alternate tightening during measurements. Ten 2-mm piezo-electric crystals were sutured around the MV annulus and at the bases and tips of the papillary muscles. Six crystals were secured to the apex (1), septum (1), and epicardial short axis of the left ventricle (4) for 3-dimensional sonomicrometry array localization (3D-SAL) imaging. 3D-SAL measurements were performed after weaning from cardiopulmonary bypass at baseline and with each type of repair. Echocardiography was used to measure MR, MV area, and fractional shortening.

TABLE 1

MR, mitral valve area, and fractional shortening

	MR	FS	MVA (cm^2)
Baseline	3.3	0.46	5.4
DeVega	1.4	0.53	3.9
Bow-tie	1.2	0.57	3.3

FS = fractional shortening; MVA = mitral valve area (planimetry).

* $P = 0.0159$ vs. baseline

** $P = 0.0079$ vs. baseline

As shown from the results presented in Table 1, MR decreased significantly with both repairs compared with baseline. Post-operative improvements in fractional shortening was greater in the bow-tie group but did not reach statistical significance. MVA, measured by planimetry, decreased more with the bow-tie repair; nevertheless, the resultant areas were still substantial without evidence of a transvalvular gradient. Mitral valve annular contractility (% area change = (maximum area - minimum area) /maximum area) by 3D-SAL increased from 19.7% ± 4.0% at baseline to 21.5% ± 3.2% after bow-tie repair (P = 0.026). Suture annuloplasty decreased annular contractility to 15.7% ± 3.6% ($P = 0.0011$ vs. baseline, and $P = 0.0001$ vs. bow-tie).

The results obtained suggest that current techniques of mitral valve repair in ischemic MR may further impair left ventricular performance by limiting systolic function of the annulus and base of the heart. The bow-tie repair technique which is the subject of the present invention controls MR and directly addresses subvalvular dysfunction resulting in improved annular and left ventricular function.

Human Testing

The charts of eleven patients (five males and six females) undergoing mitral valve repair in conjunction with a central leaflet suture ("bow-tie" repair) were reviewed. Patients were operated on between August 1996 and April 1997. Mean age was 68 years (range, 44 to 78). Etiology of mitral regurgitation (MR) was ischemic in nine patients and degenerative in two. Mitral regurgitation was attributed to ischemia if any of the following criteria proposed by Radford et al. was met: (1) rupture of a papillary muscle chord or head (n=3); (2) infarction of the papillary muscle in the absence of leaflet pathology (n=3); (3) clear history of new onset or worsening of mitral regurgitation after documented myocardial infarction (n=3).

The diagnosis of MR was established by echocardiography in 10/10 patients, and semiquantitatively graded as severe (4+), moderate/severe (3+), mild/moderate (2+), mild (1+), and trace. Left sided cardiac catheterization confirmed the presence of MR in nine patients and the presence of critical coronary artery disease (CAD) invariably involving the circumflex and posterior descending artery territories in all patients with ischemic MR. Preoperative diagnoses and hemodynamics obtained during catheterization are shown in Table 2. All patients were in NYHA class III or IV at the time of surgery.

Table 2. Preoperative diagnosis and hemodynamics.

Patient	Diagnosis	Age	CO	PCWP	v-wave
1	Unstable angina	59	4.2	30	80
2	CAD/torn post. chord	78	2.4	6	10
3	CAD	74	n/a	14	15
4	CAD/MIx3	64	n/a	n/a	n/a
5	Unstable angina/MIx2	44	4.0	26	41
6	Ischemic VSD	77	4.0	28	21
7	AI/MR	77	4.5	29	39
8	CAD/APM rupture	67	4.3	27	65
9	CAD/V-tach arrest	71	4.1	20	28
10	Degenerative MR	70	3.5	20	21
11	AMI/PPM rupture	67	4.1	33	60

AI-aortic insufficiency; AMI-acute myocardial infarction; APM-anterior papillary muscle; CAD-coronary artery disease; post-posterior; PPM-posterior papillary muscle; VSD-ventricular septal defect; v-tach-ventricular tachycardia

With the patient under anesthesia, the valve is visualized on transesophageal echocardiogram (TEE) and the likely mode of failure determined, with special emphasis on the presence of leaflet prolapse and site and direction of the regurgitant jet. After the heart was stopped, a bulb syringe with cold saline is used to distend the left ventricle and confirm the mode of valve failure. A conventional repair using an annuloplasty right is generally performed and the valve is reinspected with saline injection. If the leaflet edges do not oppose each other in a concentric circle parallel to the annuloplasty ring, and continued regurgitation is observed, then a "bow-tie" repair is initiated. If the repair is performed from the transventricular or transaortic exposure, a single figure of eight 4-0 prolene suture is placed without screening leaflet

eight 4-0 prolene suture is placed without screening leaflet coaptation. Using a 4-0 prolene suture, the anterior leaflet is attached to the corresponding posterior leaflet at the site of malapposition. The figure of 8 suture is placed through each leaflet just as the edge turns down to attach to the primary chordae. This is usually the most cephalad site where the 2 leaflets would touch during systole and creates the largest area of coaptation possible.

At time the suture is very close to a commissure and the result is a narrowing of single valve orifice. More commonly, the suture is closer to the center of the valve and a double orifice valve is created which resembles a "bow-tie". After visually confirming that the repair is satisfactory with cold saline injection, the atrium is closed, the patient weaned from CPB, and an intraoperative TEE used to confirm the adequacy of the repair. Standard as well as exercise transthoracic echocardiograms were performed prior to discharge to establish the competency of the "bow-tie" repair as well as the absence of a significant gradient across the valve.

Six patients were operated on electively for worsening MR leading to intractable congestive heart failure or unstable angina. Four patients underwent emergent operation due to acute worsening of MR secondary to ischemic anterior papillary muscle rupture (n=2), acute MI with cardiogenic shock requiring intraaortic counterpulsation balloon, severe MR and malignant arrhythmias (N=1), and acute worsening of chronic degenerative MR (n=1). One patient had moderate (3+0 MR in association with critical aortic insufficiency. Mean degree of preoperative MR by echo was 3.5 ± 0.7, with mean ejection fraction (EF) of 42% ± 17%. Nine patients underwent preoperative cardiac catheterization. Mean pulmonary capillary wedge pressure was 23 mmHg ± 8 mmHg, with mean

atrial v-wave of 39 mmHg ± 25 mmHg; mean CO as measured by thermodilution technique was 3.9 1/min (range 2.4 to 4.5 1/min) (Table 2). Concomitant procedures performed at the time of MR included coronary artery bypass grafting (CABG) in eight patients. Of the two patients with a degenerative etiology of valvular disease, one required aortic valve replacement, whereas the second underwent posterior leaflet quadrangular resection and annuloplasty. Two patients, not included in this series, with end-stage congestive heart failure (CHF) secondary to ventricular dilation had "bow-tie" repairs during partial left ventriculectomy. Nine patients had a posterior ring annuloplasty as primary procedure for treatment of MR (Table 3). One patient required repair of ischemic ventricular septal defect (VSD) through a ventriculotomy, which made insertion of an annuloplasty ring impractical. This patient's mitral valve was successfully repaired with a "bow-tie" alone. A second patient presented with acute MR secondary to rupture of the anterior head of the ppm. Repair of the papillary muscle was performed using pericardial pledgets. Due to the lack of annular dilatation and persistence of MR a "bow-tie" suture was placed without an annuloplasty ring. Control of MR assessed intraoperatively by direct cold saline injection and TEE was satisfactory in all patients.

Table 3. Operative indications and concomitant procedures

Patient	Operative indication	Other procedures
1	MR, unstable angina	CABG, C-E#28
2	Torn post chord, MR	Post quad resection, C-E #32
3	CAD,MR	CABG, C-E#32
4	CAD,MR	CABG, C-E#30
5	Unstable angina, MR	CABG, C-E#28
6	Ischemic VSD, MR	CABG
7	Critical AI, MR	AVR, C-E#30
8	CAD, ALM rupture, MR	CABG, C-E#26
9	CAD, MR	CABG, C-E#28
10	MR, CHF	C-E#30
11	PPM rupture, MR	CABG, primary PPM repair

AVR-aortic valve replacement; C-E Cosgrove ring; CHF congestive heart failure; PPM posterior papillary muscle

It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in the constructions set forth without departing from the spirit and scope of the invention, it is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

DRAWING COMPONENTS

No.	Component
10	mitral valve
12	left ventricle
14	distal end of grasper
16	grasper
18	incision
20	suture
22	anterior leaflet or cusp
24	posterior leaflet or cusp
26	anterior cusp distal section
28	posterior cusp distal section
30	jaw
32	closure loop
36	grasper end
38	percutaneous apparatus
40	jaw
42	joint
44	fastener holder
46	fastener clip
48	jaw
50	grasper end
52	jaw
54	joint
56	valve leaflet
58	protruding grasping surface
60	control number
62	upper anvil
64	lower anvil
66	staple type fastener
68	staple action rod
71	recess
72	anvil slanted surface

80	grasper
81	grasper sheath
82	jaw
84	jaw
86	rod
87	pivot point
88	pivot point
90	rod
92	rod
94	pivot
96	valve leaflet
98	sheath
100	drive mechanism
102	coil fastener
110	grasper device
112	jaw
114	sheath
116	fastener
118	grasping surface
120	leaflet
122	cooperating grasping surface
124	pusher
130	grasper device
132	jaw
134	closure member
136	grasping surface
138	closure crimper
140	rod distal end
142	device rod
144	valve leaflet
150	clip-type closure
152	valve leaflet
156	staple-type closure
158	valve leaflet

160 spiral closure
162 valve leaflet
164 barbed-clip closure
166 valve leaflet

WHAT IS CLAIMED IS:

1. An apparatus for the repair of a cardiovascular valve having leaflets comprising a grasper capable of grabbing and coapting the leaflets of the valve.

2. The apparatus of Claim 1, where the valve to be repaired is a cardiac valve.

3. The apparatus of Claim 2, where the valve to be repaired is a mitral heart valve.

4. The apparatus of Claim 3, where the patient suffers from mitral regurgitation.

5. The apparatus of Claim 2, where the valve to be repaired is an aortic valve.

6. The apparatus of Claim 5, wherein the patient suffers from aortic insufficienty.

7. The apparatus of Claim 1, which comprises a coaptor to coapt the valve leaflets with a fastener.

8. The apparatus of Claim 1, wherein the grasper has a distal end comprising a multiplicity of jaws which are freely movable about a joint to permit a range of motion of said jaws when the apparatus is manipulated by an operator.

9. The apparatus of Claim 1, wherein the grasper end is removable from the apparatus.

10. The apparatus of Claim 9, wherein the grasper distal end is disposable.

11. The apparatus of Claim 7, wherein the coaptor is adjunctive to, and capable of operating in concert with, the grasper distal end.

12. The apparatus of Claim 7, wherein the coaptor is separate from the grasper distal end.

13. The apparatus of Claim 1 which can be inserted percutaneously.

14. The apparatus of Claim 1, wherein the grasper is capable of adjusting the leaflets of the valve to obtain optimal coaptation.

15. The apparatus of Claim 8, wherein the jaws of the grasper can be independently manipulated to ensure optimal valve leaflet apposition.

16. An apparatus for the repair of a cardiovascular valve, comprising a grasper having two jaws each having a closure member removably attached thereto wherein each closure member has a proximal end and the grasper also comprises a positioning member that is capable of positioning a binding member around the closure member proximal ends to secure the closure members together to coapt leaflets of the cardiovascular valve

17. A method of repairing a heart valve in a patient suffering from regurgitation or insufficiency wherein an apparatus of Claim 1 is inserted into a patient's heart, the grasper is used to grasp and immobilize the leaflets of the valve, and a fastener is inserted to coapt the leaflets.

18. The method of Claim 17, wherein the apparatus is inserted into the heart through the chest via a thorascope.

19. The method of Claim 17, wherein the apparatus is inserted through the jugular vein.

20. The method of Claim 17, wherein the apparatus is inserted through the femoral artery and advanced percutaneously.

21. The method of Claim 17, wherein the heart valve is a mitral valve or an aortic valve.

22. The method of Claim 21, wherein the heart valve is

a mitral valve.

23. The method of Claim 21, wherein the heart valve is an aortic valve.

24. The method of Claim 17 for repairing a mitral valve in a patient suffering from mitral valve regurgitation wherein the leaflets of the mitral valve are grasped and immobilized by jaws of the grasper and a fastener is inserted into the immobilized mitral valve leaflets to coapt the leaflets.

25. The method of Claim 17 for repairing an aortic valve in a patient suffering from aortic valve insufficiency wherein the leaflets of the aortic valve are grasped and immoblized by jaws of the grasper and a fastener is inserted into the immobolized aortic valve leaflets to coapt the leaflets.

26. A method of repairing a heart valve in a patient suffering from regurgitation or insufficiency comprising:

inserting an apparatus of Claim 1 into a patient's heart;

grasping the leaflets of the heart valve;

immobilizing said leaflets of the heart valve;

inserting a fastener into the patient's heart in proximity to the grasped valve leaflets;

coapting the leaflets of the said heart valve together by affixing the fastener; and

removing the grasper while leaving the fastener in place.

27. The method of Claim 26, wherein the patient suffers from mitral regurgitation and a mitral valve is repaired.

28. The method of Claim 26, wherein the patient suffers from aortic insufficiency and an aortic valve is repaired.

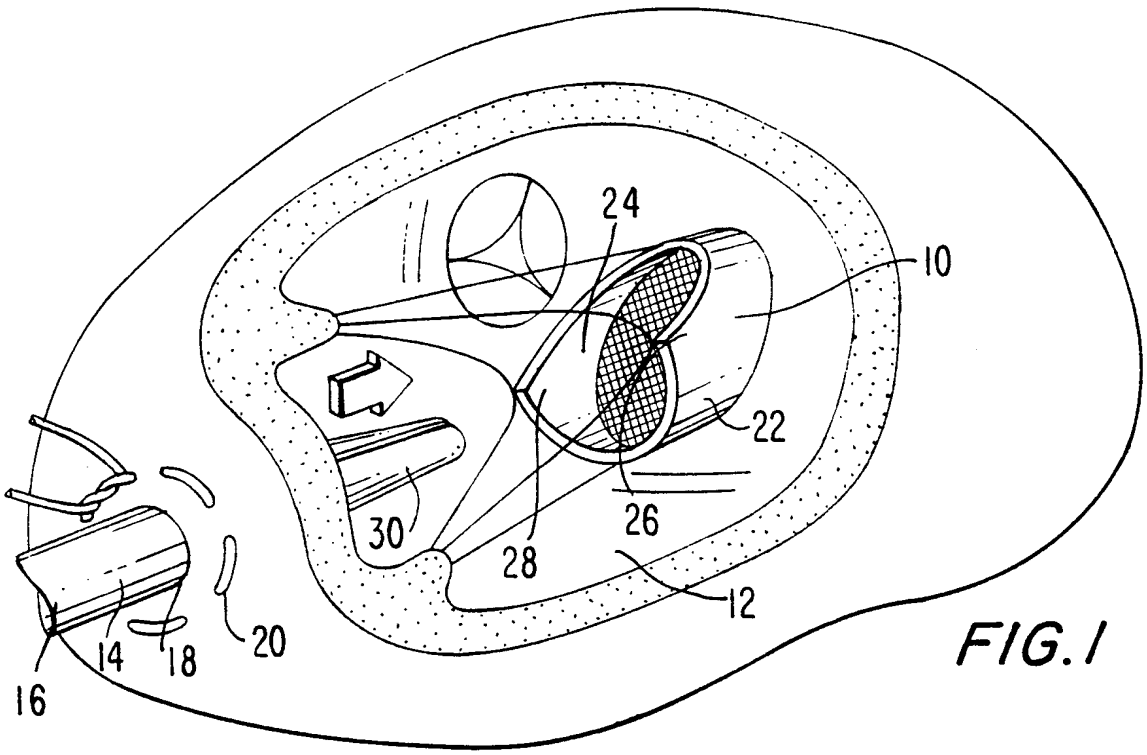
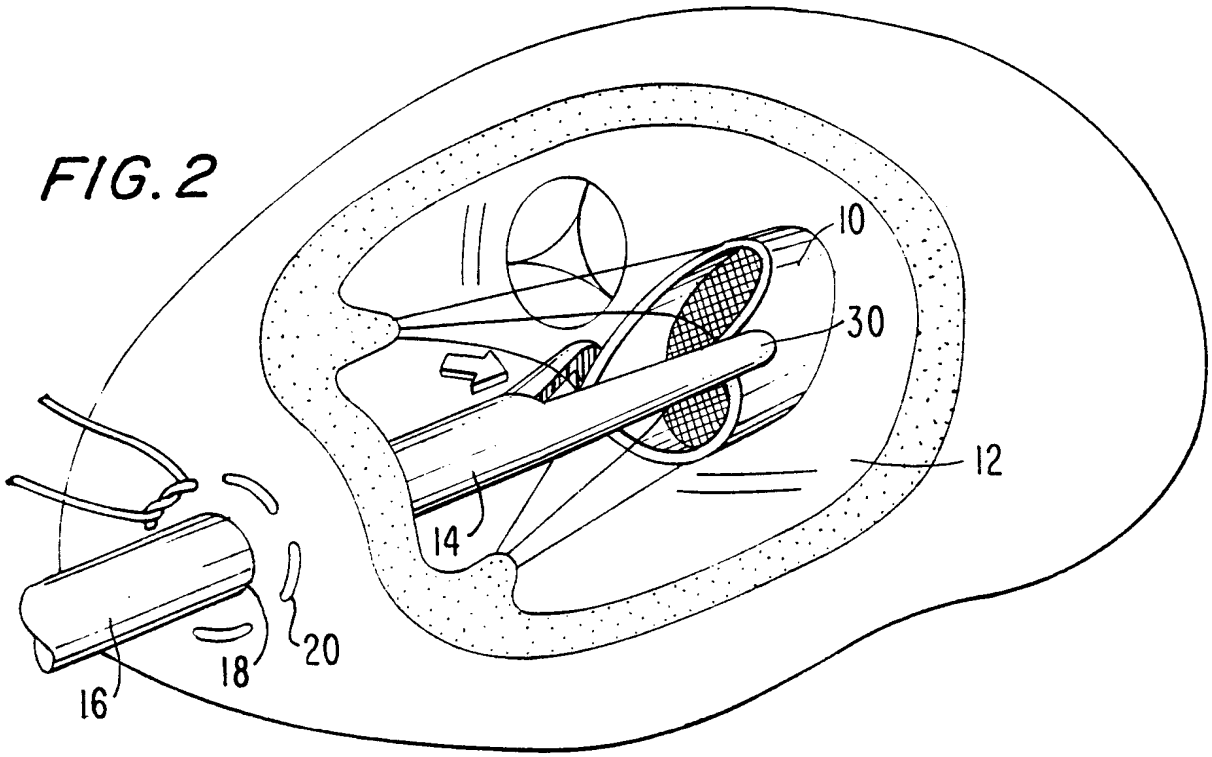


