UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

CHASE MEDICAL, LP,	§	
	§	
Plaintiff,	§	**Civil Action No. 304 CV 2570 M**
v.	§	
	§	
CHF TECHNOLOGIES, INC. and ENDOSCOPIC TECHNOLOGIES, INC.	§	**JURY TRIAL DEMANDED**
	§	
	§	
Defendants.	§	

SECOND AMENDED COMPLAINT

The Parties

1. Plaintiff Chase Medical LP (hereinafter "Chase Medical") is a Texas corporation with an address at 1876 Firman Drive, Richardson, Texas 75081.

2. Defendant CHF Technologies, Inc. ("CHF") is a California corporation with its principal place of business at 4135 Blackhawk Plaza Circle, Suite 280, Danville, California 94506-4657.

3. Defendant Endoscopic Technologies, Inc. ("ESTECH") is a California corporation with its principal place of business at 4135 Blackhawk Plaza Circle, Suite 150, Danville, California 94506. Upon information and belief, Arthur Angelo Bertolero, 4135 Blackhawk Plaza Circle, Suite 150, Danville, California 94506, is the agent for service for ESTECH.

4. CHF and ESTECH are collectively referred to herein as the "Defendants," unless individually specified otherwise.

Jurisdiction and Venue

5. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331 and 1338 because this action is for patent infringement and arises under the Patent Laws of the United States, Title 35 of the United States Code.

6. Upon information and belief, venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

GENERAL AVERMENTS

Plaintiff's Patent Rights

7. Chase Medical is an innovator of cardiovascular technology.

8. United States Patent No. 6,681,773 ("the '773 Patent") was duly and legally issued.

9. Chase Medical is the owner of all rights in and to the '773 Patent.

10. A true and correct copy of the '773 Patent is attached hereto as **Exhibit A**.

11. Chase Medical has marked its products pursuant to 35 U.S.C. § 287(a).

Defendants and their Infringing Activity

12. Defendants have made, sold, imported, and/or used left ventricular restoration products, which include Defendants' "Blue Egg" left ventricular restoration products with catalog numbers CHF-90k, CHF-100k, CHF-110k, CHF-120k, CHF-130k, and CHF-140k (collectively, the "Products"). *See, e.g.,* **Exhibit B**. Defendants teach a method whereby the Products are used for left ventricular restoration.

13. Defendants sell the Products and teach a method for using the Products in a wide range of locations, including through CHF's Internet web site www.chftech.com, the relevant pages of which are attached hereto as composite **Exhibit C**.

14. Defendants seek to directly and/or indirectly sell the Products, and teach a method to use the Products, to the general public, hospitals, physicians, companies, distributors, and/or facilities in the state of Texas and this district.

15. Upon information and belief, Defendants have sold the Products and/or taught a method to use the Products in the state of Texas and this district.

16. The activities of Defendants with regard to their sales, importation, manufacture and/or use of the Products, and teaching of methods for use of the Products, are and have been without authorization from Chase Medical.

COUNT I - PATENT INFRINGEMENT

17. This cause of action arises under the Patent Laws of the United States, Title 35, United States Code.

18. Chase Medical repeats and realleges each and every allegation contained in Paragraphs 1 through 17 of this Complaint as if fully set forth herein.

19. Defendants have infringed and continue to infringe the '773 Patent under 35 U.S.C. § 271 *et seq*. This infringement was and is willful and intentional.

20. Defendants have, without authority, consent, right or license, and in direct infringement of the '773 Patent, imported, made, used, and/or sold the Products in this country, and used and/or disseminated/taught methods to use the Products in this country, and, upon information and belief, such Products have been sold and used in the state of Texas, and such methods have been used and/or disseminated/taught in the state of Texas.

21. Defendants' infringing conduct is willful, intentional, and unlawful and, upon information and belief, will continue unless enjoined by this Court.

COUNT II - INDUCEMENT OF PATENT INFRINGEMENT

22. This cause of action arises under the Patent Laws of the United States, Title 35, United States Code, in particular under 35 U.S.C. § 271(b).

23. Chase Medical repeats and realleges each and every allegation contained in Paragraphs 1 through 22 of this Complaint as if fully set forth herein.

24. Defendants have, in this country, actively and/or intentionally induced others to (a) make, import, use and/or sell products that infringe the '773 Patent, and/or (b) to use methods that infringe the '773 Patent.

25. Defendants' infringing conduct is willful, intentional, and unlawful and, upon information and belief, will continue unless enjoined by this Court.

COUNT III - CONTRIBUTORY PATENT INFRINGEMENT

26. This cause of action arises under the Patent Laws of the United States, Title 35, United States Code.

27. Chase Medical repeats and realleges each and every allegation contained in Paragraphs 1 through 26 of this Complaint as if fully set forth herein.

28. Defendants are furthermore liable for contributory infringement, pursuant to 35 U.S.C. § 271(c), in that Defendants have made, imported and/or sold within the United States a component of a patented machine, manufacture, composition, combination, or system, and/or a material or apparatus for use in practicing a patented method or process, including a material part of the invention, knowing the same to be especially made or adapted for use in the infringement of the '773 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

29. Defendants' infringing conduct is willful, intentional, and unlawful and, upon information and belief, will continue unless enjoined by this Court.

COUNT IV - DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY

30. Chase Medical repeats and realleges each and every allegation contained in Paragraphs 1 through 29 of this Complaint as if fully set forth herein.

31. Defendant ESTECH has alleged that it owns by assignment United States Patent No. 6,309,349 ("the '349 Patent") entitled "Surgical Retractor and Stabilizer Device and Method for Use," which issued on October 30, 2001. A true and correct copy of the '349 Patent is attached as **Exhibit D**.

32. On December 15, 2004, Defendants filed a complaint against Chase Medical in the United States District Court for the Northern District of California, Case No. C 04 5317 (the "California Action"). *See* **Exhibit E**. The California Action was filed after Chase Medical filed this action against the Defendants in this Court. The California Action seeks a declaratory judgment that Defendants do not infringe the '773 Patent and that the '773 Patent is invalid and unenforceable. The California Action also alleges that Chase Medical infringes the '349 Patent.

33. On December 22, 2004, Eric B. Meyertons, an attorney for Chase Medical, sent Robert Krebs, an attorney for the Defendants, a letter requesting clarification as to why Chase Medical allegedly infringes the '349 Patent and specifically requesting that Defendants "identify the specific product or method of Chase Medical that [allegedly] infringes, or induces infringement of the '349 Patent." *See* **Exhibit F**.

34. On January 7, 2004, Marc S. Friedman, an attorney for the Defendants, sent Eric B. Meyertons a reply to his December 22, 2004 letter, but did not provide Chase Medical with an identification of Chase Medical's product or method that allegedly infringes the '349 Patent. Instead, Defendants merely listed a claim in the '349 Patent that Chase Medical allegedly induces others to infringe. *See* **Exhibit G**.

35. ESTECH's allegations of Chase Medical's infringement of the '349 Patent are without merit and supporting evidence. Upon information and belief, ESTECH has brought its allegation of infringement of the '349 Patent in bad faith and for an improper purpose. Upon further information and belief, ESTECH has also alleged infringement of the '349 Patent in an attempt to create jurisdictional and/or venue issues for this case, and to seek transfer of this case

and consolidation with the California Action. While Chase Medical believes that the California Action is without basis or foundation, and was brought in bad faith by CHF and ESTECH, in light of ESTECH's refusal to dismiss its meritless allegations of infringement of the '349 Patent against Chase Medical, an actual controversy currently exists between the parties with respect to the infringement and validity of the claims of the '349 Patent.

36. For these reasons, a judicial determination of the respective rights of the parties with respect to the infringement and validity of the '349 Patent is necessary and appropriate pursuant to 28 U.S.C. § 2201.

37. Chase Medical has not directly or indirectly infringed any valid and enforceable claim of the '349 Patent.

38. The claims of the '349 Patent are invalid for failure to meet one or more of the requirements of Title 35, United States Code, including the requirements of Sections 102, 103, 112, and/or other applicable statutes.

39. By reasons of, *inter alia*, amendments and/or statements made in and to the United States Patent and Trademark Office, during the prosecution of the '349 Patent, Defendants are estopped from construing the claims of the '349 Patent in such a way that may cover Chase Medical's products or activities.

DAMAGES

40. Chase Medical repeats and realleges each and every allegation contained in Paragraphs 1 through 39 of this Complaint as if fully set forth herein. Chase Medical has suffered, is suffering, and will continue to suffer irreparable harm and injury as a result of Defendants' aforesaid activities. Defendants will, unless restrained and enjoined, continue to act in the unlawful manner complained of herein, all to Chase Medical's irreparable damage. Chase Medical's remedy at law is not adequate to compensate it for the injuries suffered and threatened.

By reason of Defendants' acts complained of herein, Chase Medical has suffered monetary damages in an amount that has not yet been determined.

REQUEST FOR JURY TRIAL

41. Chase Medical hereby demands that this cause be tried by a jury.

PRAYER

42. WHEREFORE, Chase Medical demands:

A. That Defendants, their agents, officers, directors, employees, servants, representatives, privies, successors and assigns, and all holding by, through or under Defendants, and all those acting for or on the behalf of Defendants, or in active concert, participation, or combination with Defendants, be enjoined and restrained, immediately and preliminarily, during the pendency of this action and permanently thereafter from:

(1) making, using, selling and/or importing the Products, or any colorable imitation thereof, or teaching methods to use such Products,

(2) inducing others from infringing the '773 Patent, and/or contributing to the infringement of the '773 Patent by others;

(3) otherwise infringing upon the '773 Patent; and

(4) alleging that Chase Medical infringes the '349 Patent.

B. That this Court order Defendants, and their officers, agents, servants and employees, to deliver up to this Court, and to permit the seizure by officers appointed by the Court of all articles and materials infringing upon the rights of Chase Medical, and particularly, without limitation, all products or other merchandise which embodies or includes the Products or teaches any methods to use the Products, and to be delivered up for destruction on the issuance of a final Order in this action, including all Products, and all equipment and other matter for reproducing such Products, and Defendants submit in writing, under oath, a description of all actions taken to comply with this portion of the Order.

C. That Defendants be required to pay to Chase Medical such damages as Chase Medical has sustained in consequence of Defendants' infringement of the '773 Patent.

D. That in the alternative, a reasonable royalty be awarded to Chase Medical pursuant to 35 U.S.C. § 284.

E. That Defendants be ordered to account for and pay over to Chase Medical all their respective gains, profits and advantages derived from the infringement of the '773 Patent or such damages as to the Court shall appear proper within the Patent Laws.

F. That Defendants be ordered to pay Chase Medical enhanced damages (*e.g.*, treble damages).

G. That Defendants be ordered to pay to Chase Medical the costs of this action, prejudgment interest, and post-judgment interest.

H. That this case be found to be exceptional.

I. That Defendants be ordered to pay Chase Medical's reasonable attorneys' fees, experts' fees, and costs.

J. That a declaratory judgment be entered finding that Chase Medical has not infringed any valid and enforceable claim of the '349 Patent.

K. That the '349 Patent is invalid and/or unenforceable.

L. That Chase Medical be awarded such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Eric B. Meyertons
Texas State Bar No. 14004400
Dwayne K. Goetzel
Texas State Bar No. 08059500
Ryan T. Beard
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ATTORNEYS FOR PLAINTIFF
CHASE MEDICAL, LP

CERTIFICATE OF SERVICE

This certifies that a true and correct copy of the foregoing pleading has been sent by first class U.S. mail, postage prepaid, to CHF Technologies and Endoscopic Technologies, Inc. attorney of record as follows:

Marc S. Friedman
Sills Cummis Epstein and Gross
399 Park Avenue
New York, New York 10022

on this 13th day of January 2005.

Ryan T. Beard

US006681773B2

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

(10) **Patent No.: US 6,681,773 B2**
(45) **Date of Patent: Jan. 27, 2004**

(54) **KIT AND METHOD FOR USE DURING VENTRICULAR RESTORATION**

(75) Inventors: **Gregory Murphy**, Richardson, TX (US); **Mitta Suresh**, Richardson, TX (US); **Albert Davis**, Richardson, TX (US)

(73) Assignee: **Chase Medical, Inc.**, Richardson, TX (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 247 days.

(21) Appl. No.: **09/864,794**

(22) Filed: **May 24, 2001**

(65) **Prior Publication Data**

US 2002/0133182 A1 Sep. 19, 2002

Related U.S. Application Data

(60) Provisional application No. 60/272,073, filed on Feb. 28, 2001.

(51) **Int. Cl.**[7] **A61B 19/00**; A61F 2/02

(52) **U.S. Cl.** **128/898**; 600/16; 600/587; 623/3.1; 33/512

(58) **Field of Search** 606/151; 128/898; 600/16, 37, 587; 623/3.1; 33/512

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,568,659 A	3/1971	Karnegis	
3,874,388 A	4/1975	King et al.	
3,983,863 A	10/1976	Janke et al.	
4,685,446 A	8/1987	Choy	
4,690,134 A	9/1987	Snyders	
4,771,765 A	9/1988	Choy et al.	
4,785,795 A	11/1988	Singh	
4,821,723 A	4/1989	Baker, Jr. et al.	
4,861,330 A	8/1989	Voss	
4,902,273 A	2/1990	Choy et al.	
4,917,089 A	4/1990	Sideris	
4,957,477 A	9/1990	Lundback	
4,973,300 A	11/1990	Wright	
5,041,130 A	8/1991	Cosgrove et al.	
5,089,005 A	2/1992	Harada	
5,131,905 A	7/1992	Grooters	
5,139,517 A	8/1992	Chorral	
5,167,628 A	12/1992	Boyles	

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

WO	WO 99/56655	11/1999

OTHER PUBLICATIONS

Marisa Di Donato et al., "Effects of the Dor Procedure on Left Ventricular Dimension and Shape and Geometric Correlates of Mitral Regurgitation One year After Surgery", The Journal of Thoracic and Cardiovascular Surgery, Jan. 2001, pp. 91–96.

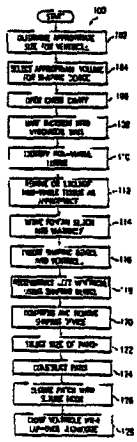
(List continued on next page.)

Primary Examiner—Ralph A. Lewis
(74) *Attorney, Agent, or Firm*—Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C.; Eric B. Meyertons

(57) **ABSTRACT**

Apparatuses and methods are provided to reconstruct an enlarged left ventricle of a human heart, using a shaper, having a size and shape substantially equal to the size and shape of an appropriate left ventricle, wherein the shaper is adapted to be temporarily placed into the enlarged left ventricle during a surgical procedure. Another aspect of one embodiment comprises a ventricular patch adapted for placement into the left ventricle of a heart made from a sheet of biocompatible material, and having a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch. In another aspect of one embodiment, a device is presented, comprising of a handle and a sizing template adapted to be coupled to the handle. Such components are also presented as a kit for use during ventricular restoration surgery.

28 Claims, 10 Drawing Sheets



U.S. PATENT DOCUMENTS

5,169,378	A		12/1992	Figuera
5,171,299	A		12/1992	Heitzmann et al.
5,176,619	A		1/1993	Segalowitz
5,192,314	A		3/1993	Daskalakis
5,255,678	A		10/1993	Deslauriers et al.
5,258,000	A		11/1993	Gianturco
5,334,146	A		8/1994	Ozasa
2,701,559	A		2/1995	Cooper
5,409,000	A	*	4/1995	Imran 128/642
5,425,744	A		6/1995	Fagan et al.
5,433,727	A		7/1995	Sideris
5,451,235	A		9/1995	Lock et al.
5,465,717	A	*	11/1995	Imran et al. 128/642
5,489,296	A		2/1996	Love et al.
5,507,811	A		4/1996	Koike et al.
5,509,428	A		4/1996	Dunlop
5,526,810	A		6/1996	Wang
5,603,337	A		2/1997	Jarvik
5,609,157	A		3/1997	Panescu et al.
5,702,343	A		12/1997	Alferness
5,722,401	A		3/1998	Pietroski et al.
5,725,552	A		3/1998	Kotula et al.
5,736,626	A		4/1998	Jarvik
5,797,960	A		8/1998	Stevens et al.
5,800,528	A		9/1998	Lederman et al.
5,843,177	A	*	12/1998	Vanney et al. 623/2
5,846,260	A		12/1998	Maahs
5,846,261	A		12/1998	Kotula et al.
5,885,228	A		3/1999	Rosenman et al.
5,908,445	A		6/1999	Whayne et al.
5,921,935	A		7/1999	Hickey
5,923,770	A		7/1999	O'Donnell et al.
5,944,738	A		8/1999	Amplatz et al.
5,951,543	A	*	9/1999	Brauer 606/10
5,957,977	A		9/1999	Melvin
5,971,911	A		10/1999	Wilk
6,004,329	A	*	12/1999	Myers et al. 606/108
6,019,739	A	*	2/2000	Rhee et al. 600/587
6,024,096	A	*	2/2000	Buckberg 128/898
6,109,852	A		8/2000	Shahinpoor et al.
6,125,852	A		10/2000	Stevens et al.
6,143,012	A		11/2000	Gausepohl
6,162,168	A	*	12/2000	Schweich, Jr. et al. 600/16
6,162,537	A		12/2000	Martin et al.
6,179,791	B1	*	1/2001	Krueger 600/587
6,183,411	B1	*	2/2001	Mortier et al. 600/16
6,205,411	B1		3/2001	DiGioia, III et al.
6,210,338	B1		4/2001	Afremov et al.
6,216,043	B1		4/2001	Swanson et al.
6,221,104	B1	*	4/2001	Buckberg et al. 623/3.1
6,231,601	B1		5/2001	Myers et al.
6,322,588	B1		11/2001	Ogle et al.
6,350,281	B1		2/2002	Rhee et al.
6,360,749	B1		3/2002	Jayaraman
6,366,684	B1		4/2002	Gerard et al.
6,368,356	B1		4/2002	Zhong et al.
6,406,420	B1	*	6/2002	Mc Carthy et al. 600/16
6,439,237	B1	*	8/2002	Buckberg et al. 128/898
6,450,171	B1	*	9/2002	Buckberg et al. 128/898
6,544,167	B2	*	4/2003	Buckberg et al. 600/37
2002/0026092	A1		2/2002	Buckberg et al.
2002/0029783	A1		3/2002	Stevens et al.
2002/0056461	A1		5/2002	Jayaraman

OTHER PUBLICATIONS

Hisayoshi Suma et al., "Nontransplant Cardiac Surgery For End-Stage Cardiomyopathy", The Journal of Thoracic and Cardiovascular Surgery, Jun. 2000, pp. 1233–1245.

Rufus Baretti et al., "Batista Procedure: Elliptical Modeling Against Spherical Distention", European Journal of Cardio-Thoracic Surgery 17, 2000, pp. 52–57.

Randas Batista, "Partial Left Ventriculectomy–The Batista Procedure", European Journal of Cardio–Thoracic Surgery 15, 1999, pp. S12–S19.

Gerald D. Buckberg, M.D., "Commonality of Ischemic and Dilated Cardiomyopathy: Laplace and Ventricular Restoration", The UCLA Medical Center, Department of Surgery, Los Angeles, California, 1999, pp. 53–59.

F. Fantini et al., "Effects of Reconstructive Surgery For Left Ventricular Anterior Aneurysm on Ventriculoarterial Coupling", Heart 1999, 81, pp. 171–176.

V. Dor et al., "Endoventricular Patch Reconstruction in Large Ischemic Wall–Motion Abnormalities", The Centre Cardio–Thoracique, Monaco, 1999, pp. 46–52.

Randall C. Starling and Patrick M. McCarthy, "Partial Left Ventriculectomy: Sunrise or Sunset?", European Journal of Heart Failure, 1999, pp. 313–317.

V. Dor et al., "Endoventricular Patch Plasty for Large L.V. Akinesia" Video tape from Centre de Cardio–Thoracique de Monaco, Sep. 1998.

Gerald D. Buckberg, MD, "Surgery for Adult Cardiovascular Disease: Editorial: Defining the Relationship Between Akinesia and Dyskinesia and the Cause of Left Ventricular Failure After Anterior Infraction and Reversal of Remodeling to Restoration", 1998, pp. 47–49.

Sakamoto et al., "Restoring the Remodeled Enlarged Left Ventricle: Experimental Benefits of In Vivo Percine Cardioreduction in the Beating Open Heart", Department of Cardiology, UCLA School of Medicine, 1998, pp. 429–439.

Athanasuleas, MD et al., "Restoration of Contractile Function in the Enlarged Left Ventricle by Exclusion of Remodeled Akinetic Anterior Segment: Surgical Strategy, Myocardial Protection, and Angiographic Results", Journal of Cardiovascular Surgery, 1998, pp. 418–428.

V. Dor, MD et al., "Endoventricular Patch Plasties with Septal Exclusion for Repair of Ischemic Left Ventricle: Technique, Results and Indications from A Series of 781 Cases", The Japanese Journal of Thoracic and Cardiovascular Surgery, 1998, pp. 389–398.

V. Dor, MD et al., "Ventricular Remodeling in Coronary Artery Disease", Centre Cardio–Thoracique de Monaco, 1997, pp. 533–537.

Di Donatio, MD et al., "Akinetic Versus Dyskinetic Postinfarction Scar: Relation to Surgical Outcome in Patients Undergoing Endoventricular Circular Patch Plasty Repair" America College of Cardiology, vol. 29, 1997. pp. 1569–1575.

Vincent Dor, "The Treatment of Refractory Ischemic Ventricular Tachycardia by Endoventricular Patch Plasty Reconstruction of the Left Ventricle", Seminars in Thoracic and Cardiovascular Surgery, vol. 2, No. 2, Apr. 1997, pp. 146–155.

Vincent Dor , "Reconstructive left Ventricular Surgery for Post–Ischemic Akinetic Dilatation", Seminars in Thoracic and Cardiovascular Surgery, vol. 2, No. 2, Apr. 1997, pp. 139–145.

Vincent Dor, "Left Ventricular Aneurysms: The Endoventricular Circular Patch Plasty", Seminars in Thoracic and Cardiovascular Surgery, vol. 9, No. 2, Apr. 1997, pp. 123–130.

James L. Cox, "Surgical Management of Left Ventricular Aneurysms: A Clarification of the Similarities and Differences Between the Jatene and Dor Techniques", Seminars in Thoracic and Cardiovascular Surgery, vol. 9, No. 2, Apr., 1997, pp. 131–138.

Di Donato et al., "Outcome of Left Ventricular Aneurysmectomy with Patch Repair in Patients with Severly Depressed Pump Function", The American Journal of Cardiology, vol. 76, Sep. 15, 1995, pp. 557–561.

V. Dor et al., Surgery For Acquired Heart Disease, Late Hemodynamic Results After Left Ventricular Patch Repair Associated with Coronary Grafting in Patients with Postinfarction Akinetic or Dyskinetic Aneurysm of The Left Ventricle, The Journal of Thoracic and Cardiovascular Surgery, Nov. 1995, pp. 1291–1301.

Elefteriades et al., "Left Ventricular Aneurysmectomy in Advanced Left Ventricular Dysfunction", Cardiology Clinics, vol. 13, No. 1, Feb. 1995, pp. 59–72.

V. Dor et al., "Left Ventricular Shape Changes Induced by Aneurysmectomy with Endoventricular Circular Patch Plasty Reconstruction", The European Society of Cardiology, 1994, pp. 1063–1069.

Cooley, MD et al., "Intracavitary Repair of Ventricular Aneurysm and Regional Dyskinesia", Departments of Cardiovascular Surgery and Cardiology, Texas Heart Institute, Houston, TX., Jan. 1992, pp. 417–242.

Di Donato et al., "Early Hemodynamic Results of Left Ventricular Reconstructive Surgery for Arterior Walls Left Ventricular Aneurysm", The American Journal of Cardiology, vol. 69, Apr. 1, 1992, pp. 886–890.

Francis Fontan, MD, "Transplantation of Knowledge", The Journal of Thoracic and Cardiovascular Surgery, 1990, pp. 387–395.

Denton A. Cooley, MD, "Ventricular Endoaneurysmorrhaphy: A Simplified Repair for Extensive Postinfarction Aneurysm", Journal of Cardiac Surgery, vol. 4, No. 3, 1989, pp. 200–205.

V. Dor et al., "Left Ventricular Aneurysm: A New Surgical Approach", Thorac.Cardiovasc.Surgery37, Jun. 16, 1988, pp. 11–19.

Dor et al, "Endoventricular Patch Reconstruction in Large Ischemic Wall–Motion Abnormalities", J. Card. surg 14:46–52 (1999).*

Dor, "Left Ventricular Restoration by Endoventricular Circular Patch Plasty (EVCPP)", Z Kardiol 89.Supp 7 pp. 70–75 (2000).*

T. Shiga et al. "Deformation of Polyelectrolyte Gels under the Influence of Electric Field" *Journal of Applied Polymer Science*, 1990, 39, 2305.

J. Bohm et al. "Endoventricular Patch Plasty for Restoration of Ventricular Geometry and Pump Function in Ventricular Aneurysm" *Z. Kardiol*, 1996, 85, Supplement No. 4, 43–46.

Di Donato et al., "Early Hemodynamic Results of Left Ventricular Reconstructive Surgery for Anterior Wall Left Ventricular Aneurysm" *The American Journal of Cardiology*, 1992, 69, 886–890.

Di Donato et al., "Akinetic Versus Dyskinetic Postinfarction Scar: Relation to Surgical Outcome in Patients Undergoing Endoventricular Circular patch Plasty Repair" *J Am Coll Cardiol*, 1997, 29, No. 7, 1569–75.

V. Dor, "Left Ventricular Aneurysms: The Endoventricular Circular Patch Plasty" *Seminars in Thoracic and Cardiovascular Surgery*, 1997, 9, No. 2, 123–130.

V. Dor et al., "Ventricular remodeling in coronary artery disease" *Current Opinion in Cardiology*, Centre CardioThoracique de Monaco, 1997, 12, 533–537.

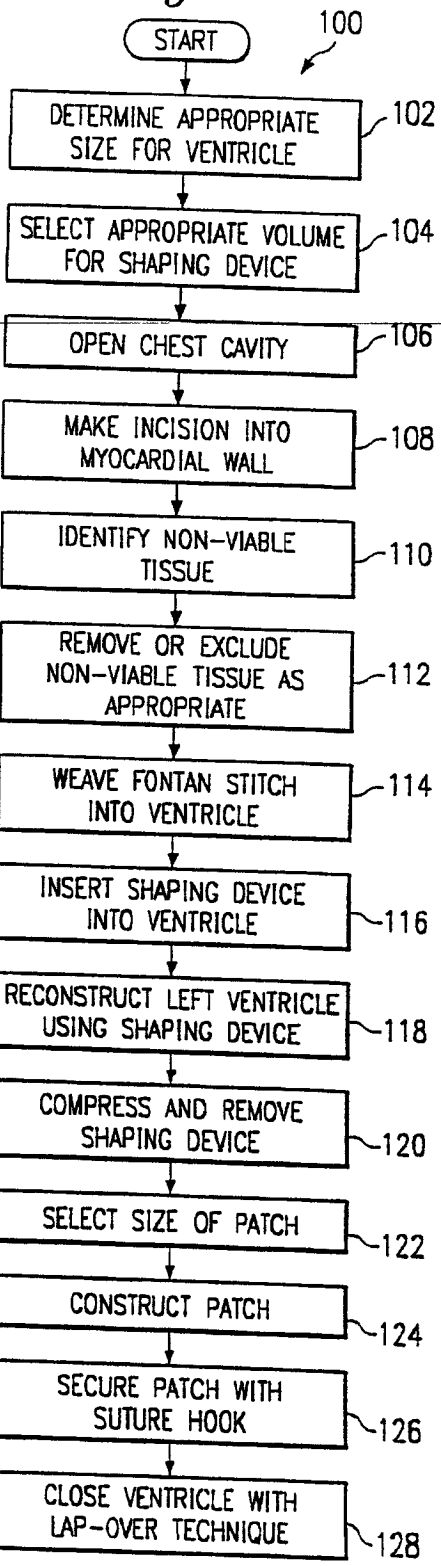
A. D. Jatene, "Left Ventricular aneurysmectomy: Resection or reconstruction" *The Journal of Thoracic and Cardiovascular Surgery*, 1985, 89, 321–331.

K. Emmrich, "Contribution to the Discussion of the Lecture by J. Bohm, Berlin" *Z. Kardiol*, 1996, 85, Supplement No. 4, 47–48.

V. Dor, "Reconstructive Left Ventricular Surgery for Post–Ischemic Akinetic Dilatation" *Seminars in Thoracic Surgery*, 1997, 9, No. 2, 139–145.