FIG. 1

FIG. 2



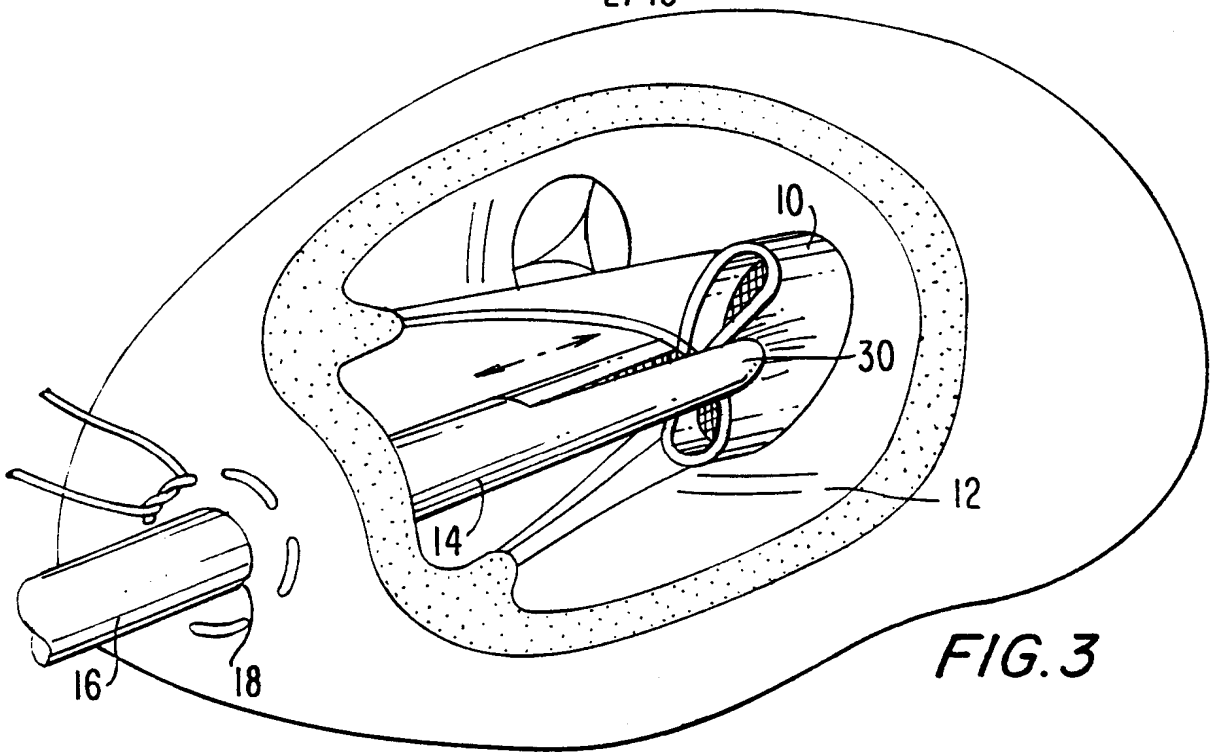


FIG. 3

FIG. 4

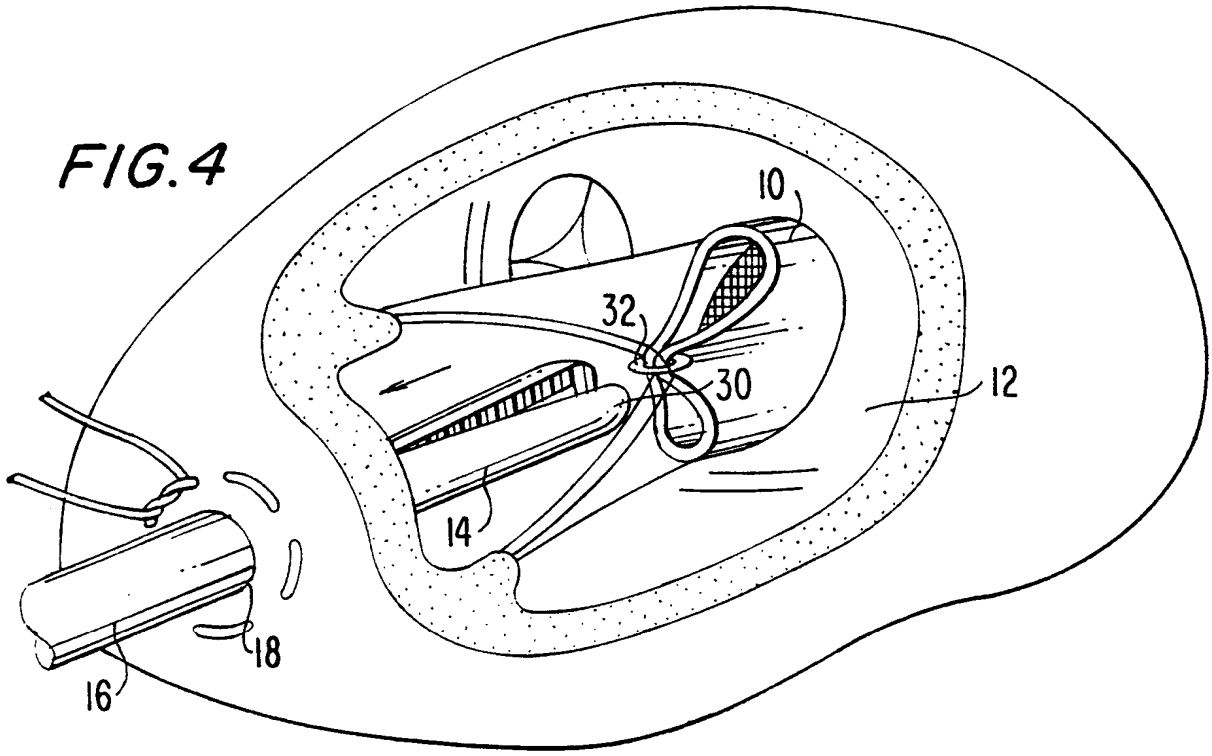


FIG. 5

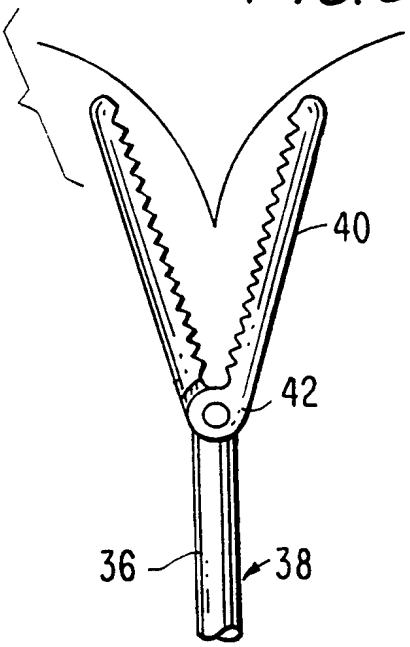


FIG. 6

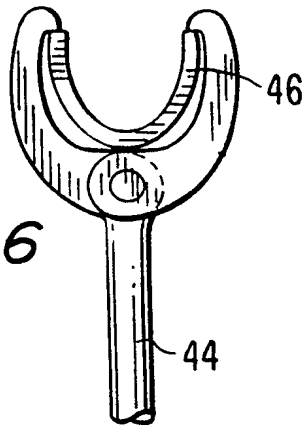
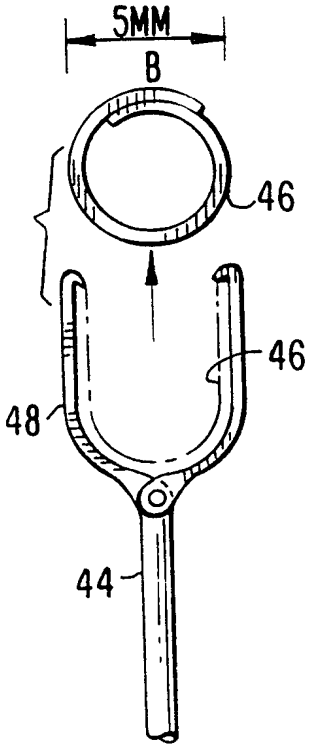


FIG. 7



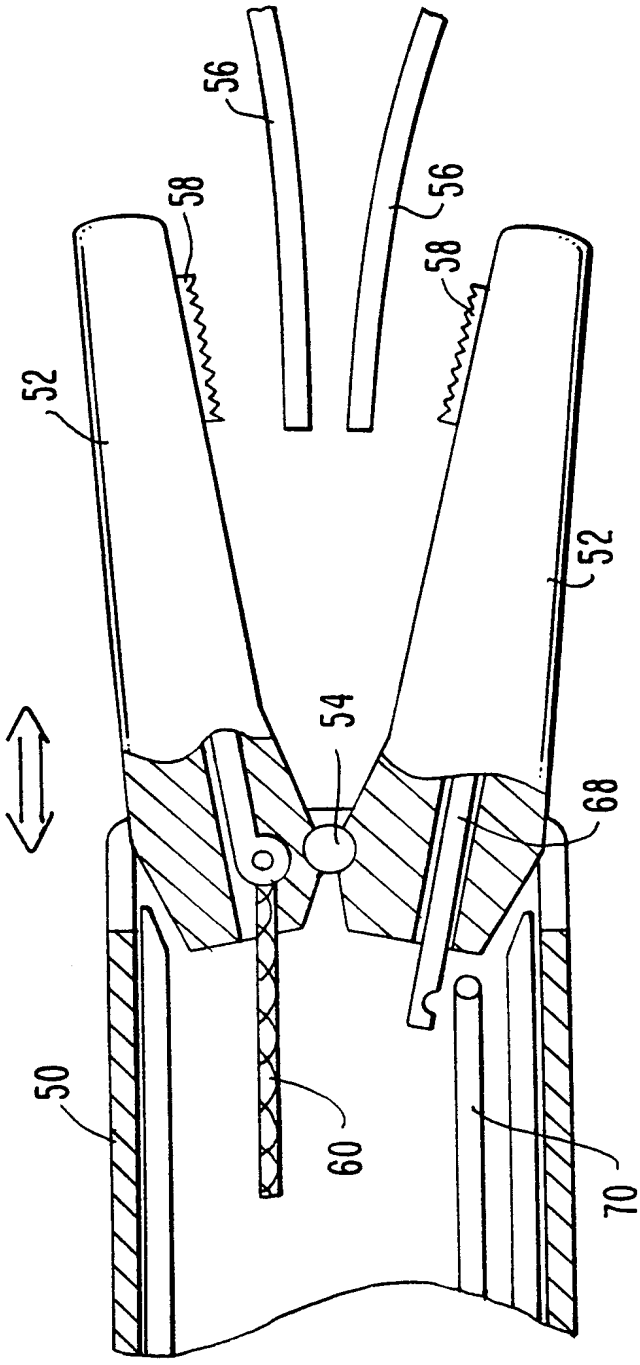


FIG.8

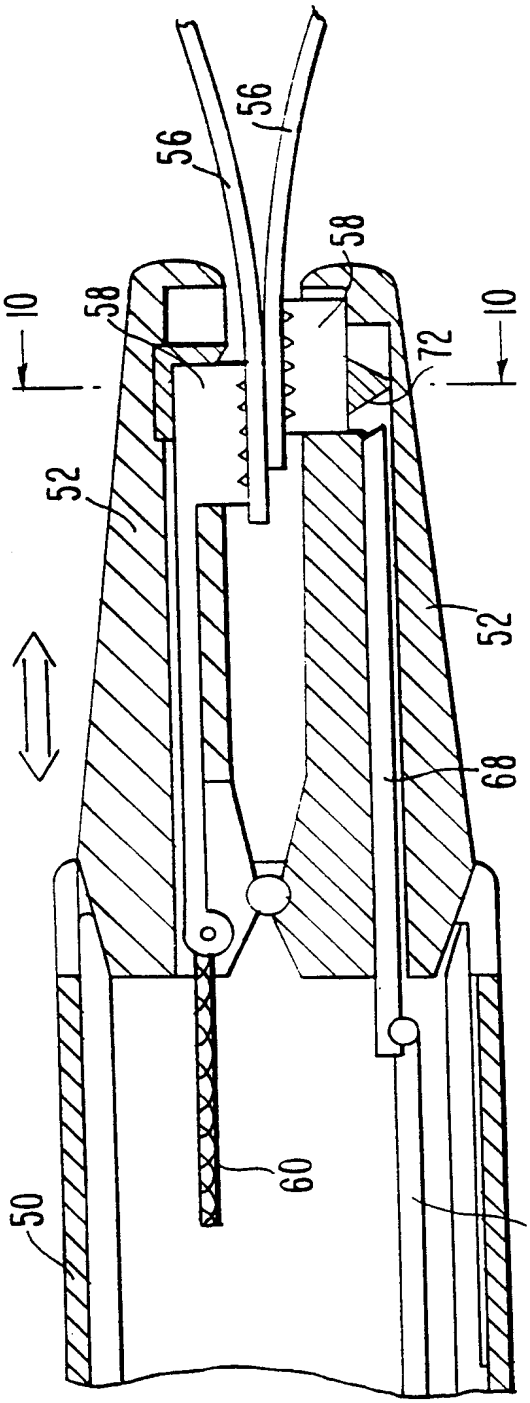


FIG. 9

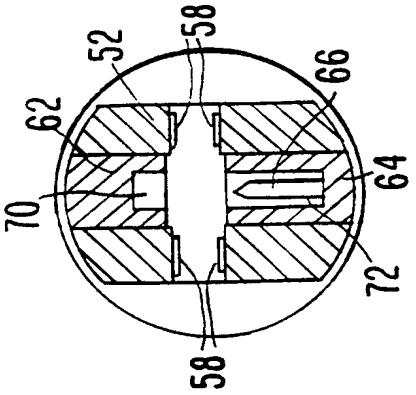


FIG. 10

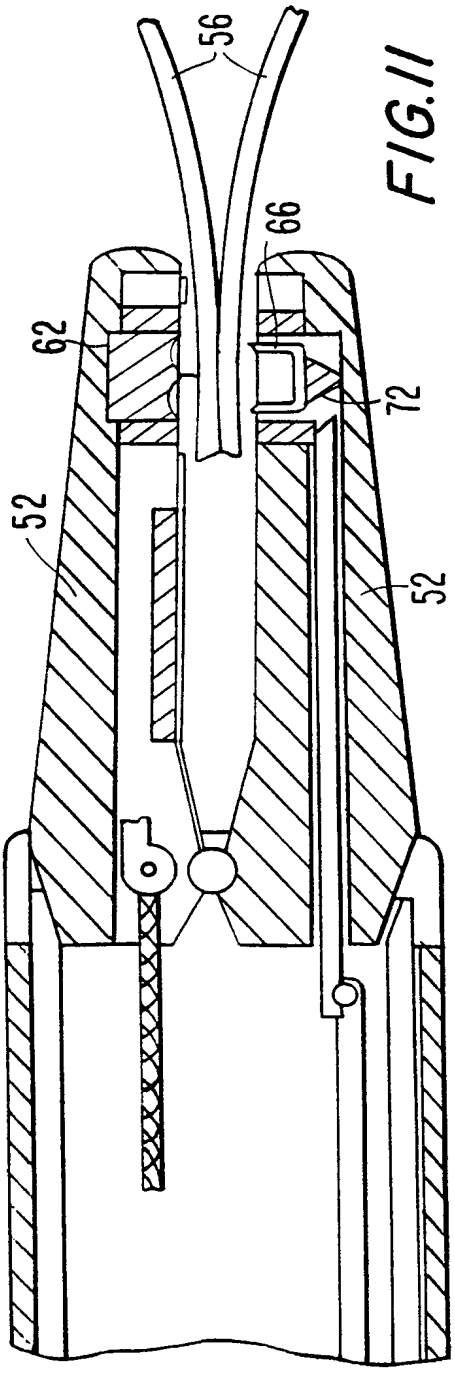


FIG. 11

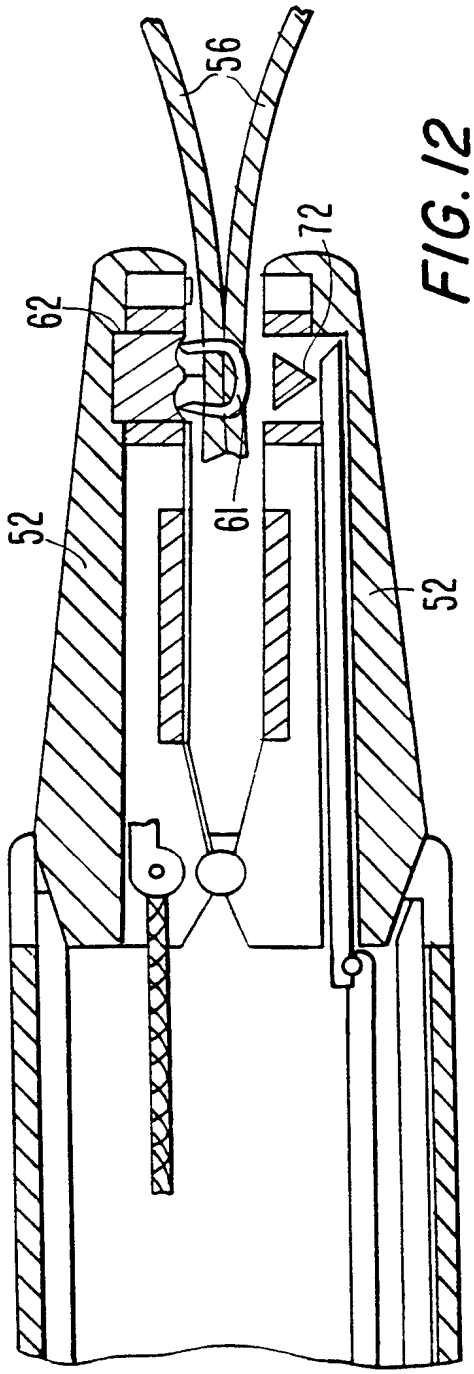


FIG. 12

FIG. 13

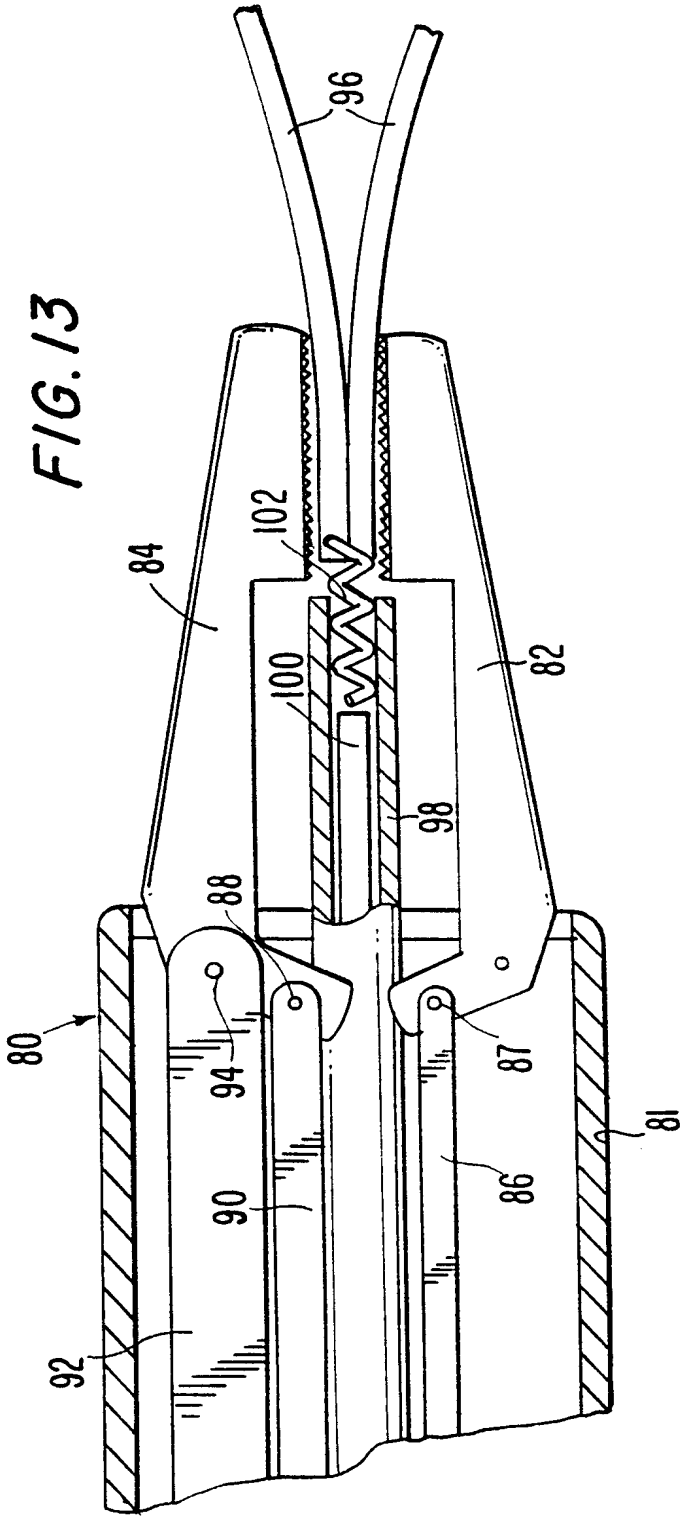


FIG.17

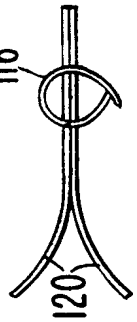


FIG.14

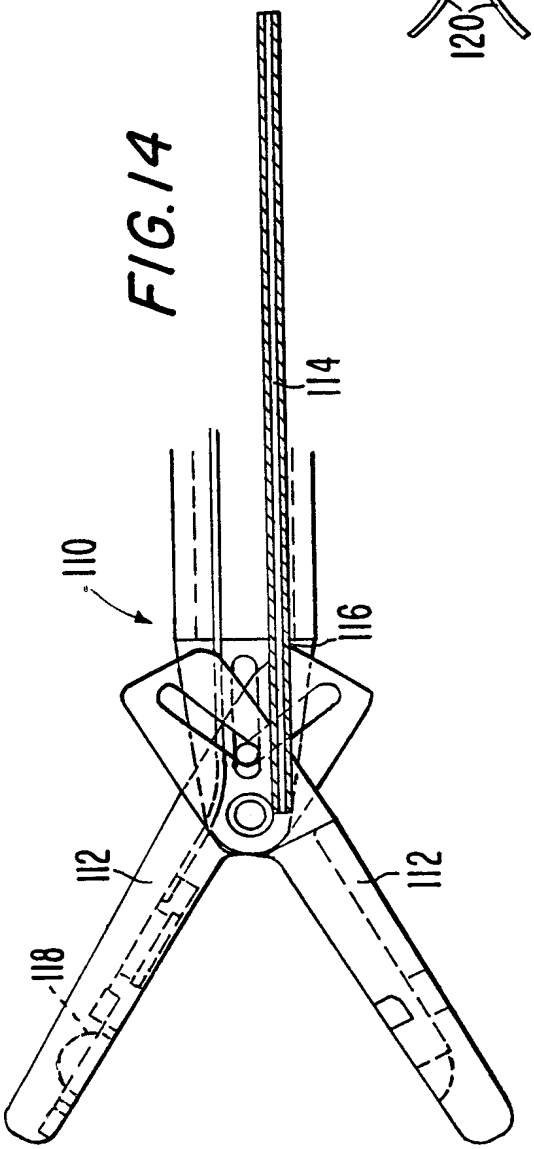


FIG.15

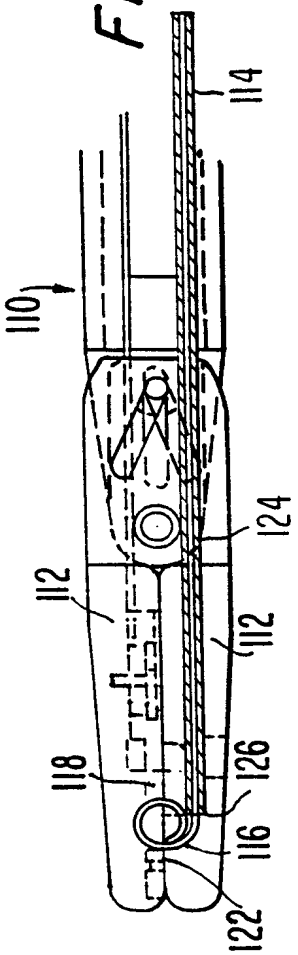
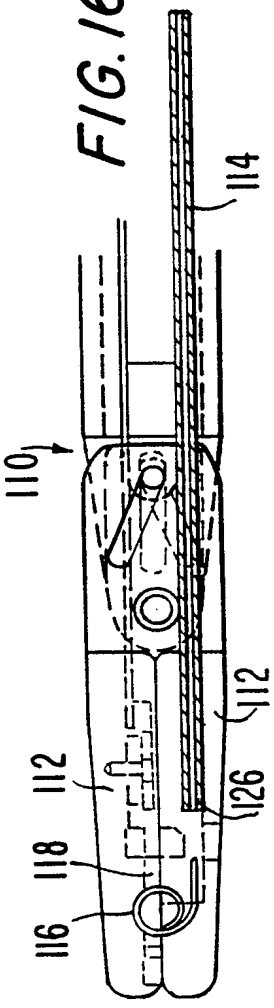