* cited by examiner

Fig. 1


START
100
DETERMINE APPROPRIATE SIZE FOR VENTRICLE
102
SELECT APPROPRIATE VOLUME FOR SHAPING DEVICE
104
OPEN CHEST CAVITY
106
MAKE INCISION INTO MYOCARDIAL WALL
108
IDENTIFY NON-VIABLE TISSUE
110
REMOVE OR EXCLUDE NON-VIABLE TISSUE AS APPROPRIATE
112
WEAVE FONTAN STITCH INTO VENTRICLE
114
INSERT SHAPING DEVICE INTO VENTRICLE
116
RECONSTRUCT LEFT VENTRICLE USING SHAPING DEVICE
118
COMPRESS AND REMOVE SHAPING DEVICE
120
SELECT SIZE OF PATCH
122
CONSTRUCT PATCH
124
SECURE PATCH WITH SUTURE HOOK
126
CLOSE VENTRICLE WITH LAP-OVER TECHNIQUE
128

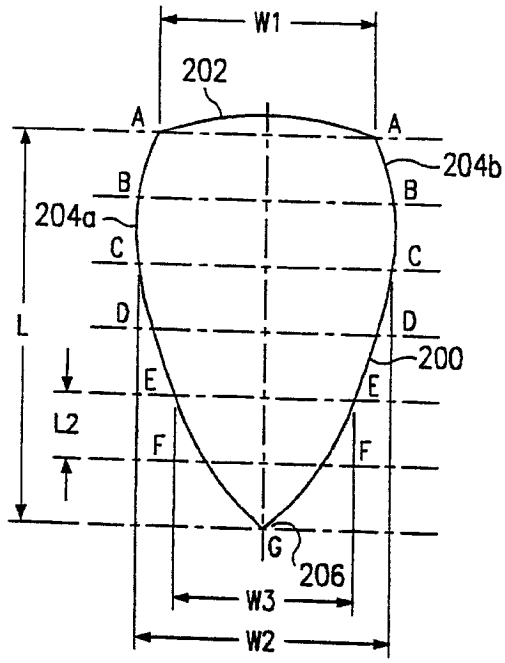

W1
202
A
A
204b
B
B
204a
C
C
D
D
L
200
E
E
L2
F
F
G
206
W3
W2

Fig. 2a

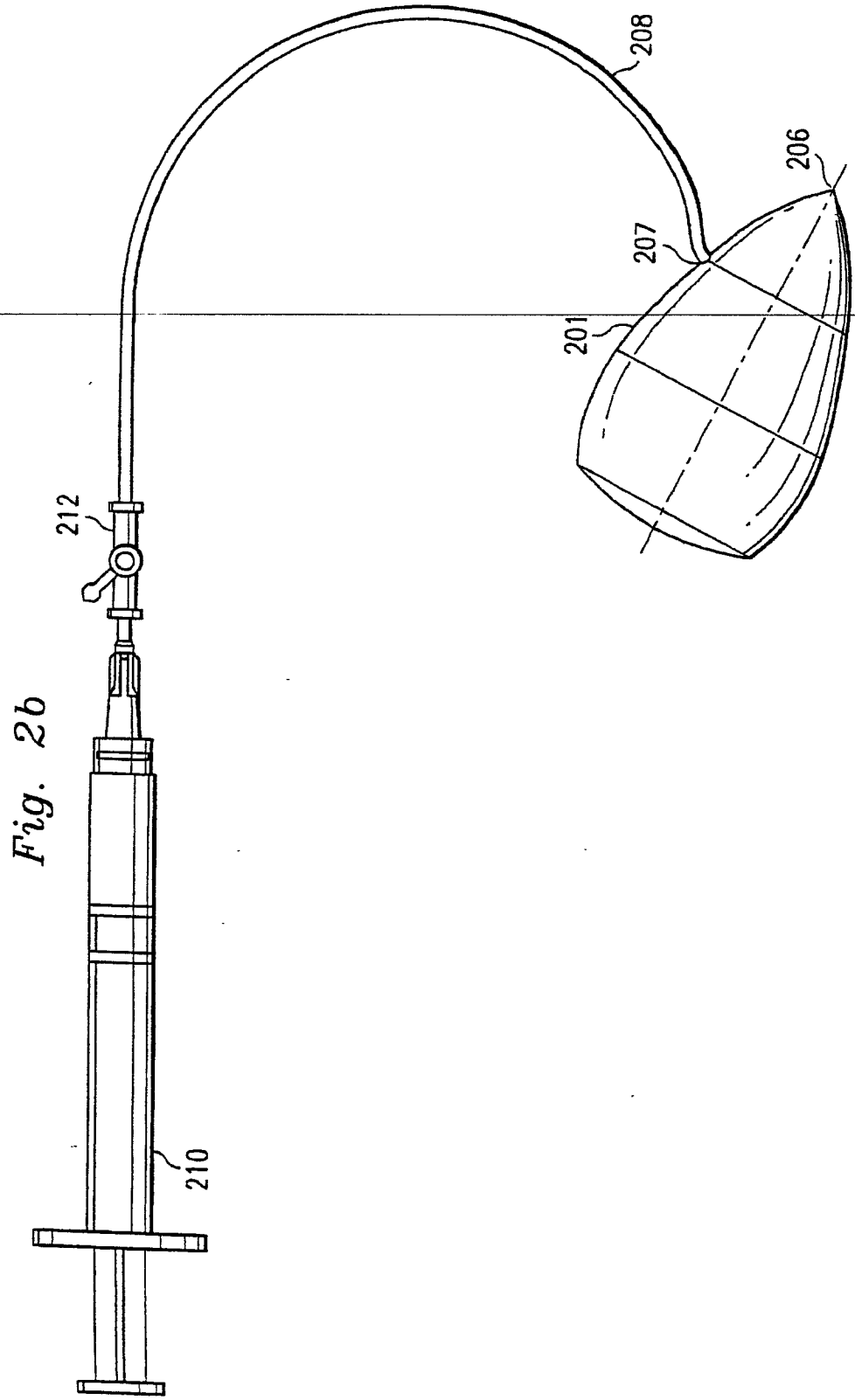


Fig. 2b

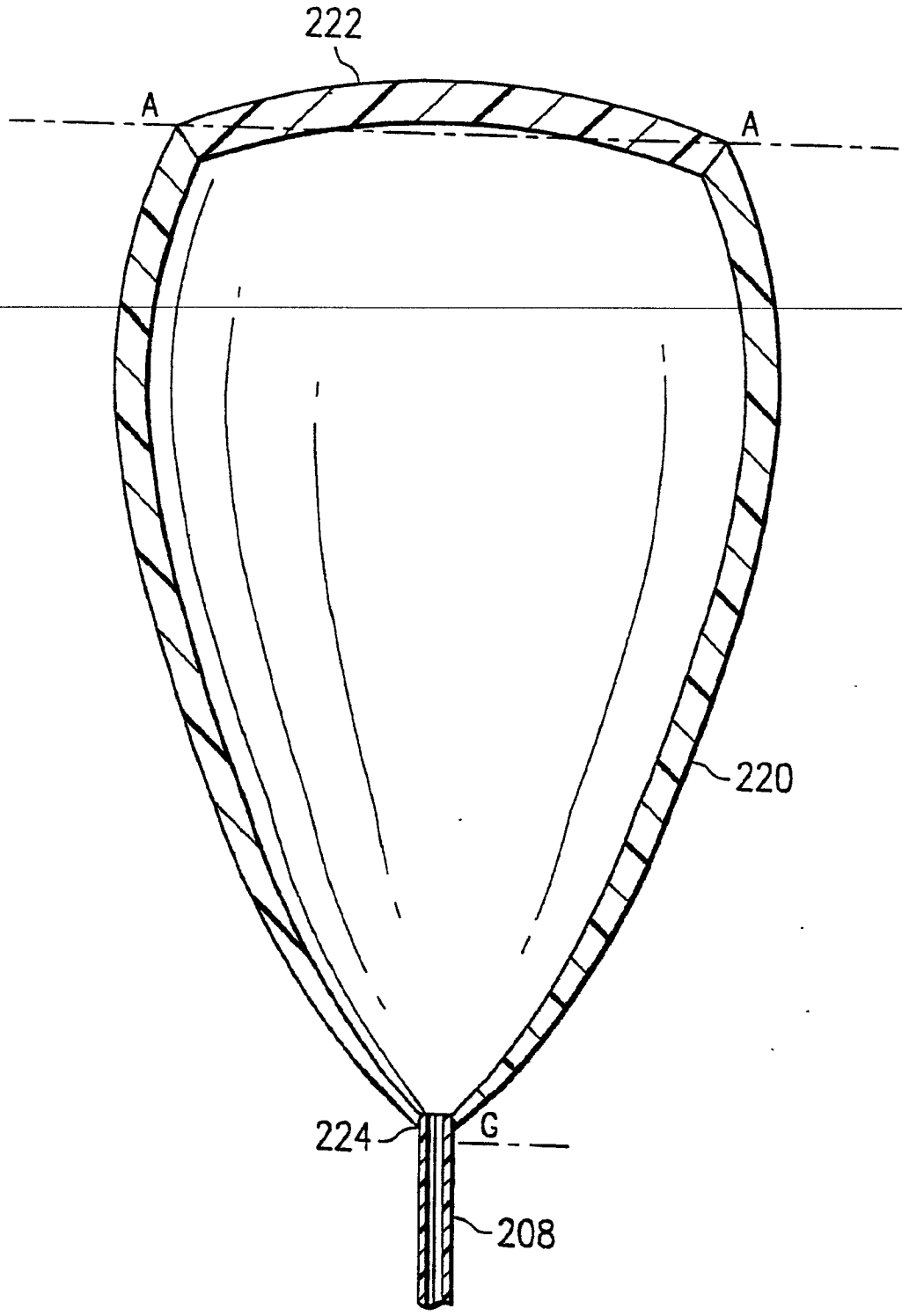


Fig. 2c

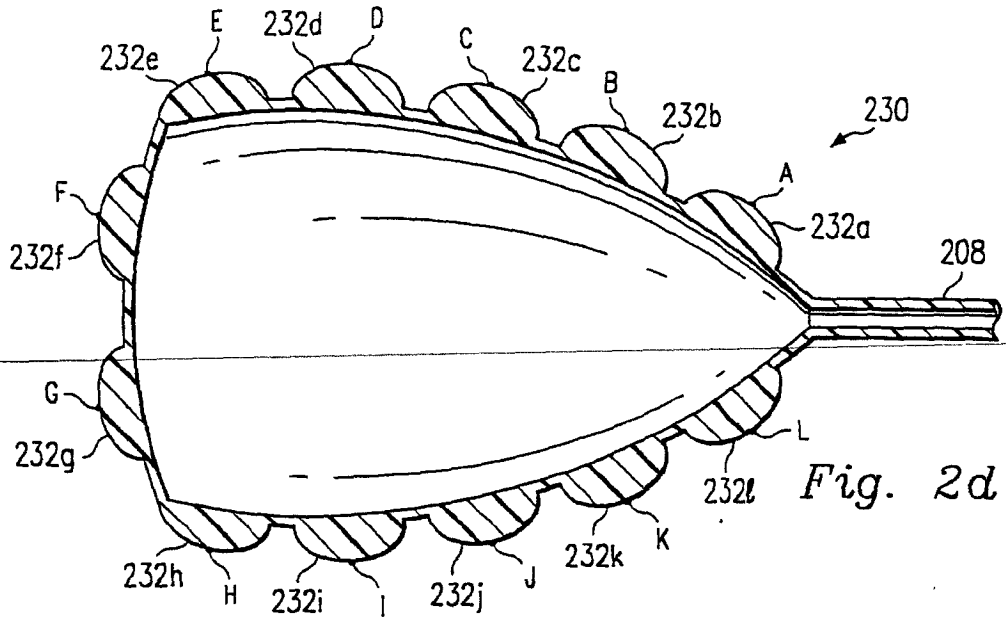


Fig. 2d

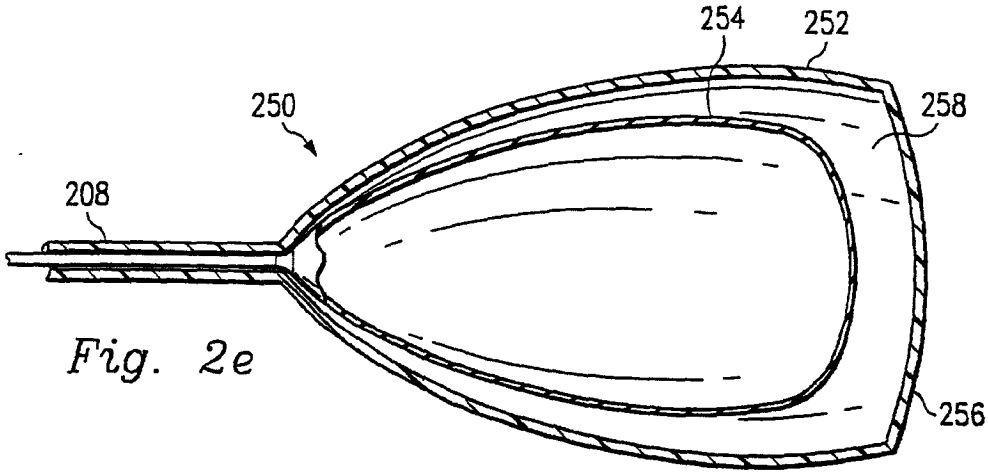


Fig. 2e

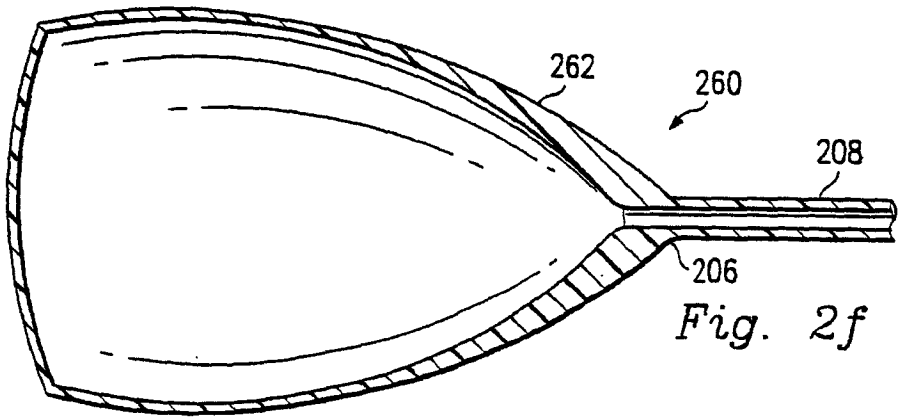


Fig. 2f

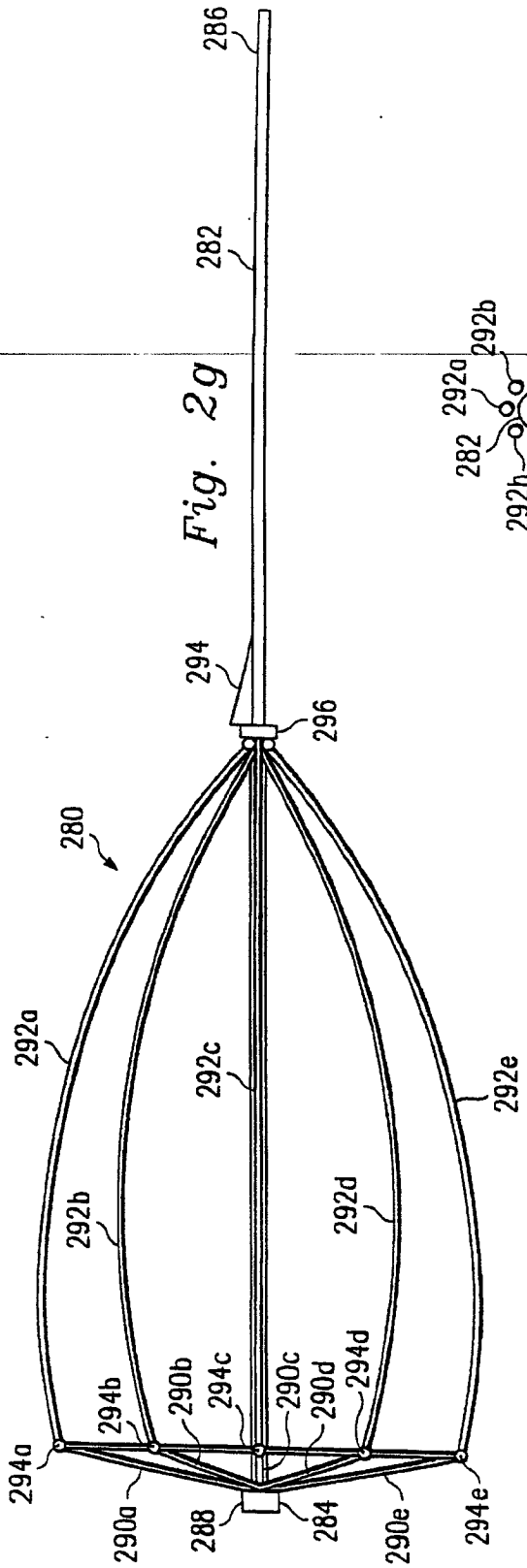


Fig. 2g

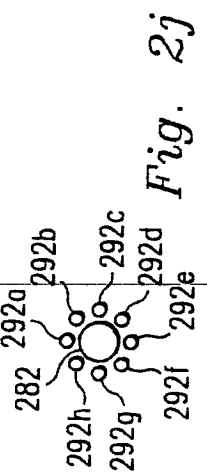


Fig. 2j

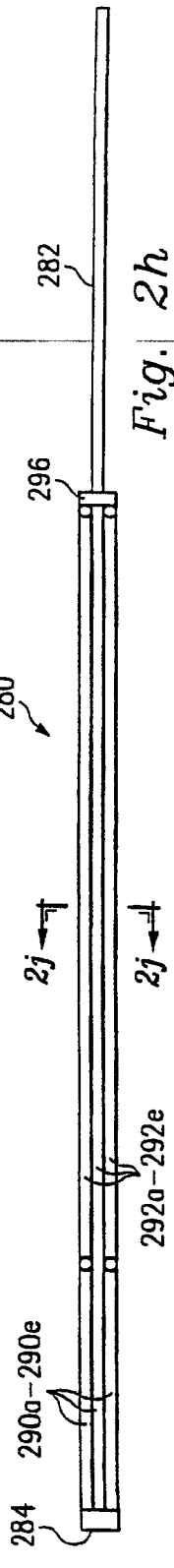


Fig. 2h

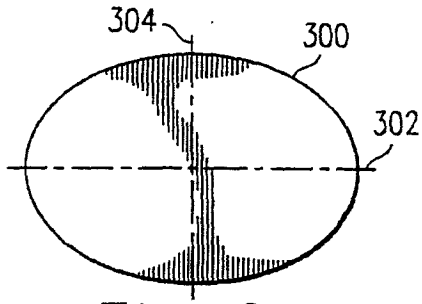


Fig. 3a

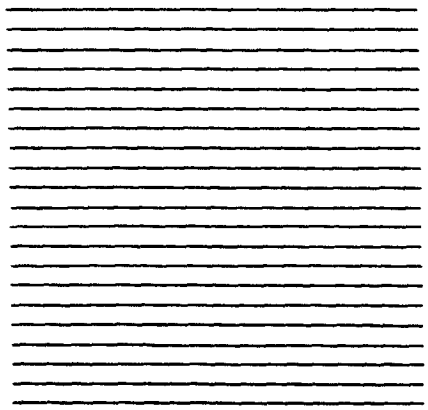


Fig. 3b

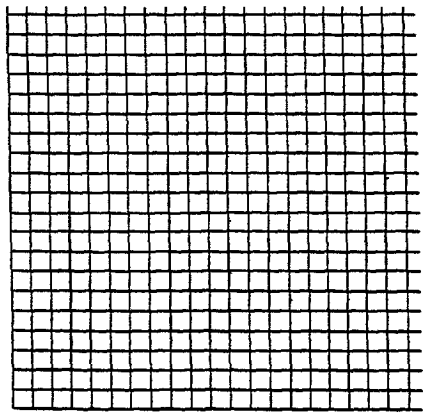


Fig. 3c

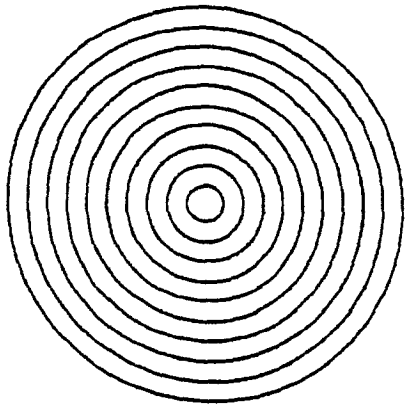


Fig. 3d

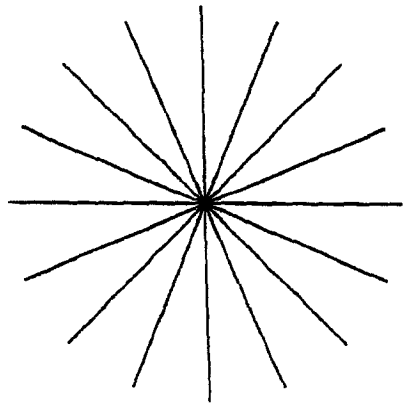


Fig. 3e

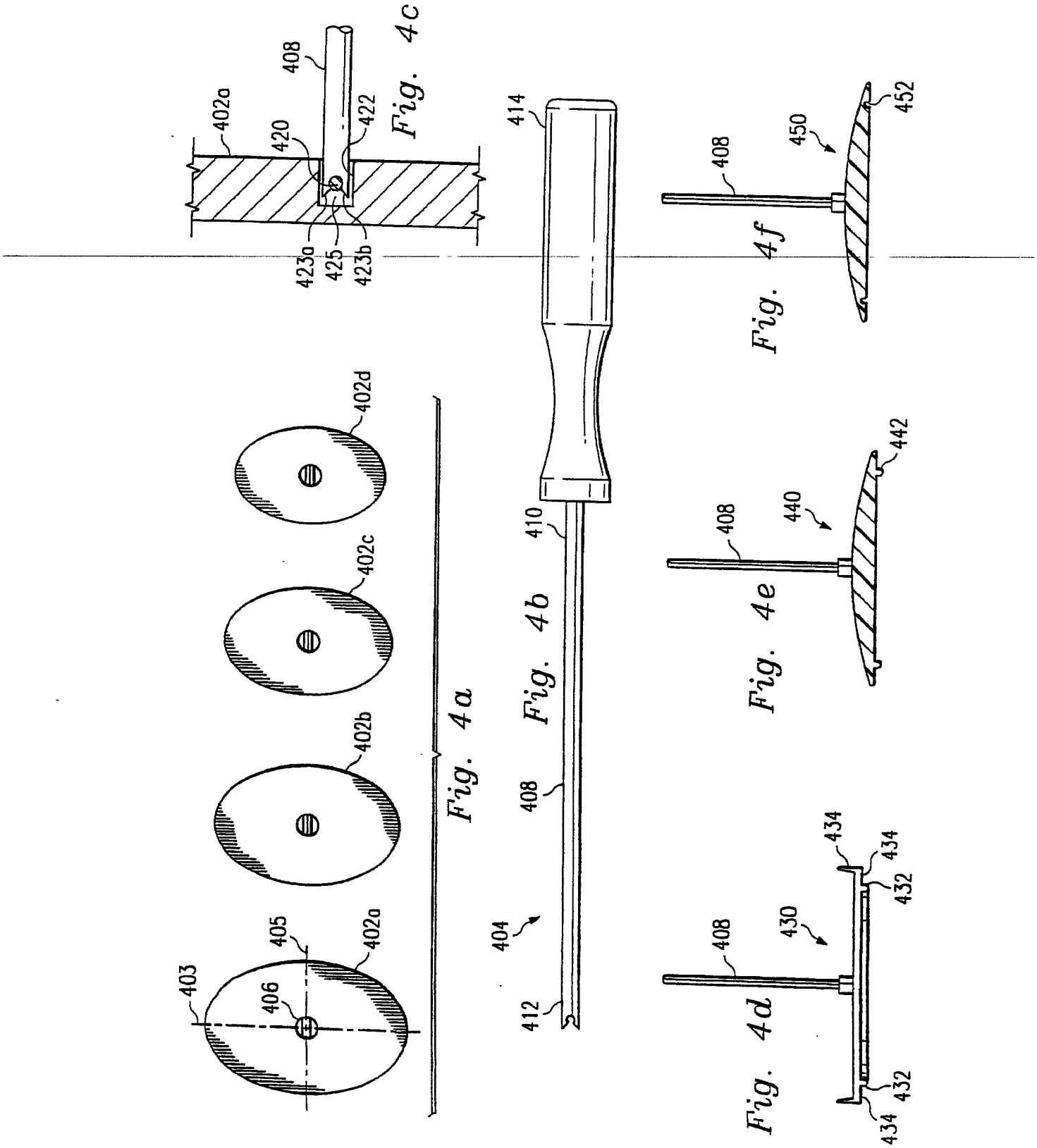


Fig. 4c

Fig. 4b

Fig. 4a

Fig. 4f

Fig. 4e

Fig. 4d

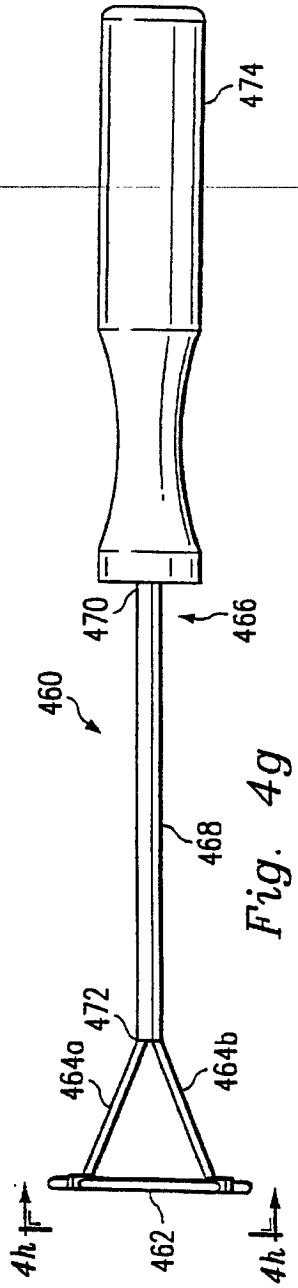


Fig. 4g

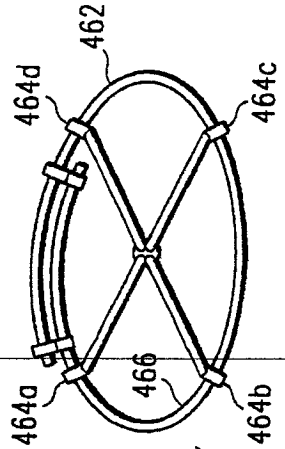


Fig. 4h

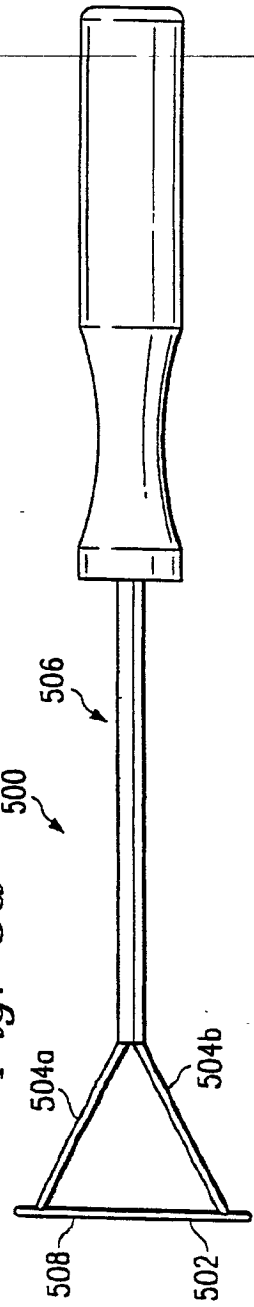


Fig. 5a

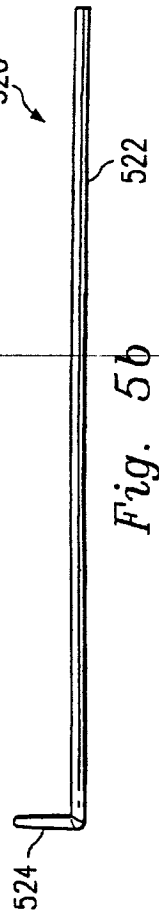


Fig. 5b

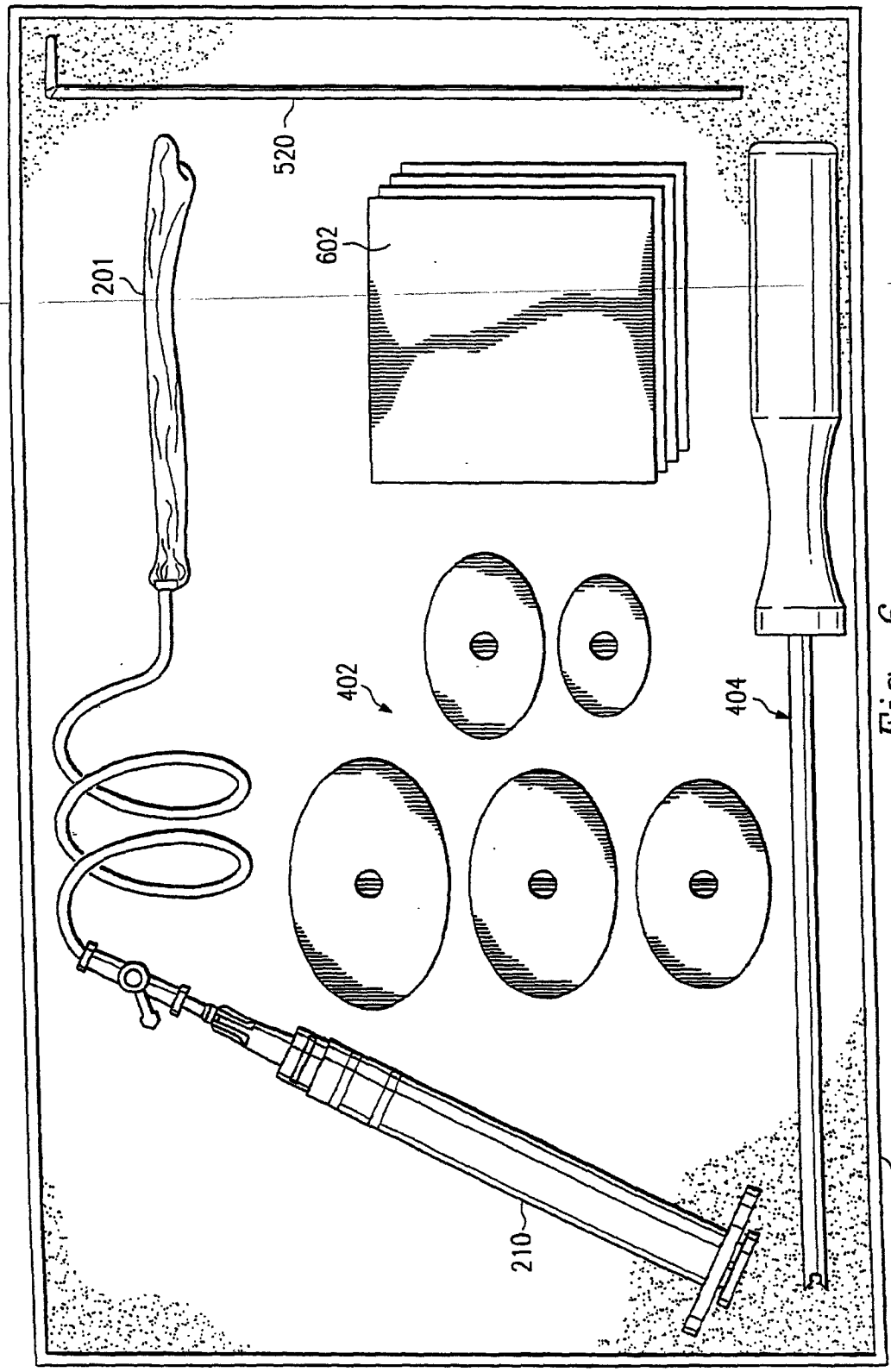


Fig. 6

Fig. 7a

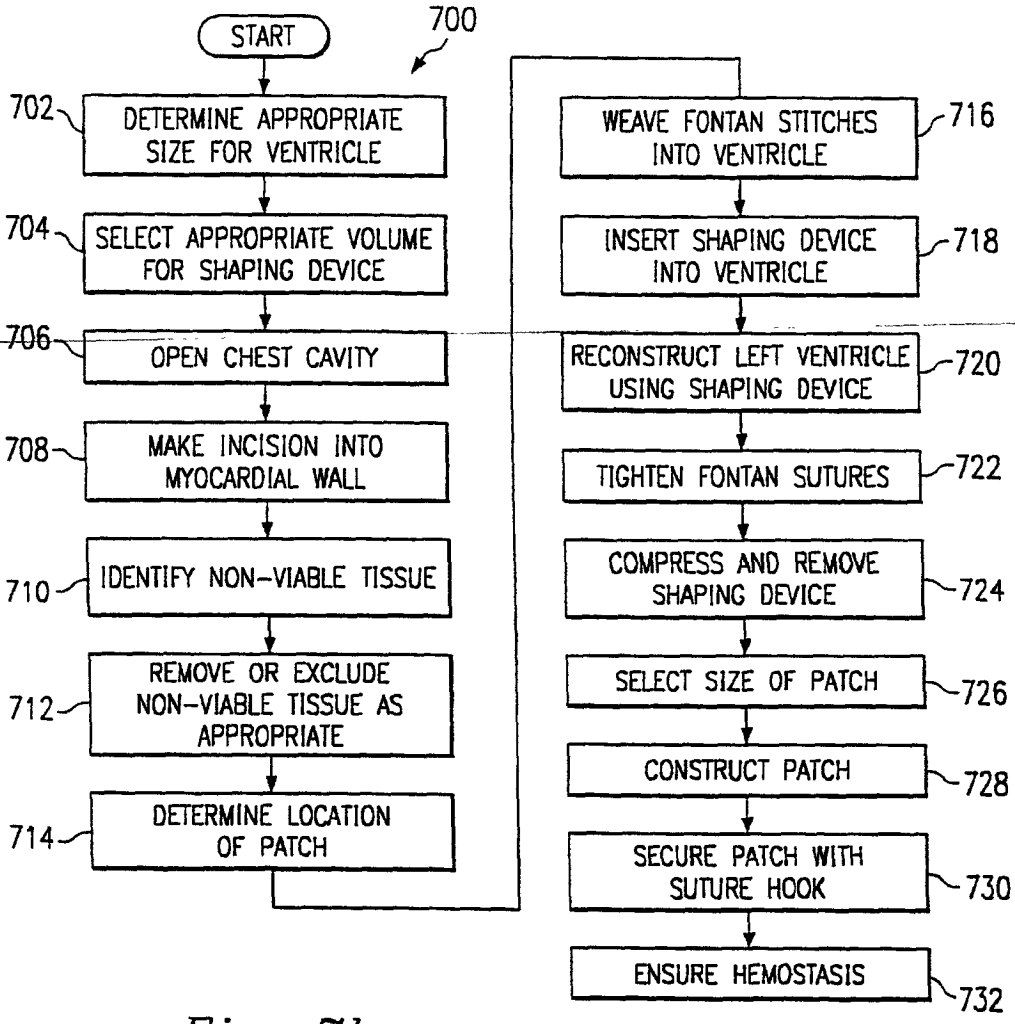
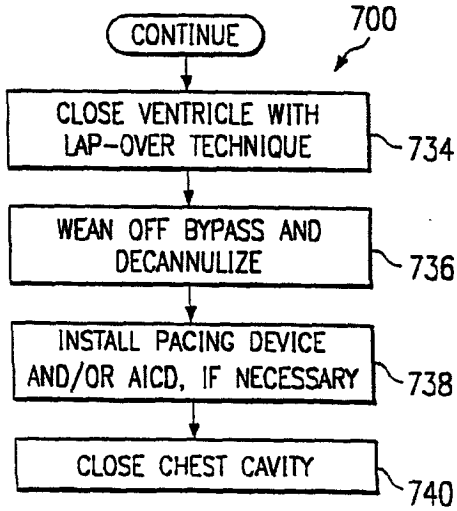