FIG.16



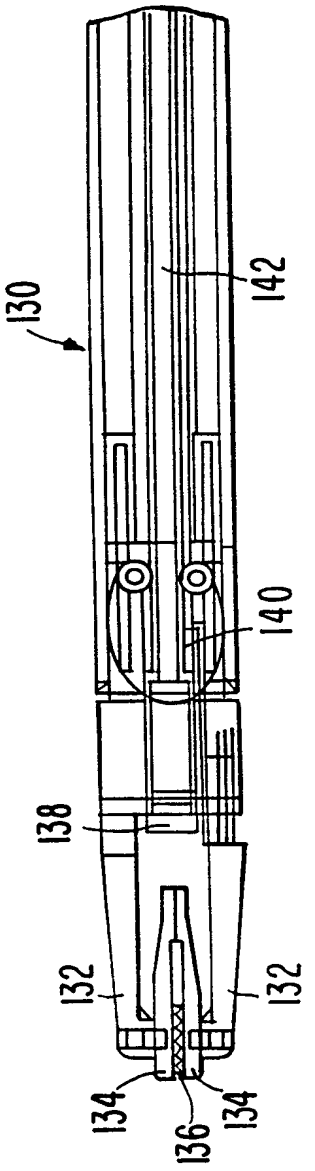


FIG. 18

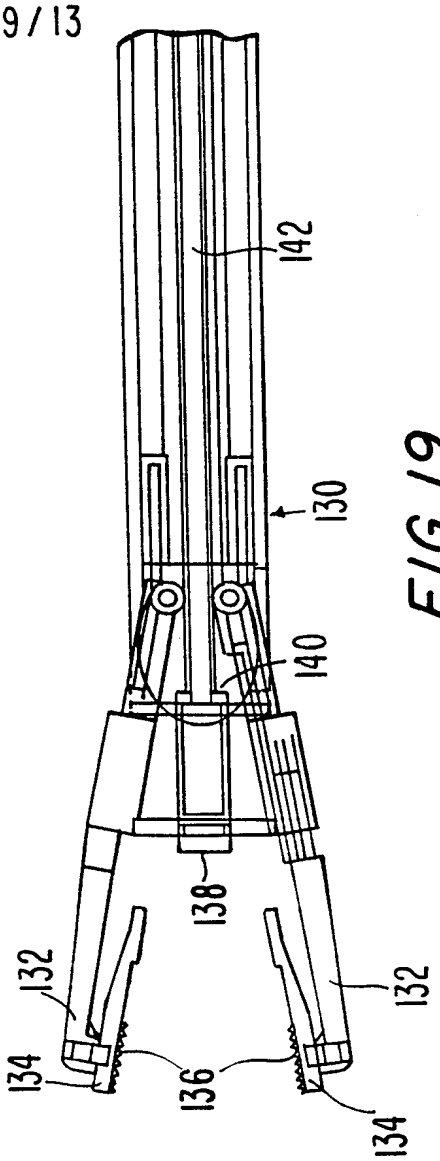


FIG. 19

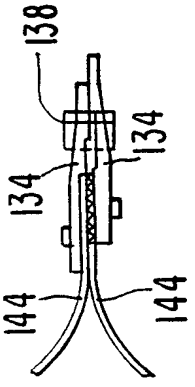


FIG. 20

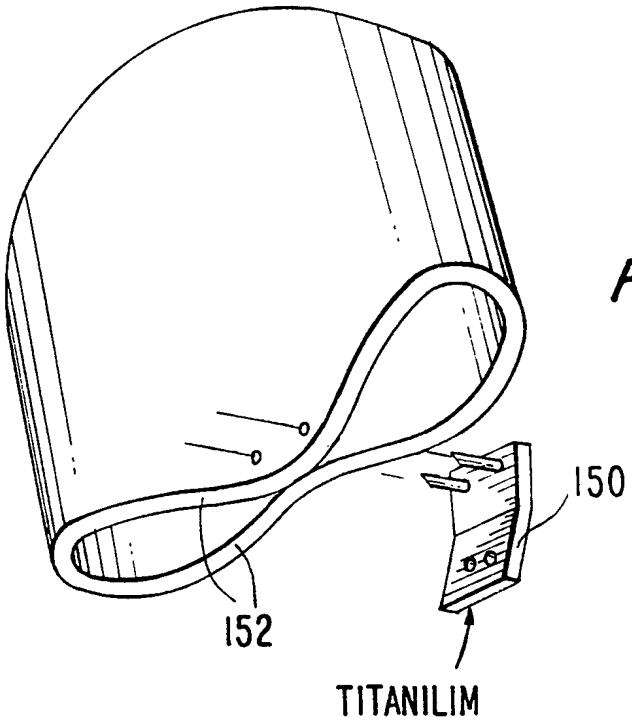


FIG. 21

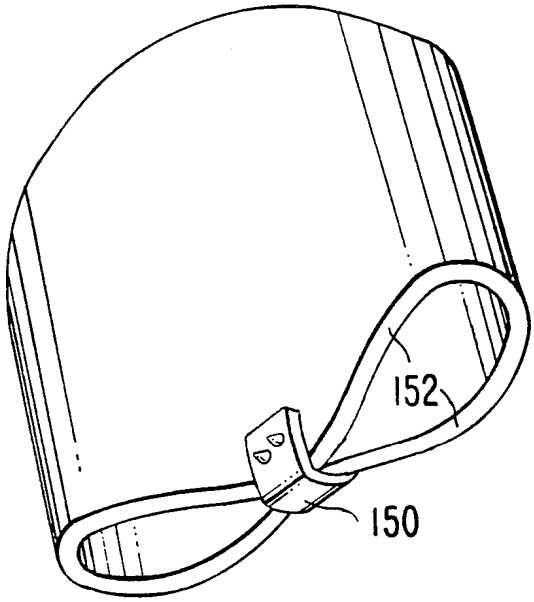


FIG. 22

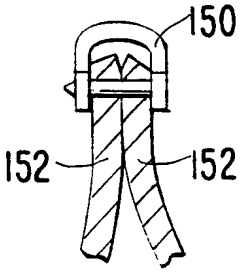


FIG. 23

FIG. 24

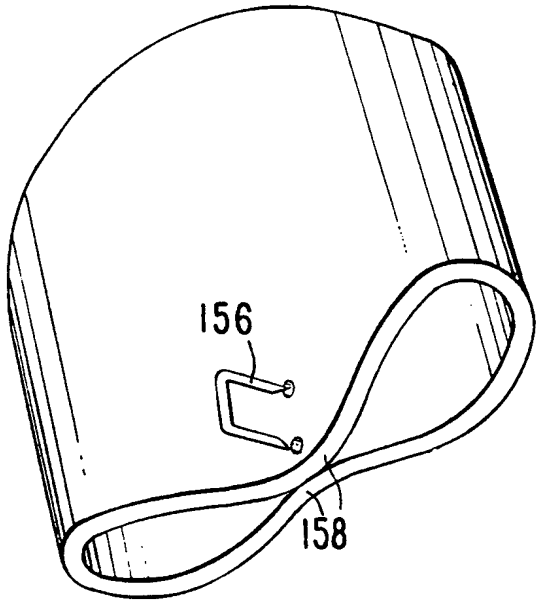
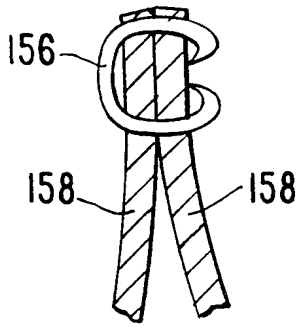


FIG. 25



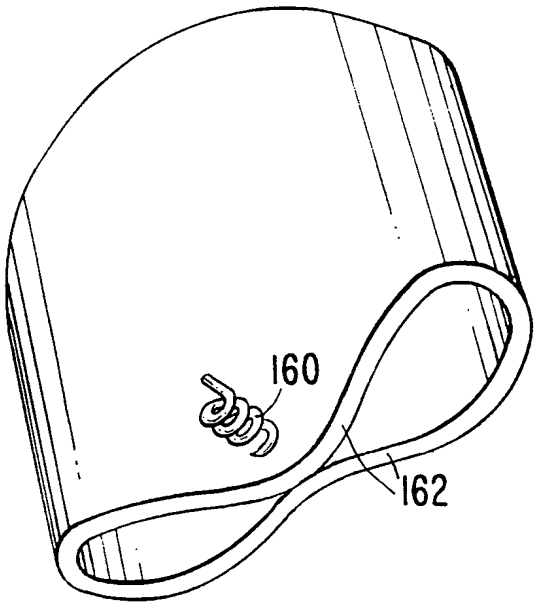


FIG. 26

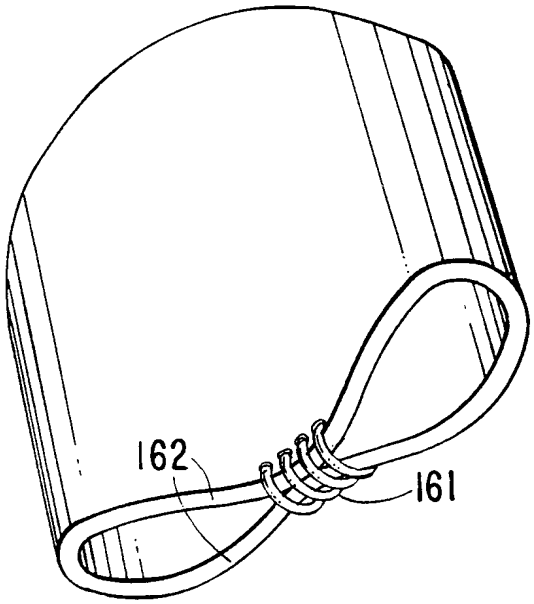


FIG. 27

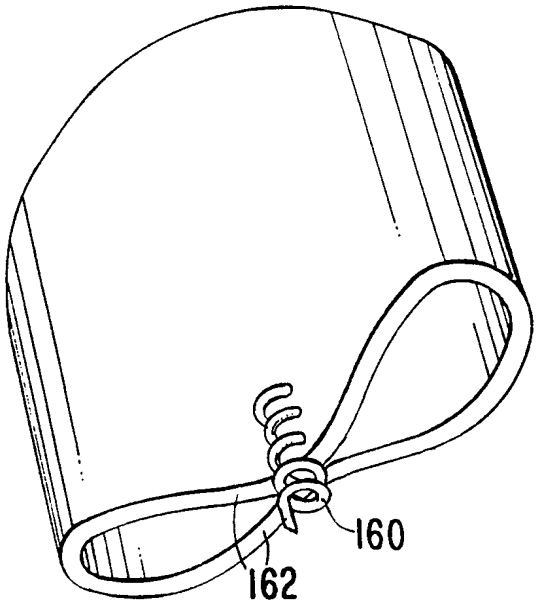


FIG. 28

13/13

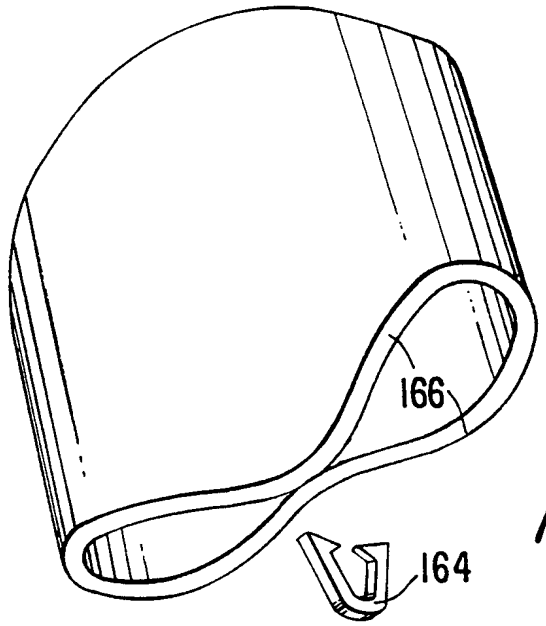
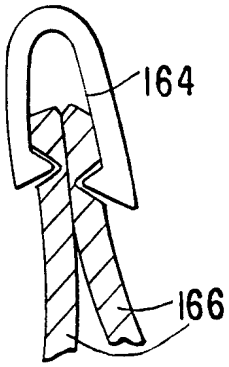


FIG. 29

FIG. 30



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/13240

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/10
US CL :606/139

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)

U.S. : 606/139, 142, 143, 151, 205-207, 216, 217, 219-221

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)

APS
Search Terms: heart, valve, coapt, clip, forceps

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 3,378,010 A (CODLING et al) 16 April 1968, whole document.	1, 7-14 --- 2-6
A	US 5,520,701 A (LERCH) 28 May 1996, whole document.	16
A	US 5,634,932 A (SCHMIDT) 03 June 1997, whole document.	16

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	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 document 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 18 SEPTEMBER 1998	Date of mailing of the international search report 19 OCT 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JULIAN W. WOO Telephone No. (703) 308-0421

Form PCT/ISA/210 (second sheet)(July 1992)★

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/24

A1

(11) International Publication Number: **WO 99/30647**

(43) International Publication Date: 24 June 1999 (24.06.99)

(21) International Application Number: PCT/US98/26667

(22) International Filing Date: 16 December 1998 (16.12.98)

(30) Priority Data:
08/992,316 17 December 1997 (17.12.97) US

(71) Applicant *(for all designated States except US)*: MYOCOR, INC. [US/US]; Suite 200W–B, 1380 Energy Lane, St. Paul, MN 55108 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: MORTIER, Todd, J. [US/US]; 3022 DuPont Avenue South, Minneapolis, MN 55408 (US). SCHWEICH, Cyril, J., Jr. [US/US]; 1685 Hillcrest Avenue, St. Paul, MN 55116 (US).

(74) Agents: GARRETT, Arthur, S. et al.; Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., 1300 I Street, N.W., Washington, DC 20005–3315 (US).

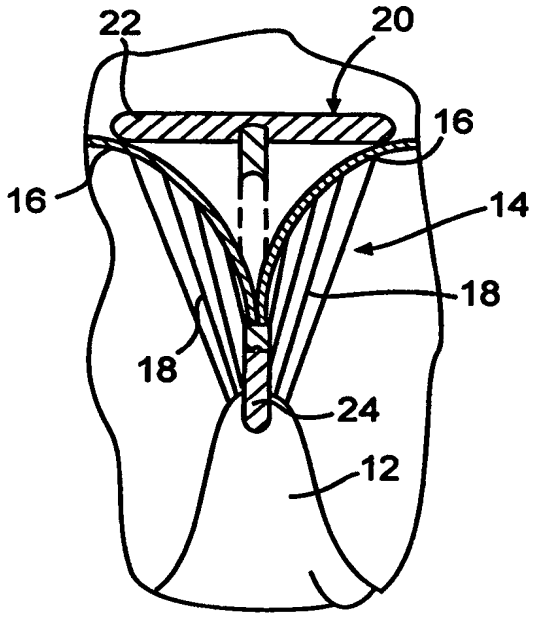
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: VALVE TO MYOCARDIUM TENSION MEMBERS DEVICE AND METHOD

(57) Abstract

A device for heart valve repair including at least one tension member having a first end and second end. A basal anchor is disposed at the first end of the tension member and a secondary anchor at the second end. The method includes the steps of anchoring the basal anchor proximate a heart valve and anchoring the secondary anchor at a location spaced from the valve such that the chamber geometry is altered to reduce heart wall tension and/or stress on the valve leaflets.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

VALVE TO MYOCARDIUM TENSION MEMBERS DEVICE AND METHOD

Background of the Invention

The present invention pertains generally to the field of heart valve repair. More specifically, the present invention pertains to a device and method for the reduction of myocardial wall tension and the repair of mitral valve insufficiency.

Dilated cardiomyopathy is often accompanied by mitral valve insufficiency. There are several reasons for the presence of mitral valve insufficiency associated with a dilated heart. First, chamber dilation and associated high wall stresses increase the diameter of the mitral valve annulus. Additionally, as the heart dilates, the positioning of the papillary muscles is altered. Papillary muscles and chordae in a dilated heart will have moved both radially away and down from the mitral valve. This rearrangement of the vascular apparatus and enlargement of the annulus prevent the valve from closing properly.

Currently mitral valve insufficiency is treated by either repairing or replacing the valve. Surgical procedures used to repair the valve including ring posterior annuloplasty which consists of sewing a C or D-shaped ring around the posterior leaflet of the mitral valve and drawing in the annulus, reducing its previously enlarged diameter. Another method is to approximate the anterior and posterior mitral leaflets (Alfieri repair) by placing one suture through the center of both leaflets. This gives the valve a figure 8-shaped appearance when the valve is opened. When the mitral valve is replaced, the original leaflets are removed and the chordae are cut. An artificial valve consists of mechanical or tissue leaflets suspended on struts attached to a metal stent, and is sutured into place on the mitral annulus.

It has been argued that valve repair is preferable to valve replacement if the leaflet-chordae-papillary connections can be maintained. Heart wall stress will increase if the chordae are cut during valve replacement. It has been shown that by severing the chordae there can be 30 percent (30%) reduction in chamber function. Mitral valve replacement has high morality in very sick, chronic heart failure patients.

Summary of the Invention

The present invention pertains to a device and method for mitral valve repair. The mitral valve is generally defined as its leaflets or cusps, but in reality, it actually consists of the entire left ventricle chamber. By creating an improved chamber geometry, both chamber and valve function will be improved. The device of the present invention and method for valve repair/replacement can include treatment for chronic heart failure by reducing left ventricular wall tension.

In one embodiment of the present invention, the valve repair device includes an elongate tension member having a first end and second end. The basal anchor is disposed at the first end and the secondary anchor is disposed at the second end.

The basal anchor could include a pad and annuloplasty ring or the like. Alternately an artificial heart valve could serve as the basal anchor.

Tension members can be substantially rigid or substantially flexible. The secondary anchor can include a hook-shaped papillary muscle tissue loop, screw-shaped tissue anchor or transmural anchor pad.

The method of the present invention providing a tension member having a first end and a second end. The tension member has a basal anchor at the first end and a

secondary anchor at the second end. The basal anchor is anchored proximate to the valve such that the tension member is disposed in the chamber. The secondary anchor is anchored to a portion of the heart spaced from the basal anchor such that the tension member is under tension and the geometry of the chamber has been altered by placement of the tension member.

The basal anchor can include an artificial heart valve, annuloplasty ring or the like. The secondary anchor can be anchored to a papillary muscle or transmurally anchored.

More than one tension member can be used. Additionally, a transverse tension member can be placed across the chamber generally perpendicular to the other tension members to further alter the geometry of the heart, reducing wall stress and improving chamber performance.

Brief Description of the Drawings

Figure 1 is a transverse cross section of the left ventricle of a human heart taken from Figure 2;

Figure 2 is a vertical cross section of the left ventricle of a human heart;

Figure 3 is a modified, transverse, cross section of the left ventricle of a human heart taken from Figure 4;

Figure 4 is modified, vertical cross section of a human heart, modified by a device in accordance with the present invention;

Figure 5 is a cross section of an insufficient mitral valve of a left ventricle of a human heart;

Figure 6 is a cross section of a repaired valve and device in accordance with the present invention;

Figure 7 is an embodiment of the device of the present invention;

Figure 8 is an alternate embodiment of a device in accordance with the present invention;

Figure 9 is yet another alternate embodiment of a device in accordance with the present invention;

Figure 10 is yet another alternate embodiment of the device in accordance with the present invention;

Figure 11 is yet another alternate embodiment of a device in accordance with the present invention;

Figure 12 is a view of a basal anchor for the device of the present invention;

Figure 13 is a suture ring serving as a basal anchor for the device of the present invention;

Figure 14 is a replacement valve serving as a anchor for the device of the present invention;

Figure,15 is a top view of an alternate embodiment of a suture ring acting as an anchor for the device of the present invention;

Figure 16 is a side view of the suture ring of Figure 15;

Figure 17 is a view of an alternate embodiment of a suture ring which can act as basal anchor for the device of the present invention;

Figure 18 is a view of yet another alternate embodiment of a suture ring which can act as a basal anchor for the present invention;

Figure 19 is a embodiment of a secondary anchor for the device of the present invention;

Figure 20 is a view of an alternate embodiment of a secondary anchor for the device of the present invention; and

Figure 21 is yet another embodiment of a secondary anchor for the device of the present invention.