700
START
702
DETERMINE APPROPRIATE SIZE FOR VENTRICLE
704
SELECT APPROPRIATE VOLUME FOR SHAPING DEVICE
706
OPEN CHEST CAVITY
708
MAKE INCISION INTO MYOCARDIAL WALL
710
IDENTIFY NON-VIABLE TISSUE
712
REMOVE OR EXCLUDE NON-VIABLE TISSUE AS APPROPRIATE
714
DETERMINE LOCATION OF PATCH
716
WEAVE FONTAN STITCHES INTO VENTRICLE
718
INSERT SHAPING DEVICE INTO VENTRICLE
720
RECONSTRUCT LEFT VENTRICLE USING SHAPING DEVICE
722
TIGHTEN FONTAN SUTURES
724
COMPRESS AND REMOVE SHAPING DEVICE
726
SELECT SIZE OF PATCH
728
CONSTRUCT PATCH
730
SECURE PATCH WITH SUTURE HOOK
732
ENSURE HEMOSTASIS

Fig. 7b


700
CONTINUE
734
CLOSE VENTRICLE WITH LAP-OVER TECHNIQUE
736
WEAN OFF BYPASS AND DECANNULIZE
738
INSTALL PACING DEVICE AND/OR AICD, IF NECESSARY
740
CLOSE CHEST CAVITY

KIT AND METHOD FOR USE DURING VENTRICULAR RESTORATION

CROSS-REFERENCE

This invention claims the benefit of U.S. Provisional Application Ser. No. 60/272,073 filed on Feb. 28, 2001 and is also related to U.S. application Ser. Nos. 09/864,503, 09/864,510, and 09/864,793, all of which were filed on May 24, 2001.

TECHNICAL FIELD

This invention relates generally to surgical methods and apparatus for addressing cardiomyopathy, and more specifically to methods and apparatus for restoring the architecture and normal function of a mammalian heart.

BACKGROUND

The function of a heart in an animal is primarily to deliver life-supporting oxygenated blood to tissue throughout the body. This function is accomplished in four stages, each relating to a particular chamber of the heart. Initially deoxygenated blood is received in the right auricle of the heart. This deoxygenated blood is pumped by the right ventricle of the heart to the lungs where the blood is oxygenated. The oxygenated blood is initially received in the left auricle of the heart and ultimately pumped by the left ventricle of the heart throughout the body. It can be seen that the left ventricular chamber of the heart is of particular importance in this process as it is relied upon to pump the oxygenated blood initially through an aortic valve into and ultimately throughout the entire vascular system.

The amount of blood pumped from the left ventricle divided by the amount of blood available to be pumped is referred to as the ejection fraction of the heart. Generally, the higher the ejection fraction the more healthy the heart. A normal heart, for example may have a total volume of one hundred milliliters and an ejection fraction of 60 percent. Under these circumstances, 60 milliliters of blood are pumped with each beat of the heart. It is this volume in the normal heart of this example that is pumped with each beat to provide nutrients including oxygen to the muscles and other tissues of the body.

The heart is part of the body tissue, and the heart muscle also requires oxygenated blood. Its normal function is greatly upset by clotting or closure of the coronary arteries. When the coronary arteries are blocked, an associate portion of the heart muscle becomes oxygen-starved and begins to die. This is clinically referred to as a heart attack. Ischemic cardiomyopathy typically occurs as the rest of the heart dilates in an attempt to maintain the heart's output to the body.

As the ischemia progresses through its various stages, the affected myocardium dies losing its ability to contribute to the pumping action of the heart. The ischemic muscle is no longer capable of contracting so it cannot contribute to either squeezing or twisting motion required to pump blood. This non-contracting tissue is said to be "akinetic." In severe cases the akinetic tissue, which is not capable of contracting, is elastic so that blood pressure tends to develop a bulge or expansion of the chamber. In this situation, this muscle tissue is not only akinetic, in that it does not contribute to the pumping function, but it is in fact "dyskinetic," in that it detracts from the pumping function. This situation is particularly detrimental as the heart loses even more of its energy due to pumping the blood to the bulge instead of through the aorta.

After a heart attack, the body seems to realize that with a reduced pumping capacity, the ejection fraction of the heart is automatically reduced. For example, the ejection fraction may drop from a normal 60 percent to 20 percent. Realizing that the body still requires the same volume of blood for oxygen and nutrition, the body causes its heart to dilate or enlarge in size so that the smaller ejection fraction pumps about the same amount of blood. As noted, a normal heart with a blood capacity of seventy milliliters and an ejection fraction of 60 percent would pump approximately 42 milliliters per beat. The body seems to appreciate that this same volume per beat can be maintained by an ejection fraction of only 30 percent if the ventricle enlarges to a capacity of 140 milliliters. This increase in volume, commonly referred to as "remodeling", not only changes the volume of the left ventricle, but also its shape. The heart becomes greatly enlarged. An enlarged heart will tend to change its architecture from the normal conical or apical shape, to a generally spherical shape.

On the level of the muscle fibers, it has been noted that enlargement or dilation of the heart causes the fibers to reorient themselves so that they are directed away from the inner heart chamber containing the blood. As a consequence, the fibers are poorly oriented to accomplish even the squeezing action, as the lines of force become less perpendicular to the heart wall. This change in fiber orientation occurs as the heart dilates and moves from its normal elliptical shape to its dilated spherical shape. The spherical shape further reduces pumping efficiency since the fibers which normally encircle the apex to facilitate writhing are changed to a more flattened formation as a result of these spherical configurations. The resulting orientation of these fibers produces lines of force, which are also directed laterally of the ventricle chamber. Thus, the dilation and resulting spherical configuration greatly reduces contraction efficiency.

Perhaps the most notable symptom of ischemic cardiomyopathy is the reduction in the ejection fraction which may diminish, for example, from a normal 60 percent to only 20 percent. This results clinically in fatigue and in an inability to do stressful activities that require an increase in output of blood from the heart. The output of blood by the enlarged heart at rest is kept normal, but the capacity to increase output of blood during stress (i.e., exercise, walking) is significantly reduced. Of course, the change in architecture has a dramatic effect on wall thickness, radius, and stress on the heart wall. In particular, it will be noted that absent the normal conical shape, the twisting motion of the heart, which can account for as much as one half of the pumping action, is lost. As a consequence, the more spherical architecture must rely almost totally on the lateral squeezing action to pump blood. This lateral squeezing action is inefficient and very different from the more efficient twisting action of the heart. The change in architecture of the heart will also typically change the structure and ability of the mitral valve to perform its function in the pumping process. Valvular insufficiency can also occur due to dilatation.

Although the dilated heart may be capable of sustaining life, it is significantly stressed and rapidly approaches a stage where it can no longer pump blood effectively. In this stage, commonly referred to as congestive heart failure, the heart becomes distended and is generally incapable of pumping blood returning from the lungs. This further results in lung congestion and fatigue. Congestive heart failure is a major cause of death and disability in the United States with approximately 400,000 new cases annually.

Following coronary occlusion, successful acute reprefusion by thrombolysis, (clot dissolution) percutaneous

angioplasty, or urgent surgery can decrease early mortality by reducing arrhythmias and cardiogenic shock. It is also known that addressing ischemic cardiomyopathy in the acute phase, for example with reperfusion, may salvage the epicardial surface. Although the myocardium may be rendered akinetic, at least it is not dyskinetic. Post-infarction surgical re-vascularation can be directed at remote viable muscle to reduce ischemia. However, it does not address the anatomical consequences of the akinetic region of the heart that is scarred. Despite these techniques for monitoring ischemia, cardiac dilation and subsequent heart failure continue to occur in approximately 50 percent of post-infraction patients discharged from the hospital.

Various surgical approaches have been tried to treat the dilation of the ventricle by primarily reducing the ventricular volume. Some of these procedures involve removing or excluding dyskinetic and akinetic regions of the heart, then surgically joining the viable portions of the myocardial walls, typically with the use of a patch surgically placed in the walls using a Fontan stitch.

Typically, the exact placement of the patch has been visually determined using only a visual indication where the typically white scar tissue meets the typically red normal tissue. Location of the patch has been facilitated in a further procedure where a continuous suture has been placed around the ventricular wall to define a neck for receiving the patch. The neck has been formed in the white scar tissue rather than the soft viable muscle. This procedure has relied on cardioplegia methods to stop the beating of the heart and to aid in suture placement.

These surgical procedures have been met with some success as the ejection fraction has been increased, for example, from 24 percent to 42 percent. However, despite this level of success, it is often difficult for the surgeon to reconstruct the shape and size of the left ventricle. If the reconstructed ventricle is too small, the patient will not be able to pump enough oxygenated blood. If the reconstructed ventricle is too large, the ejection fraction may diminish. In addition to the size, the shape of the reconstructed ventricle is also important. If the left ventricle is reconstructed in a spherical shape, a twisting motion of the heart about its apex, which can account for as much as one half of the pumping action, is lost. As a consequence, the spherical shaped reconstructed ventricle must rely almost totally on the lateral squeezing action to pump blood. This lateral squeezing action is inefficient and very different from the more efficient twisting action of the heart. What is needed, therefore is a reliable method and apparatus to allow a surgeon to reconstruct the left ventricle to the appropriate shape, size and contour.

SUMMARY

In response to these and other problems, an improved apparatus and method is provided for restoring the geometry of the left ventricle to counteract the effects of cardiac remodeling. One embodiment of the present invention provides an apparatus and method to reconstruct an enlarged left ventricle of a human heart, using a shaper, having a size and shape substantially equal to the size and shape of an appropriate left ventricle, wherein the shaper is adapted to be temporarily placed into the enlarged left ventricle during a surgical procedure. Another aspect of one embodiment comprises a ventricular patch adapted for placement into the left ventricle of a heart made from a sheet of biocompatible material, and having a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch. In another aspect of one embodiment, a device is presented, comprising of a handle and a sizing template adapted to be coupled to the handle. Such components are also presented as a kit for use during ventricular restoration surgery.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 illustrates one embodiment of a process utilizing several aspects of the present invention.

FIG. 2*a* is a side view of one embodiment of a shaping device.

FIG. 2*b* is a side view of a balloon embodiment of a shaping device.

FIG. 2*c* is a section view of another balloon embodiment of a shaping device.

FIG. 2*d* is a section view of another balloon embodiment of a shaping device.

FIG. 2*e* is a section view of another balloon embodiment of a shaping device.

FIG. 2*f* is a section view of another balloon embodiment of a shaping device.

FIG. 2*g* is a side view of a wire frame embodiment of a shaping device in an expanded condition.

FIG. 2*h* is a side view of a wire frame embodiment of a shaping device in an expanded condition.

FIG. 2*j* is a section view cut transversely through the embodiment of FIG. 2*h*.

FIG. 3*a* is a top view of one embodiment of a patch.

FIG. 3*b* is a top view of one embodiment of markings which may be coupled to the patch of FIG. 3*a*.

FIG. 3*c* is a top view of one embodiment of markings which may be coupled to the patch of FIG. 3*a*.

FIG. 3*d* is a top view of one embodiment of markings which may be coupled to the patch of FIG. 3*a*.

FIG. 3*e* is a top view of one embodiment of markings which may be coupled to the patch of FIG. 3*a*.

FIG. 4*a* is a top view of one embodiment of a set of sizers.

FIG. 4*b* is a top view of one embodiment of a handle to be used with the set of sizers illustrated in FIG. 4*a*.

FIG. 4*c* is a detailed section view illustrating a connection between the handle and a sizer.

FIG. 4*d* is a section view of one embodiment of a sizer.

FIG. 4*e* is a section view of one embodiment of a sizer.

FIG. 4*f* is a section view of one embodiment of a sizer.

FIG. 4*g* is a top view of one embodiment of a sizer made of malleable wire.

FIG. 4*h* is a side view of the sizer illustrated in FIG. 4*g*.

FIG. 5*a* is a top view of one embodiment of a patch holder.

FIG. 5*b* is a top view of one embodiment of a suture hook.

FIG. 6 is a top view of one embodiment of a kit for surgically reshaping a ventricle.

FIG. 7*a* illustrates one embodiment of a process utilizing several aspects of the present invention.

FIG. 7*b* is a continuation of the process illustrated in FIG. 7*a*.

DETAILED DESCRIPTION

An overview method of one embodiment is presented which introduces the primary components of one embodiment. A detailed discussion of these components then follows. Finally, a method of using the components is discussed in detail.

OVERVIEW

Turning to FIG. 1, there is presented an overview method **100** for performing and using one embodiment of the present invention. A more complete discussion of this method will be presented below. The method **100** may use the following components: a shaping device **200** (FIG. 2*a*), a patch **300** (FIG. 3*a*), a sizer **402***a* (FIG. 4*a*), and a suture hook **520** (FIG. 5). Referring back to FIG. 1, at step **102**, a surgeon determines the appropriate size for the patient's left ventricle based on the patient's height, weight, body surface area and other patient specific conditions. Once the patient's appropriate ventricle size has been determined, at step **104**, the surgeon can then select the appropriate volume for the shaping device **200**. At step **106**, the surgeon opens up the chest cavity in a conventional manner. An incision is cut into the myocardial wall of an enlarged heart in step **108**. At step **110**, the surgeon may remove all or some of the non-viable tissue (i.e., the dyskentic and akinetic areas) of the myocardium. A continuous round stitch, known in the art as a Fontan stitch, may then be woven into the ventricle, at step **114**. The stitch produces an annular protrusion, which forms an opening. At step **116**, the shaping device **200** may be inserted into the ventricle through this opening. The musculature of the myocardium may be pulled over the shaping device to form a left ventricle having a predetermined volume, shape and contour. The shaping device **200** may then be compressed and removed at step **120**. At step 122, with the aid of the sizer **402***a*, the surgeon may determine the preferred location of and size of the patch **300** which may be placed in the left ventricle. The patch **300** is then cut to size in step **124** and secured to the inside of the myocardium in step **126**. At step **128**, with the patch **300** suitably placed, the ventricle is closed by joining the myocardial walls over the patch.

DESCRIPTION OF COMPONENTS

The Shaping Device:

FIG. 2*a* illustrates one embodiment of a shaping device **200**. In an inflated condition, the shaping device **200** is pre-shaped to generally model the appropriate volume and shape of the left ventricle.

The shape of the normal heart is of particular interest as it dramatically affects the way that the blood is pumped. The left ventricle which is the primary pumping chamber, is somewhat conical or apical in shape in that it is longer (long axis longest portion from aortic valve to apex) than it is wide (short axis widest portion from ventricle wall to septum) and descends from a base with a decreasing cross-sectional circumference to a point or apex. The left ventricle is further defined by a lateral and posterior ventricle wall and a septum, which extends between the auricles and the ventricles. The pumping of the blood from the left ventricle is accomplished by two types of motion. One of these motions is a simple squeezing motion, which occurs between the lateral wall and the septum. The squeezing motion occurs as a result of a thickening of the muscle fibers in the myocardium. This compresses the blood in the ventricle chamber and ejects it into the body. The thickness changes as the ventricle contracts. This is seen easily by echocardiogram and can be routinely measured.

The other type of motion is a twisting or writhing motion, which begins at the apex and rises toward the base. The rising writhing motion occurs because the heart muscle fibers run in a circular or spiral direction around the heart. When these fibers constrict, they cause the heart to twist initially at the small area of the apex, but progressively and ultimately to the wide area of the base. These squeezing and twisting motions are equally important, as they are each responsible for moving approximately one-half of the blood pumped. Turning now to FIG. 2*a*, there is shown a shaping device **200** that allows the left ventricle to be reconstructed back to a pre-enlarged operating condition. When the surgeon uses shaping device **200** as a guide in reconstructing the left ventricle, the reconstructed heart can be formed closer to the size and shape of the pre-enlarged heart. Consequently, the heart performs better post operatively than with conventional methods. As illustrated, the shaping device **200** is generally conical or "tear drop" in shape. The length "L" of the shaping device **200** may vary with each patient and will typically be a function of the volume selected for the shaping device. Depending on the patient, the length "L" may be in the three to four inch range to generally match the length of the pre-enlarged left ventricle. A surgeon may select the appropriate volume for the shaping device by estimating the volume of the pre-enlarged left ventricle. The appropriate volume of the pre-enlarged left ventricle for a patient may be estimated to be 50 to 70 cc per square meter of body surface area. The body surface area may be estimated according to the following formula; as known in the art:

$$BSA = 0.001 * 71.84 w^{0.425} * h^{0.725}$$

Where: BSA=body surface area,

w=body weight in kilograms, and

h=body height in centimeters.

The shaping device may be of an "appropriate shape" for a patient. In other words, the shaping device may be of a shape similar to the shape of the left ventricle. In one embodiment, the shaping device **200** may be a generally conical shaped object composed of portions of spherical elements having different radii. Referring back to FIG. 2*a*, the illustrative embodiment of the shaping device may be divided lengthwise into six sections where each section is a length "L2" apart. L2, therefore, may be determined from the formula: L2=0.1665*L. At line "A—A", a width W1 of the shaping device **200** is approximately 0.543*L. The back surface **202** of the shaping device **200** is generally shaped as a portion of a sphere, having a radius of 0.802*L. At a line "C—C", a width W2 of the shaping device **200** is approximately 0.628*L. The side surfaces **204***a* and **204***b* are combinations of portions of spheres with different radii. Between the line A—A and the line C—C, the side surfaces **204***a* and **204***b* have a radius of 0.515L.

At a line "E—E", a width W3 of the shaping device **200** is 0.435*L. Between the line C—C and the line E—E, the side surfaces **204***a* and **204***b* have a radius of 0.945L. The shaping device **200** narrows from the line designated "E—E" through a line designated as "F—F" to a vertex **206** at point "G". It is important to note that the above discussion is illustrative of only one embodiment of the present invention and is not meant to limit the invention to the above ratios or shapes.

In some embodiments, such as illustrated in FIG. 2*b*, the shaping device may be an inflatable balloon **201**, having a thickness of in the range of 0.02 to 0.08 inches, preferably 0.03 inches. A distal end of a filler tube **208** may be coupled to a point **207** along the exterior surface of balloon **201**. For instance, the point **207** could be located approximately ⅓ along balloon's **201** length, as illustrated in FIG. 2*b*. In other embodiments, the filler tube **208** may be coupled vertex **206**. Such tubes are well known in the art, and illustratively may be made of materials such as PVC. A proximal end of the filler tube **208** may be connected to a fluid reservoir, such as

a syringe **210** which may inject a pre-specified amount of fluid into the balloon **201** through the filler tube **208**. Also coupled to the distal end of the filler tube **208** may be a fluid control device such a stopcock **212**. The injection of fluid through the filler tube **208** inflates the balloon **201** to an inflated condition, as illustrated in FIG. **2***b*. Once inflated, the fluid inside the shaping device may be prevented from escaping by locking the stopcock **212**. This allows the balloon **201** to stay inflated with the proper volume, shape and contour during the reconstruction procedure.

The fluid pressure inside the balloon **201** may also be monitored by a pressure transducer, such as a piezoelectric transducer (not shown) coupled to the filler tube **208** with a y-connection (not shown). In other words, one lead of the y-connection would be coupled to a pressure monitor, the other lead would be coupled to the fluid source. Alternatively, the pressure monitor could be coupled to a three way stopcock (not shown), which would monitor the pressure on the filler tube side of the three way stopcock.

The fluid used to fill the balloon **201** may be any one of a number of fluids, such as saline solution or distilled water. Alternatively, another embodiment could use a sealed balloon containing a silicone gel, such as a liquid methyl silicone resin capable of being vulcanized blended with a dimethyl silicone fluid. Such gels are available from Applied Silicon Inc. (Ventura, Calif.). An embodiment using a sealed balloon would not need an external fluid reservoir, such as syringe **210**.

The balloon **201** may be conventionally formed on a mandrel (not shown) having dimensions corresponding to the shape, contour and size of the shaping device. As is known in the art, the mandrel can be made of metal, glass or a hardened gelatin. To form the balloon **201**, the mandrel is dipped into a polymer solution, which leaves a thin polymer coating on the mandrel surface. After the polymer has cured, the balloon **201** is removed by peeling the thin coating off the mandrel or by flushing mandrel material out of the shaping device.

Shaping Device—Other Embodiments:

The shaping device of the present invention may be made out of a variety of materials in a number of configurations creating a number of embodiments. For instance if the shaping device is molded from a thermoplastic polymer such as PVC or polyethylene or a similar material, the balloon may be "non-expandable" when inflated. In other words, once the balloon is inflated, the balloon **201** will not significantly expand beyond the original shape. To illustrate, several shaping devices might have volumes ranging from 100 cc to 150 cc at 10 cc increments. If a surgeon predetermines that a patient's pre-enlarged left ventricle was 128 cc., then the surgeon might select a non-expandable balloon having a volume of 130 cc. A surgeon could also request a custom non-expandable balloon with a volume specifically sized for an individual patient.

In contrast, if the balloon **201** is made from an elastomeric material, the balloon **201** may significantly expand. Such elastomeric materials may include latex, polyurethane, silicone, and other elastomers sold under the trade names KRATON (Shell Chemical, New York; N.Y.), C-FLEX (Concept Polymer, Largo, Fla.) and SANTOPRENE (Monsanto, St. Louis, Mo.) Once the balloon is substantially inflated, the influx of additional fluid causes additional expansion of the balloon. Using this embodiment, the surgeon would simply inflate the balloon to a specific volume. The original shape of the balloon may be maintained during this expansion by selectively thickening the walls of the balloon. FIG. **2***c* is a section view of an embodiment showing thickened walls of an "expandable balloon" **220**. An insertion or distal end **222** of the balloon **220** has walls at a maximum thickness. From the line A—A, the wall thickness progressively decreases to a vertex **224** at point G. In some embodiments, the vertex **224** connects to the filler tube **208**. The wall thickness will depend on the expansion range of the balloon. For example, for an expansion of 100 to 150 cc, the thickness of the balloon would vary from 0.01" at a thin end to 0.05" at the thick end. Thus, this size or volume of this embodiment may be controlled by controlling the amount and pressure of the fluid injected into the balloon **220**.

In another embodiment, the shaping device could have walls that are relatively thick and are coupled to foam spacers or thermoplastic polymer pads surrounding the exterior of the balloon. Turning now to FIG. **2***d*, there is shown a section view of an embodiment having polymer pads **232***a* through **232***l* coupled to the exterior of a balloon **230**. In a substantially inflated condition, polymer pads **232***a*–**232***l* provide a plurality of contact points: "A" through "L". Contact points "A" though "L", if connected, would define a space of approximately the same volume occupied by the balloon **201** (FIG. **2***a*). Consequently, the balloon **230** would need less fluid for inflation and the polymer pads **232***a* through **232***l* would also provide puncture resistance.

In yet another embodiment, the shaping device could be a balloon within a balloon. FIG. **2***e* illustrates such an embodiment. A balloon **250** is generally shown in FIG. **2***e*. The balloon **250** comprises a outer balloon **252** and an inner balloon **254**. In one embodiment, the inner balloon **254** is inflatable with a fluid, such as saline solution fluid. As in other embodiments, the inner balloon **254** may be inflated through the filler tube **208**. A space **256** between the inner balloon **254** and the outer balloon **252** may be pre-filled with a gel **258**, such as a silicone gel or saline solution.

FIG. **2***f* is a section view illustrating another embodiment of a balloon **260** formed to be puncture resistant. In this embodiment, the wall **262** proximal to the vertex **206** is progressively thickened to protect the proximal side of the balloon **260** from punctures during the reconstruction procedure. In an alternative embodiment, the wall **262** could be coupled to protective pads located around the vertex **206** to protect the balloon **260** from punctures. In yet another embodiment, the balloon could be made from a thick, self sealing latex rubber. Such latex compounds are well known in the industry.

The shaping device is not limited to polymeric balloon embodiments. FIG. **2***g* illustrates a shaping device **280** made from a wire skeleton or frame. The wire frame could be made from surgical grade stainless steel, titanium, tantalum, or nitinol, which is a commercially available nickel-titanium alloy material that has shape memory and is superelastic. Nitinol medical products are available from AMF of Reuilly, France, and Flexmedics Corp., of White Bear Lake, Minn.

The shaping device **280** illustrated in FIG. **2***g* is in an expanded condition. Running through the center of shaping device **280** is a main shaft **282**. The main shaft **282** has a distal end **284** and a proximal end **286**. At the distal end **284** is a joint **288**. Coupled to the joint **288** is a series of back ribs **290***a* though **290***h* (only back ribs **290***a* through **290***e* are visible in FIG. **2***g*). Back ribs **290***a* through **290***h* are connected to front ribs **292***a*–**292***h* by hinges **294***a* though **294***h* (only front ribs **292***a*–**292***e* and hinges **294***a*–**294***e* are visible in FIG. **2***f*). The proximal end of front ribs **292***a* through **292***e* are connected to a collar **296** through a series of hinges (not shown) radially spaced around collar **296**. The use of hinges around collar **296** encourages front ribs **292***a*–**292***h* to form a convex angle with respect to shaft **282** at collar **296**.

FIG. 2*h* shows the shaping device **280** in a collapsed position. In a collapsed position, back ribs **290***a*–**290***h* and front ribs **292***a*–**292***h* surround shaft **282** as illustrated in FIG. 2*j*. FIG. 2*j* is a section view cut transversely through shaft **282** and the front ribs **292***a*–**292***h*. In operation, once the shaping device **280** is inserted into the left ventricle, a surgeon may slide collar **296** along shaft **282** towards distal end **284**. The force exerted on collar **296** will cause the ribs to buckle radially outward as illustrated in FIG. 2*g*. Eventually, the front ribs **292***a*–**292***h* will bend under the applied force. Because the front ribs **292***a*–**292***h* are under stress, they will tend to push the collar **296** towards proximal end **286**. A lock **294** prevents any desired movement towards proximal end **286**. Thus, the collar **296** is held firmly in place along shaft **282** by the front ribs **292***a*–**292***h* exerting a force through collar **296** to lock **294**. The lock **294** is spring (not shown) activated and is designed such that the collar **296** may easily slide over the lock when moving from the proximal end **286** to the distal end **288**. When the surgeon is ready to remove the shaping device **280**, the surgeon may collapse the shaping device **280** by pressing down on lock **294** which will allow the collar **296** to slide past the lock **294** towards the proximal end **286**.

Patch

As will be explained in greater detail below, a patch is often used in the ventricle reconstruction procedure. A patch is made from sheet material and may be a variety of shapes, including circular, elliptical, or triangular, preferably sized and configured with a shape similar to a Fontan neck, as discussed below. As illustrated in FIG. 3*a*, an elliptical patch **300** may have a length between 30 and 50 millimeters along a major axis **302** and a width along a minor axis **304** of between 20 and 30 millimeters. The preferable thickness of the patch is in the range of 0.3 to 0.7 mm. The water permeability is preferably less than 5 ml per cm sq. per minute at 120 mm Hg. The burst strength of the patch is preferably 30 to 35 kg/cm . Finally, the 45° angle suture retention strength of the patch should be greater than 3 kg.

The sheet material for the patch **300** may be formed from a biocompatible synthetic material, for example, from polyester, Dacron (Hemoshield) manufactured by the DuPont Corporation, or polytetrafluoroethylene (Gortex). The sheet material may also be autologous pericardium, or some other fixed mammalium tissue such as bovine pericardium or porcine tissue. The biocompatible synthetic material patch may be collagen impregnated to assist in hemostasis, or it may be sprayed with a hemostatic sealant to achieve better and instantaneous hemostasis.