Detailed Description of the Invention

Referring now the drawings wherein like reference numerals refer to like elements throughout the several views, Figure 1 shows a transverse cross section of the left ventricle 10 of a failing heart taken from Figure 2. The papillary muscles 12 are shown in cross section. Figure 2 is a vertical cross section of human heart 10. A mitral valve is disposed near the top of left ventricle 10. Mitral valve 14 includes two leaflets or cusps 16. Chordae 18 extend between leaflets 16 and papillary muscles 12.

Figure 3 is a cross section of heart 10 modified from that shown in Figure 1 by placement of valve repair device 20 in accordance with the present invention as shown in Figure 4. Figure 4 is a vertical cross section of left ventricle 10 with geometry modified by device 20. In this embodiment of the invention, device 20 includes a basal anchor 22 such as an annuloplasty or suture ring sewn proximate the annulus of valve 14. Extending from basal anchor 22 are elongate tension members 24. Each have a first end connected to basal anchor 22 and a second end anchored to papillary muscles 12 or the heart wall.

As can be seen in Figures 3 and 4, both the transverse radius and vertical dimension of left ventricle 10 has been reduced in comparison to that of Figures 1 and 2 by drawing papillary muscles 12 toward valve 14 with tension members 24. This change in geometry reduces heart wall stress and consequently increasing chamber function. Valve function is also improved as explained in more detail by reference to Figures 5 and 6.

Figure 5 is a generally vertical cross section of an insufficient mitral valve of a heart suffering from chronic heart failure. In this case as the failing heart has dilated, papillary muscle 12 has been drawn away from

mitral valve 14. The chordae connections between papillary muscles 12 and valve 14 in turn draws leaflets 16 apart such that during the normal cardiac cycle, leaflets 16 may not completely close. Thus, an opening 26 is left between leaflets 16 throughout the cardiac cycle. Opening 26 will allow blood to leak, reducing chamber efficiency.

Figure 6 is a view of the mitral valve 14 of Figure 5 which has been modified by placement of valve repair device 20 as shown. Suture ring 22 is sewn proximate the annulus of valve 14, as known to those skilled in the use of suture rings. The annulus of valve 14 can be decreased in size by drawing the annulus toward the suture ring by the sutures used to connect ring 22 to the valve. Drawing the annulus of valve 14 toward suture ring 22 will help to eliminate opening 26. Tension member 24 is then anchored to papillary muscle 12 such that papillary muscle 12 is drawn toward valve 14. Whether or not the suture ring alone is sufficient to eliminate opening 26, drawing papillary muscle 12 toward valve 14 will provide additional stress relief on leaflet 16 promoting complete closure of valve 14. Drawing papillary muscle 12 toward 14 also reduces heart wall stress and increases chamber efficiency as discussed previously.

Figure 7 is a highly simplified view of left ventricle 10 and valve repair device 20 as shown in Figure 4. It can be noted that tension members 24 extend from basal anchor 22 to an adjacent papillary muscle 12. In contrast, Figure 8 is a similar cross sectional view of left ventricle 10, but a valve repair device 120 is placed such that its tension members 124 extend between a basal anchor 122 and a papillary muscle 12 transversely opposite the point at which tension member 124 is connected to basal anchor 122. This arrangement, as opposed to that shown in Figure 7, can increase the

transverse component of the tension force in tension members 124 relative to the vertical component of that tensile force.

Figure 9 shows yet another embodiment of the valve repair device in accordance with the present invention referred to by numeral 220. In this embodiment, device 220 is disposed in left ventricle 10 in a manner similar to that of device 20 shown in Figure 7 in that tension members 224 of device 220 extend from a basal anchor 222 to an adjacent secondary anchor point. The secondary anchor point is established by transverse extension of a tension member 225 across left ventricle 10. Tension member 225 is anchored transmurally to the heart wall at its opposite ends by pads 227. In turn, tension members 224 are anchored or connected to tension member 225.

Tension member 225 can be used to further alter the geometry of left ventricle 10 in a manner disclosed in U.S. Patent Application Serial No. 08/933,456, entitled "HEART WALL TENSION REDUCTION APPARATUS AND METHOD", which was filed on September 18, 1997 and is incorporated herein by reference.

Figure 10 shows yet another embodiment of a valve repair device in accordance with the present invention referred to by numeral 320. This embodiment includes a basal anchor 322 and tension members 324 and a transverse tension member 325 having anchor pads 327 similar to those of device 220. With respect to device 320, however, tension members 324 are crossed similar to those of device 120 of Figure 8 to increase the horizontal component relative to the vertical component of the tensile force in tension member 324.

Figure 11 is a yet another embodiment 420 of the valve repair device of the present method. Valve repair device 420 includes a basal anchor 422 and tension members 424. Tension members 424 are disposed in an

arrangement similar to tension members 24 of device 20 shown in Figure 7 except that tension members 424 are anchored transmurally by pads 427 rather than into papillary muscles 12. The relatively greater thickness of tension members 424 shown in Figure 11, as compared to tension members 24 shown in Figure 7, merely illustrates that the tension members can be substantially rigid or in the case of tension members 24, substantially flexible. It should be understood, however, that in any of the embodiments shown herein, the tension members could be advantageously formed to be substantially flexible or substantially rigid.

Figure 12 is a top or posterior view of valve 14. In this embodiment, the basal anchor for the valve repair device is shown as discrete pads 28 which can be sewn to the posterior side of valve 14. Tension members 24 are shown extending from respective pads 28 into the left ventricle.

Figure 13 is the same view of valve 14 as Figure 12. In Figure 13, however, the basal anchor 22 is shown as a crescent-shaped suture ring. Tension members 24 extends from basal anchor 22 through valve 14 into the left ventricle.

Figure 14 is a side view of an artificial heart valve 30. If it is necessary to replace the valve rather than merely repair it, artificial valve 30 can be used as a basal anchor for tension members 24.

Figure 15 is a top view of an alternate embodiment of a suture ring basal anchor 32. Ring 32 has a crescent shape and a pylon 34 extending through the mitral valve. Figure 16 is a side view of suture ring 32 showing tension members 24 attached to pylon 34.

Tension members 24 preferably extend through the tissue of valve 14 rather than through the valve opening. It can be appreciated, however, that tension members 24

could be disposed through the valve opening. In the case of the embodiment of Figures 15 and 16, however, pylon 34 would be disposed through the valve opening. Tension members 24 associated with pylon 34 would be disposed on the opposite side of valve 14 from suture ring 32. Pylon 34 would preferably be disposed through the valve opening rather than the tissue forming valve 14.

Figures 17 and 18 are yet additional alternate embodiments of suture rings which can be used as basal anchors in accordance with the present invention. The shape of the rings is selected such that as they are sewn into place on valve 14, the sutures can be used to draw tissue toward the inside of the ring, thus reducing the transverse and/or vertical cross sectional area of the associated heart chamber. This will advantageously reduce heart wall stress which is of particular benefit if the patient has a failing heart.

It can be appreciated that tension members 24 can be fixably or releasably attached to the basal anchor. Preferably, the tension members are fixably attached to the basal anchor during the valve repair procedure.

Figures 19-21 show various configurations of anchoring devices shown at the second end of tension member 24. It can be appreciated that these anchoring devices could be used with each of the tension members described above. In Figure 19, the second end of tension member 24 includes a secondary anchor 40 formed as screw which is shown augured into papillary muscle 12. Figure 20 shows a secondary anchor 42 including a loop sewn through papillary muscle 12. Figure 21 shows a tension member 24 extending transmurally to an exterior pad 44 to which it is connected. Tension member 24 could be sewn to pad 44 or otherwise mechanically connected thereto.

It can be appreciated that various biocompatible materials can be advantageously used to form the various

components of the device of the present invention. It is anticipated that the present device will usually be chronically implanted. Thus, when selecting materials to form each of the components consideration should be given to the consequences of long term exposure of the device to tissue and tissue to the device.

Numerous characteristics and advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of parts without exceeding the scope of the invention. The inventions's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A valve repair device, comprising:

an elongate tension member having a first end and second end;

a basal anchor disposed at the first end; and

a secondary anchor disposed at a second end.

2. A valve repair device in accordance with claim 1, wherein the basal anchor includes a pad.

3. A valve repair device in accordance with claim 1, wherein the basal anchor includes annuloplasty ring.

4. A valve repair device in accordance with claim 1, wherein the basal anchor includes an artificial heart valve.

5. A valve repair device in accordance with claim 1, wherein the basal anchor includes a suture ring having a varying radius of curvature.

6. A valve repair device in accordance with claim 1, wherein the tension member is substantially rigid.

7. A valve repair device in accordance with claim 1, wherein the tension member is substantially flexible.

8. A valve replacement device in accordance with claim 1, wherein the secondary anchor includes a hook-shaped papillary muscle tissue loop.

9. A valve repair device in accordance with claim 1, wherein the secondary anchor includes a screw-shaped tissue anchor.

10. A valve repair device in accordance with claim 1, wherein the secondary anchor includes a transmural anchor pad.

11. A method of repairing a heart valve having leaflets and chordae disposed in a heart chamber, comprising the steps of:

providing a tension member having a first end and a second end, the tension member having a basal anchor at the first end and a secondary anchor at the second end;

anchoring the basal anchor proximate the valve such that the tension member is disposed in the chamber; and

anchoring the secondary anchor to a portion of the heart spaced from the basal anchor such that the tension member is under tension and the geometry of the chamber has been altered by placement of the tension member.

12. The method in accordance with claim 11, wherein the basal anchor includes an artificial heart valve.

13. The method in accordance with claim 11, wherein the basal anchor includes an annuloplasty ring.

14. The method in accordance with claim 11, wherein the secondary anchor is anchored to a papillary muscle.

15. The method in accordance with claim 11, wherein the secondary anchor is transmurally anchored.

16. The method in accordance with claim 11, wherein at least two tension members are provided.

17. The method in accordance with claim 11, further comprising the step of placing a transverse tension member across the chamber, generally perpendicular to the

tension member, to further alter the geometry of the chamber.

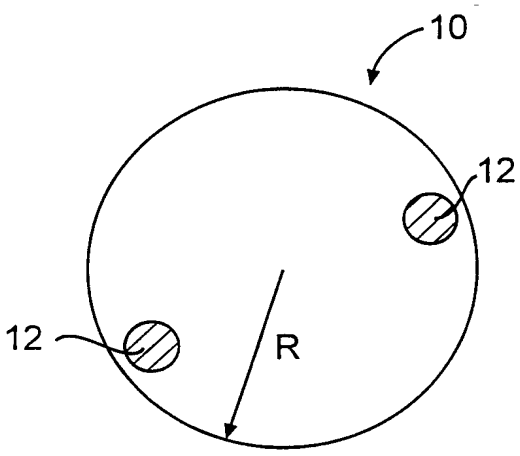


FIG. 1

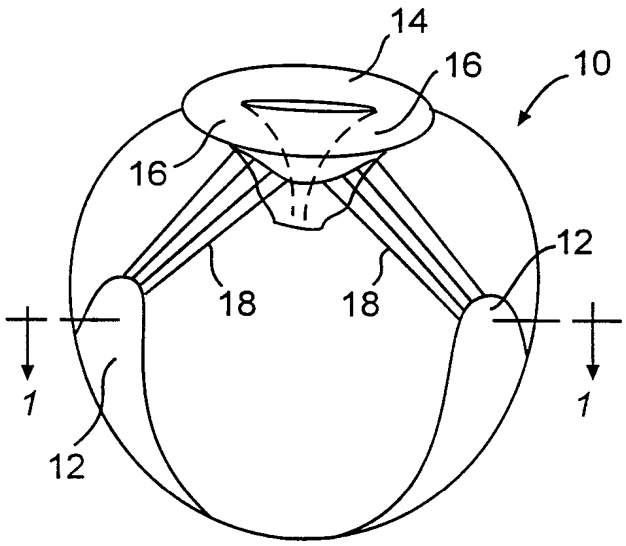


FIG. 2

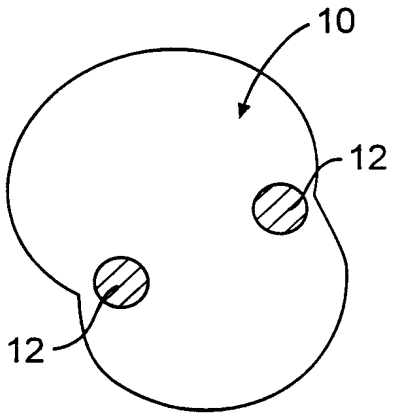


FIG. 3

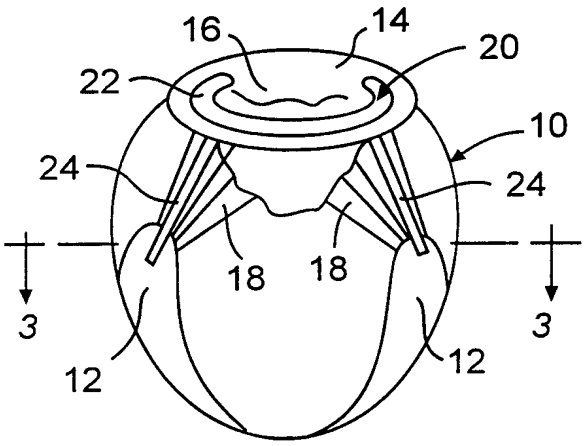


FIG. 4

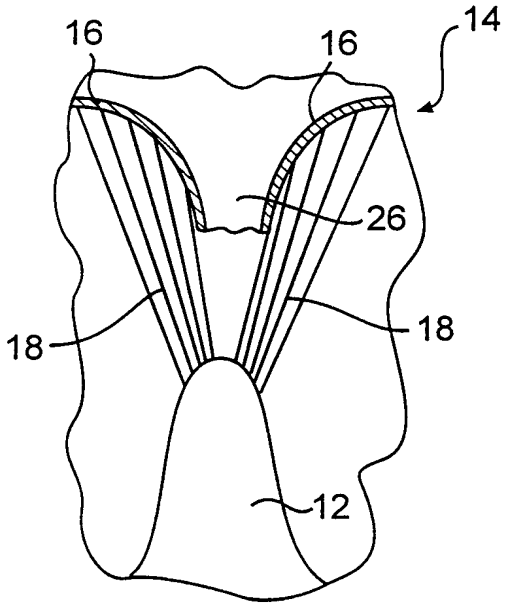


FIG. 5

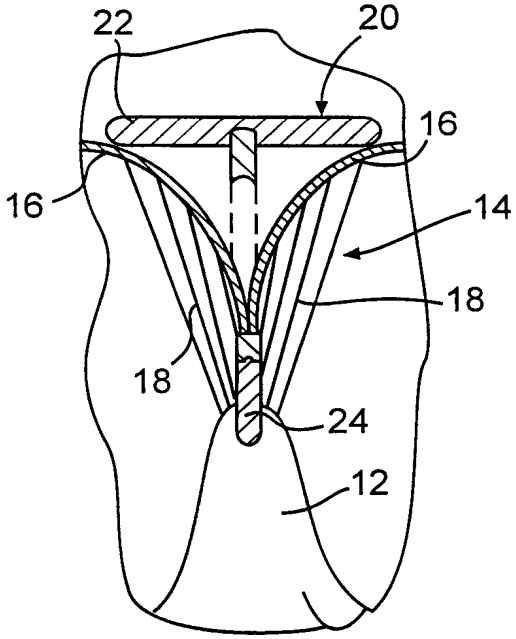


FIG. 6

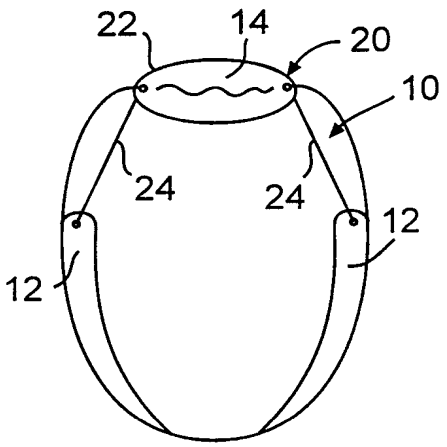


FIG. 7

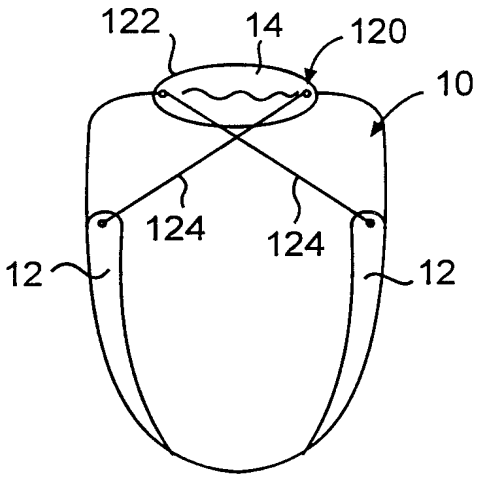


FIG. 8

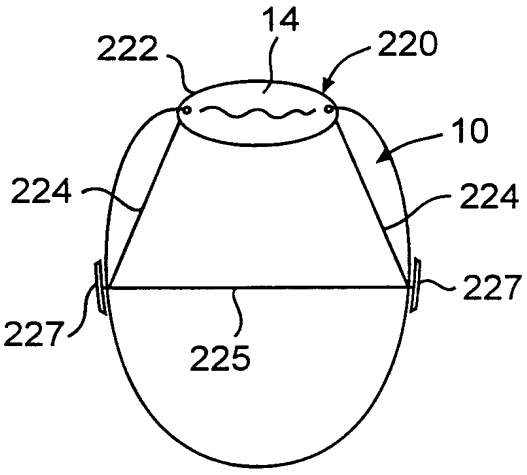


FIG. 9

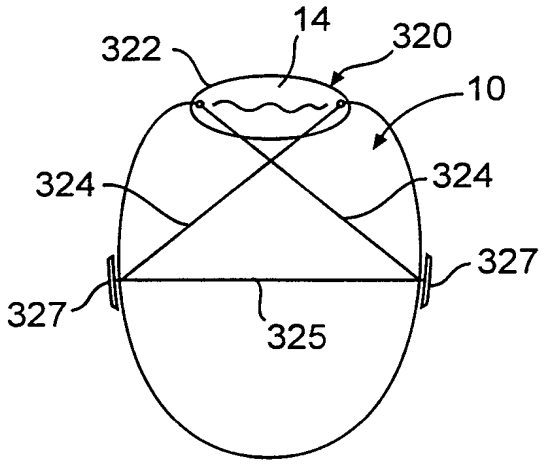


FIG. 10

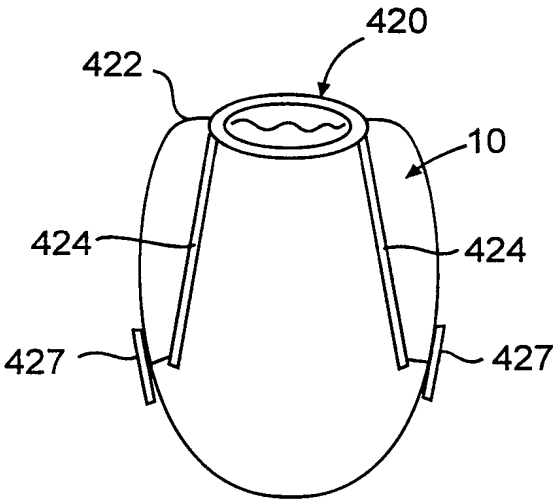


FIG. 11

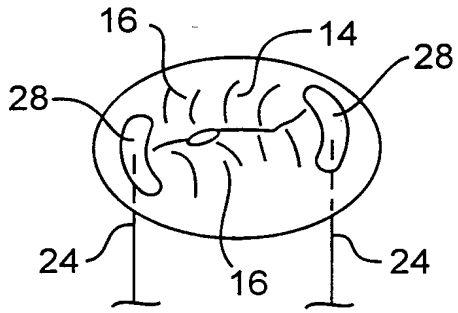


FIG. 12

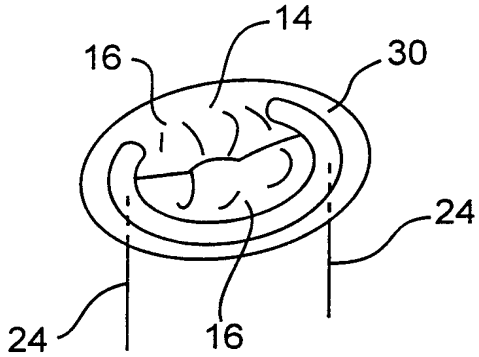


FIG. 13

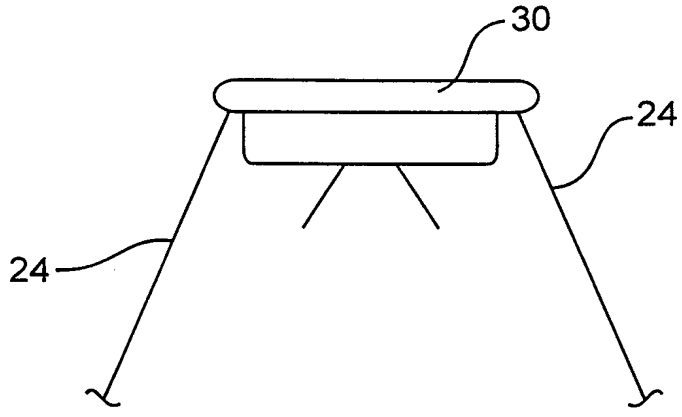


FIG. 14

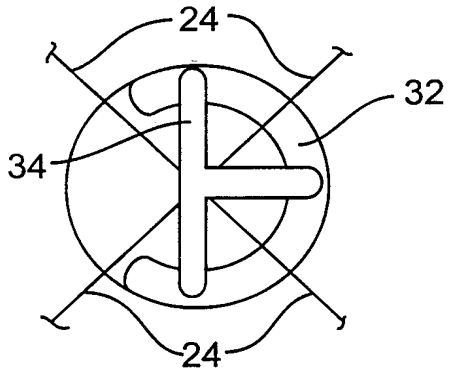


FIG. 15

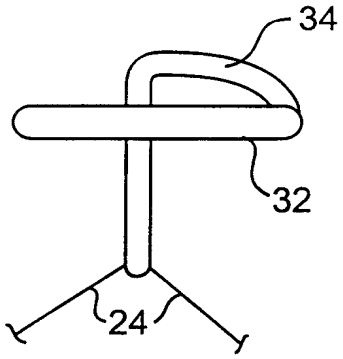


FIG. 16

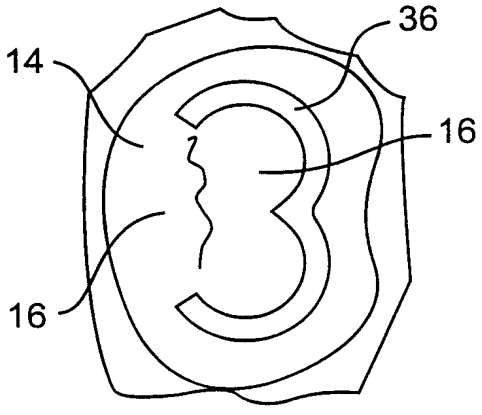


FIG. 17

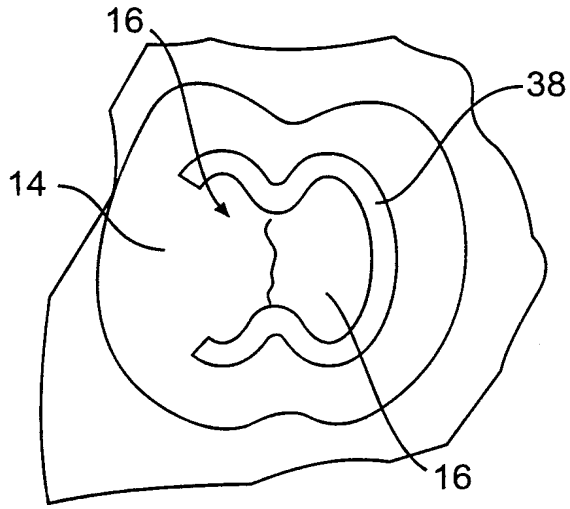


FIG. 18

FIG. 19

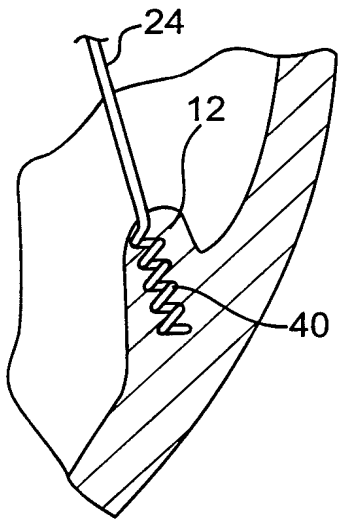


FIG. 20

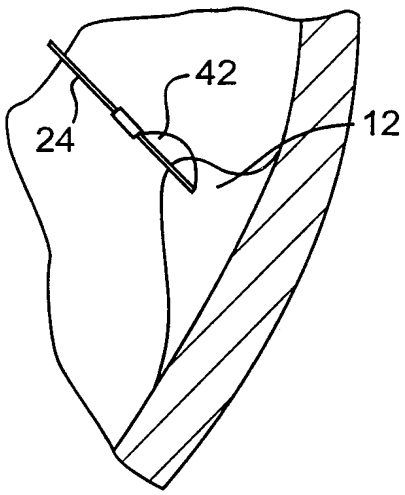
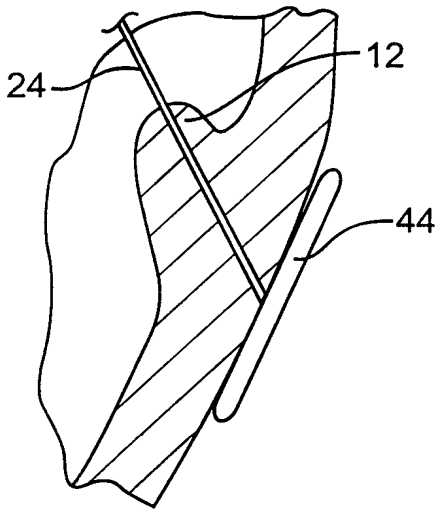


FIG. 21



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/26667

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/24

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 6 A61F

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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 95 06447 A (W.L. GORE & ASSOCIATES, INC.) 9 March 1995 see page 16, line 26 - page 17, line 2; figures 16,17	1
A	WO 96 04852 A (NORTHRUP) 22 February 1996	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° 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 document 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	Date of mailing of the international search report
19 April 1999	26/04/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/26667

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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. [X] Claims Nos.: 11-17
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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 II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

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 an additional fee, this Authority did not invite payment of any additional fee.

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.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 98/26667

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9506447 A	09-03-1995	US 5450860 A	19-09-1995
		AU 5320694 A	22-03-1995
WO 9604852 A	22-02-1996	US 5593424 A	14-01-1997
		AU 700530 B	07-01-1999
		AU 3322495 A	07-03-1996
		CA 2197069 A	22-02-1996
		EP 0779793 A	25-06-1997
		JP 10504481 T	06-05-1998
		US 5709695 A	20-01-1998
		ZA 9506672 A	04-07-1996

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : **A61B 17/00** | **A1**

(11) International Publication Number: **WO 00/16700**

(43) International Publication Date: 30 March 2000 (30.03.00)

(21) International Application Number: PCT/US99/21310

(22) International Filing Date: 17 September 1999 (17.09.99)

(30) Priority Data:
09/157,486 21 September 1998 (21.09.98) US

(71) Applicant *(for all designated States except US)*: MYOCOR, INC. [US/US]; Suite 200W–B, 1380 Energy Lane, St. Paul, MN 55108 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: MORTIER, Todd, J. [US/US]; 3008 Colfax Avenue South, Minneapolis, MN 55408 (US). SCHWEICH, Cyril, J., Jr. [US/US]; 1685 Hillcrest Avenue, St. Paul, MN 55116 (US). VIDLUND, Robert, M. [US/US]; 1811 Kennard Street, Maplewood, MN 55109 (US). KEITH, Peter, T. [US/US]; 1477 Grantham Street, St. Paul, MN 55108 (US). PAULSON, Thomas, M. [US/US]; 4322 York Avenue South, Minneapolis, MN 55410 (US). KUSZ, David, A. [US/US]; 3229 – 39th Avenue South, Minneapolis, MN 55406 (US).

(74) Agents: GARRETT, Arthur, S. et al.; Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., 1300 I Street, N.W., Washington, DC 20005–3315 (US).

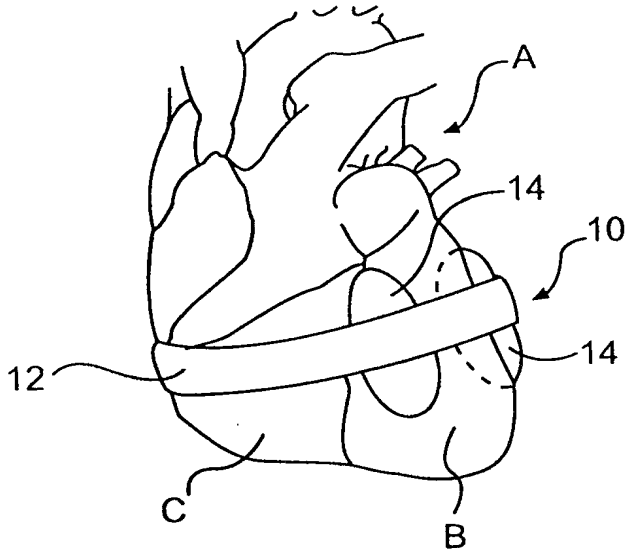
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: EXTERNAL STRESS REDUCTION DEVICE AND METHOD

(57) Abstract

An external heart wall stress reduction apparatus is provided to create a heart wall shape change. The device is generally disposed to the exterior of a heart chamber to reshape the chamber into a lower stress configuration.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

EXTERNAL STRESS REDUCTION DEVICE AND METHOD

Field of the Invention

The present invention pertains to the field of heart failure in devices and methods for treatment thereof.

Background of the Invention

The syndrome of heart failure is a common course for the progression of many forms of heart disease. Heart failure may be considered to be the condition in which an abnormality of cardiac function is responsible for the inability of the heart to pump blood at a rate commensurate with the requirements of the metabolizing tissues, or can do so only at an abnormally elevated filling pressure. There are many specific disease processes that can lead to heart failure with a resulting difference in pathophysiology of the failing heart, such as the dilatation of the left ventricular chamber. Etiologies that can lead to this form of failure include idiopathic cardiomyopathy, viral cardiomyopathy, and ischemic cardiomyopathy.

The process of ventricular dilatation is generally the result of chronic volume overload or specific damage to the myocardium. In a normal heart that is exposed to long term increased cardiac output requirements, for example, that of an athlete, there is an adaptive process of ventricular dilation and myocyte hypertrophy. In this way, the heart fully compensates for the increased cardiac output requirements. With damage to the myocardium or chronic volume overload, however, there are increased requirements put on the contracting myocardium to such a level that this compensated state is never achieved and the heart continues to dilate.

The basic problem with a large dilated left ventricle is that there is a significant increase in wall tension and/or stress both during diastolic filling and during systolic contraction. In a normal heart, the adaptation of muscle hypertrophy (thickening) and ventricular dilatation maintain a fairly constant wall tension for systolic contraction. However, in a failing heart, the ongoing dilatation is greater than the hypertrophy and the result is a rising wall tension requirement for systolic contraction. This is felt to be an

ongoing insult to the muscle myocyte resulting in further muscle damage. The increase in wall stress is also true for diastolic filling. Additionally, because of the lack of cardiac output, there is generally a rise in ventricular filling pressure from several physiologic mechanisms. Moreover, in diastole there is both a diameter increase and a pressure increase over normal, both contributing to higher wall stress levels. The increase in diastolic wall stress is felt to be the primary contributor to ongoing dilatation of the chamber.

Prior art treatments for heart failure fall into four general categories. The first being pharmacological, for example, diuretics. The second being assist systems, for example, pumps. Third, surgical treatments have been experimented with, which are described in more detail below. Finally, multi-site pacing contract the heart muscles at the same time.

With respect to pharmacological treatments, diuretics have been used to reduce the workload of the heart by reducing blood volume and preload. Clinically, preload is defined in several ways including left ventricular end diastolic pressure (LVEDP), or left ventricular end diastolic volume (LVEDV). Physiologically, the preferred definition is the length of stretch of the sarcomere at end diastole. Diuretics reduce extra cellular fluid which builds in congestive heart failure patients increasing preload conditions. Nitrates, arteriolar vasodilators, angiotensin converting enzyme inhibitors have been used to treat heart failure through the reduction of cardiac workload through the reduction of afterload. Afterload may be defined as the tension or stress required in the wall of the ventricle during ejection. Inotropes such as digoxin are cardiac glycosides and function to increase cardiac output by increasing the force and speed of cardiac muscle contraction. These drug therapies offer some beneficial effects but do not stop the progression of the disease.

Assist devices include, for example, mechanical pumps. Mechanical pumps reduce the load on the heart by performing all or part of the pumping function normally done by the heart. Currently, mechanical pumps are used to sustain the patient while a donor heart for transplantation becomes available for the patient.

There are at least three surgical procedures for treatment of heart failure: 1) heart transplant; 2) dynamic cardiomyoplasty; and 3) the Batista partial left ventriculectomy. Heart transplantation has serious limitations including restricted availability of organs and

adverse effects of immunosuppressive therapies required following heart transplantation. Cardiomyoplasty includes wrapping the heart with skeletal muscle and electrically stimulating the muscle to contract synchronously with the heart in order to help the pumping function of the heart. The Batista partial left ventriculectomy includes surgically remodeling the left ventricle by removing a segment of the muscular wall. This procedure reduces the diameter of the dilated heart, which in turn reduces the loading of the heart. However, this extremely invasive procedure reduces muscle mass of the heart.

Summary of the Invention

The present invention pertains to a device and method for reducing mechanical heart wall muscle stress. Heart wall muscle stress is a stimulus for the initiation and progressive enlargement of the left ventricle in heart failure. Reduction in heart wall stress with the devices and methods disclosed herein is anticipated to substantially slow, stop or reverse the heart failure process, some or reverse the heart failure process, improve contractile function with decrease in isovolumetric contractions and improved isotonic shortening. Although the primary focus of the discussion of the devices and methods of the present invention herein relates to heart failure and the left ventricle, these devices and methods could be used to reduce stress in the heart's other chambers.

The devices and methods of the present invention are primarily external devices which need not necessarily penetrate the heart wall or transect a heart chamber. These devices can be used instead of, or in addition to, internal or transventricular devices. Unlike transventricular devices, however, avoidance of internal ventricular structures such as valves or chordae is not a concern. It is desirable to limit the size of the external devices to limit inflammatory response that may be created by implanting the device. Additionally, the weight of the device should be limited to reduced movement and forces which can induce inflammatory response or other negative physiologic responses as well. To limit the weight and size of the device, the devices can be constructed with materials with high strength to weight ratios and high stiffness to weight ratios. Size and weight interact to effect the stability of the device on the heart. The devices are preferably stabilized on the heart by tissue ingrowth, sutures, friction fit or the like.

The devices and methods of the present invention can reduce heart wall stress throughout the cardiac cycle including end diastole and end systole. Alternately they can be used to reduce wall stress during the portions of the cardiac cycle not including end systole. Those devices which operate throughout the cardiac cycle can be referred to as "full cycle" devices whereas those that do not operate to reduce wall stress during end stage systole can be referred to as "restrictive" devices.

Brief Description of the Drawings

Figure 1 is a perspective view of a heart wall tension reduction device in accordance with the present invention;

Figure 2 is a generally horizontal cross section of the device of Figure 1;

Figure 3 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 4 is a generally horizontal cross sectional view of the device of Figure 3;

Figure 5 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 6 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 7 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 8 is a view of the device of Figure 7 connected to a skeleton of a patient;

Figure 9 is a generally horizontal cross sectional view of the device of Figure 7 disposed within a patient;

Figure 10 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 11 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 12 is a generally horizontal cross sectional view of the device of Figure 11;

Figure 13 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 14 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 15 is a perspective view of the device of Figure 14;

Figure 16 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 17 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 18 is a perspective view of the device of Figure 17;

Figure 19 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 20 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 21 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 22 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 23 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 24 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 25 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 26 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 27 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 28 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 29 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 30 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 31 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 32 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 33 is a generally horizontal cross sectional view taken from Figure 32;

Figure 34 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 35 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention;

Figure 36 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention; and

Figure 37 is a view of an alternate embodiment of a heart wall tension apparatus in accordance with the present invention.

Detailed Description of the Invention

Referring now to the drawings wherein like reference numerals refer to like elements throughout the several views, Figure 1 is a generally vertical view of human heart A having a left ventricle B and right ventricle C. Disposed on heart A is a heart wall stress reduction apparatus 10 including a band 12 disposed generally honizontally around heart A. Disposed between band 12 and heart A are generally ellipsoidal balloons 14. In Figure 2, heart A is shown in context, in a generally transverse cross sectional view of a human torso. Heart A is shown disposed generally between left lung D and right lung E. In Figure 2 it can be seen that band 12 retains balloon 14 with sufficient force to deform left ventricle B from a generally circular cross sectional configuration to a bi-lobe configuration. It is anticipated that device 10 could be adjusted for full cycle shape change of left ventricle B or be more loosely placed on the heart as a restrictive

device, not creating a shape change at end systole. In addition to the bi-lobe configuration of Figure 2, the shape change could also be of such a substantial magnitude that the chamber is substantially bifurcated by bringing the oppositely disposed heart walls into contact with each other.

Band 12 preferably does not substantially elongate under operational loads, but could be formed from material which deforms elastically under operational loading. Band 12 is preferably formed from a biocompatible material such as expanded PTFE or a polyester such as Dacron™. Balloon 14 could be a pre-inflated balloon filled with saline or curable polymer prior to placement between band 12 and heart A. Balloon 14 could also be inflated after placement between band 12 and heart A and then sealed by means known to those skilled in the art. It can be appreciated that balloons 14 need not, in fact, be balloons but could be solid or hollow ellipsoidal members made from biocompatible metals or plastics. Balloon 14 preferably includes an expanded PTFE or Dacron™ surface which has a pore size disposed toward heart A which would allow tissue ingrowth. It may be desirable to have a pore size of material covering band 12 and balloons 14 disposed away from the heart which does not promote tissue ingrowth, however. The pore size to promote tissue ingrowth is preferably between about 10 and about 100 microns and more preferably, between about 20 and about 40 microns. With respect to expanded PTFE, the intemodal dimension is preferably between about 10 to about 100 microns and more preferably between about 20 to about 40 microns.

Figure 3 is a generally vertical view of heart A. Disposed on heart A is an alternate heart wall stress reduction device 20 including a generally rigid frame 22. Frame 22 preferably includes generally horizontal cross members 24 and generally vertical cross members 26. Extending from cage 22 are struts 28 having one end connected to frame 22 and an opposite end connected to anchors 29. By adjusting the lengths of struts 28, pads 29 can engage left ventricle B to create a shape like that shown in Figure 4.

Frame 22 is preferably made from a biocompatible metal or plastic and is substantially rigid during operational loading. Frame 22 could, however, be formed of a material which would allow elastic deformation during use. The materials used to form device 20 are preferably relatively light to enhance stability of device 28 on heart A.

Light metals which could be used to form device include Co-Cr-Mo alloys, Co-Ni-Cr-Mo alloy (MP35N), carbon and titanium alloys (Ti-6AL-4V). In addition to plastics such as polyester, device 20 could be formed from composites such as carbon fibers/epoxy, polyester/epoxy, or amide fiber/epoxy, for example. Anchors 29 are preferably pad or disk shaped, atraurnatic and include material coating having a pore size such as that described above with respect to device 10 which promotes tissue ingrowth. Additionally, sintered metal could create a pore size which would promote tissue ingrowth.

Figure 5 is an alternate embodiment of a heart wall stress reduction device 30 disposed on heart A which is shown in a generally vertical orientation. Device 30 preferably includes a sock 31 formed from a porous mesh of biocompatible fabric such as polyester. Sock 31 preferably does not substantially stretch or elongate under operational loads. Sock 31 could, however, be made from a material which deforms elastically at operational loads. Disposed between sock 31 and heart A is an elongate bar 32. Bar 32 is preferably held against left ventricle B with sufficient force to create a shape change such as that shown in Figure 2 when a second bar 32 is disposed between sock 31 and the posterior side of heart A. Sock 31 is preferably held in place on heart A by sutures.

Figure 6 is yet alternate embodiment 40 of a heart wall stress reduction device. Device 40 is similar to device 30 except that it includes a shell 42 which is substantially rigid under operational loads rather than a sock 31 and inwardly protruding members 40 rather than a bar 32. Shell 42 can be slipped over heart A to create a shape change similar to that shown in Figure 2. Members 44 are thus preferably profiled such that they can be slid atraurnatically over heart A to place device 40.

Device 40 is preferably made from those materials described with respect to device 20 above. The surface of protrusions 44 preferably include a surface which promotes tissue ingrowth as described above. Device 40 can be held in place on heart A by sutures placed through apertures (not shown) in shell 42.

Figure 7 is yet another embodiment of a heart wall stress reduction device 50 in accordance with the present invention. Device 50 includes a preferably substantially rigid ring 51. Ring 51 could, however, be made from a material which deforms elastically under operational loads. Ring 51 preferably has a plurality of apertures 52 disposed

circumferentially on opposite sides of ring 51. Extending through an aperture 52 on opposite sides of ring 51 are struts 53. Struts 53 can be extended inwardly from ring 51 by adjusting threaded fasteners 54. Threaded fasteners 54 are preferably provided on strut 53 such that strut 53 can be retained in place while acted upon by outward or inwardly directed forces. At the inward end of strut 53 is an elongate anchor or pad 55. It can be appreciated that ring 51 could be placed around heart A and the position of pads 55 adjusted such that a shape change of left ventricle B could be created similar to that shown in Figure 2.

Device 50 could advantageously be made from those materials described with respect to device 20. Anchors 55 preferably include a porous surface which allows for tissue ingrowth as described above.

Figure 8 is a generally vertical view of the skeleton of a human torso. A device 50 is shown disposed within ribs F. Device 50 is held in position by a tether 56 anchored by a loop or bone screw 57 to ribs F and an oppositely disposed tether 56 and loop or bone screw 57 attached to spinal column G. Figure 9 is a generally transverse cross sectional view taken through Figure 8 of device 50 and short soft tissue organs including heart A and lungs D and F.