The patch may have markings that enable the movement and position of the patch to be post-operatively observed and analyzed under imaging systems, such as Magnetic Resonance Imaging ("MRI"), x-ray machines, fluoroscopy or other external visualization methods, for post-operative clinical evaluation. Such markings will allow identification of the patch and allow for analysis of the heart's contractility in future post-operative evaluations.

The markings may be radiopaque. Radiopaque markings are made from material that are impenetrable to radiation such as x-rays. Radiopaque markings may be applied to the patch material in a wide variety of methods. For instance, if the patch material is from a woven fabric, then radiopaque threads could be woven into the fabric at regular intervals. Such radiopaque threads could be metal and made from alloys of gold, nitinol, platinum, or stainless steel. Radiopaque threads could also be made of a biocomptabile polymeric material mixed with a metal powder, such as barium sulfate. Radiopaque markings could also be imprinted onto the fabric with radiopaque ink. Such ink is available from Creative Imprints Inc., (Norton, Mass.).

Other techniques for marking the patch **300** might include chemical vapor deposition, physical vapor deposition, electroplating and ion-beam assisted deposition. In ion-beam assisted deposition, an electron beam evaporator is used to create a vapor of atoms that coats the surface of the material.

Radiopaque threads might interfere with MRI scans because MRI is extremely sensitive to metal and metal can substantially mask MRI signals. However, if metal markings are made sufficiently small, they will show as bands in an MRI scan. Using metal fibers 0.1 mm to 0.05 mm to create the grid or pattern by weaving into the patch can make a patch MRI sensitive. Also, the metal can be applied to the patch by ion deposition which could deposit a layer of metal 0.01 mm thick onto the patch material. Small tubular strands filled with fatty acids could also be used as be used as MRI sensitive markings. Such strands could be woven into the patch material.

The markings may be Positron Emission Tomography ("PET") sensitive by making the markings slightly radioactive. However, such markings would probably only be useful for a relatively short time frame after the procedure because of radioactive decay.

The markings may also be attached to the material by a variety of mechanical means such as sewing or weaving the markings into patch material or using microclips. Similarly, the markings such as metal threads may also be attached to the material by adhesive means, such as a bio-compatible glue. Such bio-compatible glues are available from Bioglue, Cryolife Inc. (Kennesaw, Ga.) or Cyanoacrylate, by Loc Tite Corp.

In order to be useful, the markings must be arranged in a pattern that allows post operative evaluation. One such pattern is a series of equally spaced substantially parallel lines as illustrated in FIG. 3*b*. Another pattern is a grid of substantially parallel lines as illustrated in FIG. 3*c*. The distance between these parallel lines may be in standard units, such as 1 centimeter. Another pattern could be in the form of concentric circles, as illustrated in FIG. 3*d*. Yet, another pattern could be a series of lines radiating from a single point at, for instance, a set angle apart. Such a pattern is illustrated in FIG. 3*e*.

Sizers

Turning now to FIG. 4*a*, there is illustrated a set of sizers **402***a*–**402***d*. The sizers **402***a*–**402***d* are shaped to be the approximate size of the patch **300** (FIG. 3*a*). Similar to the patch, the sizers **402***a*–**402***d* will be of various geometries, length and width combinations. For illustrative purposes, the sizers **402***a*–**402***d* discussed herein will be elliptical in shape. For posterior repairs to the ventricle, however, the sizers may have a general triangular shape. Referring back to FIG. 4*a*, the length of the sizers along a major axis **403** may be in the range of 2 to 7 cm in length. The length along a minor axis **405** may be 1 to 5 cm in length. The sizers may have a connection **406** for attachment to a handle **404** (FIG. 4*b*). The sizers **402***a*–**402***d* can be made out of plastic or stainless steel or any rigid material. Four sizers **402***a*–**402***d* are illustrated in FIG. 4*a*, however, any number of sizers in a variety of could be provided.

Turning now to FIG. 4*b*, the handle **404** may also be made from stainless steel, plastic or any other suitable material. The handle **404** includes a shaft **408** having a proximal end **410** and a distal end **412**. The distal end **412** couples to the connection **406** of the sizers **402***a*–**402***d*. The proximal end **410** is coupled to a hand grip **414**. The hand grip **414** is sized to fit a human hand. Such hand grips are well known in the

art. A surgeon may connect any of the sizers 402*a*–402*d* to the handle 404. The use of handle 404 with a sizer allows the surgeon to easily estimate the size of the opening to be patched by holding the sizer up to and into the opening. If the sizer is to small, another one may be selected. This process may be repeated until the surgeon feels he has a sizer of the correct shape and size. As will be explained in greater detail below, once the proper size has been determined the sizer may be placed on material and be used as a template to cut the patch 300 to the appropriate size.

FIG. 4*c* is a section view illustrating the connection 406 between the distal end 412 of shaft 408 and the sizer 402*a*. In this embodiment, the connection 406 comprises a circular opening 422. Embedded in the walls of the opening 422 and running through the opening 422 is a rod 420. The rod 420 may be made of surgical stainless steel or another appropriate rigid material. In the illustrative embodiment, the distal end 412 includes a slot 425 with angular walls forming two flanges 423*a* and 423*b*. At the base of the slot 425 is a circular groove. The circular grove runs generally parallel to the slot 425 and has an interior diameter slightly larger than the exterior diameter of rod 420. The base of the slot 425 is slightly smaller than the diameter of rod 420. When distal end 412 is inserted into circular groove, flanges 423*a* and 423*b* slide over rod 420 until rod 420 is in the circular groove. Thus, flanges 423*a* and 423*b* are "snapped" over rod 420, and thus, will keep rod 420 in the cylindrical groove. The sizer 402*a* may rotate with respect to shaft 408. The sizer 402*a* may be removed from handle 404 by pulling on the sizer 402*a* which causes a sufficient amount of force on rod 420 to lift flanges 423*a* and 423*b* over rod 420. In other embodiments, connection 406 may be a screw connection.

In another embodiment, the sizers may have a cutting edge which can be used to cut the patch 300 to the appropriate shape. Turning now to FIG. 4*d*, a sizer 430 is shown connected to the handle 408. In this embodiment, the sizer 430 may have a ridge 432 concentric to the shape of the sizer 430. The ridge 432 allows a surgeon to accurately estimate the size of the opening by placing the ridge 432 into the opening. The sizer 430 may also have a circumferential flange or lip 434 around the perimeter of the sizer to assist in defining the patch size. The patch will typically be slightly larger than the size of the opening. The width of the lip 434 will preferably have a constant width around its circumference, typically in the range between 5 and 8 centimeters. A cutting edge 434 may also be coupled to the perimeter of the lip. In operation, the surgeon may use the sizer as illustrated in FIG. 4*d* to estimate the size of the opening, remove the sizer 430 from the handle 408, turn the handle over with respect to the handle 408, and re-attach the sizer 430 to the handle 408. The cutting edge 434 may then be used to cut the patch material to the correct size and shape by pressing the cutting edge into the patch material.

A set of cutting dies could also be provided which corresponds to the set of sizers. In other words, for each sizer provided in a set of sizers, there would be a corresponding cutting die, sized to be slightly larger than the sizer. Once a surgeon has determined the correct sizer, he could then select the corresponding cutting die and use the cutting die to cut the patch material to the appropriate size. Alternatively, a set of pre-cut patches could be provided, each pre-cut patch corresponding to a particular sizer in the set of sizers. The use of pre-cut patches would eliminate the need to cut the patch material to the required shape. The pre-cut patches may also have pre-printed suture lines which may be used as a guide for the surgeon when attaching the patch to the heart.

FIG. 4*e* illustrates an embodiment of a sizer 440 having a protrusion 442 concentric to the shape of the sizer 440. The protrusion 442 may also be used to define a suture line on the patch material by pressing the protrusion 442 against the patch material causing an indentation in the patch material which the surgeon can use as a guide to suture the patch. Turning now to FIG. 4*f*, which illustrates embodiment of a sizer 450 having a slot or groove 452 concentric to the shape of the sizer. The groove 452 may be used by the surgeon to define a suture line by allowing the surgeon to use a marking instrument, such as a pen, to trace the suture line on the patch material.

FIG. 4*g* illustrates yet another embodiment of a sizer. The sizer 460 may be a malleable wire 462 coupled to movable legs 464*a*–464*d* (464*a* and 464*b* are visible in FIG. 4*g*). The moveable legs 464*a*–464*d* are coupled to a handle 466. The handle 466 includes a shaft 468 having a proximal end 470 and a distal end 472. The distal end 472 couples to the movable legs 464*a*–464*d*. The proximal end 470 is coupled to a hand grip 474. The hand grip 474 is similar to the handgrip 414 of FIG. 4*b*. FIG. 4*h* is a section view of the sizer 460 cut through the movable legs 464*a*–464*d*. The malleable wire 462 may be manipulated by the surgeon into any appropriate shape. Additionally, because one end 466 of the malleable wire 462 is free to slide past the moveable legs 464*a* and 464*d*, the perimeter of the shape formed by the wire may be lengthened or shortened as desired.

Patch Holder

Turning now to FIG. 5*a*, there is illustrated a patch holder 500. The patch holder 500 comprises a patch plate 502 coupled to legs 504*a*–504*d* (504*a* and 504*b* are visible in FIG. 5*a*). The legs 504*a*–504*d* are coupled to a handle 506, which is similar to handle 466 discussed above. The patch plate 502 has an adhesive means on side 508, such as an adhesive backing or nylon hooks, which temporarily adheres to the patch. In operation, after a surgeon has constructed the appropriate patch, the surgeon may use patch holder 500 to place the patch into the opening, after suturing has begun, the patch holder may be removed, leaving the patch in place.

Suture Hook

Turning now to FIG. 5*b*, there is illustrated a suture hook 520. The suture hook 520 is "L" shaped and made of stainless steel, plastic or another rigid material. The suture hook 520 has a long leg 522 which may be approximately 6 inches long. Coupled to long leg 522, is short leg 524 which may be in the range of one-eighth to one-quarter inch long. The suture hook 520 is adapted to be used to pull up on the sutures in the patch 300 to secure the patch 300 to the heart.

Kit

In yet another embodiment of the present invention, a kit 600 for surgically reshaping the left ventricle of the heart is illustrated in FIG. 6. The kit 600 may include any of the components discussed above, including: the balloon 201 coupled to the syringe 210, a set of the sizers 402*a*–402*d* in various shapes and sizes, a handle 404 to attach to the sizers 402*a*–402*d*, material 602 for creating the patch 300 (not shown), the suture hook 520 and, the patch holder 500 (not shown). The components of the kit 600 may be packaged in a sterile manner as known in the relevant art.

Operation

With the primary purpose of restoring the ventricle's size, shape and contour, the intent of the procedure initially is to remove that portion of the wall, which is not capable of contracting. Such portions include the scarred dyskinetic segments, which are easy to see visually, and may also include akinetic segments, which do not contract.

Referring now to FIG. 7, which illustrates generally a method 700 for performing and using at least one embodi-

ment of the present invention. At step **702**, a surgeon determines the appropriate size for the patient's left ventricle based on the patient's height, weight, body surface area and other patient specific conditions (as discussed previously in reference to FIG. 2*a*). Once the patient's appropriate ventricle size has been determined, at step **704**, the surgeon can then select the appropriate volume for the shaping device.

In step **706**, the patient's chest cavity is opened up in a conventional manner. In step **708**, an incision is cut into the myocardial wall of the dilated heart. If the surrounding tissue is dyskinetic, it will typically be formed entirely of thin, elastic scar tissue. It is the elasticity of this scar tissue, which causes the detrimental ballooning, or bulging effects previously discussed.

In step **710**, a determination as to where the akinetic portions of the tissue begin and end must be made. The determination between viable and non viable tissue can be made by multiple methods, including: visual inspection, electrical methods, marking with dyes, echocardiography, radionuclear imaging, and palpation of a beating heart.

The electrical methods might include the use of an electromyogram which detects electrical impulses from active tissue to distinguish between the akinetic and viable tissue. Positron Emission Tomography (PET) scanning, Single Proton Emissions Computer Tomography and Electrical Mapping Electrophysiology are all other examples of a method to determine viable tissue from akinetic tissue with by electrical means. With Electrical Mapping Electrophysiology, a catheter is inserted into the heart to find areas void of electrical activity.

Marking with dyes can be accomplished by staining the myocardium tissue with a dye that adheres to viable tissue and does not adhere to scar tissue. Triphenyltetrazolium chloride, Tropinin I or T, and Creatine Kinase are all examples of dyes that perform this marking function.

Once the extent of the non-viable areas are determined, in step **712**, the portion of the tissue in the ventricle and septal walls may be excised from the epicardium from the incision to the borderline separating akinetic tissue from viable tissue. This border between akinetic and viable tissue becomes the preferred location of the patch and forms an imaginary circumferential line between the non viable areas and viable areas of the myocardium.

In step **714**, the preferred location of the patch **300** is been determined relative to the circumferential line. In step **716**, a continuous Fontan stitch may be placed in proximity to the line, along the long axis of the heart. The Fontan stitch produces an annular protrusion, which forms a neck relative to the circumferential line. The annular protrusion may be further defined by placing a rim support around its perimeter. This neck initially may have a round circular configuration. A second Fontan stitch may be placed 90 degrees from the initial stitch along the short axis of the heart. Other stitches may be placed as needed to form the heart to the shaping device. The stitch will serve to shape the heart along the short axis of the heart if needed.

In step **718**, the shaping device **200** may then be inserted into the ventricle. The shaping device **200** is then inflated or expanded, the volume of which is equivalent to the appropriate volume of the ventricle for the patient. The shaping device **200** provides the model upon which the ventricle can be shaped and contoured through the use of the Fontan suture in step **720**. The Fontan suture may then tightened with the aid of the suture hook **520**, in step **722**. As the suture or sutures are tightened, the musculature of the myocardium will form the physiologically correct volume, shape and contour over the shaping device. The appropriately oval-shaped opening in the neck defines the area where the patch will be placed. Once the suture is tightened down, the shaping device **200** may be collapsed and removed in step **724**. The size of the opening in the neck formed by the Fontan stitch will vary from patient to patient. If the patch **300** is used to close the ventricle, the surgeon should determine the size of the patch to be used (step **726**). To determine the appropriate size of the patch, the surgeon may connect any of the sizers **402***a*–**402***d* to the handle **404** to measure the size of the opening, and thus, the size patch **300** that is needed to fit into the neck formed by the Fontan stitch or stitches. In step **728**, the surgeon may then construct a patch. In embodiments with different sizers, once the proper sizer has been selected, the sizer can be placed on the patch and be used as a template to cut the patch **300** to the appropriate size. Alternatively, a surgeon may select a precut patch.

In a preferred method for placing the patch, continuous or interrupted sutures can be threaded through the rim covered annular protrusion. The rim covering acts as a large continuous pledget along the perimeter. After the patch has been moved into position on the neck, the sutures can be tied, in step **730**.

Alternatively, in cases of extensive nonfibrotic trabecular tissue on the lateral ventricle, another suture method can be placement of mattressed braided sutures over a pericardial strip from outside the ventricle to its interior through the inner oval of the patch. This procedure can be done in conjunction with other procedures such as; Mitral valve repair, ablation of ventricular arrhythmias for treatment of refractory ischemic ventricular tachycardia.

With the patch suitably placed, in step **732**, the suture line can be sprayed with a hemostatic agent or an agent can be applied to achieve better and instantaneous hemostasis. In step **734**, the operative site can be closed by joining or folding over the myocardial walls. Care should be taken not to distort the right ventricle by folding the septum wall over the ventricular wall. Alternatively, the lateral wall can be disposed interiorly of the septum wall so a majority of the force on the patch is diverted to the lateral wall. These walls can be overlapped in close proximity to the patch in order to avoid creating any cavity between the patch and the walls.

When air evacuation is confirmed by transesophageal echo, the patient can be weaned off bypass usually with minimal, if any inotropic support. Decannulasation may be accomplished with conventional methods (step **736**).

As is well known, the human heart contains an electrical conduction system which sends electrical impulses to spark the heart muscle into regular cycles of contraction. This conduction system includes a Sinoatrial node (SA node), Atrioventricular Node (AV node), and Purkinie Fibers which act as conduits for the electrical pulses. The SA node is located in the right atrium. The electrical impulse leaves the SA node and travels to the right and left Atria, causing them to contract together. This takes 0.04 seconds. There is now a natural delay to allow the Atria to contract and the Ventricles to fill up with blood. The electrical impulse has now traveled to the Atrioventricular Node (AV node). The electrical impulse now goes to the Bundle of His, then it divides into the Right and Left Bundle Branches where it rapidly spreads using Purkinje Fibers to the muscles of the Right and Left Ventricle, causing them to contract at the same time.

Because ventricular restoration may compromise the conduction system due to the fact that a ventricle portion has been severed or excluded, the pacing or rhythm of the impulses between the right and left ventricles of the heart

may get out of synchronization after ventricular restoration. This asynchronous pacing contributes to a reduced output by the left ventricle. Thus, restoring or assuring synchronization would assist the reconstructed left ventricle to maximize the output of the left ventricle. Synchronization may be restored or controlled by implanting a pacemaker or a Biventricular pacing device ("BVP") before closing the chest cavity.

A pacemaker comprises: (1) an implantable controller that sets the heart rate to the desired interval, and (2) two leads that deliver electrical impulses to specific regions of the heart (i.e., one lead is placed in the right atrium and the second lead in right ventricle) to artificially cause contractions of the ventricle at the appropriate time and synchronization. In contrast, BVPs have a third lead designed to conduct signals directly into the left ventricle. When using a BVP, one lead is placed in the right atrium, the second lead in right ventricle and third lead is placed to pace the left ventricle (i.e., in a tributary of the coronary sinus in the left ventricle). Thus, with a BVP, simultaneous electrical impulses are given to both left and right ventricles so the time delay in traveling of electrical impulse is significantly reduced which aids in restoring the normal physiology of the heart and improves the pumping action of the heart.

Pacemakers and biventricular pacing devices are available from Medtronic, Inc. (Minneapolis, Minn.), Guidant Corporation (Menlo Park, Calif.), and St. Jude Medical Inc. (St. Paul, Minn.).

The mortality associated with ventricular restoration is primarily from sudden death caused from extremely fast arrthymias. The higher risk of arrthymias may be caused from the removal of a portion of the left ventricle. This risk may be prevented by implanting a defibrillator at the time of the ventricle restoration. The automatic implantable cardioverter/defibrillator is commonly referred to as an AICD. The AICD is a device that is similar to a pacemaker, but continuously monitors the heart rhythm. If the AICD detects an abnormally fast or slow heart rhythm, it either electrically paces the heart very fast or delivers a small electrical shock to the heart to convert the heart rhythm back to normal.

Some BVP devices have defibrillators built into the circuitry that controls the pacing. Implanting a bi-ventricular pacing device with defibrillator after surgical ventricular restoration will not only optimize the output of the ventricle but also prevent many sudden deaths.

After a BVP has been installed in step **738**, closure of the chest cavity may be accomplished in step **740** by conventional methods.

It is further understood that other modifications, changes and substitutions are intended in the foregoing disclosure and in some instances some features of the disclosure will be employed without corresponding use of other features. Accordingly, it is appropriate that the appended claims be construed broadly and in a manner consistent with the scope of the disclosure.

What is claimed is:

1. A pre-fabricated, sterile kit for use during left ventricle reconstructive surgery to provide tools and apparatus to interoperatively construct a heart patch, reconstruct a left ventricle, and close an incision using the heart patch, the kit comprising:

bio-compatible material having markings, wherein the markings are configured in distinct patterns for post operatively evaluating the movement of the patch;

a series of sizing templates differing in size in which a surgeon can selectively position one such sizing template into an opening in the left ventricle, the one such sizing template to be used as a guide in cutting the bio-compatible material, wherein each sizing template has a lip coupled to a periphery of the sizing template for defining the size of a patch; and

a shaper, having a size and shape substantially equal to the size and shape of an appropriate left ventricle, wherein the shaper is adapted to be temporarily placed into the left ventricle during the reconstructive surgery.

2. The kit of claim **1** further comprising:

an expandable shaper, and

a source for inflating the shaper.

3. The kit of claim **2** wherein the source for inflating the shaper is a syringe coupled to the shaper.

4. The kit of claim **1** further comprising a cutter die for cutting out a portion of the bio-compatible material along a perimeter of one sizing template.

5. The kit of claim **1** further comprising a suture hook.

6. The kit of claim **1** further comprising a handle, wherein each sizing template is adapted to be coupled to the handle.

7. A pre-fabricated, sterile kit for use during left ventricle reconstructive surgery to provide tools and apparatus to interoperatively construct a heart patch, reconstruct a left ventricle, and close an incision using the heart patch, the kit comprising:

bio-compatible material having markings, wherein the markings are configured in distinct patterns for post operatively evaluating the movement of the patch;

a series of sizing templates of different size in which a surgeon can selectively position one such sizing template into an opening in the left ventricle, the one such sizing template to be used as a guide in cutting the bio-compatible material, wherein each sizing template has a slot on one surface of the sizing template and concentric to the shape of the sizing template for allowing tracing of a suture line onto the patch material, and

a shaper, having a size and shape substantially equal to the size and shape of an appropriate left ventricle, wherein the shaper is adapted to be temporarily placed into the left ventricle during a surgical procedure.

8. The kit of claim **7** further comprising:

an expandable shaper, and

a source for inflating the shaper.

9. The kit of claim **8** wherein the source for inflating the shaper is a syringe coupled to the shaper.

10. The kit of claim **7** further comprising a cutter die for cutting out a portion of the bio-compatible material along a perimeter of the one such sizing template.

11. The kit of claim **7** further comprising a suture hook.

12. The kit of claim **7** further comprising a handle, wherein each sizing template is adapted to be coupled to the handle.

13. A pre-fabricated, sterile kit for use during left ventricle reconstructive surgery to provide tools and apparatus to interoperatively construct a heart patch, reconstruct a left ventricle, and close an incision using the heart patch, the kit comprising:

bio-compatible material having markings, wherein the markings are configured in distinct patterns for post operatively evaluating the movement of the patch,

a series of sizing templates of different size in which a surgeon can selectively position one such sizing template into an opening in the left ventricle, the one such sizing template is to be used as a guide in cutting the

bio-compatible material, wherein each sizing template has a protrusion on one surface of the sizing template and concentric to the shape of the sizing template to create a suture line onto the patch material when the protrusion is pressed against the bio-compatible material, and

a shaper, having a size and shape substantially equal to the size and shape of an appropriate left ventricle, wherein the shaper is adapted to be temporarily placed into the left ventricle during a surgical procedure.

14. The kit of claim 13 further comprising:

an expandable shaper, and

a source for inflating the shaper.

15. The kit of claim 14 wherein the source for inflating the shaper is a syringe coupled to the shaper.

16. The kit of claim 13 further comprising a cutter die for cutting out a portion of the bio-compatible material along a perimeter of the one such sizing template.

17. The kit of claim 13 further comprising a suture hook.

18. The kit of claim 13 further comprising a handle, wherein each sizing template is adapted to be coupled to the handle.

19. A method for reconstructing an enlarged left ventricle of a human heart, the method comprising:

opening the enlarged left ventricle,

placing a shaper into the enlarged left ventricle, the shaper having a size and shape substantially equal to the size and shape of an appropriate left ventricle,

reforming the enlarged left ventricle over the shaper,

determining the size and shape of the opening,

constructing a patch to be used in closing the opening,

removing the shaper from the enlarged left ventricle, and

closing the opening using the patch, such that the enlarged left ventricle is reconstructed into a shape and volume of an appropriate left ventricle.

20. The method of claim 19 wherein the determining step comprises placing a sizing template into the opening in the left ventricle for determining the size of the opening, wherein the periphery of the sizing template is substantially the size and shape of the opening.

21. The method of claim 19 further comprising:

determining a demarkation line between non-viable tissue and viable tissue,

excluding some of the non-viable tissue,

placing at least one suture along the demarkation line, and

pulling the suture such that the left ventricle is pulled around the shaper.

22. The method of claim 21 wherein the closing step comprises suturing the patch along the at least one demarkation line.

23. The method of claim 20 further comprising providing a sizing template with a lip coupled to a periphery of the sizing template for defining a size of the patch.

24. The method of claim 19 further comprising cutting the patch from biocompatible material with a cutting edge coupled to the sizing template.

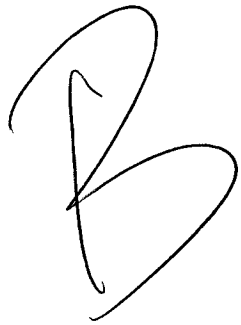
25. The method of claim 19 further comprising tracing a suture line on the patch using a slot on one surface of the sizing template.

26. The method of claim 19 further comprising creating a suture line using a protrusion coupled to one surface of the sizing template.

27. The method of claim 19 wherein the biocompatible material has markings configured in distinct patterns on the biocompatible material for post operatively evaluating movement of the patch.

28. The method of claim 19 further comprising expanding the shaper such that when the shaper is in a substantially expanded condition, the shaper is a size and shape substantially equal to the size and shape of an appropriate left ventricle.

* * * * *



CHFTechnologies, Inc.

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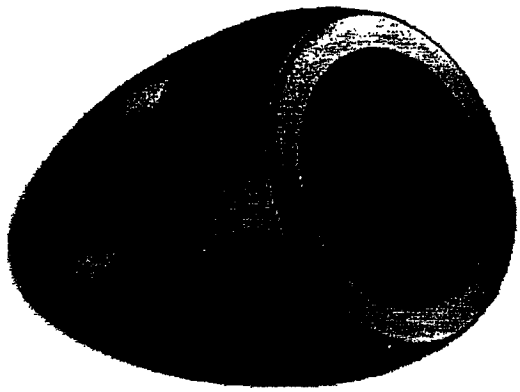
HEART RESHAPING

The Blue Egg is the next generation in heart reshaping products for ventricular restoration. Left Ventricular Restoration with the Blue Egg delivers fundamental advantages over traditional SVR or Dor procedures.



Choice - Apical ports facilitate left ventricular venting, enabling minimally invasive or beating-heart approaches.

Precision - Flexible, self-expanding construction allows easy device manipulation with definitive localization of suture or patch placement.

Safety - Sizer memory combined with optimal compressibility guarantees the desired post-restoration chamber configuration without risking trauma to the LV or the mitral apparatus.

Configuration - The surgeon determines the ideal ventricular volume. The Blue Egg assures a post-op LVEDV that matches that volume.

Durability - Unlike inflatable reservoir-type devices, the Blue Egg holds its size and is unaffected by incidental needle perforation.

Efficiency - The Blue Egg compresses and auto-expands, making insertion into the LV a one-step process. Likewise, tension at the lip causes the Blue Egg to easily collapse, making removal a fluid maneuver.

Exposure - The Blue Egg is easily compressed for fragile interior wall exposure. Inflatable shapers are uncompressable, requiring the heart to be retracted to perform the procedure.

Blue Egg Placement | Securing Stitch | Collapse/Removal | Patch Replacement | Restored Ventricle

Devices for ventricular restoration are changing the reliability and predictability of surgical outcomes. **The Blue Egg** ensures that **the LVEDV post-op:**

- is not too small, which leads to inadequate ventricular filling and failure to separate from cardio-pulmonary bypass;
- is not too large, which has been shown to lead to recurrence in as little as one year
- is not too round, which may lead to new or worsening mitral regurgitation

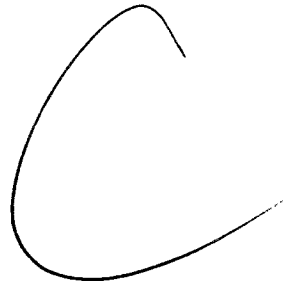
The Blue Egg when positioned in the left ventricle (correctly on the mitral annulus) demonstrates accurate location of the reconstructed apex. This creates optimal annular-papillary-apical alignment. Functional recovery requires restoration of the helical muscle fiber relationship, and an epliptical post-op ventricle is essential. As the number and complexity of

left ventricular restoration procedures increases and as more surgeons learn how to perform the operation, a precision shaping device will improve the outcomes and become a standard.

The Blue Egg is available in 90cc, 100cc, 110cc, 120cc, 130cc and 140cc configurations to accommodate different ventricular size requirements.

Catalog Number	Product Description
CHF - 90k	CHF Blue Egg Sizer 90cc
CHF - 100k	CHF Blue Egg Sizer 100cc
CHF - 110k	CHF Blue Egg Sizer 110cc
CHF - 120k	CHF Blue Egg Sizer 120cc
CHF - 130k	CHF Blue Egg Sizer 130cc
CHF - 140k	CHF Blue Egg Sizer 140cc

All kits include Boston Scientific 2" x 3" Medi-Tech Hemashield, woven double velour fabric patch.



CHF Technologies, Inc.

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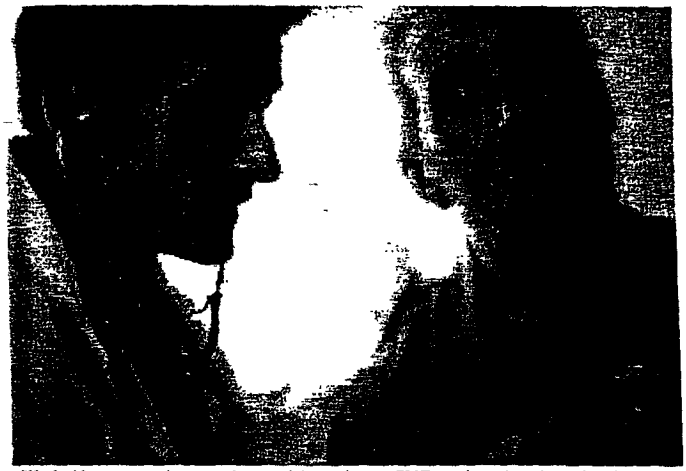
WELCOME to CHF Technologies.

We help patients overcome congestive heart failure through:



- Minimally invasive products to reshape and reconstruct the heart
- Integrated heart failure programs for hospitals
- Educational materials for patients and medical professionals

Click Here to view a short video about CHF and reshaping the heart

Patients

Learn more about Congestive Heart Failure and treatment options.

Ms. Brown had Heart Reshaping surgery for congestive heart failure. Here's what she has to say

Dr. Wendel Smith discusses Heart Reshaping Surgery on Channel 28, PBS in Tacoma, WA

Medical professionals

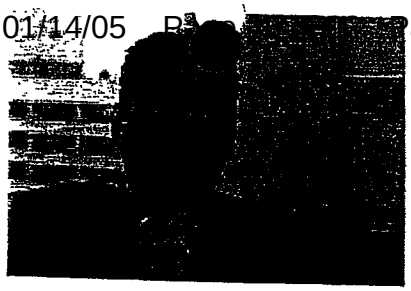
Learn more about Left Ventricular Restoration or how to implement an Integrated Heart Failure Center in your hospital or clinic.