Figure 10 is a vertical view of heart A. Disposed on heart A is an alternate embodiment 60 of a heart wall stress reduction device. Device 60 is a band shown wrapped generally horizontally around left ventricle B. Band 60 is preferably formed from polyester or other biocompatible plastic such as Dacron™. Band 60 preferably has an inwardly disposed surface which is porous to promote tissue ingrowth as described above. Band 60 preferably does not substantially elongate under operational loadings. Band 60 could, however, be formed from materials which elongate under operational loading. In addition to, or prior to tissue ingrowth band 60 could be held in place by, for example, sutures. Device 60 could be a closed loop or a loop having free ends which are buckled or fastened together by Velcro™ or other means known in the art (not shown).

Band 60 does not create a left ventricular shape change having a bi-lobe configuration in a horizontal cross section as shown in Figure 2. Rather, band 60 forms a bi-lobe configuration in vertical cross section.

Figure 11 is a vertical cross sectional view of heart A. Disposed on heart A is yet an alternate embodiment of a heart wall stress reduction device 65 in accordance with the present invention. Device 65 is substantially similar to device 60. Device 65 is, however, shown extending around the exterior of left ventricle B and placed through right ventricle C. Device 65 thus includes a band having free ends which are attachable after placement of the device through right ventricle C and around left ventricle B.

As can be seen in Figure 12, device 65 does not create a horizontally bi-lobe configuration such as that shown in Figure 2. Rather, device 65 creates a bi-lobe configuration of left ventricle B in a vertical cross sectional view.

Figure 13 is a view of device 60 placed on heart A in a manner similar to that shown in Figure 10, but used in conjunction with an additional elongate bar 62. Bar 62 can be similar to bar 32 shown in Figure 5. It can be appreciated that if bar 62 is disposed between device 60 and heart A, and a second bar 62 is similarly disposed on the posterior side of heart A, a bi-lobed shape change can be created in a generally horizontal cross section of left ventricle B. It can also be appreciated that device 60 will also create a bi-lobed shape change on left ventricle B in a generally vertical cross section.

Figure 14 is a generally vertical view of heart A. Disposed on right ventricle B of heart A are two generally C-shaped, alternate heart wall stress reduction devices 70. Device 70 preferably includes a generally C-shaped cross member 71 having two oppositely disposed ends. On opposite ends of cross members 71 are preferably disposed anchors 72. Anchors 72 are preferably disc or pad shaped and have an innerly disposed porous surface to allow tissue ingrowth as described above. As shown in Figure 14, two C-shaped devices 70 can be used together to form a bi-lobe shape change of left ventricle B in a manner similar to that shown in Figure 2.

Cross member 71 is preferably made from a malleable metal which can be bent prior to placement such that the desired spacing is obtained between oppositely disposed anchors 72. It is possible that the spacing of pad 72 could be adjusted while device 70 is placed on the heart, but preplacement spacing adjustment is preferred. In addition to malleable materials or metals, cross member 71 could also be formed from plastics or composites such as those described above with respect to device 20. Figure 15 is a perspective view of device 70 not including heart A.

Figure 16 is yet alternate embodiment of a heart wall stress reduction apparatus 75 in accordance with the present invention. Device 75 is essentially similar to device 70, except that cross member 76 is shown in a band shape and anchors 77 are generally elongate. Elongate anchors may be desirable for both device 75 and 70 to create a bi-lobe shape change over a greater generally vertical extent of left ventricle B.

Figure 17 is a generally vertical view of heart A. Yet another altemate embodiment of a heart stress reduction device 80 is shown disposed on heart A. Device 80 is similar to device 70, except that it includes elongate anchors 82 and a cross member 81 disposed generally in alignment with the longitudinal axis of anchor 82. This allows cross member 81 to rest on an upper surface of heart A to resist gravitational displacement of device 80 from heart A. Figure 18 is a view of device 80 apart from heart A.

As an altemative to a C-shaped device such as device 70 which is preferably adjusted or sized prior to placement on heart A, devices such as those shown in Figures 19-28 can readily be adjusted in place on the heart. The devices of Figures 19-28 include mechanical mechanisms for adjusting anchor spacing. Each of these devices could be positioned in heart A to create a shape change similar to that of Figure 2. The devices of Figures 19-28 are preferably made from light biocompatible metal and/or plastics. The anchors or pads preferably have a porous heart engaging surface to promote tissue ingrowth.

Figure 19 is a view of yet another alternate embodiment of a heart wall stress reduction device 90 in accordance with the present invention. Device 90 includes two oppositely disposed arms 91 and 92 pivotally attached by a pin 93 to form a C-shape. Disposed at the free ends of each arm 91 and 92 is an anchor or anchor pad 94 pivotally attached to arms 91 and 92 by pins 95. Pivotally attached to the opposite ends of arms 91 and 92 are internally threaded members 96 into which is threaded a rod 97. Disposed along, and fixably attached to rod 97 is a thumb wheel 98 for rotating rod 97. Rod 97 is preferably flexible enough that as it is rotated to draw the ends of arms 91 and 92 together, it can be deformed such that wheel 98 will move to the right as upper member 96 pivots counterclockwise and lower member 96 pivots clockwise.

Figure 20 is a view of yet an alternate embodiment 100 of a C-shaped heart wall stress reduction device. Device 100 includes arms 101 and 102. Disposed at the free ends of arms 101 and 102 are pads 94 pivotally connected thereto by pins 95. At the opposite ends of arms 101 and 102, they are joined by a bolt 103 and wing nut 104. Wing nut 104, when loosened will allow arms 101 and 102 to pivot around bolt 103. Wing nut 104 can be tightened to fix the relative position of arms 101 and 102 when the desired spacing of pads 94 has been achieved.

Figure 21 is a view of yet an alternate embodiment 110 of a C-shaped heart wall stress reduction device. Device 110 is similar to device 100 except that oppositely disposed arms 116 and 117 are cantilevered beyond their pivotable attachment point at pin 112 to a bolt 114 and a wing nut 115. Arm 117 includes a plate 111 having an arc-like aperture 113 formed therein. Bolt 114 extends through aperture 113 and arm 116 such that when wing nut 115 is loose, bolt 114 can slide in aperture 113 to rotate arm 116 about pin 112 to adjust the spacing between pads 94. When the desired spacing is achieved, wing nut 115 can be tightened to fix the relative position of arms 116 and 117.

Figure 22 is a view of yet another alternate embodiment of a generally C-shaped heart wall stress reduction device 120. Device 120 includes two oppositely disposed arms 126 and 127. Pads 94 are pivotally attached by pins 95 to the free ends of arms 126 and 127. The opposite end of arm 126 is slidably disposed through a receiving housing 121 at the opposite end of arm 127. The end of arm 127 extending through housing 121 includes teeth 122. Disposed between housing 121 and pad 94 and along arm 127 is a screw gear housing 123 which positions the threads of a screw gear 124 between teeth 122. Gear 124 includes a shaft having a thumb knob 125 attached thereto. Knob 125 can be used to rotate screw 124 to engage successive teeth 122 to move arm 126 relative to arm 127 in the directions shown by the arrow. Thus, in this manner, arm 126 can be moved to adjust the spacing between pads 94.

Figure 23 shows yet another alternate embodiment of a generally C-shaped heart wall stress reduction device 130 in accordance with the present invention. Device 130 is similar to device 100 except for oppositely disposed arms 134 and 135 are pivotable about pin 131 and fixable in position by ratchet teeth 132 of arm 134 and an elongate

member 133 connected to arm 135. Ratchet teeth are sloped such that as arm 134 is pivoted about pin 131 to bring pads 94 closer together, member 133 rides over successive teeth 132. If, however, it is attempted to rotate 134 in the opposite direction, teeth 132 are sloped to engage member 133 and resist the rotation of arm 134 about pin 131. Member 133 can be pulled away from teeth 132 to allow arm 134 to be pivoted in a clockwise direction.

Figure 24 is a view of yet an alternate embodiment of a generally C-shaped heart wall tension reduction device 140 in accordance with the present invention. Device 140 includes oppositely disposed arms 144 and 145. Anchors 94 are pivotally attached by pins 95 to the free ends of arms 144 and 145. The opposite ends of arms 144 and 145 include slots 141 and 142. As shown in Figure 24, where slots 141 and 142 overlap, nut and bolt assemblies 143 are disposed therethrough. As can be appreciated, if nut and bolt assemblies 143 are loosened they will be free to slide within slots 141 and 142 such that the ends of arms 144 and 145 disposed opposite pads 94 can be slid over each other to adjust the distance between pads 94. Once the desired distance between pads 94 is obtained, nut and bolt assemblies can be tightened to fix the relative position of arms 144 and 145.

Figure 25 is a view of yet an alternate embodiment of a generally C-shaped heart wall stress reduction device 150 in accordance with the present invention. Device 150 includes two oppositely disposed arms 153 and 154. Pads 94 are pivotally attached by pins 95 to the pins of arms 153 and 154. The opposite end of arm 153-is slidably received within an aperture of a receiving housing 151 connected to the opposite end of arm 154. A set screw 152 is threaded into housing 151 such that when set screw 152 is loose, arm 153 can slide within housing 151 to vary the distance between pads 94. Once the desired distance between pads 94 has been obtained, set screw 152 can be tightened to engage arm 153 and fix its position relative to arm 154.

Figure 26 is a view of yet an alternate generally C-shaped heart wall stress reduction apparatus 160 in accordance with the present invention. Device 160 includes a generally C-shaped arm 161 which has two oppositely disposed free ends. Pads 94 are pivotally connected by pins 95 to each of the free ends. Disposed along the interior arc of arm 161 are eyelets 163. Disposed through eyelets 163 is a line or cable 164 having

two oppositely disposed ends fixably attached to opposite pads 94. A more centrally located portion of line 164 is at least partially wrapped around a spool 165. Spool 165 is rotatably connected to a generally central portion of member 161. A knob 166 is connected to spool 165 to allow rotation thereof. It can be appreciated that if spool 165 is rotated into the paper in the direction of the arrow, that the spacing between pads 94 will decrease as line 164 is pulled through eyelets 163 toward spool 165. It can be appreciated that if spool 165 is rotated in an opposite direction, pads 94 will move apart to the extent that member 161 is biased to expand outwardly. The position of spool 165 can be fixed when the desired spacing of pads 94 is obtained by tightening a set screw 167 disposed adjacent knob 166.

Figure 27 is a view of yet an alternate embodiment of a generally C-shaped heart wall tension apparatus 170. Heart wall tension reduction apparatus 170 includes two oppositely disposed arms 171 and 172. Disposed at the free end of arms 171 and 172 are anchors 173 and 174, respectively. Anchors 173 and 174 can be anchor pads each having a disc-like heart engaging surface similar to that of anchor 94. The portion of anchors 173 and 174 opposite the disc-shaped portion includes socket shaped portions 175 and 176, respectively. These socket shaped portions 175 and 176 are shaped similarly to that of the socket portions of ball and socket joints. Disposed along the length of arms 171 and 172 are ball and socket members 179. Each member 179 includes a generally ball shaped or hemispherical end 181 and a complimentary concaved socket end 180. As shown, a series of members 179 are placed ball end to socket end to form each arm 171 and 172. The final ball end 181 of each arm 171 and 172 is disposed within sockets 175 and 176 respectively of anchors 173 and 174, respectively.

Each member 179 includes a longitudinal lumen extending therethrough. A line 182 extends through successive of these lumens in arms 171. A line 183 extends through arm 172 in a similar fashion. Lines 182 and 183 are free to move within the lumens but are fixably attached at their ends to anchors 173 and 174, respectively. The opposite ends of lines 182 and 183 pass over pulleys 185 and are connected to a spool or takeout reel 186 which in turn is pivotally connected to a central housing 184. Housing 184 includes oppositely disposed ball portions 188 and 189, which engage the sockets of the adjacent members 179. A knob 187 is provided to rotate spool 186. If spool 186 is rotated in the

direction shown by the arrow, lines 182 and 183 will be drawn toward spool 186, which in turn will draw the adjacent ball and socket ends toward each other. When the force exerted by lines 182 and 183 is sufficient, friction between adjacent ball and socket ends will hold arms 171 and 172 in any position in which they have been placed. Thus, when the desired spacing between anchors 173 and 174 is obtained and lines 182 and 183 tightened, a set screw 177 can be tightened to retain spool 186 in position to maintain the spacing between anchors 173 and 174. Not only can the spacing between anchors 173 and 174 be controlled in this manner, but the shape of the arm can be altered along its length to be straight or arcuate to conform to the shape of the heart.

Figure 28 is a view of an alternate arm configuration 190 which could be used in a generally C-shaped heart wall stress reduction apparatus. The principle of its operation would be similar to that of the device of Figure 23, except that a plurality rather than one ratcheting member would be provided. By providing a plurality of ratcheting members, the shape of the arm can be altered along its length to be relatively straighter, or more arcuate depending upon the degree to which the various members are ratcheted with respect to each other.

Arm 190 includes a plurality of ratcheting members 191. A first end 192 of each member 191 is pivotally connected to the opposite end 193 of each member 191 by a pin 194. Each member can be rotated about pins 194 in the direction shown by the arrows. Teeth 195 are disposed at each end 193 to engage a ratcheting arm 196 extending from end 193 toward end 192. It can be appreciated that member 196 should be flexible enough that a physician can ratchet arm 196 over teeth 195 until the desired rotational position is obtained. The arms should also, however, be rigid enough that during normal operational heart loadings, member 126 remains between the teeth 129 selected by the physician.

Figure 29 is a generally vertical view of heart A. Yet another alternate embodiment of a heart wall stress reduction device 197 is shown on left ventricle B. Device 197 is preferably a sheet which has been wrapped around a portion of left ventricle B. The sheet includes a generally vertical elongate concave trough 197a on the anterior side of left ventricle B and a similar trough 197b on the posterior side of left

ventricle B. The base of the trough can be made to engage opposite sides of the ventricle to create a-bi-lobe shape similar to that shown in Figure 2.

The sheet is preferably formed in place on heart A to create the troughs 197a and 197b. The sheet can be formed from an epoxy or a composite including two or more of the following: epoxy, Dacron™, silicone or UV curable adhesive. The sheet, if made using a curable adhesive or epoxy should be placed prior to curing such that the sheet can be readily formed in a shape similar to that shown in Figure 29. During the curing process, the sheet can be held in place using one or more generally C-shaped heart wall tension reduction devices such as those shown in Figures 14-28.

The sheet material used to form device 197 could also be a malleable metal such as stainless steel. If a metal such as stainless steel were used to form the sheet, it could be bent to form a shape similar to that shown in Figure 29 prior to placement on the heart or while being placed on heart A.

Figure 30 is a generally vertical view of a heart A. Yet another embodiment of a heart wall stress reduction device 198 is shown disposed on left ventricle B. As shown in Figure 30, device 198 has a shell or helmet shape which substantially surrounds left ventricle B. Device 198 could be formed from materials in a manner described above with respect to device 197. In particular, troughs could be created in opposite sides of shell 198 to create a bi-lobe shape similar to that shown in Figure 2.

Figure 31 is a view yet another embodiment of a heart wall stress reduction device 199 shown disposed on left ventricle B of heart A. Device 199 has a generally U-shape including an anterior arm 199a and a posterior arm 199b. Arms 199a and 199b can be positioned on left ventricle B to create a bi-lobe shape of left ventricle B similar to that shown in Figure 2. The materials and methods used to make and place device 199 are similar to those used to make and place device 197 of Figure 29.

Figure 32 is a view of yet another alternate embodiment of a heart wall stress reduction device 200. Device 200 is generally C-shaped and includes an arm 201 and arm 202. As can be appreciated by reference to Figure 33, which is a generally horizontal cross sectional view taken from Figure 32, arm 22 is disposed within right ventricle C and arm 201 is disposed opposite to give left ventricle B a generally bi-lobe cross sectional shape.

Device 200 can be formed from a biocompatible metal or plastic. Device 200 can include a porous coating or surface to promote tissue ingrowth as described above and/or be held in place on heart A by sutures through apertures (not shown) in device 200.

Figure 34 is a yet another alternate embodiment of a heart wall stress reduction device 210 shown disposed within heart A. Device 210 has a generally V-shape and includes an arm 211 and another arm 212. Device 210 can be made from a biocompatible metal or plastic. Device 210 can be held in place by sutures extending through apertures in device 210 (not shown) and/or by providing a porous surface which promotes tissue ingrowth as described above. The free ends of arms 211 and 212 are preferably sufficiently narrowed such that they can be advanced through and disposed within the ventricular walls and/or septum rather than alongside the wall and/or septum. The device can be configured to, and placed to form a bi-lobe cross sectional shape of left ventricle B such as that shown in Figure 2 or 32.

Figure 35 is a view of yet another embodiment of a heart wall stress reduction device 220 shown disposed on the right ventricle of heart A. Device 220 has a generally V-shape and includes an arm 221 and an opposite arm 222. Arms 221 and 222 have a generally multiple wave or ungulating shape. When placed on the surface of the heart, the wave shape focuses pressure on the heart wall at space locations rather than continuously. It is anticipated that by spacing the contact points of device 220 that there will be a limited interruption of coronary blood flow as a result of impingement of the device on heart A.

Device 220 is preferably made from similar materials to that of device 210. Device 220 can be configured and placed on a heart to form a bi-lobe cross sectional shape of left ventricle B in a shape similar to that shown in Figure 2.

Figure 36 is a view of yet an alternate embodiment of a heart wall stress reduction device 230 in accordance with the present invention. Device 230 has a generally U-shape including an arm 233 and opposite arm 234. Device 230 preferably is formed from a tubular shell 231 and can be made from a biocompatible material such as PTFE. Disposed within tube 231 is a curable material such as epoxy urethane 232. Similarly to device 199 of Figure 31, device 30 is placed on the heart prior to curing of material 232 within tube 231. Arms 233 and 234 can be positioned to create a bi-lobe cross sectional

shape of left ventricle B such as that shown in Figure 2. One or more heart wall tension reduction devices similar to those shown in Figures 14-28 can be used to temporarily hold arms 233 and 234 in place until material 232 has cured.

Figure 37 is a view of yet an alternate embodiment 240 of a heart wall stress reduction device in accordance with the present invention. Device 240 is formed from a sheet configured in a generally U-shape having a side 241 and an opposite side 242 shown disposed on the anterior and posterior sides of left ventricle B. Device 240 is preferably formed from a malleable sheet 243. An inner sheet 244 of expanded PTFE or other material can be disposed on the inside surface of device 240 to allow tissue ingrowth. Sheet 243 could, however, also be sintered to promote tissue ingrowth and inner sheet 244 not used. Device 240 could be bent to obtain the desired configuration prior to placement on heart A or bent in place on heart A to obtain the desired cross section of left ventricle B. With device 240, a generally bi-lobe shape such as that shown in Figure 2 can be obtained in a configuration similar to that of device 197 of Figure 29. Additionally, device 240 could be placed without troughs formed in opposite sides such as those of device 197, but rather with generally planar arms 241 and 242. In such a case, if generally planar arms 241 and 242 are brought into a generally parallel configuration, left ventricle B can be compressed to create generally oblong, generally horizontal cross sectional configuration.

As shown herein the various heart wall stress reduction devices and methods have been applied to form a bi-lobe configuration of the left ventricle. It can be appreciated that the devices and methods disclosed herein can also be used to create three or more lobes in the left ventricle. Additionally, the heart wall stress reduction devices and methods disclosed herein can also be used to change the shape of the remaining chambers of the heart in addition to the left ventricle. The external device as disclosed herein could also be used in conjunction with transventricular heart wall stress reduction-devices. In such instance, both devices could be full cycle, restrictive, or one of the devices could be full cycle and the other restrictive. It can also be appreciated that the rotational positioning of the device about the heart can be varied to create a shape change between posterior and anterior anchors or between lateral anchors.

Numerous characteristics and advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size and ordering of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A method for reducing heart wall stress in a heart chamber, comprising the steps of:

providing a device having a first heart engaging surface, a second heart engaging surface and a member interconnecting the surfaces; and

placing the first and second surfaces on the wall of the chamber to deflect the heart wall proximate at least one of the heart engaging surfaces, while the interconnecting member is disposed externally of the heart.

2. The method in accordance with claim 1, wherein the deflection appears concave from outside the chamber.

3. The method in accordance with claim 1, wherein the deflection results in a inflection point along the wall of the heart.

4. The method in accordance with claim 1, wherein the first heart engaging surface includes a balloon.

5. The method in accordance with claim 1, wherein the first heart engaging surface includes an elongate pad.

6. The method in accordance with claim 1, further comprising the step of attaching the device to a bone.

7. The method in accordance with claim 1, wherein the surface is porous to allow tissue ingrowth.

8. The method in accordance with claim 1, further comprising the step of adjusting the distance between the surfaces.

9. The method in accordance with claim 1, wherein the member is malleable.

10. The method in accordance with claim 1, wherein the member is cast in place on the heart.

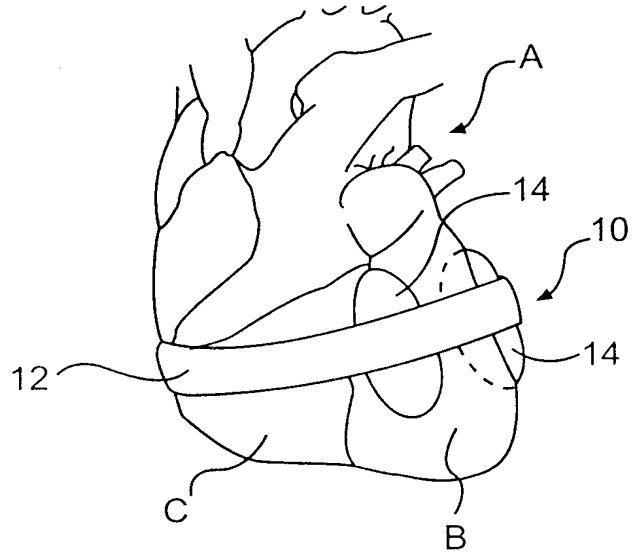


FIG. 1

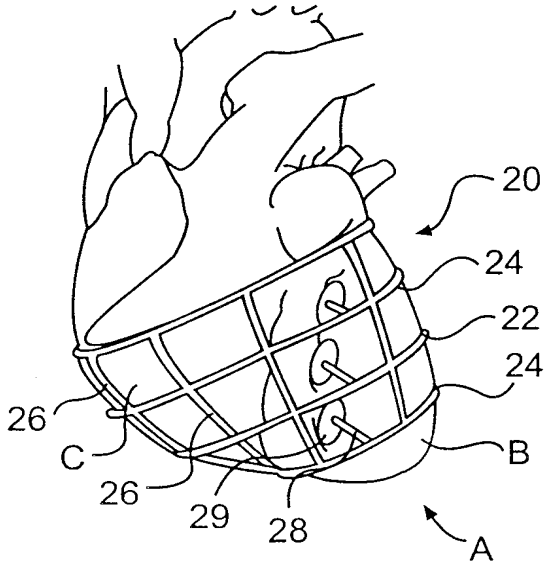


FIG. 3

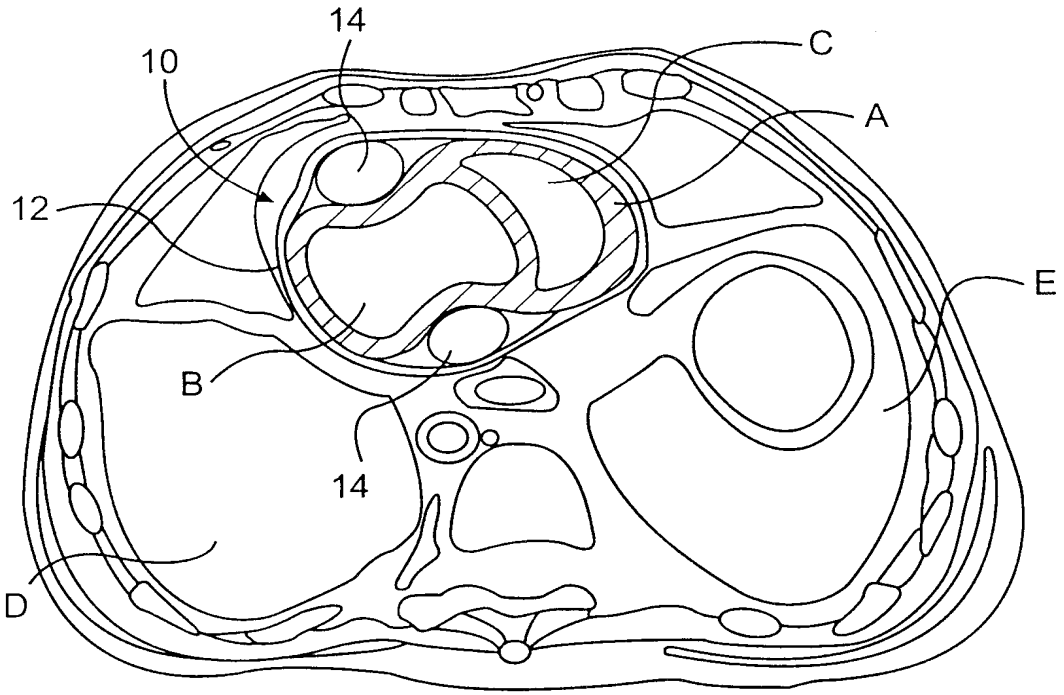


FIG. 2

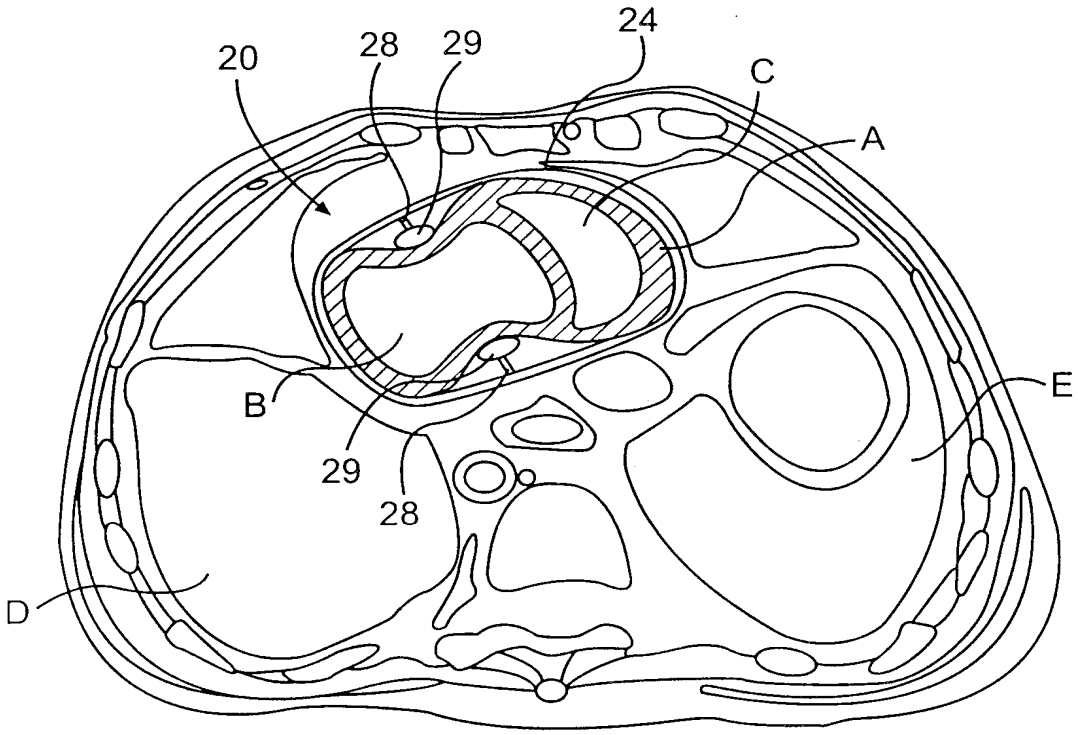


FIG. 4

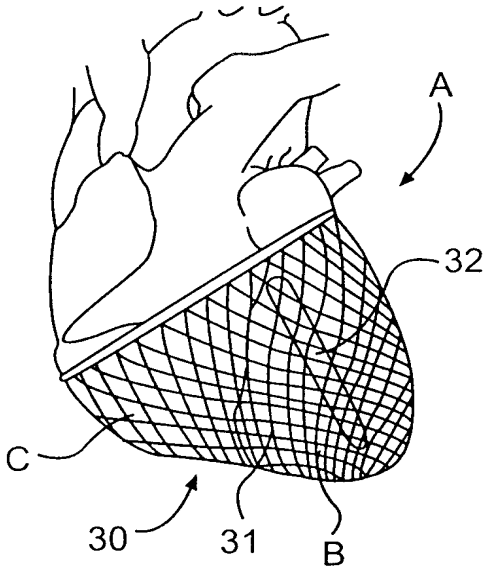


FIG. 5

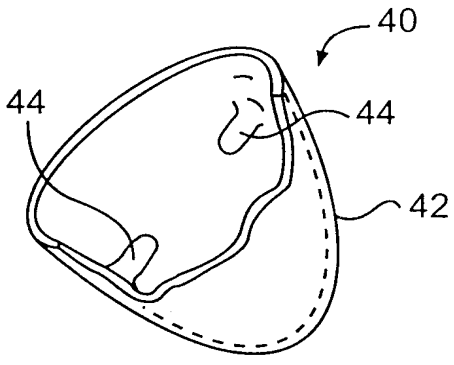


FIG. 6

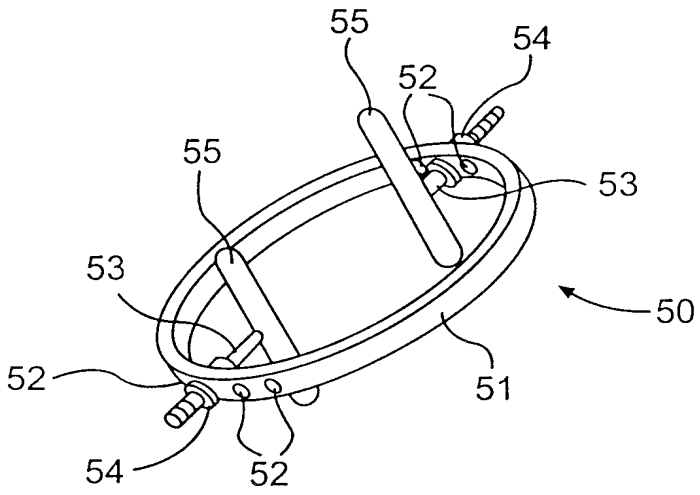


FIG. 7

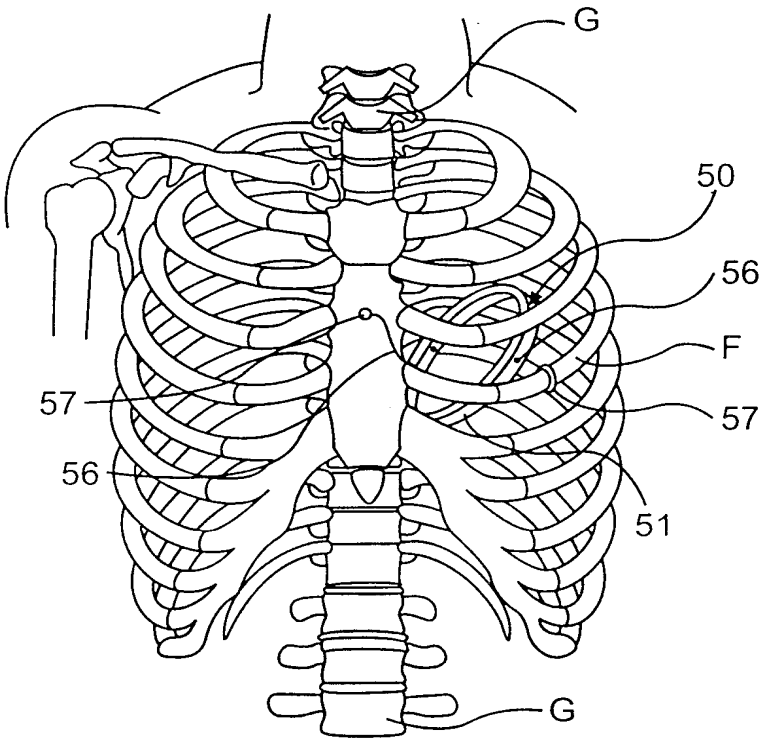


FIG. 8

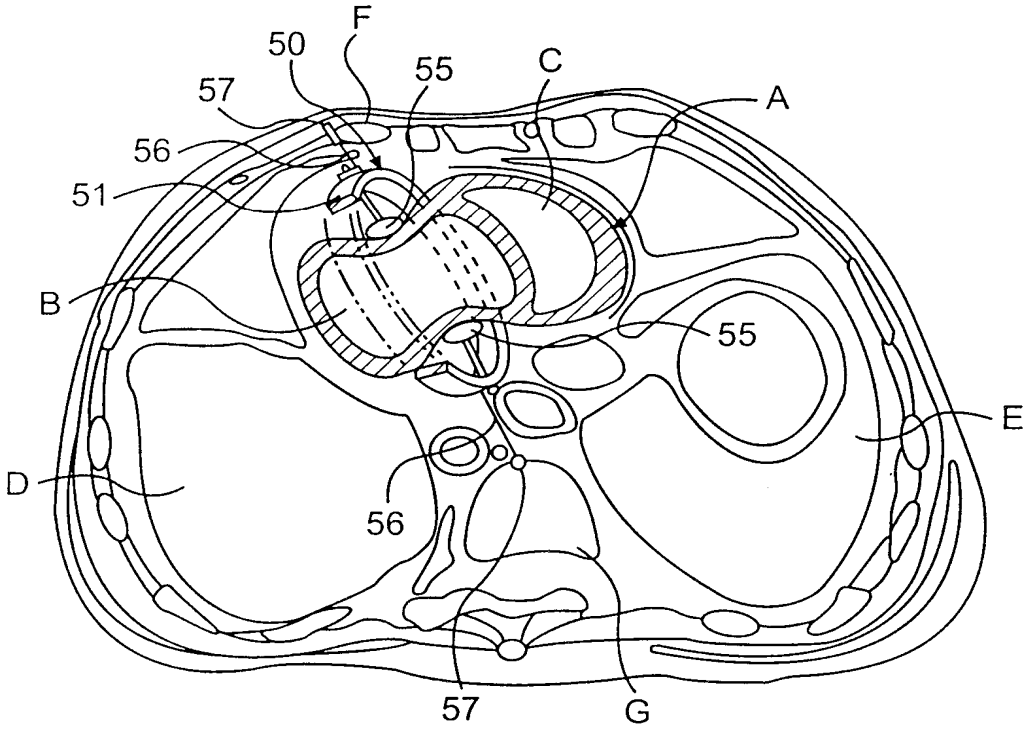


FIG. 9

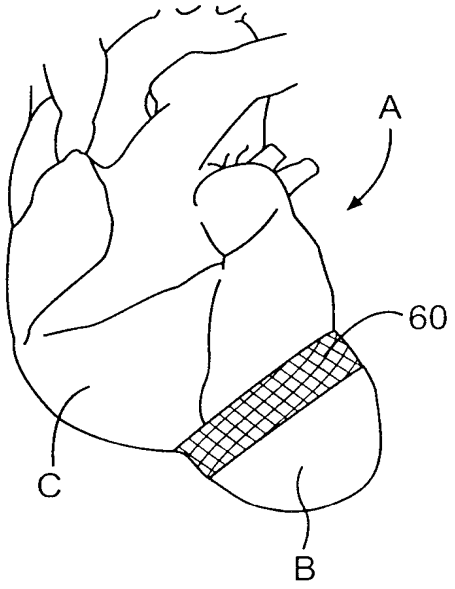


FIG. 10

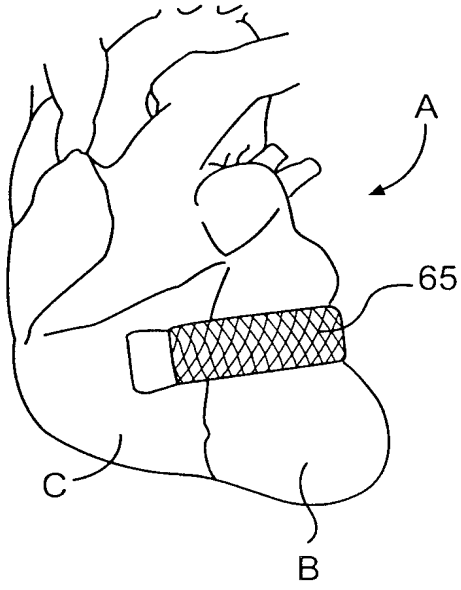


FIG. 11

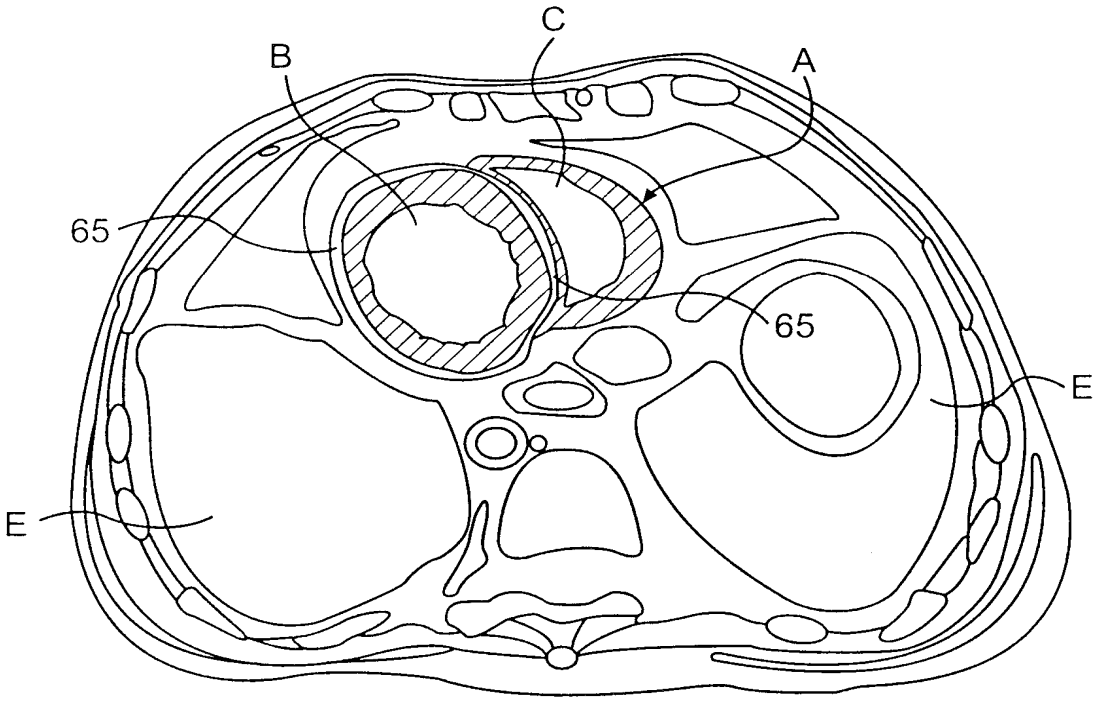


FIG. 12

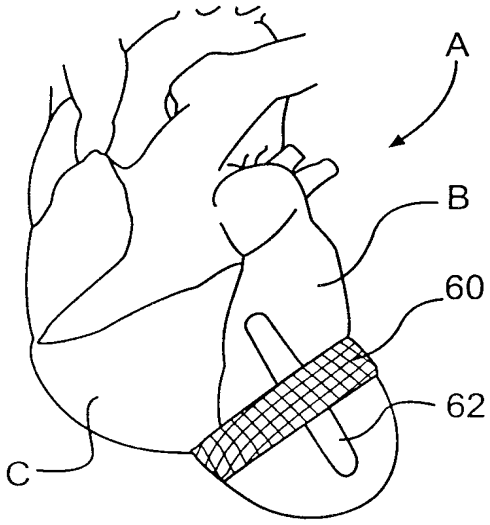


FIG.13

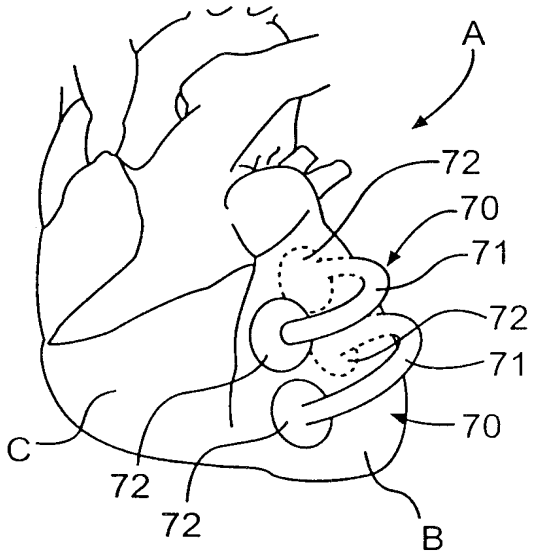


FIG.14

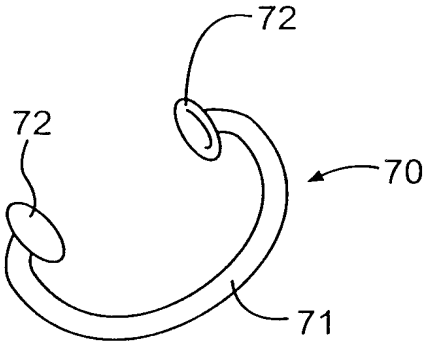


FIG.15

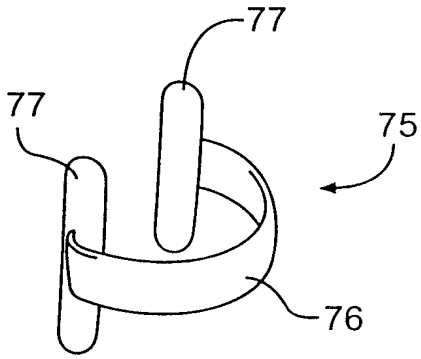


FIG.16

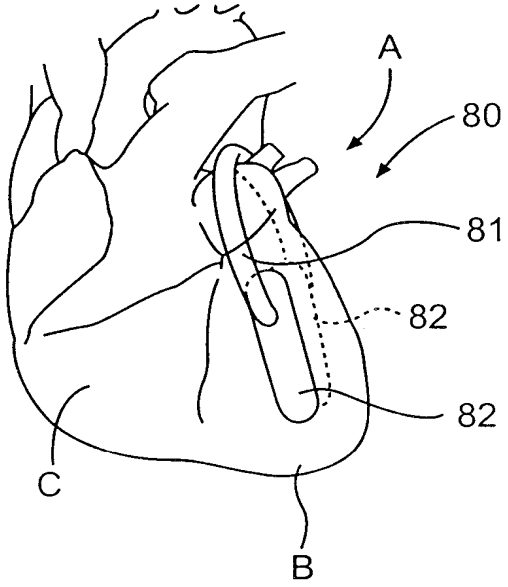


FIG. 17

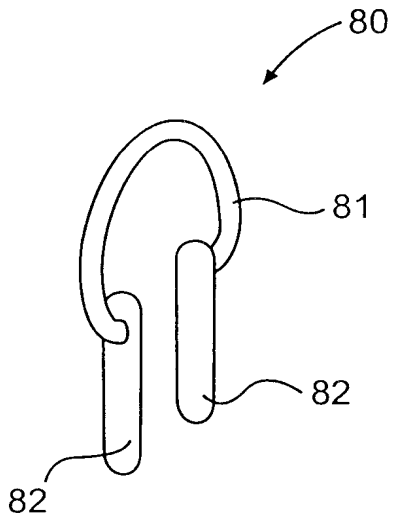


FIG. 18

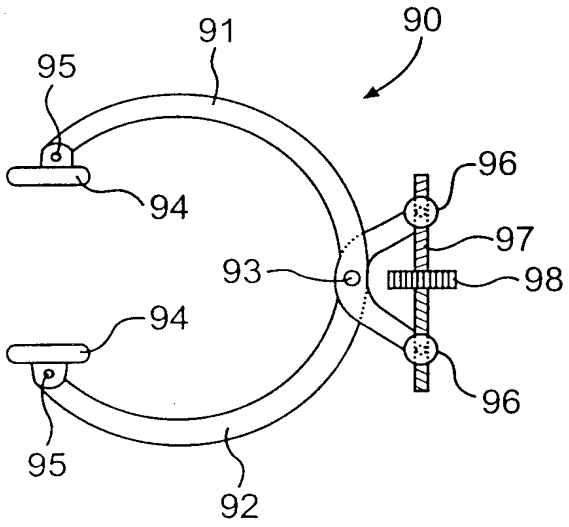


FIG. 19

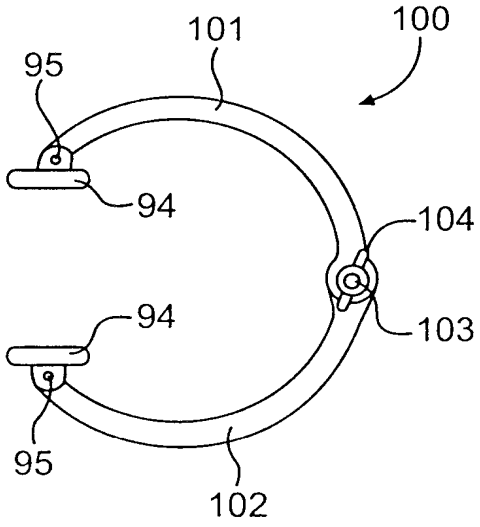


FIG. 20

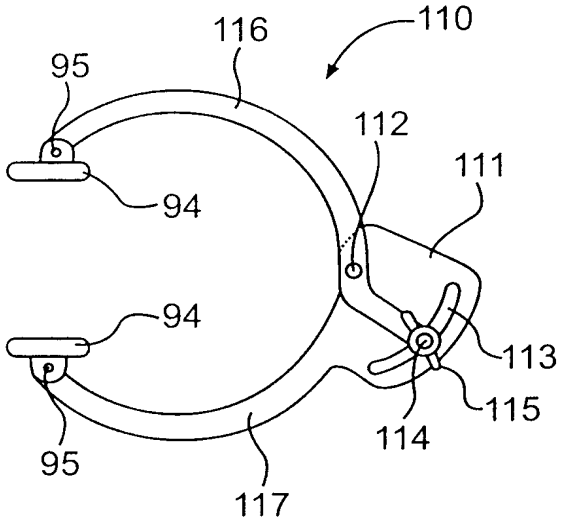


FIG. 21

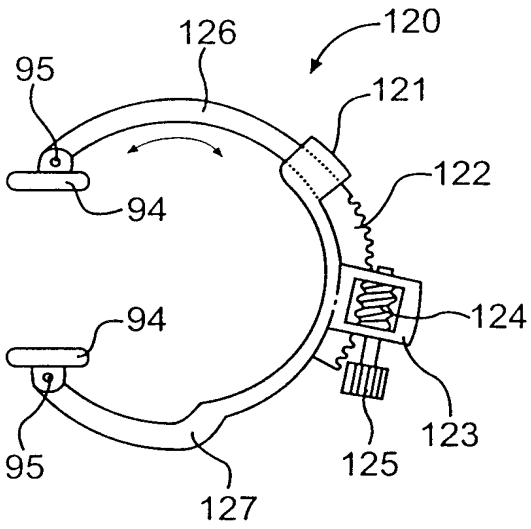


FIG. 22

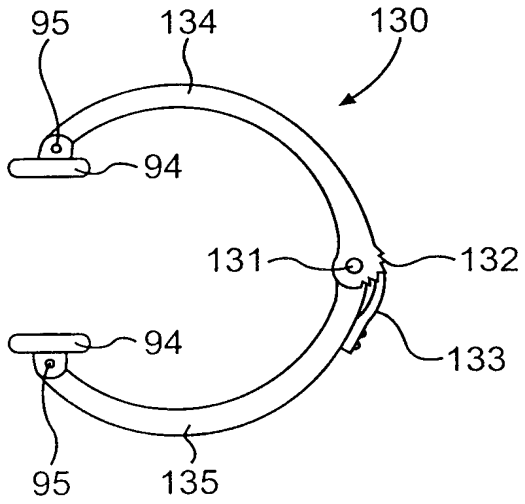


FIG. 23

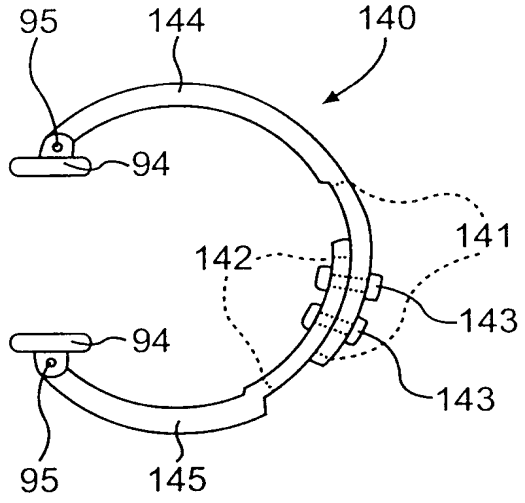


FIG. 24

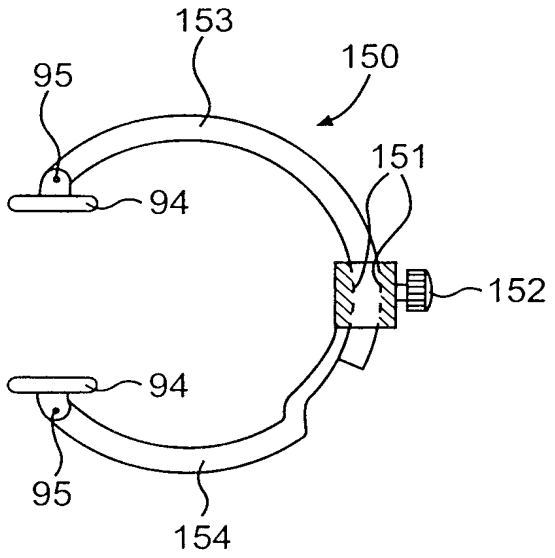


FIG. 25

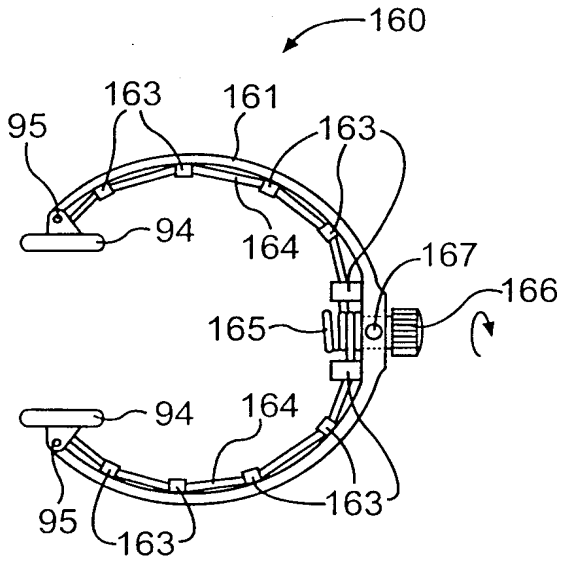


FIG. 26

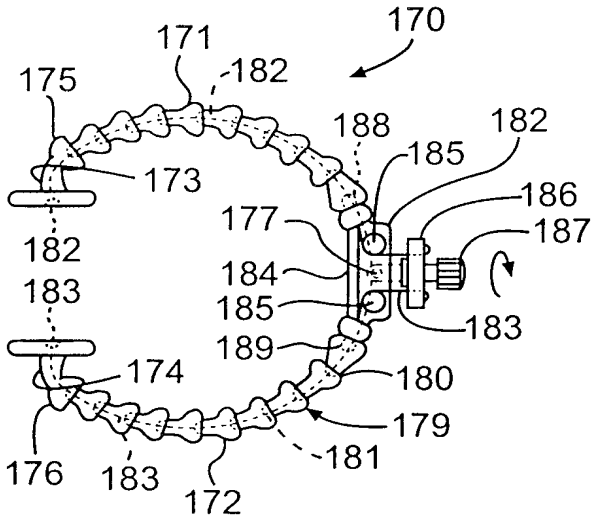


FIG. 27

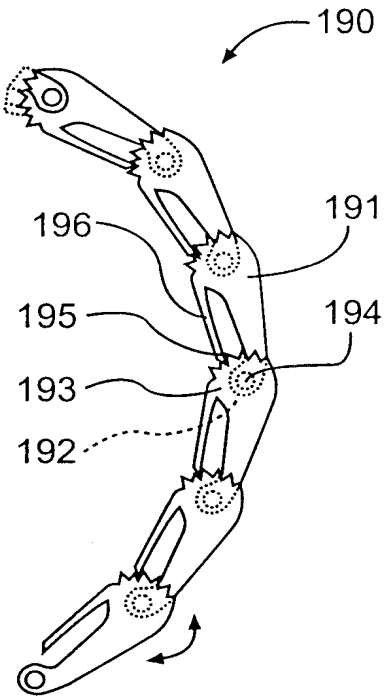


FIG. 28

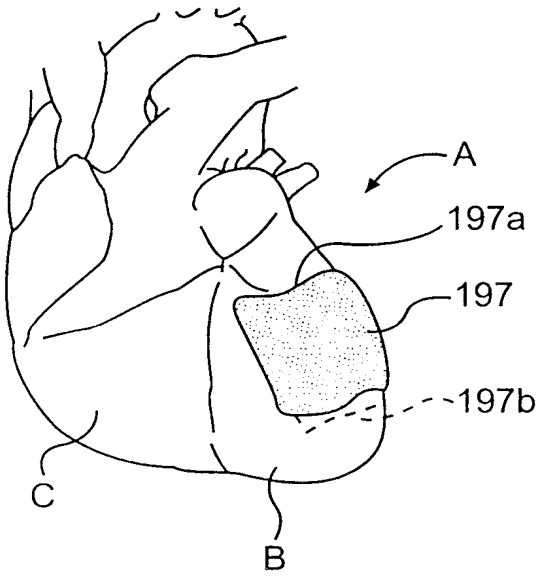


FIG. 29

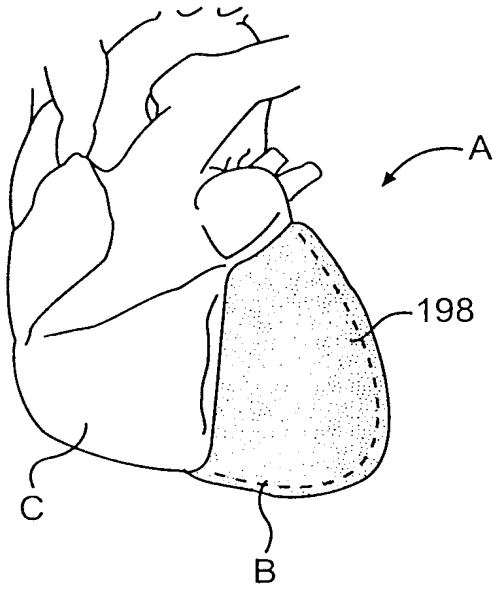


FIG. 30

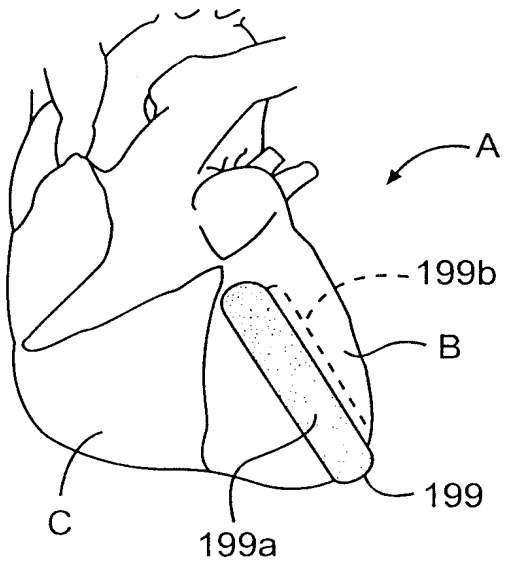


FIG. 31

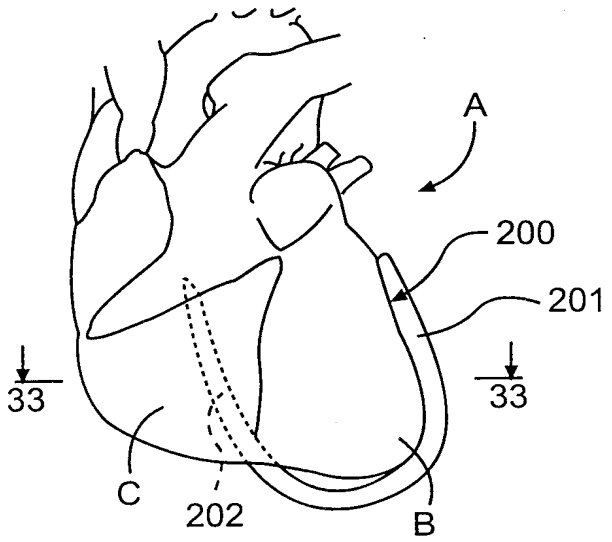


FIG. 32

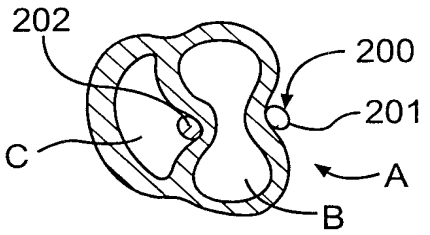


FIG. 33

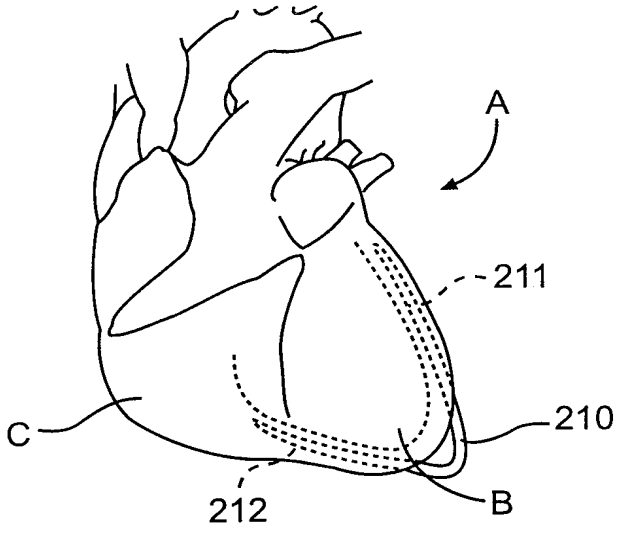


FIG. 34

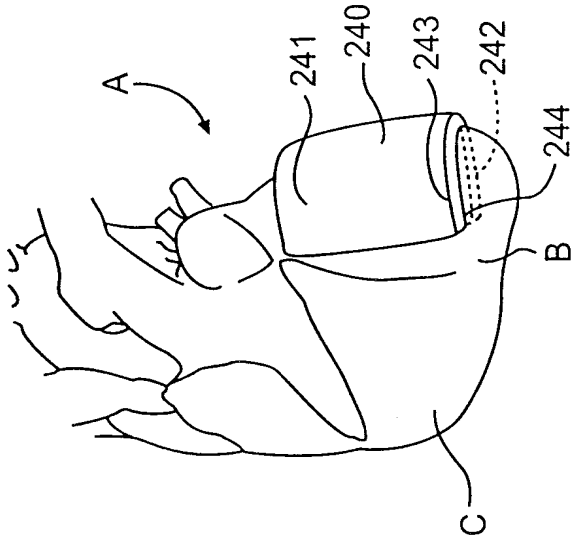


FIG. 37

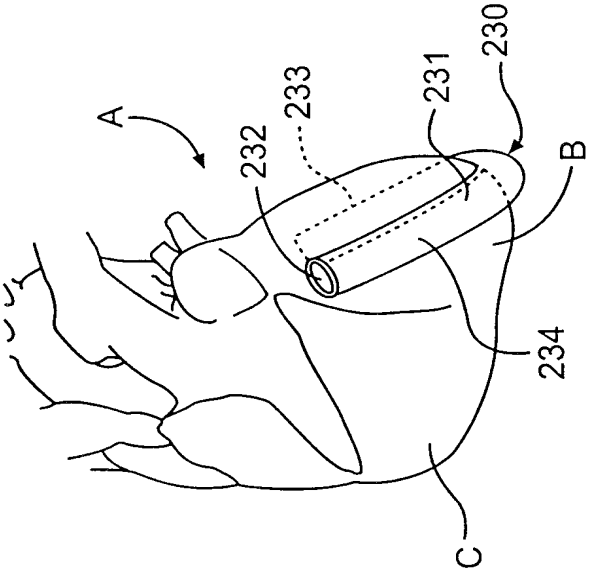


FIG. 36

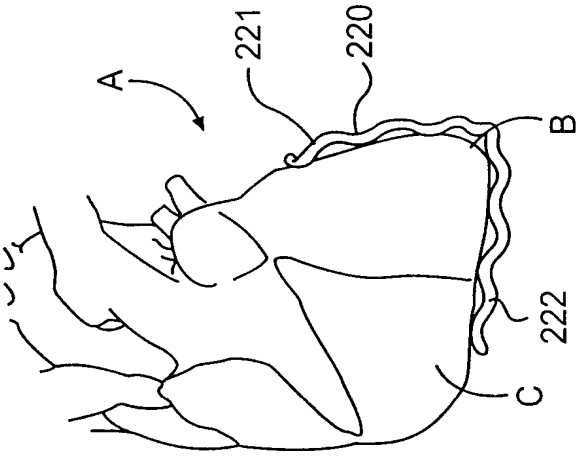


FIG. 35

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/21310