Experts comment on
Surgical Ventricular Restoration/Heart Reshaping

Wendel Smith, MD
St. Joseph Hospital,
Tacoma, WA

Andrew Wechsler, MD
Hahnemann Hospital,
Philadelphia, PA

Aubrey Galloway, MD



NYU Medical Center, New York, NY

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Reshaping the heart of...

ABOUT HEART FAILURE

What is Heart Failure?
What are the signs and symptoms of heart failure?
What Causes Heart Failure?
What are the latest advances in care?

What is Heart Failure?

Heart failure is a condition that occurs when the heart cannot deliver enough blood supply to adequately meet the demands of the body. Often, this happens because of a weakness in the heart muscle, but may also happen if the heart doesn't fill with blood normally before it pumps. As a result, the body tries to increase the blood supply by activating the body's "emergency response systems," pumping out more adrenalin and other chemicals that can cause even more strain on an already weak heart. These chemicals signal the body to hold on to sodium (salt) and water, which can cause swelling and congestion of the lungs and other body tissues. Without proper treatment, the heart becomes even less able to do its job, and worsens over time. The term "Congestive Heart Failure" or "CHF" comes from the tendency of heart failure patients to swell and have chest congestion. Cardiomyopathy is a term used to describe the heart's condition in CHF where it becomes enlarged and does not function normally.

What are the signs and symptoms of heart failure?

The Heart Failure Society of America suggests the "FACES" to remember the signs and symptoms of heart failure:

F: Fatigue (tiredness with usual activities)
A: Activity Limited (because of symptoms)
C: Congestion (coughing, chest congestion)
E: Edema (swelling of the feet, legs, abdomen)
S: Shortness of breath (may be during the day or night during sleep)

What Causes Heart Failure?

Heart Failure is a very common condition. Over 5 million Americans have the disease, and more than 550 thousand new cases are found each year. Both young and old alike can develop heart failure, but it becomes more common as people get older. Heart attack and coronary artery blockages are the most common cause of heart failure. Other common causes are high blood pressure, heart valve problems, viral illnesses, and toxins like alcohol. Sometimes, the specific cause cannot be found.

It is possible for heart failure symptoms to be the first sign of heart disease. If you think you may be having symptoms of heart failure, do not wait to see if it gets better or worse. seek medical attention! People who are at risk for having heart failure are those who have had a heart attack in the past, a family history of heart disease, high blood pressure (especially if not treated adequately) low physical activity, smoking and being overweight.

What are the Latest Advances in Care?

In recent years, enormous progress has been made in the medical and surgical management of heart failure which has allowed patients to lead longer and healthier lives. Many patients with CHF continue to work, play and live comfortably. Most Heart Failure Centers of Excellence require heart failure patients to: be taught important skills related to monitoring their daily progress; be prescribed the right medicines at the right doses; be properly evaluated to determine if other treatments may be beneficial; and have quick access to their heart care specialists.

You may be a candidate for:

Medication prescribed by cardiac care specialists affects the heart primarily by decreasing the heart's workload: diuretics help promote excretion of water and sodium from the body. ACE Inhibitors help relax and increase the diameter of

blood vessels. This reduces the amount of work the heart has to perform. Angiotensin II Receptor Blockers are similar to ACE inhibitors but cause less side effects, Beta-blockers help slow the heart rate and reduce blood pressure. Digoxin increases the strength of the heart's contraction and slows the heart rate.

Implantable devices like pacemakers and defibrillators are helpful for certain heart failure patients to help the heart work more efficiently, and to stop dangerous heart rhythms before they lead to serious problems.

A new and innovative surgical treatment is now being offered called the Heart Reshaping Procedure or HRP. HRP can actually restore the heart to a more normal pump and can be done through a minimally invasive or mini-incision in the chest wall. Click here to view an informational video on Heart Reshaping.

A team of heart failure specialists has been organized to assure that patients receive the strong support they need to succeed in dealing with this devastating disease. The team consists of cardiologists, cardiovascular surgeons, primary care physicians, nurse practitioners, physician's assistants, nurses, medical assistants, nutrition and exercise experts, in addition to specialized services such as psychological, home and hospice care. Emphasis is placed on selecting the right treatment for each patient and close monitoring, especially while at home.

CHF Technologies, Inc.

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FREQUENTLY Asked Questions regarding Congestive Heart Failure

Q. What is Congestive Heart Failure?

A. Congestive Heart Failure (CHF), or simply "Heart Failure", is a progressive, disabling condition where the heart is unable to supply the rest of the body's cells with adequate blood circulation. With insufficient forward flow, the blood backs up into the lungs, adding shortness of breath to the symptoms, hence the term "Congestive". The heart is overworked, becomes enlarged and ultimately an ineffective pump. CHF is an insidious disease whose symptoms can occur slowly over many years.

Q. What causes Congestive Heart Failure?

A. CHF is actually a syndrome, or a complex of symptoms. Anything that causes heart damage may play a role in weakening the heart muscle and creating an ineffective pump. These include coronary artery disease, heart attack, heart valve abnormalities, high blood pressure and alcohol abuse. Other less common causes are arrhythmias and viral infections.

Q. How is Congestive Heart Failure diagnosed?

A. While there are no one universal criteria for diagnosing heart failure, it is most commonly identified through the presence of its multiple signs and symptoms, which include dyspnea (difficulty breathing), fatigue, weakness, and fluid accumulation in the lungs (pulmonary edema) and extremities. The inadequate pumping action of the heart eventually affects other organ systems in the body causing kidney, lung, and intestinal failure. A thorough physical examination is performed in addition to a chest x-ray to identify fluid present in the lungs and heart enlargement. An echocardiogram (ultrasound of the heart) is a simple non-invasive test that can be done in the doctor's office and will reveal heart chamber function and structural as well as valvular abnormalities.

Q. Who suffers from Congestive Heart Failure?

A. Over 5 million Americans are diagnosed with CHF and 550,000 additional cases occur annually. Men and women are afflicted in the same numbers and the disease occurs most often in the elderly, affecting over ten percent of people over the age of 70. Congestive heart failure is the most common hospital discharge diagnosis for patients over 65 years of age.

Q. How is Congestive Heart Failure treated?

A. The treatment corresponds to the source and the degree of failure. CHF patients with less severe symptoms are treated conservatively with diet, exercise and medications. As the disease progresses, more aggressive therapy is required. This could include interventional procedures like stenting, angioplasty, or bypass surgery to increase the coronary artery blood supply. In many patients, placement of pacing devices can improve heart function. Surgical repair or replacement of damaged heart valves is also an option in some cases, and now Heart Reshaping [or Left Ventricular Reconstruction] is a possibility in many patients. Ultimately, in very severe cases, heart transplant or ventricular assisted devices may be considered.

Q. What is Heart Reshaping?[Left Ventricular Reconstruction]

A. In certain cases of CHF, the left ventricle can actually be repaired or reshaped to resume adequate pumping function. This procedure is referred to as Heart Reshaping or left ventricular reconstruction (since of the four heart chambers, the left ventricle, is dysfunctional). The procedure in its most common form was initially developed by Dr. Vincent Dor in Monaco. Recent advances in the devices used to assist surgeons in creating the ideal ventricle size have become available, such as the Blue Egg Sizer™ as developed by CHF Technologies, Inc. In some cases, the procedure can be

performed with the Blue Egg using minimally invasive techniques to reduce trauma to the patient and shorten the healing process.

Q. What is the Blue Egg Sizer™?

A. The Blue Egg Sizer™ is a device which provides the surgeon with the capability to conform the restored ventricle to fit his or her exact plan. All physiologic sizes are available - from 90cc to 140cc (which is the normal human range). The device allows the surgeon to make an elliptical ventricular chamber that has the exact volume he or she has calculated to be the right volume for the patient. The Blue Egg Sizer™ is made of silicone and is self expanding - it's easily compressible and pliable, which helps the surgeon identify the true apex of the heart, giving proper shape and configuration to the ventricle.

When the Blue Egg Sizer™ is taken out, a half dollar size patch stays is placed over the gap. The patch is made from the same material as arterial grafts - it is collagen impregnated, which means it grows a new lining on it that is similar to a vessel, to prevent the area from bleeding.

Q. Who is an ideal candidate for the minimally invasive procedure using this device and what are the advantages?

A. The ideal candidate for the minimally invasive procedure is a patient who does not require valve or complicated coronary surgery. It is a procedure for a patient who only requires heart reshaping.

As far as recovery is concerned, typically it takes 6-10 weeks for the breast bone to heal following a sternotomy (surgical separation of the breast bone), however many patients feel better almost immediately because their hearts are pumping in a normal capacity. patients should expect to rehab for months Following the minimally invasive procedure, patients spend less time in the hospital, and are often in less pain. Their return to normal activity is faster and there is no large scarring, so vanity is improved

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CLINICAL TRIALS

The SHAPER Trial™

A PROSPECTIVE, RANDOMIZED STUDY OF A STANDARDIZED METHOD FOR SURGICALLY RESHAPING THE ISCHEMIC, CARDIOMYOPATHIC HEART

Overview:

- Controlled
- Prospective
- Randomized
- Multi-centered

Hypothesis:

- The primary hypothesis of this study shall be that the treatment group (receiving Left Ventricular Reconstruction) shall exhibit an average 1.5 ml O2/min/kg or greater increase in maximum oxygen consumption (MVO2) compared to the control group.

For More Information Contact:
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Medical Director CHF Technologies, Inc.
lannest@msn.com
(253)279-0281

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QUALITY POLICY

CHF TECHNOLOGIES, INC. will meet or exceed the needs of patients and surgical teams by providing:

- Surgical devices that are useful in the treatment of heart failure and associated diseases.
- Surgical instruments designed to work consistently and reliably to maintain the functional quality required in complex cardiac procedures.
- Clinical inservice and instruction to give the surgeon and operating room staff the competence and knowledge to employ the devices in the surgical setting.
- Comprehensive tools to assist the hospital, clinic, medical and allied health staff in implementing an integrated heart failure program
- Direct support in implementing an integrated heart failure program by on-site, phone or electronic consulting.

The entire CHF Management Team will continually improve and maintain **CHF TECHNOLOGIES, INC.'s** Quality Systems that encompass the design, manufacturing, test, release and distribution processes to produce quality products, and meet all regulatory obligations.

CHF Technologies, Inc.

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Reshaping the Heart™

BLUE EGG™ Sizing Calculator

The BLUE EGG™ Sizing Calculator assists surgeons' selection of the appropriate Blue Egg size for a specific patient.

There are two determinates of the proper size:

1. The portion of the heart not altered by the operation
2. Demands of the ventricle post-op (patient size)

To achieve this proper post op configuration, and, therefore to retrieve the ideal Blue Egg size, the surgeon enters the patient's Short Axis at Papillary Heads and Body Surface Area (BSA)

BSA: [ ] M^2

Short Axis at Papillary Heads: [ ] cms

Blue Egg Size: cc

Calculate Reset

This calculating tool is intended only as a guide and is not a substitute for the responsibility of the clinician who will make the ultimate decision by integrating multiple factors to select the correct ventricular size.

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CHF CONSULTING SERVICES

Turn-key Integrated Program Implementation
Collaborative Approach for the Cardiologist, Surgeon, & Hospital
Customizable Program Architecture
First to Market as a Center of Excellence

The American Heart Association reports that there are 5.5 million congestive heart failure (CHF) patients in the US, with 550,000 new cases diagnosed each year. Heart Failure is the most common primary and secondary diagnosis in people over the age of 65. Life expectance for these patients is poor. The estimated $30 billion annual expenditures for this disease exceed the cost of all cancer and heart-attack treatment combined. Significantly, hospitals actively caring for CHF patients lose money on each admission.

Even more disturbing than the reimbursement disparity created by inequitable Medicare and private payor policies is the plight of the poorly served heart failure patient. Obliged to fend for themselves at home, in an environment where compliance is difficult, patients are often readmitted to the hospital within 30 days. Frequent admissions are inconvenient for the patient and costly to the hospital. In an integrated program, a patient would be treated at home, with the clinic routinely monitoring condition and adjusting medication and diet as needed. If symptoms worsen, the patient would be instructed to return to the clinic, rather than being admitted after hours through the emergency department.

CHF Technologies (CHFT) has created a service that provides hospitals with the resources needed to build an integrated heart failure program. Such a program bridges outpatient and inpatient care, tracks patients at home after discharge, uses an outpatient management protocol, promotes continuous patient education, and accumulates data for payors and research projects.

- **Bridges Outpatient and Inpatient Care:** Most hospitals administer adequate inpatient care for heart failure patients. The acknowledged problem is - what happens to the patient after discharge? In an integrated program, the clinic would seamlessly follow the patient as an inpatient and as an outpatient.

- **Tracking Patients at Home:** The resources available to the Institution will determine how the clinicians will interface with patients. In most settings, both telephone and e-mail will be utilized by Heart Failure clinic personnel to follow the patient at home. (More sophisticated systems are available but are potentially expensive). A reporting schedule is established where the patient is expected to routinely contact the clinic with their vital signs and other pertinent data. In response to the patient input, Protocol-directed management algorithms developed by the program Medical Director(s), allow Nurse Practitioners to alter medications or dosages, diet and exercise. (Patients that do not check-in at the agreed upon time will be flagged and contacted by the clinic.) In the event the patient does not respond to treatment prescribed by the NP, arrangements will be made for them to enter the clinic for evaluation rather than directly admitted to the hospital or admitted through the ED.

- **Continuous Patient Education:** Patient education begins while the patient is hospitalized for heart failure. A clinic representative works with the hospital intensivist and floor nurses to educate the patient about coping with their disease. The patient is seen by the clinic representative during hospitalization and at discharge. An interactive heart failure education manual is sent home with the patient. While at home, the patient is routinely contacted by a clinic representative.

- **Data Compilation and Analysis:** Data is interrogated in compliance with HIPAA guidelines. The data accumulated on heart failure patients will subsequently be used to assess the effectiveness of care, medical and surgical intervention, and outcomes for research investigation.

Heart Failure Services provide an in-depth architecture for developing and implementing an integrated Congestive Heart Failure Program in the hospital or clinic setting. Emphasis is on the analysis of current hospital organizational support systems, current path of care for heart failure patients, reimbursement for heart failure hospital admissions and related procedures, and ancillary services. Utilizing program development expertise and support provided by CHF Technologies can lessen the lead-time required to bring the program to an operational level.

CHF Technologies' "Information Hot Line", patient acquisition/management program, marketing package, and educational opportunities for physicians and allied health professionals, are part of the consulting services designed to assist the hospital in offering enhanced treatment modalities, delivering quality patient care, and achieving sustainable profitability.

For more information on our consulting services please email sales@pexheat.com.

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Reshaping the heart™

DISTRIBUTION

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LINKS

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http://www.aats.org/

Heart Failure Society of America
http://www.hfsa.org/

Promedica International
http://www.promedicacme.com

The Society of Thoracic Surgeons
Helping Cardiothoracic Surgeons Serve Patients Better
http://www.sts.org/

The European Association for Cardio-thoracic Surgery
http://www.eacts.org/

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Reshaping the heart™

PRESS RELEASES

November 17, 2004: Patient's Heart Size is Surgically Reduced to Help Overcome Congestive Heart Failure

October 20, 2004: New Surgical Treatment for Congestive Heart Failure

July 22, 2004: Methodist Dallas Medical Center One of First in Country to Use New Heart Reshaping Device

May 12, 2004: St. Joseph Medical Center performs nation's first minimally invasive `heart reshaping' surgery

Please visit us again soon for more news about CHF Technologies

CHF Technologies, Inc.

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PRESS RELEASES

November 17, 2004

Patient's Heart Size is Surgically Reduced to Help Overcome Congestive Heart Failure

CHF Technologies, Inc. provides Philadelphia-area patients with an innovative treatment for congestive heart failure

Dr. Andrew Wechsler, a cardiovascular surgeon from Hahnemann Hospital located in the heart of Philadelphia, recently performed a procedure known as "Left Ventricular Restoration" or reshaping the heart, on a patient with severe congestive heart failure. Dr. Wechsler used a new device called the Blue Egg Sizer™ from CHF Technologies, Inc. This procedure is part of the Heart Failure Center program Hahnemann Hospital is developing to accommodate the needs of the Philadelphia community and surrounding region. In the United States, congestive heart failure affects more than 5 million people, most of whom have suffered a previous heart attack which leads to this weakened and debilitating state. Healthcare costs attributed to CHF are estimated to be over $30 Billion annually.

Dr. Wechsler's patient, Robert Glynn, has had problems with his heart most of his life. At age 18 the valve separating his left atrium and left ventricle was malfunctioning due to congenital abnormalities. The valve was replaced through a large incision in his breastbone. By age 38 his condition had deteriorated to the late stages of congestive heart failure. In congestive heart failure or CHF, the heart becomes an inefficient pump, sometimes enlarging 2-3 times its normal size. This inefficiency creates a backup of fluids in the lungs and extremities, which severely impact the quality and duration of the patient's life.

As a husband and father, Mr. Glynn should have been in the prime of his life, experiencing an active relationship with his family and friends. Instead, he was bedridden with his condition worsening. The outlook was grim. As his health declined, so did his options for medical treatment. At some point he would be placed on the heart transplant list. Over 50,000 people in the US are currently waiting for new hearts with only 2,000 actually receiving a heart transplant annually.

Fortunately, Mr. Glynn was referred to Dr. Andrew Wechsler. Dr. Wechsler performed a procedure relatively new to this country, but has been practiced in Europe for many years. This procedure is "Left Ventricular Restoration" or reshaping the heart. In heart reshaping, the enlarged left ventricle is reduced in size by excluding tissue that is either not functioning or functioning very little. By reducing the heart size and utilizing healthy wall muscle, the heart becomes an efficient pump once again.

Dr. Wechsler used a device called the Blue Egg Sizer™ to ensure the optimum ventricle shape and volume. Although he has done this operation many times before, in this instance he accessed the heart through a 2-3 inch incision between the ribs instead of through the sternum or breastbone. This minimal access surgery allows the patient to experience much faster healing and less pain after the operation. During surgery, a small incision is made in the heart and the Blue Egg Sizer™ is inserted into the left ventricle. Damaged tissue is excluded as the healthy tissue is molded around the Egg.

Just before that last portion of healthy tissue is sutured together, the Blue Egg Sizer™ is collapsed and removed. A bio-compatible patch is placed over the small opening for reinforcement. Dr. Wechsler said, "The patient is doing great. His symptoms have lessened to the point where he can resume much of his normal activity. Most of his hospitalization was for adjustment of a previously implanted heart pacing device. We finally have a viable solution for these very sick

For more information on Congestive Heart Failure contact:
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See the original article on Yahoo! news

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PRESS RELEASES

October 20, 2004

By: medinews.com staff writers

New Surgical Treatment for Congestive Heart Failure

A new minimally invasive surgical treatment for congestive heart failure involves a heart reshaping procedure (HRP) that can be performed through a small chest incision.

In severe cases of congestive heart failure, the heart is enlarged and the pumping action of the left ventricle has become inefficient. Although frequently performed through an operation that requires division of the breastbone, in many cases the ventricle can be accessed for reshaping using a minimally invasive approach.

In HRP, the surgeon introduces a custom-engineered device called the Blue Egg Sizer into the left ventricle and surgically reshapes the heart around the device. In the final step, the surgeon collapses the Blue Egg Sizer, removes it from the ventricle, and attaches a cloth patch specifically designed for this operation to seal the hole. The heart returns to its original elliptical shape and is better able to circulate blood to meet the body's needs. HRP can also be performed in conjunction with other heart failure treatments such as cardiac stenting and bypass grafting.

The first minimally invasive HRP in the United States was recently performed in St. Joseph's Hospital (Tacoma, WA, USA) by Wendel Smith, M.D., who works closely with St. Joseph's cardiologists, led by Dr. Raed Fahmy, to select patients who are candidates for the HRP procedure. "There was an immediate improvement in the patient's cardiac output following the procedure," Dr. Smith stated. The Blue Egg Sizer is being distributed by CHF Technologies, Inc. (Danville, CA, USA).

See the original article at www.medianews.com here

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PRESS RELEASES

July 22, 2004

Methodist Dallas Medical Center One of First in Country to Use New Heart Reshaping Device

Methodist Dallas Medical Center announced today that its cardiovascular team and the cardiovascular surgeons on the medical staff Methodist Health System are one of the first in the country and the only one in Texas to use a new heart-reshaping device that could radically change the treatment of patients suffering from congestive heart failure (CHF). The device is used in a minimally invasive procedure that resizes and reshapes the left ventricle of the heart to improve the heart's pumping action.

Congestive heart failure is a debilitating condition that often occurs following a heart attack, even if the injured portion of the heart heals. Congestive heart failure causes the heart to become oversized and inefficient. This inefficiency creates a back up of fluids in the lungs and swelling of the extremities, which severely impact the quality and duration of the patient's life. In the United States, congestive heart failure affects more than five million persons and is responsible for an estimated $30 billion annually in related health care costs.

Lonnie Whiddon, MD, a cardiovascular surgeon on the medical staff at Methodist Health System who performed the heart reshaping surgery, says "Heart reshaping offers certain patients an effective surgical option for relief of their heart failure symptoms." His patient, a female in her mid 50's whose heart had been damaged in a previous heart attack, has been discharged and is doing well. The patient reportedly had very little pain after surgery and now breathes much more easily.

In patients who do not require a bypass or valve repair, the surgery can be performed using a minor incision rather than the large incision caused by cutting through the breastbone in traditional cardiac surgery. After restoring the ventricle to its ideal size and shape, the resizer is collapsed and removed just prior to the end of the procedure. A tiny patch is placed over the incision to reinforce the ventricle.

The Blue Egg Resizer device, as it is called because of its color and resemblance to an egg, was designed by CHF Technologies of Danville, CA (www.chftech.com). For more information on finding a physician on the medical staff at Methodist Health System, call 214.947.0000.

About Methodist Health System

Guided by the founding principles of life, learning, and compassion, Methodist Health System (Methodist) uses some of the latest medical technology and research to bring quality health care to individuals and families throughout North Texas. Methodist Dallas Medical Center, Methodist Charlton Medical Center, and three Methodist Family Health Centers are part of the nonprofit Methodist Health System, which is affiliated by covenant with the North Texas Conference of The United Methodist Church. Additional information is available at www.methodisthealthsystem.org.

Texas law prohibits hospitals from pra[illegible]ng medicine. The physicians on the Meth[illegible]t Health System medical staff are independent practitioners who are [illegible] employees or agents of Methodist Healt[illegible]stem.

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PRESS RELEASES

May 12, 2004

St. Joseph Medical Center performs nation's first minimally invasive `heart reshaping' surgery

Innovation benefits patients with congestive heart failure

Dr. Wendel Smith

TACOMA -- A St. Joseph Medical Center cardiovascular surgical team led by Dr. Wendel Smith has become the first in the United States to perform a minimally invasive medical procedure that could radically change treatment for patients with congestive heart failure.

During the recent operation, Dr. Smith surgically entered the patient's heart through a single, three-inch incision between the ribs in order to reshape the left ventricle and improve the heart's pumping action.

The three-hour surgery in April was the first in the nation in which the "heart reshaping" surgery was performed by entering the patient's chest through a minor incision rather than the standard process of cutting through the sternum (breast bone) and spreading open the rib cage. For the patient, this less-invasive approach means less pain and fewer scars.

"By entering through a small incision between the ribs, we've eliminated the need for the large sternal incision associated with traditional cardiac surgical procedures," said Dr. Smith, a cardiovascular surgeon and medical director for research and education at the St. Joseph Heart Center in Tacoma. "The benefits of this minimally invasive approach are that the patient suffers less pain, breathes more easily during and after the operation, and has fewer scars after the healing process."

The "heart reshaping" procedure Dr. Smith performed involves surgically resizing the heart's left ventricle to restore pumping action diminished by an earlier heart attack. The procedure is relatively new in the United States but has been used in some European countries for some time. As part of the surgery, a patented synthetic cone-shaped sizer - designed to recreate the ideal ventricle shape -- is placed inside the patient's left ventricle and healthy heart muscle re-sewn around the device. Just prior to the end of the procedure, the sizer is collapsed and removed, and a permanent patch placed over the incision to reinforce the ventricle.

"Restoring ideal ventricle size and strengthening the muscle wall can dramatically improve the quality of life for patients who suffer from congestive heart failure," said Dr. Smith, who is affiliated with Northwest Cardiovascular Associates.

Until Dr. Smith performed the heart-reshaping procedure with only a small incision between the patient's ribs, U.S. surgeons had always performed this type of surgery by entering the chest through the sternum. His patient, a man in his 50s, required no pain pills only three days after surgery -- which is a much shorter time than the usual -- because of the minimally invasive chest entry. The patient has since been released from the hospital and is doing well.

Congestive heart failure is a debilitating condition that can occur following a heart attack in which the heart becomes an oversized, inefficient pump. This creates a buildup of fluids in the lungs and a swelling of the extremities that seriously impact the patient's life. In the United States, congestive heart failure affects more than 5 million people annually and is

"Heart reshaping offers patients an effective surgical option for relief of heart-failure symptoms," said Dr. Smith. In the milestone surgery, he used the newest ventricular sizer designed by CHF Technologies of Danville, Calif. and distributed by ESTECH, Inc. (www.estechlics.com), also of Danville.

The achievement by Dr. Smith proves that heart-reshaping surgery for treating congestive heart failure, in which a ventricle sizer is used, can be performed with minimal impact on the patient.

For more information about congestive heart failure, talk to your doctor or go online to www.americanheart.org and click on "Diseases and Conditions." Those who need a doctor may call Franciscan Health System's Physician Referral Service at 1-888-825-3227. St. Joseph Heart Center performs more open-heart surgeries and other cardiac procedures than any facility in the south Puget Sound region. St. Joseph Medical Center is part of the Franciscan Health System, which also includes St. Francis Hospital in Federal Way and St. Clare Hospital in Lakewood.

About Franciscan Health System: Franciscan Health System includes St. Joseph Medical Center in Tacoma, St. Clare Hospital in Lakewood, St. Francis Hospital in Federal Way, Franciscan Medical Group (a network of primary-care physicians) and the Franciscan Care Center at Tacoma, a continuing care facility. Franciscan Health System is owned by Catholic Health Initiatives, one of the largest not-for-profit health care systems in the nation. Visit the Franciscan website at www.fhshealth.org.

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MISSION STATEMENT

The mission of CHF Technologies is to expand on the successes of a proven surgical approach, the "Dor Procedure", which has improved the course of the disease in selected CHF patients, by excluding and reinforcing the dysfunctional portion of the ventricle before harm to uninvolved areas can take place.

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Reshaping the heart™

CHFT TEAM

Arthur Bertolero - CEO

Art Bertolero is the Founder and CEO of CHF Technologies, Inc. CHFT was founded as a subsidiary of ESTECH in October 2003, and was "spun-out" from ESTECH in January 2004.

Mr. Bertolero has spent 20 years in the medical device industry. He has been a senior manager and president of both start up and public companies. He is a founder and CEO of ESTECH, which recently entered into agreements with Boston Scientific Corp (BSX), giving that company an exclusive option to acquire ESTECH. In June 2004, Medical Device & Diagnostic Industry Magazine recognized Art as one the "100 Notable People" in the medical device industry.

Lon S. Annest, M.D., MBA - Co-founder and Medical Director

Dr. Annest is a cardiothoracic surgeon who practiced in the Tacoma, Washington area for 20 years, and has been actively involved in the development of medical device technology and a pioneer in cardiovascular surgical improvements. An injury to his right hand forced his retirement from surgery and prompted him to apply his expertise to business. He received his MBA from the University of Washington, with a focus on "Medical Devices and Disruptive Technologies". As one of the founders of CHF Technologies, he was uniquely involved in the creation, design, and development of the devices and related patents, as well as the surgical applications for the Company's products.

As Medical Director, he has assembled our medical advisory board, with world-class experts in the field of surgery for congestive heart failure. He continues to focus on current and future generations of product design and development. Lon also works with surgeons to perfect the surgical techniques needed to perform the heart reshaping procedure, as well as proctoring new centers as they perform their initial cases.

Roy Chin - VP Research and Development

Roy Chin has 16 years of active involvement in the research and development of medical device technologies. His career path has moved him into several different surgical specialties: orthopedic, general surgery, ENT, cardiology, and cardiovascular surgery with a focus in the area of minimally invasive surgery. He received his Bachelor of Science in Electrical Engineering from the University of Kansas. In the last 5 years, as an executive at AFx, a medical device company acquired by Guidant, he helped pioneer a 2-hour minimally invasive surgical treatment for atrial fibrillation. Roy's contributions at AFx encompassed several key areas, including the research, design, and development of the devices and their surgical applications. He was also involved in the company's strategic positioning. In Feb 2004, Guidant acquired AFx for $45 Million, with several milestones payments.

Roy has established a reputation as a clinical expert in the treatment of atrial fibrillation and is now extending his expertise into congestive heart failure. As Vice President of Research and Development, he will focus on current and future generations of product design and development, which include stand-alone therapies and therapies combined with other treatments.

Kent Richards - VP Global Marketing

Kent Richards is an executive with 17 years experience in marketing medical products and services. He has brought to market a variety of products including medical lasers, minimally invasive visualization equipment, and advanced clinical training programs. His experience with Vista Medical, in their product marketing and Bariatric center deployment compliments nicely our focus on CHF and the treatment of those patients that suffer from it.

Kent brings an in-depth clinical understanding of medical technology and surgical application to CHF Technologies. As Vice President of Global Marketing and Clinical Affairs for the Company, his aim is to surround a procedure with state-of-the-art products, training, and tools for implementation.

Robert O'Reilly - VP Business Development

Rob O'Reilly has a broad background in healthcare. He spent 15 years in cardiac rhythm management (CRM) sales and distribution, with a crossover into the cardiovascular surgical market. His industry involvement covers companies such as Cordis, Guidant, Sulzer Medical, RMI (Edwards) among others. In 1997, Rob created an online ecommerce business called MDBuy, which used the Internet to enable smaller physician practices to reduce their costs on goods and services. He successfully raised funds to develop the firm's business model and served as president of the company.

For CHF Technologies, Rob has established relationships in the Cardiology and Cardiovascular surgery industry and provides experience in developing new strategic partnerships.

Joanne Lindberg, MN, RN, CCRN

Ms Lindberg has been in the medical field for over 20 years with a career emphasis in quality improvement She received her Bachelor of Science in Nursing from Pacific Lutheran University and her Masters of Nursing from the University of Washington. Ms. Lindberg has been involved in all phases of project management from basic planning through outcome analysis.