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/00

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 7 A61B A61F

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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 29041 A (MYOCOR, INC.) 9 July 1998 (1998-07-09) the whole document ---	
A	WO 96 40356 A (EP TECHNOLOGIES, INC.) 19 December 1996 (1996-12-19) the whole document ---	
A	DE 296 19 294 U (CAIC) 17 July 1997 (1997-07-17) the whole document ---	
A	US 5 800 528 A (LEDERMAN ET AL.) 1 September 1998 (1998-09-01) abstract; figures --- -/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° 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 document 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	Date of mailing of the international search report
14 December 1999	22/12/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Giménez Burgos, R

1

INTERNATIONAL SEARCH REPORT

Inte. onal Application No
PCT/US 99/21310

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 702 343 A (ALFERNESS) 30 December 1997 (1997-12-30) abstract; figures	
A	EP 0 303 719 A (BLAGOVESHCHENSKY GOSUDARSTVENNY MEDITSINSKY INSTITUT, UL) 22 February 1989 (1989-02-22)	

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/21310

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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. [X] Claims Nos.: 1-10
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 1-10 are directed to a method of treatment of the human body, Rule 39.1(iv) PCT. The search has been carried out and based on tools and devices used for performing the claimed method of reducing heart walls stress in a heart chamber.

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 II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

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 an additional fee, this Authority did not invite payment of any additional fee.

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.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 99/21310

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9829041 A	09-07-1998	US 5961440 A	05-10-1999
WO 9640356 A	19-12-1996	CA 2223152 A	19-12-1996
		EP 0836507 A	22-04-1998
		JP 11507262 T	29-06-1999
		US 5865791 A	02-02-1999
		US 5984917 A	16-11-1999
DE 29619294 U	17-07-1997	NONE	
US 5800528 A	01-09-1998	US 5713954 A	03-02-1998
US 5702343 A	30-12-1997	AU 4745097 A	24-04-1998
		EP 0930856 A	28-07-1999
		WO 9814136 A	09-04-1998
EP 0303719 A	22-02-1989	SU 1604377 A	07-11-1990
		CN 1014956 B	04-12-1991
		JP 1502405 T	24-08-1989
		NO 884695 A,B,	21-10-1988
		WO 8806027 A	25-08-1988
		US 4936857 A	26-06-1990