Ms. Lindberg's expertise in the CHF program arena is in the mechanics of program development. She has designed data collection tools and overseen technology and resource utilization, clinical pathway design, ptient care management and staff training. She has focused on data and quality outcomes, and program development for the past 10 years .She has had administrative responsibilities in the Franciscan Health System with a focus on concept development, market place optimization and outcome analysis at the hospital and corporate level Ms. Lindberg has also been involved with the Society of Critical Care Medicine including assisting with an international project focused on Development of Lung Guidelines, as well as participating on an Interdisciplinary Team Building Committee

Cynthia D. Adams, RN, MSN, CS

Ms. Adams received her Bachelor of Science in Nursing from Ball State University in 1983. She received her Master of Science in Nursing from Indiana University School of Nursing and board certification as an Adult Nurse Practitioner in 1994. She is a Ph.D. candidate at Indiana University and is currently working on her dissertation research piloting a home-based physical activity program for heart failure patients. Her major focus area is Nursing: Acute and Chronic Illness, with a minor in Health Economics. Her areas of greatest interest include interventions and outcomes in chronic disease management, the benefits of exercise in heart failure, and secondary prevention in cardiovascular disease. She has specialized in heart failure management since 1995, and has designed and implemented both hospital-based and private practice-based outpatient programs for heart failure management, both demonstrating 51-55% reductions in hospitalization. She is currently practicing at The Care Group, LLC and supervises the CardiAction prevention program, which encompasses the Heart Failure and Lipid/Risk Factor Clinics. She has published and presented abstracts and papers nationally in the areas of heart failure management, multidisciplinary team approach to disease management, and exercise in heart failure.

Karen Rehder, RN, MPH, FNP-C

Ms. Rehder has 20 years experience working in cardiology, She held the position of CHF Program Chair at Kaiser Permanente, San Rafael, CA and helped develop the Regional CHF Patient Education Program. She created a proprietary software program specifically designed to track CHF patients at home. Her responsibilities in QI and Regulatory have been to manage all outcome data for the Kaiser CHF Program.

Virginia Vickers - Office Manager

Virginia Vickers comes to CHF Technologies uniquely qualified for her role as office manager. Her formative medical device years were spent at Lifescan, a Johnson & Johnson Company, as a New Product Planner. Virginia worked on the development of FastTake, Lifescan's first electrochemical blood glucose monitor, and later led a new product team in developing an improved lancing device. After leaving Lifescan, Virginia developed a Landscape Design business and started Fellow Citizens Project, a non-profit that works with internationals, helping them integrate into the community. Virginia also holds a Master of Arts in English.

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Reshaping the heart

CORPORATE INFORMATION

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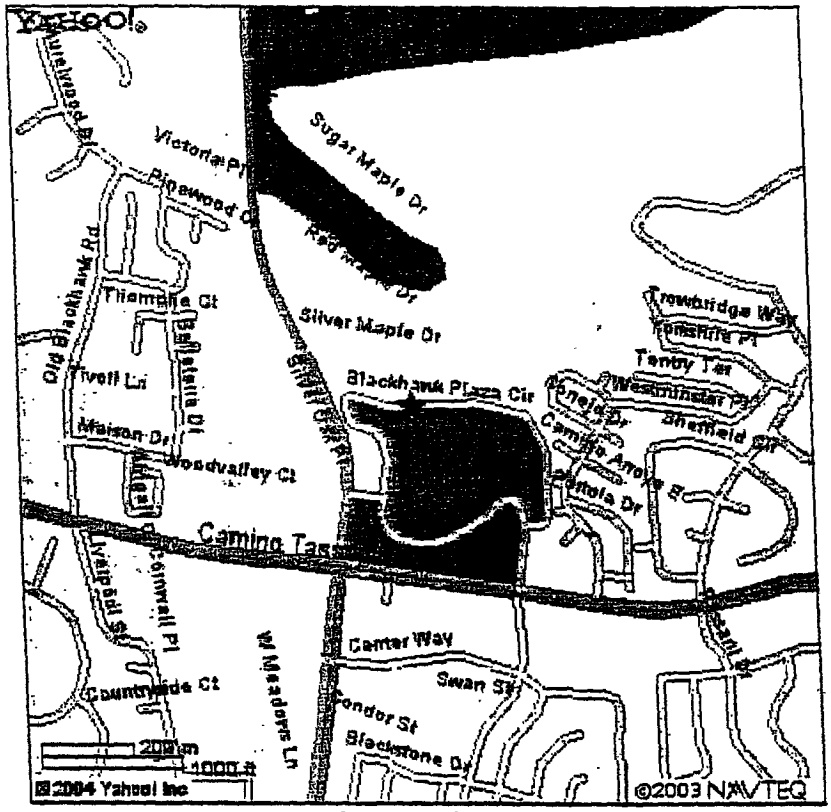

YAHOO! Maps

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Reshaping the heart of...

TRADE SHOWS & MEETINGS

Meeting schedule for 2004
Heart Failure Society of America Meeting
http://www.hfsa.org/
September 12-15, 2004
Toronto, Canada

Meeting schedule for 2005
Heart Failure Society of America
http://www.hfsa.org/
TBA

The Society of Thoracic Surgery
http://www.sts.org/
January 24-26, 2005
Tampa, FL

CHF Medical Advisor Meeting
February, 2005

Interventional Cardiology 2005: An International Symposium
March 21-25, 2005
Snowmass, CO

American Association of Thoracic Surgery
http://www.aats.org/
April 10-13, 2005,
San Francisco, CA

American Association of Thoracic Surgery
http://www.aats.org/
Apirl 25-28, 2004
Toronto, Canada

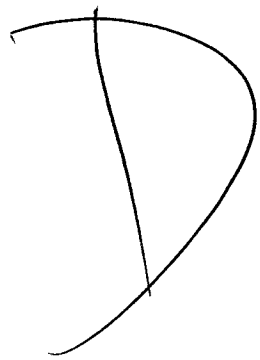
CHF Medical Advisor Meeting
August 12-15, 2004
Napa, CA

Society of Thoracic Surgeons, Heart Failure Management: Drugs to Devices
http://www.sts.org/
August 27-29, 2004
Louisville, KY

European Association for Cardio-Thoracic Surgery & European Society of Thoracic Surgeons 3rd Joint Meeting
http://www.eacts.org/
September 12-15, 2004
Leipzig, Germany

4th European Association for Cardio-Thoracic Surgery & European Society of Thoracic Surgeons Joint Meeting
http://www.eacts.org/
September 24-28, 2005
Barcelona, Spain

Controversies in Adult Cardiac Surgery
http://promedicacme.com/conf_controversies2004.html
October 6-8, 2004
Los Angeles, CA



US006309349B1

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

(10) **Patent No.: US 6,309,349 B1**
(45) **Date of Patent: Oct. 30, 2001**

(54) **SURGICAL RETRACTOR AND STABILIZING DEVICE AND METHOD FOR USE**

(75) Inventors: **Arthur A. Bertolero; Raymond S. Bertolero**, both of Danville; **Jerome B. Riebman**, Sunnyvale, all of CA (US)

(73) Assignee: **Endoscopic Technologies, Inc.**, Danville, CA (US)

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

(21) Appl. No.: **09/171,207**

(22) PCT Filed: **Apr. 10, 1997**

(86) PCT No.: **PCT/US97/05910**

§ 371 Date: **Jul. 6, 1999**

§ 102(e) Date: **Jul. 6, 1999**

(87) PCT Pub. No.: **WO97/37596**

PCT Pub. Date: **Oct. 16, 1997**

Related U.S. Application Data

(60) Provisional application No. 60/014,922, filed on Apr. 10, 1996.

(51) **Int. Cl.**[7] **A61B 1/32**

(52) **U.S. Cl.** **600/213**; 600/219; 600/210; 600/215; 600/235

(58) **Field of Search** 600/201, 206, 600/210, 213, 219, 227, 231, 232, 215, 222, 235

(56) **References Cited**

U.S. PATENT DOCUMENTS

861,356 * 7/1907 Buchfeld 600/219
1,655,962 1/1928 Lespinasse .

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

669511 8/1963 (CA) .
WO 97/37581 10/1997 (WO) .
WO 97/37597 10/1997 (WO) .
WO 97/37716 10/1997 (WO) .

OTHER PUBLICATIONS

Brochure for Snowden Pencer EndoCABG System, "Innovative Instrument for Endoscopic Coronary Artery Bypass Grafting," 3 pages (no date).

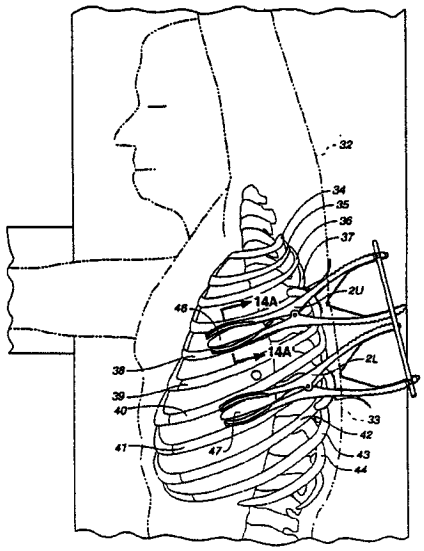
(List continued on next page.)

Primary Examiner—Jeffrey A. Smith
(74) *Attorney, Agent, or Firm*—Cooley Godward LLP

(57) **ABSTRACT**

An adjustable surgical retractor and its use for improving a surgeon's ability to perform closed-chest video-assisted exploratory, diagnostic or surgical procedures on a patient. The surgical retractor is designed to have opposable blades which can be inserted into a surgical incision in a patient undergoing a surgical procedure then spread apart to form an elongated access opening through which a instrument may be inserted to perform exploratory, diagnostic or surgical procedures. The blades used in the surgical retractor may be flexible or rigid and are attachable to the retractor. The blades are of a width, depth and thickness to provide an access to an internal cavity or subcutaneous region to allow greater degrees of freedom to the surgeon in inserting instruments into the access opening. The use of the surgical retractor forms a substantially ovoid channel, through which a medical instrument can be inserted to aid a doctor in performing surgical or other operations.

26 Claims, 18 Drawing Sheets



U.S. PATENT DOCUMENTS

2,075,534		3/1937	McCormack .	
2,977,958	*	4/1961	Seiger	600/277 X
3,035,582	*	5/1962	Seiger	600/227 X
3,038,467		6/1962	Sovatkin .	
3,766,910		10/1973	Lake .	
3,893,454		7/1975	Hagelin .	
3,965,890	*	6/1976	Gauthier .	
4,754,746		7/1988	Cox .	
4,813,401		3/1989	Grieshaber .	
4,896,661	*	1/1990	Bogert et al.	600/219 X
5,297,538		3/1994	Daniel .	
5,299,563	*	4/1994	Seton .	
5,584,803		12/1996	Stevens et al. .	
5,613,937		3/1997	Garrison et al. .	
5,618,260		4/1997	Caspar et al. .	
5,752,526	*	5/1998	Cosgrove	128/898

OTHER PUBLICATIONS

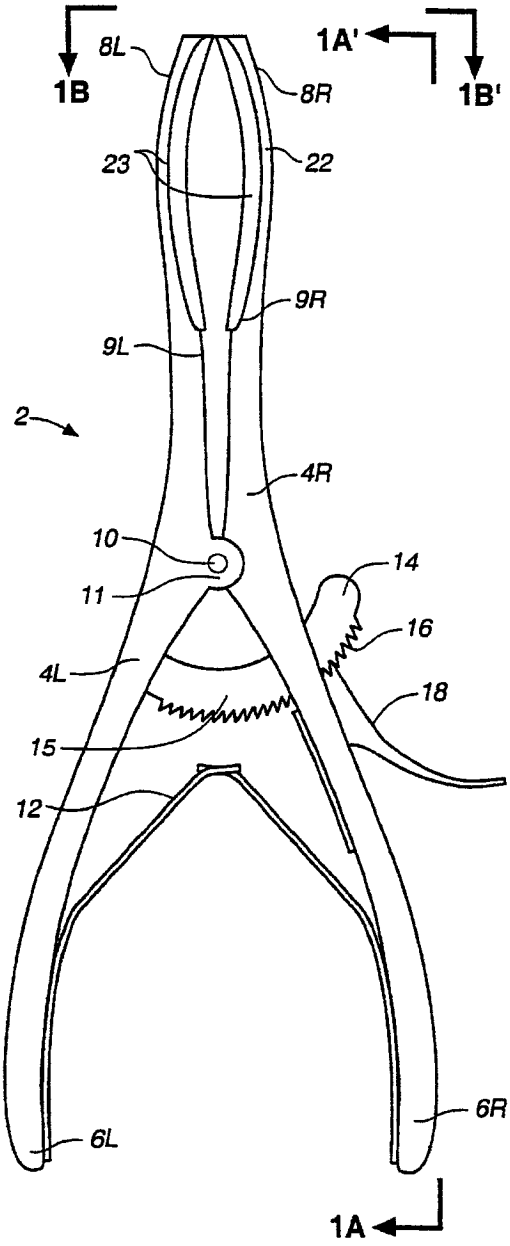
Brochure for USSC Mini–CABG Instruments, "For Minimally Invasive Cardiac Surgery," 3 pages (1997).

Online Brochure for CTS MIDCAB System, "CTS Procducts: Selective Revascularization—MIDCAB Products," http://www.cardioth.com/physician/html/products/midcab.html, 2 pages (no date).

Online Brochure for Snowden Pencer Retractor, "Plastic Surgery Instruments," http://www.snowdenpencer.com/, 3 pages (no date).

Kirkland et al., *Cardiac Surgery*, vol. 1, Chap. 2, 2nd Ed., pp. 101 (no date).

* cited by examiner


1B
8L
1A'
1B'
8R
23
22
9R
9L
2
4R
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14
11
16
4L
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15
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6R
6L
1A

FIG._1

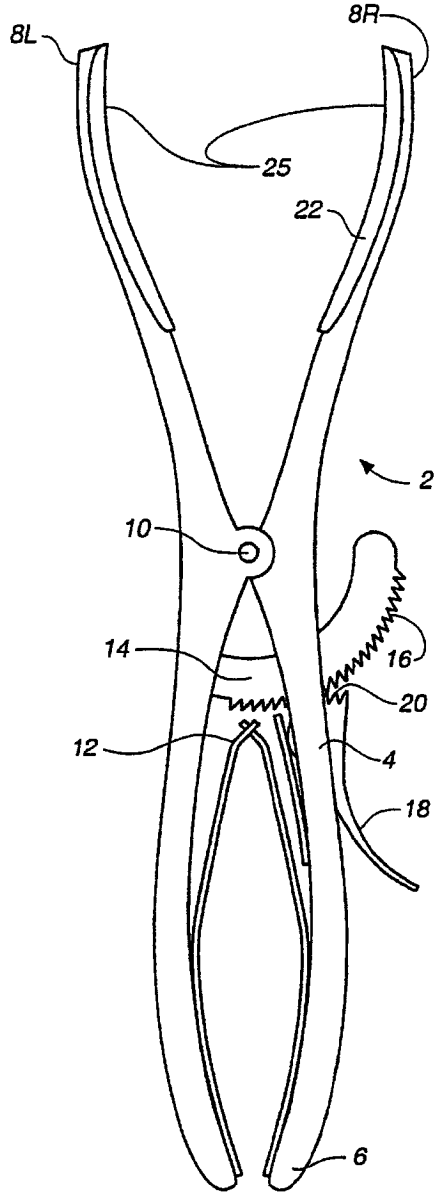
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FIG._2

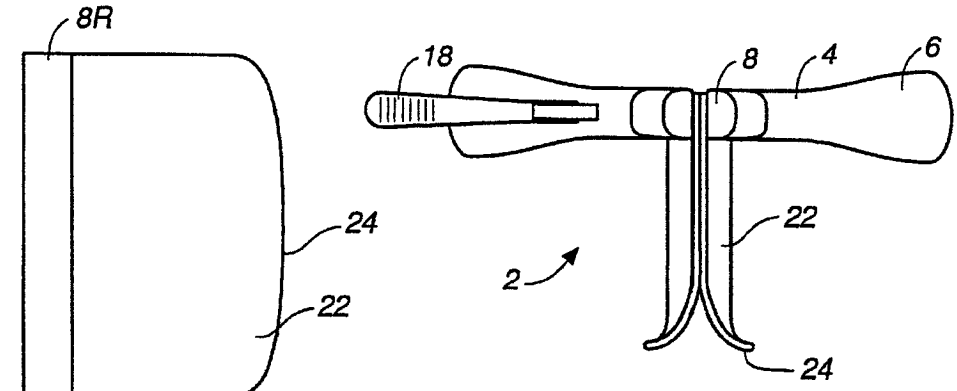


FIG._1B

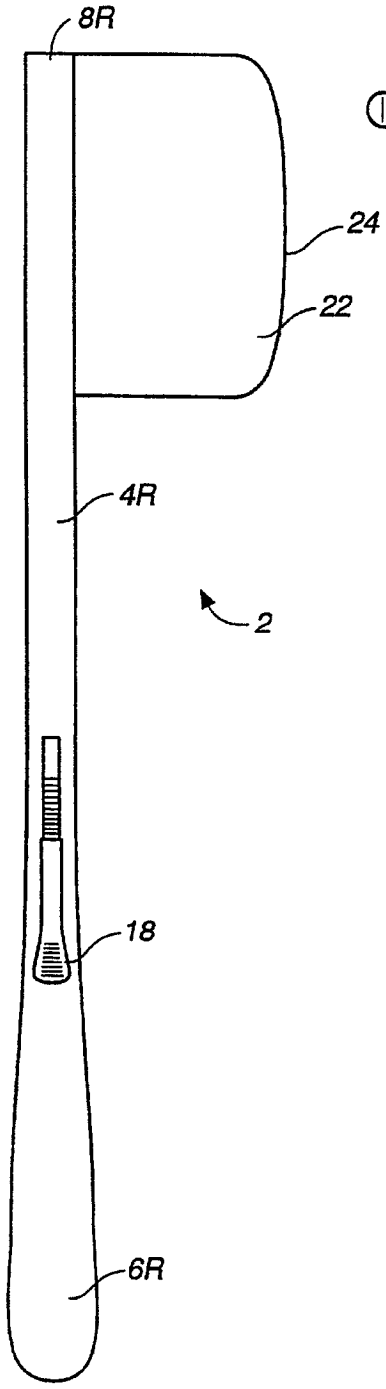
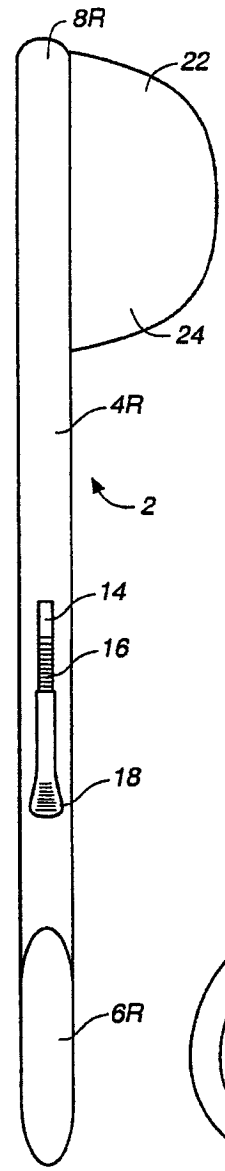


FIG._1A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4R
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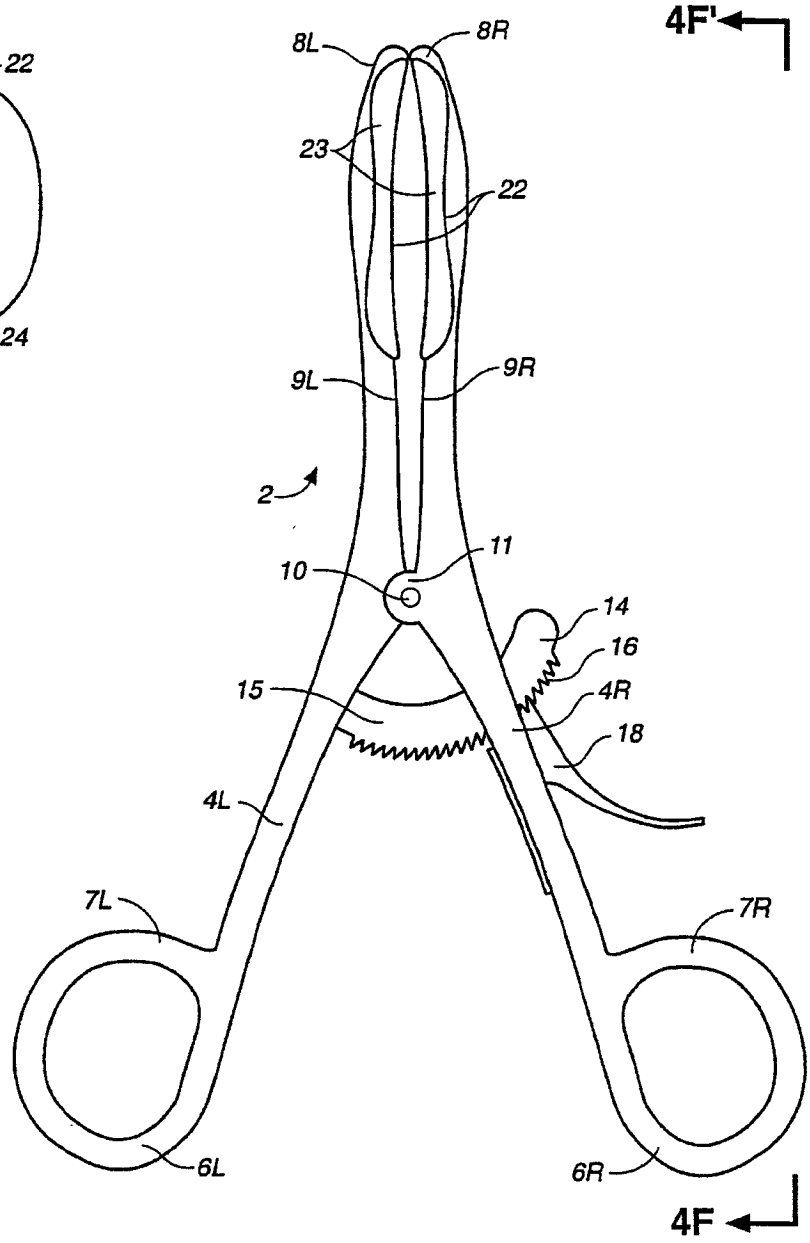
6R

FIG._4


4F'
8L
8R
23
22
9L
9R
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7L
7R
6L
6R
4F

FIG._3

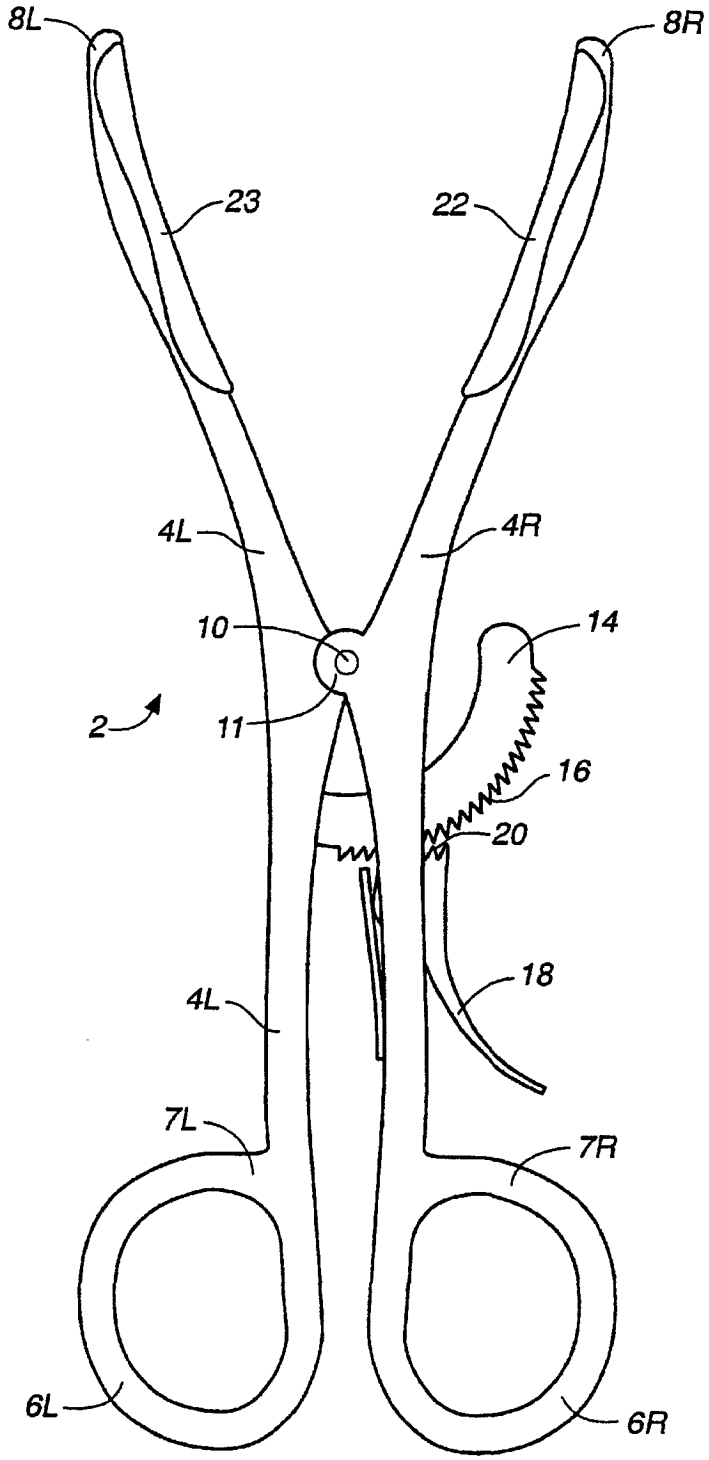


FIG._3A

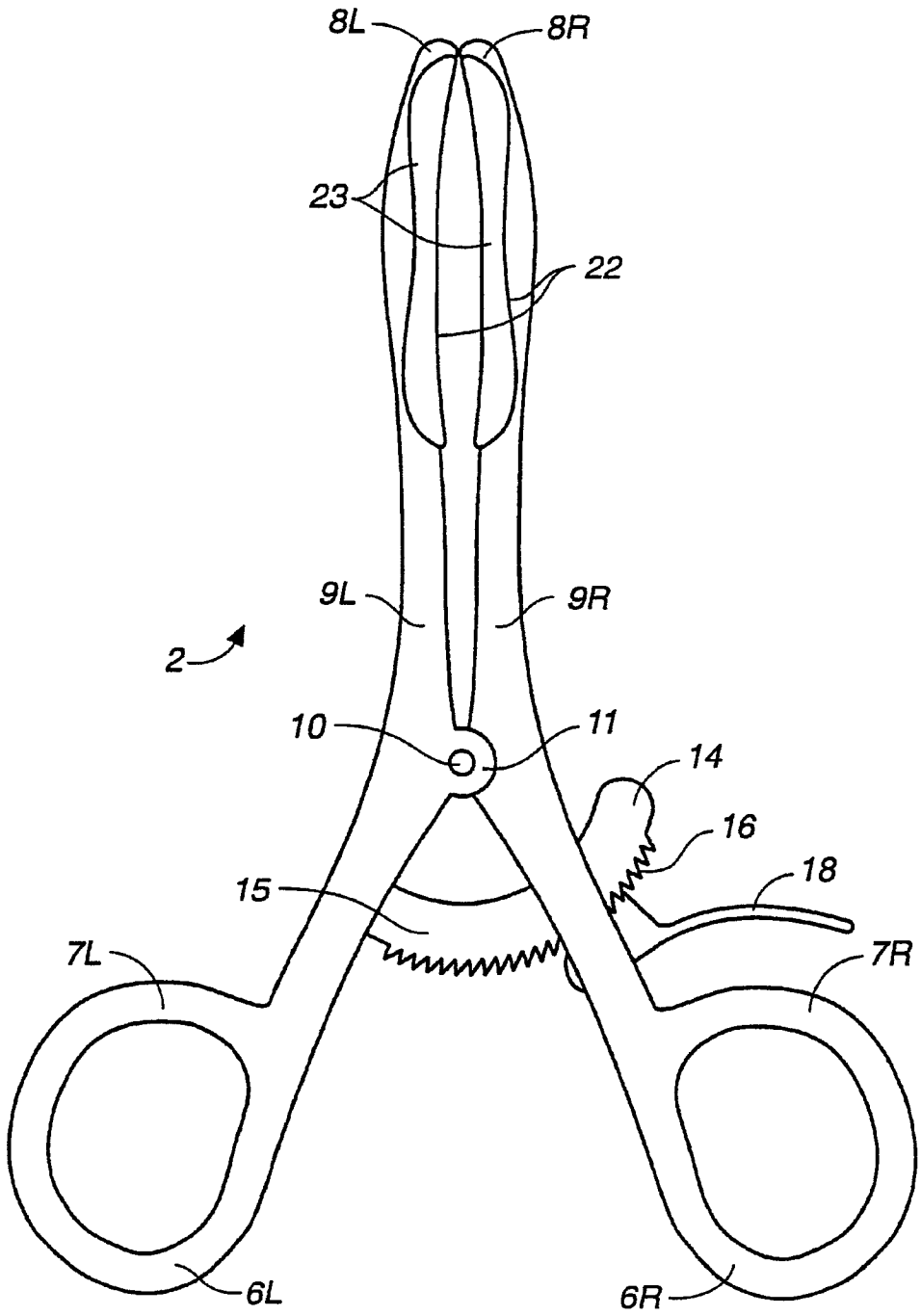
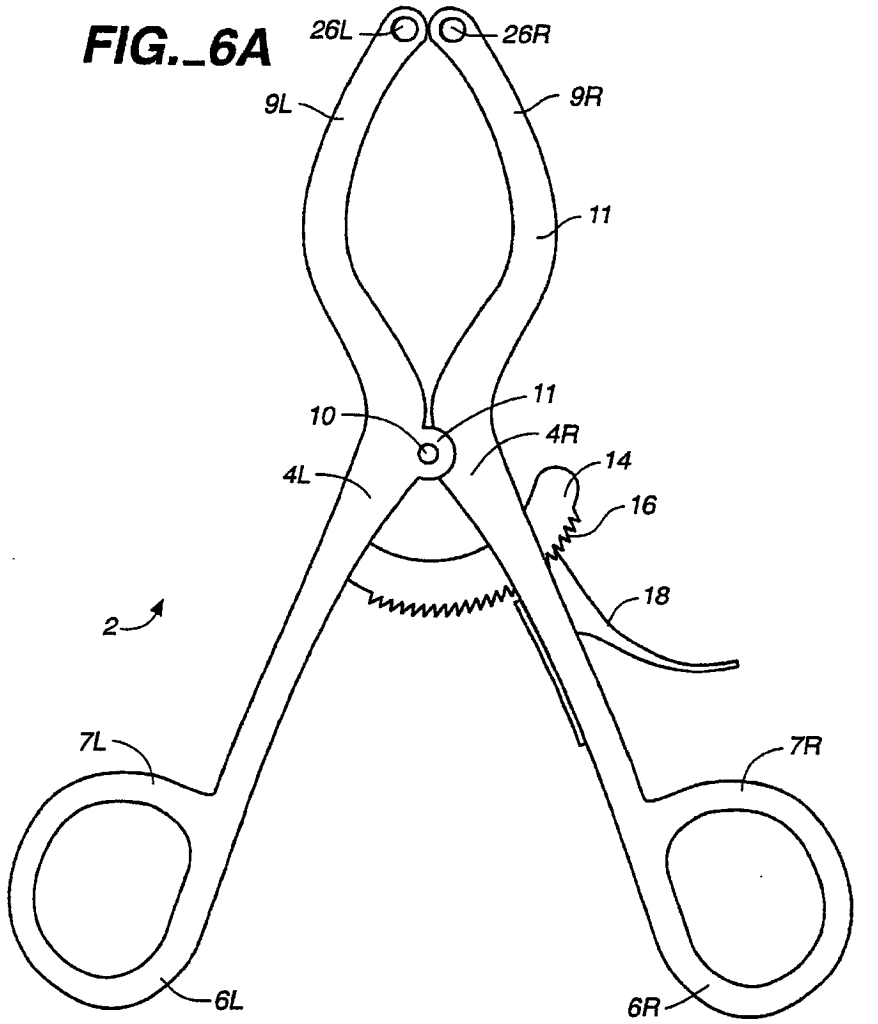


FIG._5

FIG._6A



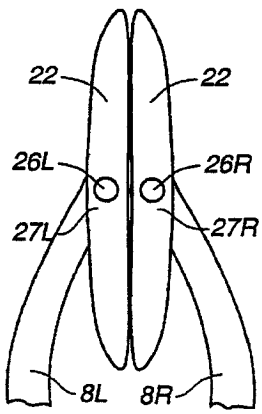


FIG._6E

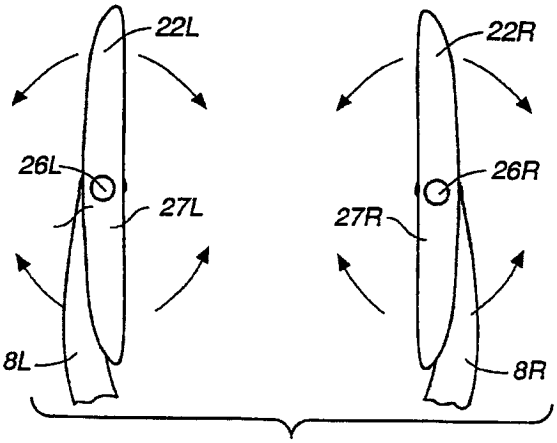


FIG._6F

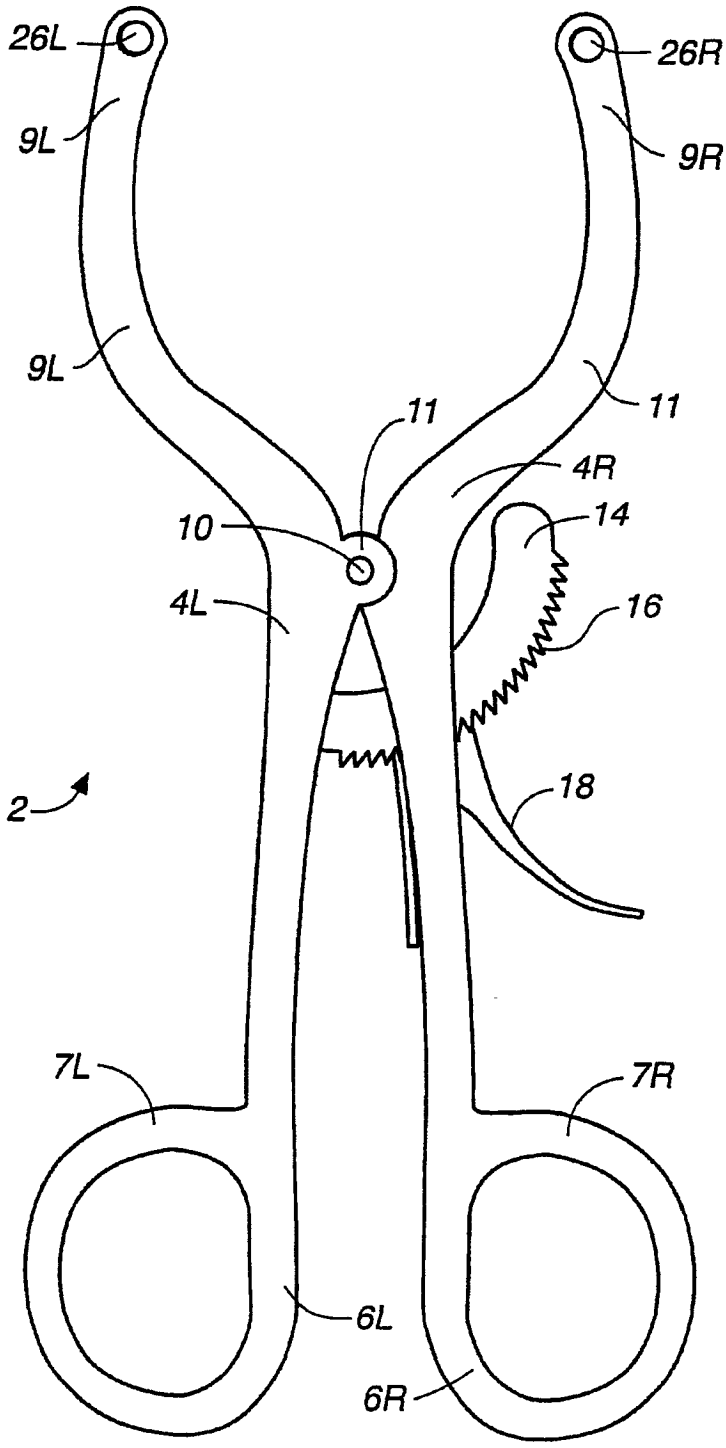


FIG._6B

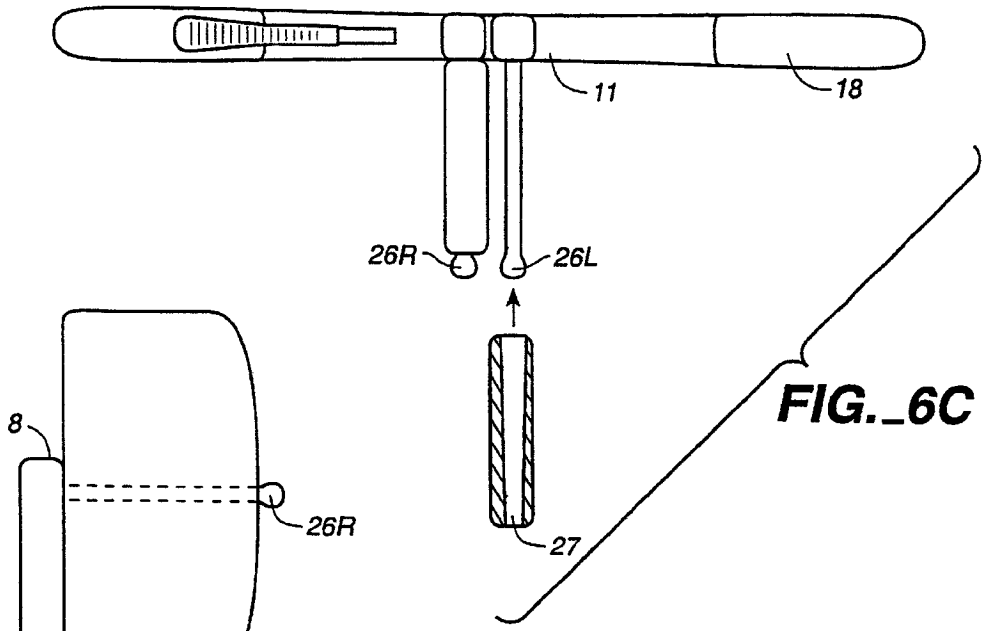


FIG._6C

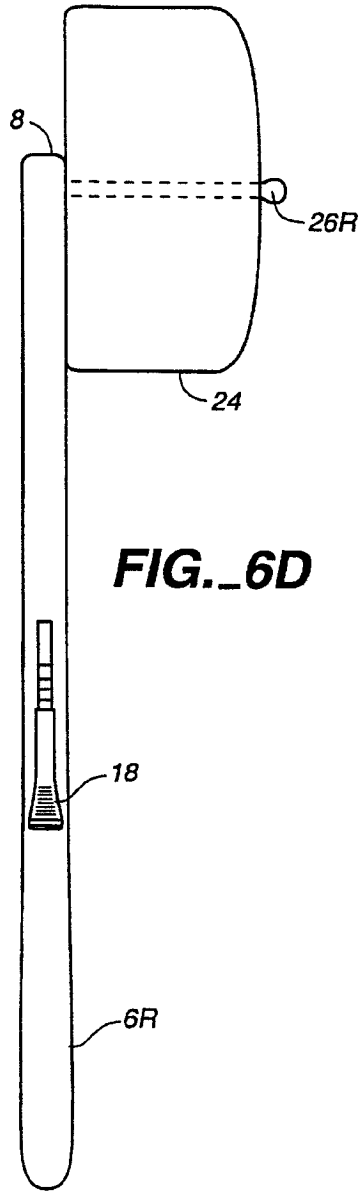


FIG._6D

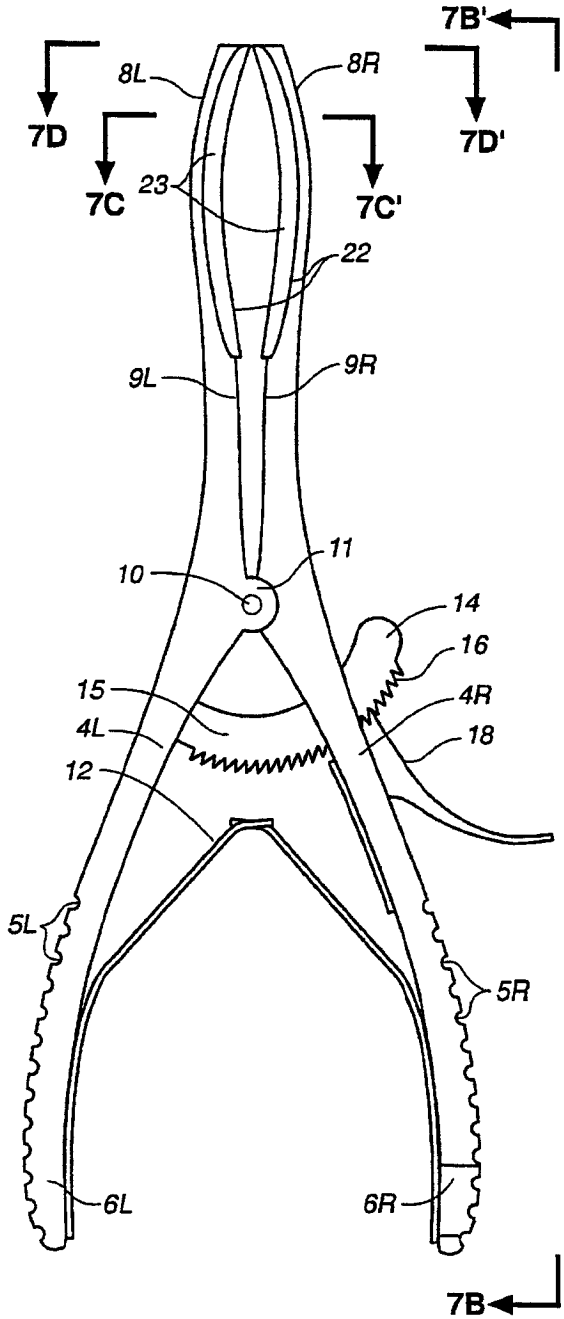

7B'
7D
7D'
8L
8R
7C
7C'
23
22
9L
9R
10
11
14
16
15
4R
4L
18
12
5L
5R
6L
6R
7B

FIG._7A

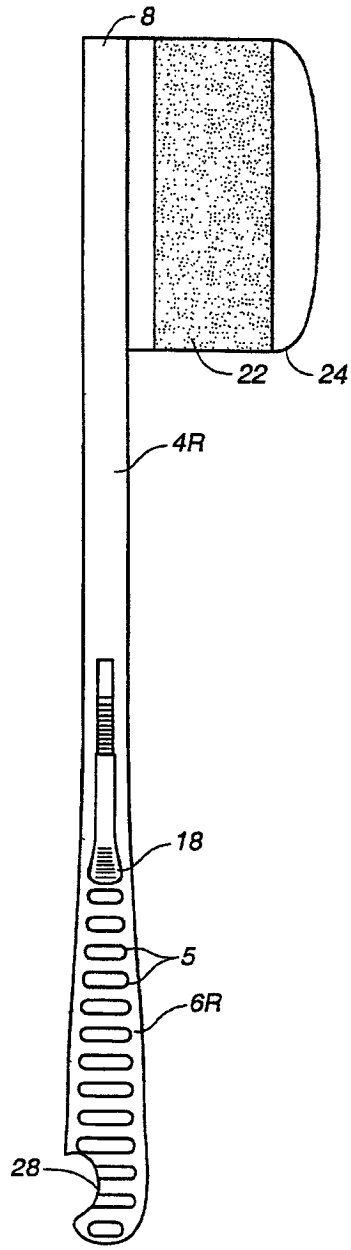

8
22
24
4R
18
5
6R
28

FIG._7B

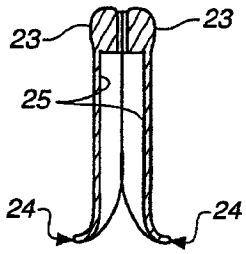


FIG._7C

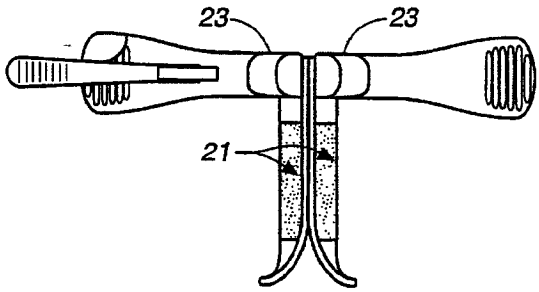


FIG._7D

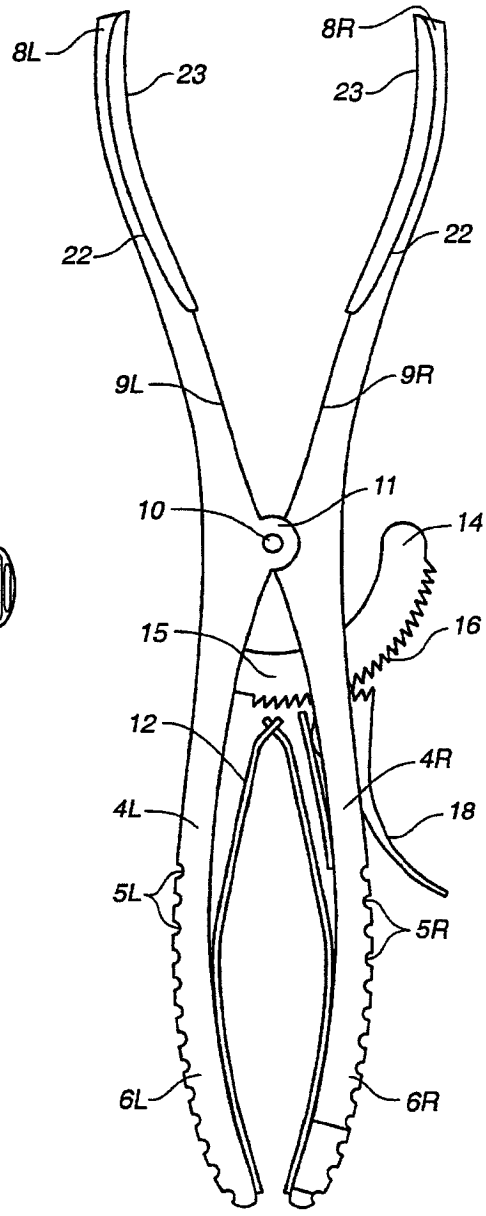


FIG._7E

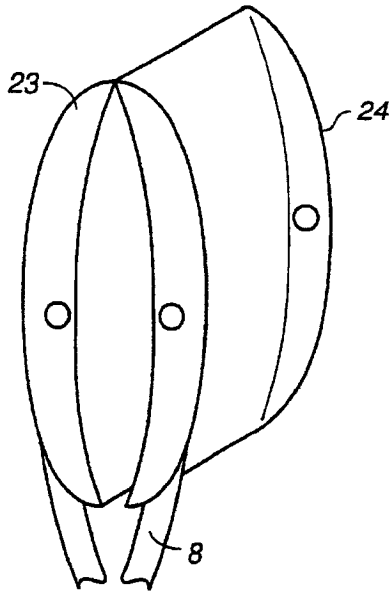


FIG._8A

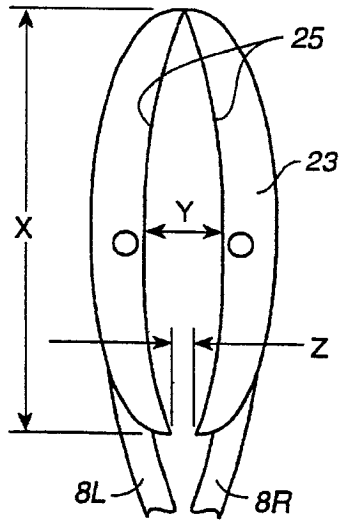


FIG._8B

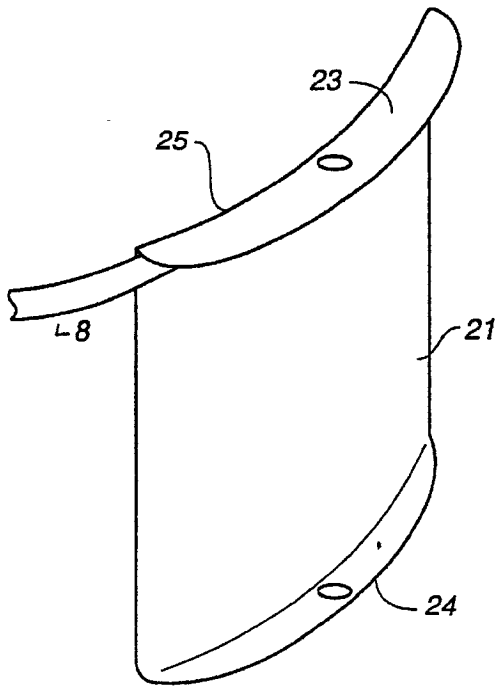


FIG._10A

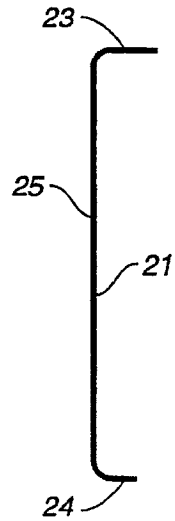


FIG._10B

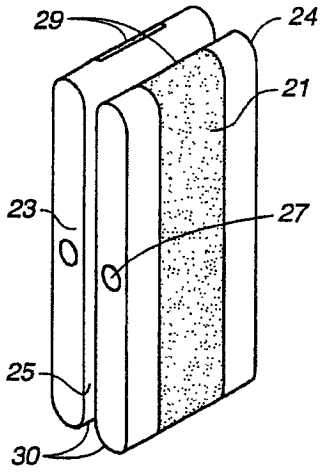


FIG._9A

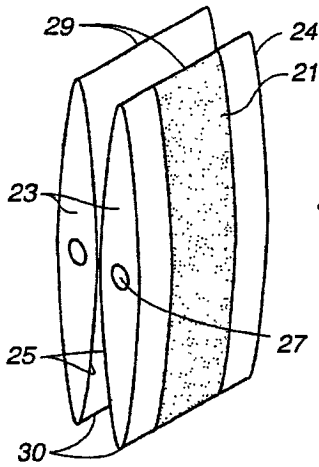


FIG._9B

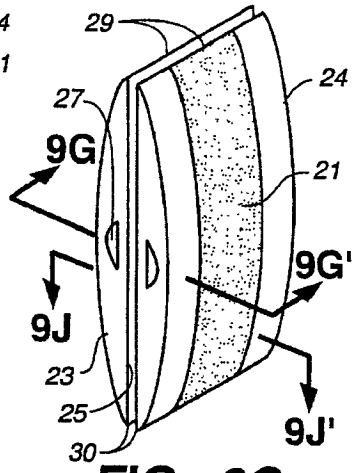


FIG._9C

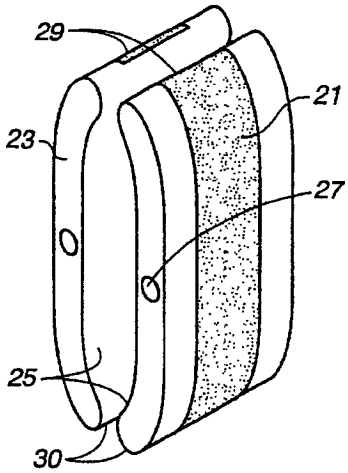


FIG._9D

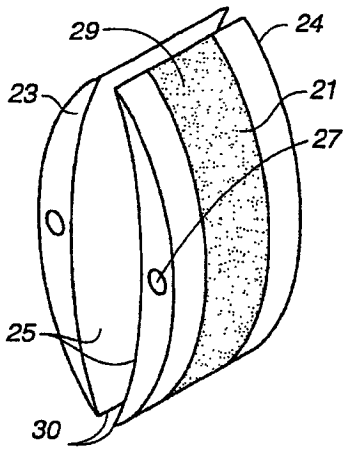


FIG._9E

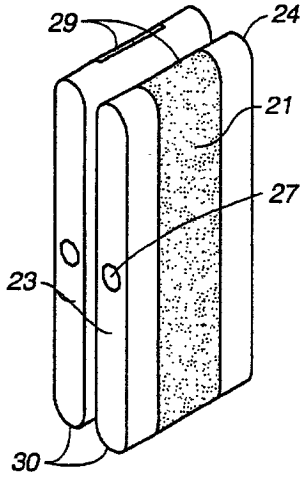


FIG._9F

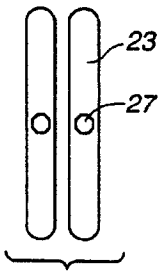


FIG._9G

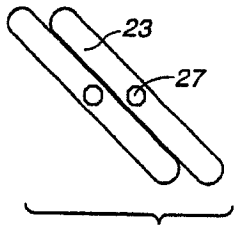


FIG._9H

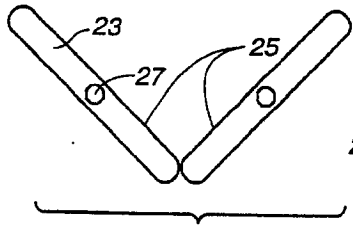


FIG._9I

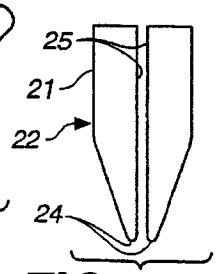


FIG._9J

FIG._11

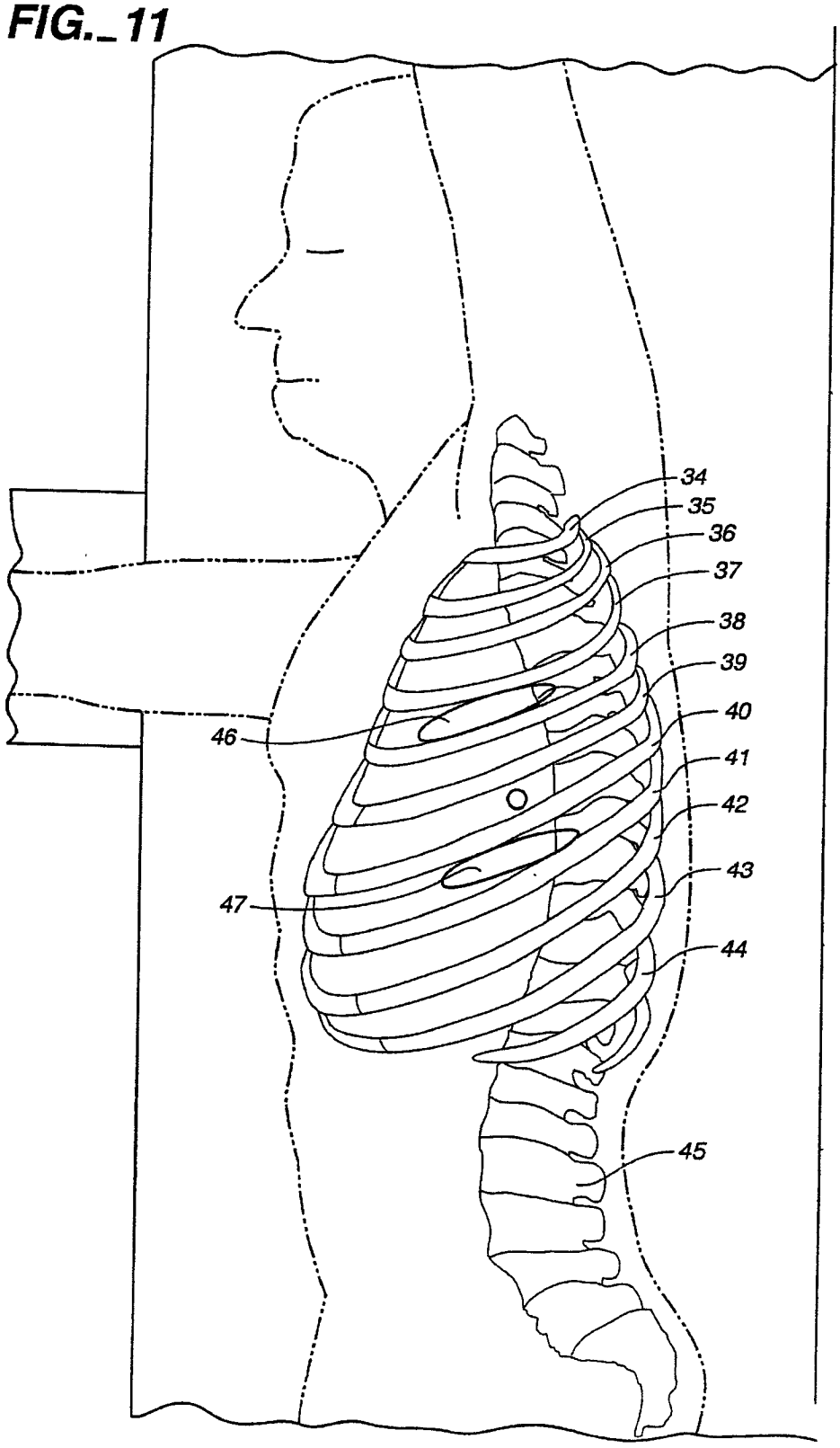
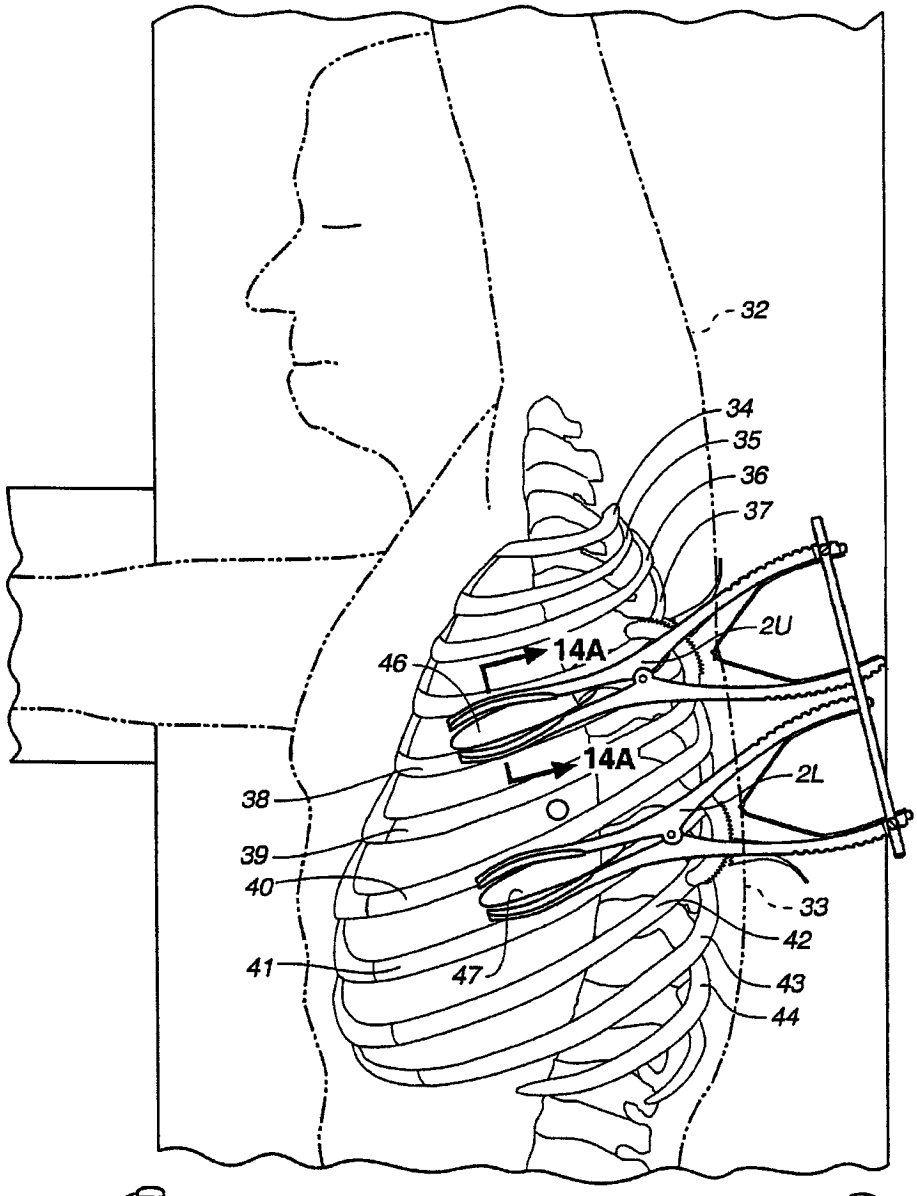


FIG._12A



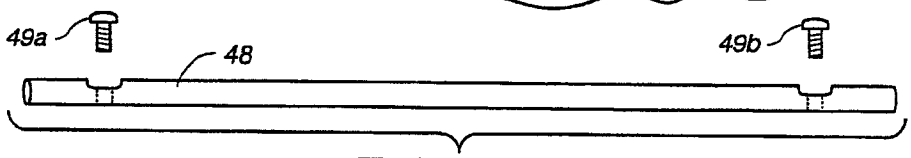


FIG._12B

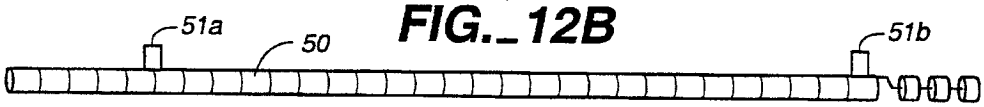
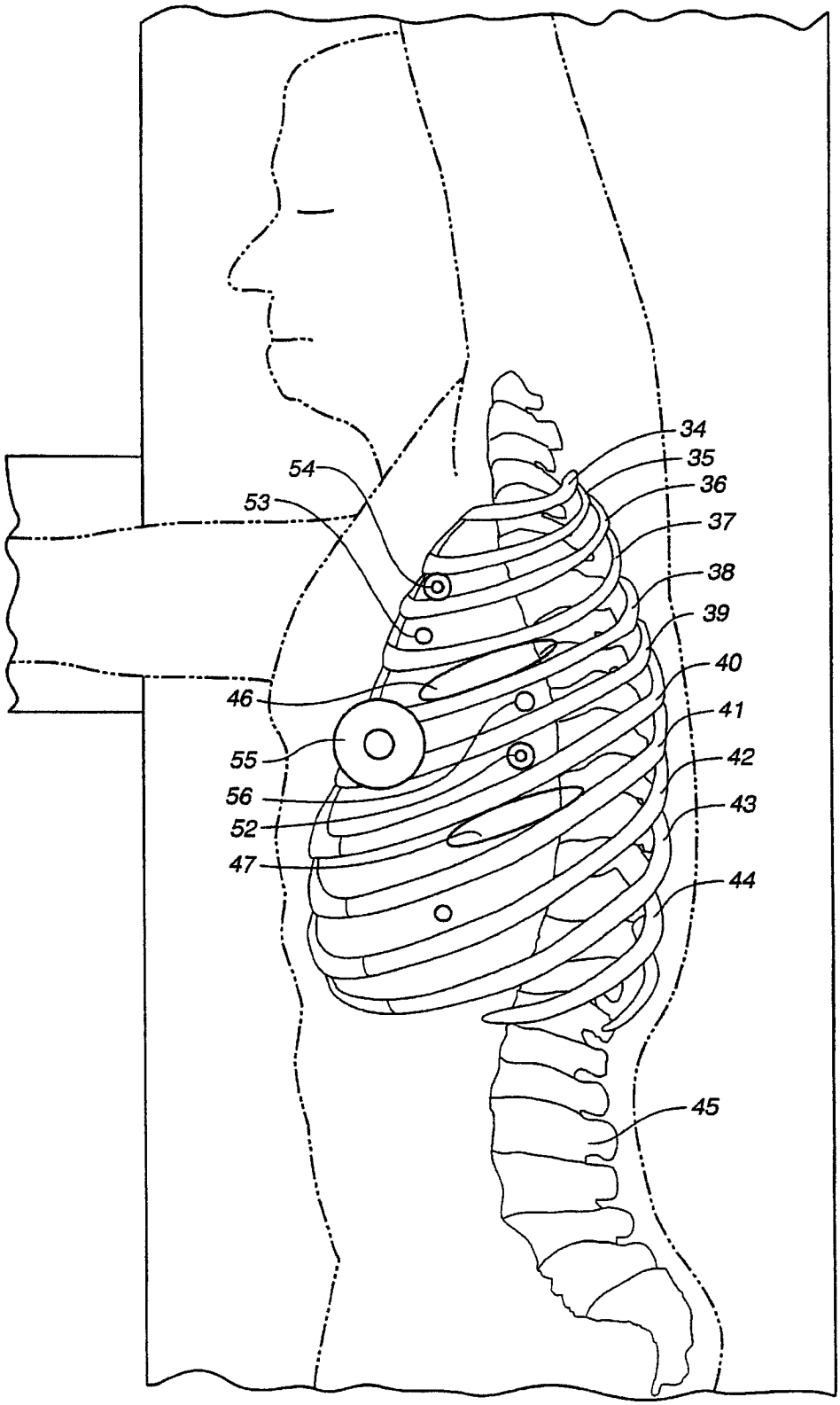


FIG._12C

FIG._13



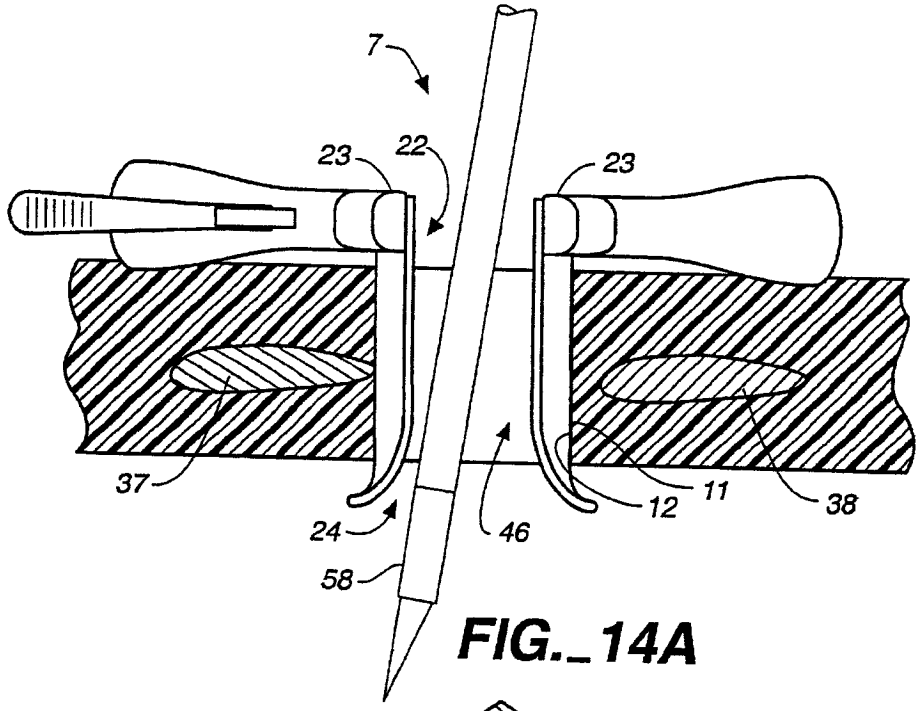


FIG._14A

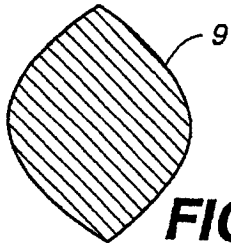


FIG._14B

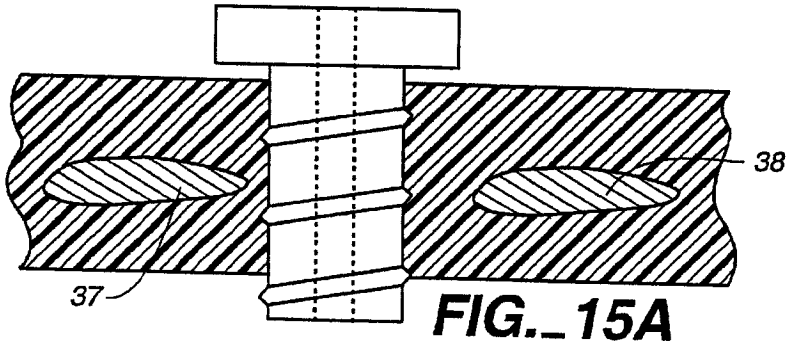


FIG._15A
(PRIOR ART)

FIG._15B

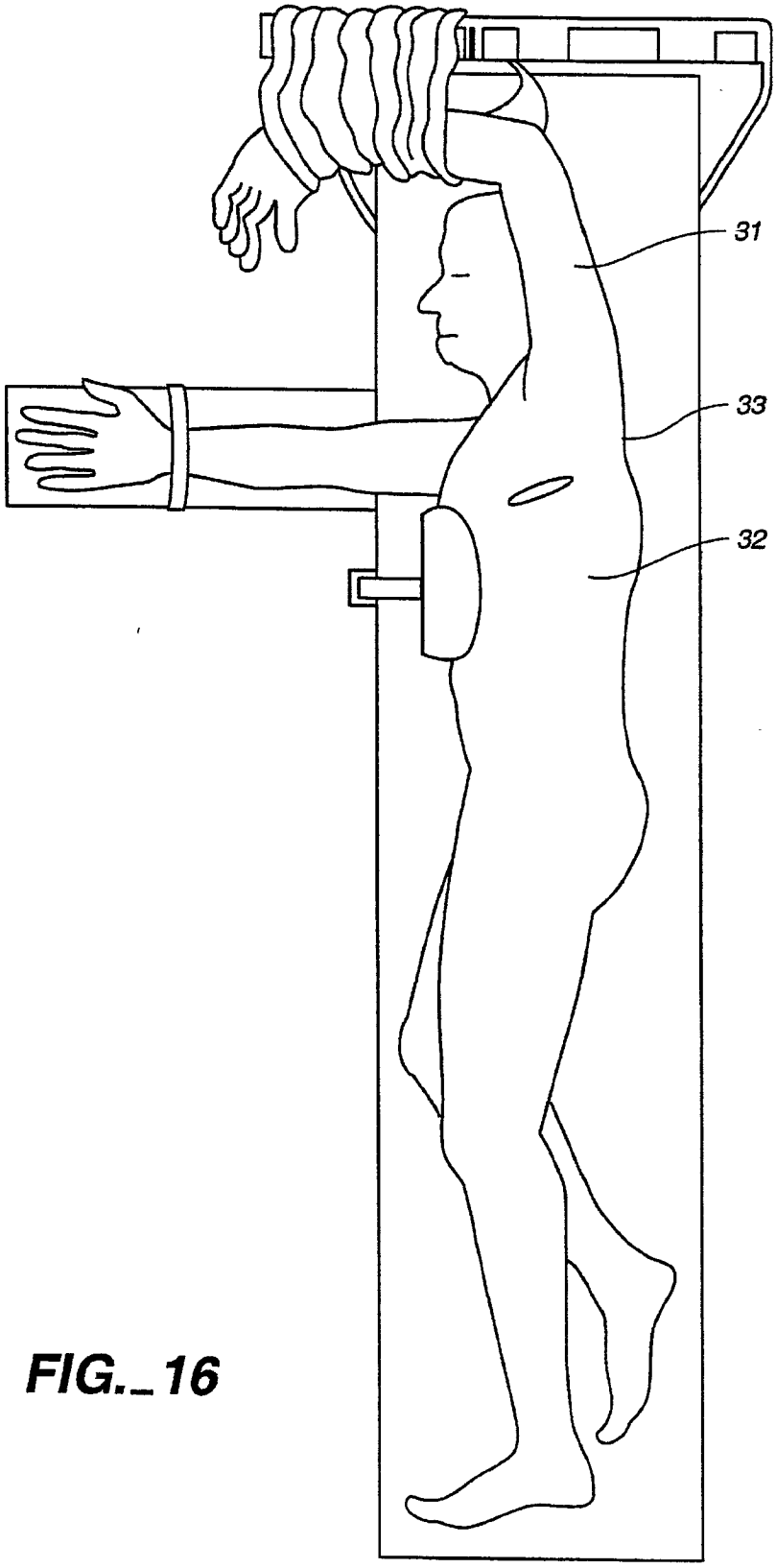


FIG._16

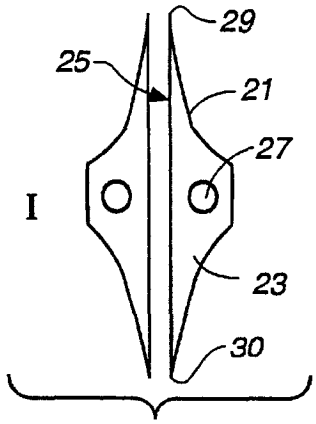


FIG._17A

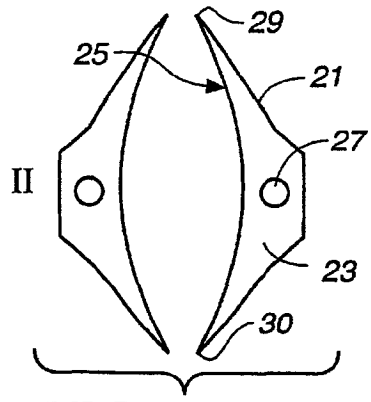


FIG._17B

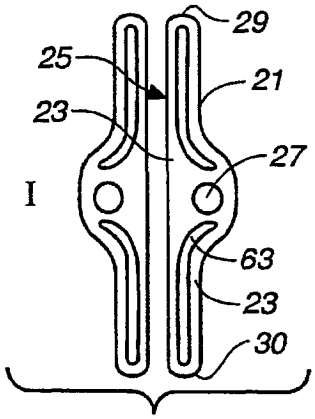


FIG._17C

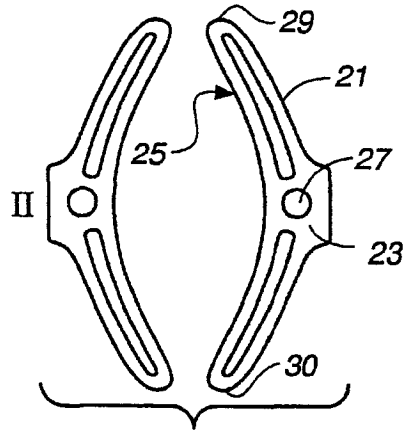


FIG._17D

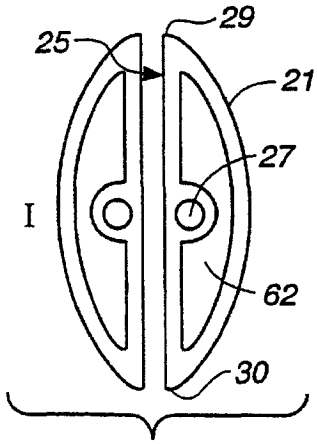


FIG._17E

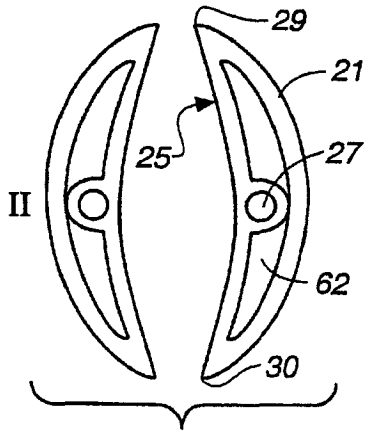


FIG._17F

SURGICAL RETRACTOR AND STABILIZING DEVICE AND METHOD FOR USE

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation-in-part of provisional patent application U.S. No. 60/014,922 filed Apr. 10, 1996 in the name of inventors Arthur Bertolero, Raymond Bertolero and Jerome Riebman. This application is related to concurrently-filed patent applications ESTC-001/00WO, ESTC-001/03WO, ESTC001/04WO AND ESTC-001/05US. Each of the above-identified patent applications is incorporated herein by reference.

INTRODUCTION

1. Technical Field

This invention relates to an adjustable surgical retractor and its use for improving a surgeon's ability to perform closed-chest, video-assisted exploratory, diagnostic or surgical procedures on a patient. The invention also relates to unique blades useful in combination with the retractor.

2. Background

Surgery on the heart is one of the most commonly performed types of surgery that is done in hospitals across the U.S. Cardiac surgery can involve the correction of defects in the valves of the heart, defects to the veins or the arteries of the heart and defects such as aneurysms and thromboses that relate to the circulation of blood from the heart to the body. In the past, most cardiac surgery was performed as open-chest surgery, in which a primary median sternotomy was performed. That procedure involves vertical midline skin incision from just below the super sternal notch to a point one to three centimeters below the tip of the xiphoid. This is followed by scoring the sternum with a cautery, then dividing the sternum down the midline and spreading the sternal edges to expose the area of the heart in the thoracic cavity. This technique causes significant physical trauma to the patient and can require one week of hospital recovery time and up to eight weeks of convalescence. This can be very expensive in terms of hospital costs and disability, to say nothing of the pain to the patient.

Recently, attempts have been made to change such invasive surgery to minimize the trauma to the patient, to allow the patient to recover more rapidly and to minimize the cost involved in the process. New surgical techniques have been developed which are less invasive and traumatic than the standard open-chest surgery. This is generally referred to as minimally-invasive surgery. One of the key aspects of the minimally invasive techniques is the use of a trocar as an entry port for the surgical instruments. In general, minimally invasive surgery entails several steps: (1) at least one, and preferably at least two, intercostal incisions are made to provide an entry position for a trocar; (2) a trocar is inserted through the incision to provide an access channel to the region in which the surgery is to take place, e.g., the thoracic cavity; (3) a videoscope is provided through another access port to image the internal region (e.g., the heart) to be operated on; (4) an instrument is inserted through the trocar channel, and (5) the surgeon performs the indicated surgery using the instruments inserted through the access channel. Prior to steps (1)–(5), the patient may be prepared for surgery by placing him or her on a cardiopulmonary bypass (CPB) system and the appropriate anesthesia, then maintaining the CPB and anesthesia throughout the operation. See U.S. Pat. No. 5,452,733 to Sterman et al. issued Sep. 26, 1995 for a discussion of this technique.

While this procedure has the advantage of being less invasive or traumatic than performing a media, sternotomy, there are numerous disadvantages to using trocars to establish the entry ports for the instruments and viewscope. For example, the trocars are basically "screwed" into position through the intercostal incision. This traumatizes the local tissues and nerve cells surrounding the trocar.

Once in place, the trocar provides a narrow cylindrical channel having a relatively small circular cross-section. This minimizes the movement of the instrument relative to the longitudinal axis and requires specially-designed instruments for the surgeon to perform the desired operation (See, e.g., the Sterman patent U.S. Pat. No. 5,452,733). In addition, because of the limited movement, the surgeon often has to force the instrument into an angle that moves the trocar and further damages the surrounding tissue and nerves. The need to force the instrument causes the surgeon to lose sensitivity and tactile feedback, thus making the surgery more difficult. The surgical retractor of this invention is designed to reduce the initial trauma to the patient in providing access to the internal region, to reduce the trauma to the patient during surgery, to provide the surgeon with greater sensitivity and tactile feedback during surgery, and to allow the surgeon to use instruments of a more standard design in performing the non-invasive surgery.

Other less invasive surgical techniques include access to the region of the heart to be corrected by anterior mediastinotomy or a thoracotomy. In a mediastinotomy, an incision is made that is two to three inches in length of a parasternal nature on the left or the right of the patient's sternum according to the cardiac structure that needs the attention in the surgery. Either the third or the fourth costal cartilage is excised depending on the size of the heart. This provides a smaller area of surgical access to the heart that is generally less traumatic to the patient. A thoracotomy is generally begun with an incision in the fourth or fifth intercostal space, i.e. the space between ribs **4** and **5** or ribs **5** and **6**. Once an incision is made, it is completed to lay open underlying area by spreading the ribs. A retractor is used to enlarge the space between the ribs.

At the present time, when either of these techniques are used, a retractor is used to keep the ribs and soft tissues apart and expose the area to be operated on to the surgeon who is then able to work in the surgical field to perform the operation. The types of retractors that are used may be seen, for example, in volume 1 of *Cardiac Surgery* by John W. Kirkland and Brian G. Barratt-Boyes, Second Edition, Chapter 2, at page 101. Commercial-type retractors for minimally-invasive surgery that are useful for a mediastinotomy or a thoracotomy are manufactured by Snowden Pencer (the ENDOCABG rib spreader and retractor), U.S. Surgical (the mini CABG system), and Cardiothoracic Systems (the CTS MIDCAB™ System). The ENDOCABG refractor is two opposing retractor arms that are interconnected by a ratchet arm having a thumbscrew which can adjust the distance between the retractor arms. While this provides a useful retractor, it has certain shortcomings in its ease of use. The mini CABG System is an oval-based platform to which a number of retractors are then fitted around the extremity of the universal ring base and adjusted by a gear tooth connection. Each of the retractors have to be separately adjusted and there are other devices that can be connected to the universal base which can aid the surgeon in damping the heart movement to better work on the artery or vessel to which the surgeon is directing his attention. The CTS MIDCAB™ System serves a similar function to the ENDOCABG retractor, but is more complex. The designation CABG refers to "coronary artery bypass graft."

Major disadvantages of these systems include their limited positioning, complexity, and lack of reusability. It has now been discovered that the shortcomings of the retractors that are known in the prior art can be overcome with a new design as set forth in the following description.

OBJECTS OF THE INVENTION

An object of this invention is to provide a surgical retractor that is useful in exploratory or diagnostic work on a patient or preparing for and/or performing cardiac and other types of surgeries.

Another object of this invention is to provide a surgical retractor that is easier to use than the surgical retractors presently available.

Another object of this invention is to provide a surgical retractor that defines a larger opening than a surgical trocar through which a surgeon can insert surgical, exploratory or diagnostic instruments.

Another object of this invention is to provide a surgical retractor that can be used for both anterior or lateral access to the thoracic cavity, access to the abdominal cavity or exposure of an subcutaneous body structure.

Another object this invention is to provide a surgical retractor having removable blades, thus providing the surgeon with the flexibility to choose a size and shape blade to fit a patient's anatomy.

A further object of the invention is to provide a retractor that is less traumatic to the patient on whom an operation is being performed. This may allow the patient to recover more rapidly and create less disability for the patient.

A further object of this invention is to provide a surgical retractor that is less complex than the retractors presently commercially available and that requires fewer steps to operate.

Still a further object of this invention to provide improved access to and dissection of the left interior mammary artery.

Still a further object of the invention to provide a retractor that allows the surgeon to perform minimally invasive surgery while providing the surgeon with a similar instrument sensitivity tactile feedback to the operation as an open chest surgery.

Still a further object of this invention to provide a surgical retractor providing access to the internal organs of a person wherein the surgeon has a smooth surface on which to stabilize his instruments during the operation.

Another object of this invention is to provide a surgical retractor that provides a surgeon with access to an internal cavity more quickly.

Other objects of the invention may be apparent to one of ordinary skill in the art upon further meeting the following specification and claims.

SUMMARY OF THE INVENTION

One aspect of this invention is an adjustable surgical retractor that comprises

(a) two handles suitable for grasping positioned opposite each other and pivotally connected so that the handles move reciprocatingly relative to each other,

(b) a head means connected to each handle so that each head means moves reciprocatingly relative to the other,

(c) a means for locking the heads at a preset distance from each other,

(d) each head means having a connector means suitable for connecting a blade, and

(e) a blade connected to each head means through the connector means with each blade having a width, depth and thickness so that the width extends substantially parallel to the length of the head and the depth extends downward from the top of the head means. The blades when taken together at the position of closest proximity to each other are of a size suitable to be inserted into a surgical incision in a patient undergoing a surgical procedure then spread apart to form an elongated access opening through which a medical instrument may be inserted to perform exploratory, diagnostic or surgical procedures.

Another aspect of this invention is a blade suitable for use as part of a surgical retractor, which blade comprises a biocompatible material having dimensions defined by a width, depth and thickness, the width and the depth defining an first and an second face separated from each other by the thickness of the blade, wherein the blade has a connector means for attaching to a head means of the surgical retractor.

Another aspect of this invention is a method of providing surgical access to a patient, which method comprises making a surgical incision through the skin and soft tissue of the patient,

inserting two blades of a surgical retractor perpendicularly through the incision, and

spreading the blades of said retractor to provide a relatively symmetrical, elongated channel for internally accessing said patient, said channel being defined by said blades wherein the internal faces of the blades have a concave surface to define a substantially ovoid channel, each blade having a smooth, continuous upper surface.

Another aspect of this invention is a method of performing minimally invasive surgery on a patient, which method comprises

making a surgical incision through the skin and soft tissue of the patient,

inserting two blades of a surgical retractor, perpendicularly through the incision,

spreading the blades of said retractor to provide a relatively symmetrical, elongated channel for internally accessing said patient, said channel being defined by said blades wherein the internal faces of the blades have a concave surface to define a substantially ovoid channel, each blade having a smooth continuous upper surface,

inserting a surgical instrument through said substantially ovoid channel, and

performing a surgical procedure using the surgical instrument so inserted.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top view of the surgical retractor of this invention in the closed position with the proximal ends of the retractor shown at the bottom of the page and the distal end at the top.

FIG. 1A is the side view taken along line 1A–1A' shown in FIG. 1.

FIG. 1B is an end view along line 1B–1B'.

FIG. 2 is a top view of the retractor of this invention with the blades spread open.

FIG. 3 is a top view of a retractor of this invention having finger holds on the proximal grasping end of the retractor, the retractor being in the closed position.

FIG. 3A is a top view of the retractor of FIG. 3 shown in the open position.

FIG. 4 is a side view along lines 4F–4F' of the retractor of FIG. 3.

FIG. 5 is a top view of the surgical retractor of this invention similar to FIG. 3 but with a shorter handle.

FIG. 6A is a top view of the retractor of this invention shown without the blades positioned on the head region of the handles and in the closed position.

FIG. 6B is a top view of the retractor of FIG. 6A in the spread open position.

FIG. 6C shows the head region of the retractor in FIG. 6A having removable blades attached to the head member on a post as the connector means.

FIG. 6D is a side view of FIG. 6C.

FIG. 6E shows the head members of the surgical retractor with swiveling blades on the head member in the closed position.

FIG. 6F shows the head members in of FIG. 6E in the open position.

FIG. 7A shows an alternative design for the retractor of this invention where the handle has a roughened surface for improved grasping.

FIG. 7B is a side view along line 7B–7B' and showing a textured surface on the outside face of the blade.

FIG. 7C is a cross-sectional end view along line 7C–7C' of the blades positioned together in the head member of the surgical retractor.

FIG. 7D is an end view along line 7D–7D' showing the conjunction of the blades of the surgical retractor.

FIG. 7E shows the surgical retractor of FIG. 7A with the blades spread in the open position and the handles pulled together.

FIG. 8A is a perspective view of a blade of this invention having a slight curvature with a concave inner surface and a resilient outer surface.

FIG. 8B shows the relative distance of the upper and lower lip at the top and bottom of the blade.

FIG. 9A shows a pair of disposable retractor blades suitable for use with the retractor of FIGS. 1 through 7.

FIG. 9B is an alternative design for a pair of disposable retractor blades.

FIG. 9C is another design of the disposable retractor blade useful in this invention.

FIG. 9D shows a pair of disposable retractor blades as shown in 9A as they would look if they were flexed and attached to the retractor head and spread in an open position pushing against a patient's ribs.

FIG. 9E shows the blades of FIG. 9B as they would appear if they would be spread apart and used to spread the ribs in accordance with the process of this invention.

FIG. 9F is another design for the disposable retractor blades for use in this invention.

FIGS. 9G–9I show the various positions blades that swivel on the posts of FIG. 6C or 6D could take.

FIG. 9J shows tapered blades viewed along lines 9J–9J' in FIG. 9C.

FIG. 10A shows a perspective view of a design of blades having a lip at the top and bottom of the blade curling toward the convex face.

FIG. 10B shows a profile view of the blades showing the lip.

FIG. 11 shows the positioning of an incision in the intercostal space as used in the process of this invention.

FIG. 12A shows two retractors in place and stabilized by interconnecting bar shown in FIGS. 12B and 12C.

FIG. 12B shows an appropriate interconnecting bar.

FIG. 12C shows a notched interconnecting bar for interconnecting two retractors and stabilizing them.

FIG. 13 shows entry incision ports suitable for use for with the retractor of this invention in comparison to other trocars which are generally used for minimally invasive surgery.

FIG. 14A shows the greater degree of freedom that a surgeon would have in using the retractor of this invention as compared to a trocar shown in FIG. 15.

FIG. 14B is a cross-section of the elongated access opening.

FIG. 15A shows a trocar inserted into a patient between the ribs.

FIG. 15B shows the small cross-section of 15A.

FIG. 16 shows a patient positioned for a lateral incision using a retractor of this invention.

FIGS. 17A–17F show various preferred embodiments of the surgical blades of this invention.

DETAILED DESCRIPTION AND PRESENTLY PREFERRED EMBODIMENTS

While the description of the surgical retractor of this invention will be discussed primarily in relation to cardiac surgery procedures, it should be understood that the surgical retractor of this invention will find use in not only cardiac surgery but also laparoscopic surgery in which a surgeon wishes to gain access to an internal cavity by cutting the skin and going through the body wall in order to keep the incision spread apart so that surgical instruments can be inserted.

Thus the surgical retractor can find use in providing surgical access generally where a limited incision is desired. It is useful for subcutaneous access as well as for surgically accessing various body cavities such as the abdominal region, the thoracic region and the extremities.

It should also be understood that the surgical retractor of this invention can be used for direct access to an internal organ for surgical purposes with direct viewing of the work that's going on but it is preferably used in conjunction with video assisted cardiac surgery. In such a case, the surgical retractor of this invention is used in combination with a video endoscope that is positioned through a similar surgical retractor, a trocar or a percutaneous access opening which allows the scope to be positioned such that the internal work on the area to be operated on is transmitted to a video screen and the surgeon then performs the operation by viewing the screen and judging the use of the instruments with the assistance of the video endoscope. The surgical retractor has particular value in minimally invasive surgical techniques used in cardiac surgery.

One aspect of this invention is an adjustable surgical retractor. The retractor comprises

(a) two handles suitable for grasping positioned opposite each other and pivotally connected so that the handles move reciprocatingly relative to each other,

(b) a head means connected to each handle so that each head means moves reciprocatingly relative to the other,

(c) a means for locking the heads at a preset distance from each other,

(d) each head means having a connector means suitable for connecting a blade, and

(e) a blade connected to each head means through the connector means with each blade having a width, depth

and thickness so that the width extends substantially parallel to the length of the head and the depth extending downward from the top of the head.

The blades, when taken together at the position of closest proximity to each other are of a size suitable to be inserted into a surgical incision in a patient undergoing a surgical procedure then spread apart to form an elongated, ovoid access opening through which a medical instrument may be inserted to perform exploratory, diagnostic or surgical procedures.

Preferably, the surgical retractor is designed so that each blade has an inside face and an outside face. The inside face of each blade faces the inside face of the other blade and the outside face of each blade is designed to (i) minimize the trauma to the patient's body at the incision when the head means and blades are spread apart, (ii) stabilize the blades in the incision and (iii) allow customization for each patient's anatomy.

Referring now to FIG. **1**, one sees the adjustable surgical retractor of the invention generally designated as **2**. The retractor is characterized by having a elongated handle **4**R and **4**L for the right and left side as shown in FIG. **1**. The elongated handles have a grasping end shown as **6**L and **6**R for the left and right sides of the device which are proximal to the user. On the opposite end, distal from the grasping handle are the ends **8**L and **8**R, again indicating the left and the right side as shown in the figure. Generally, the ends **8**L and **8**R when in the closed position shown in FIG. **1** will be in contact and there will generally be a space between opposing jaws of the device **9**L and **9**R. The handles which are suitable for grasping and are positioned opposite to each other are pivotally connected at pivot point which will have a male member pivot pin **10** which will correspond to a female receiving member **11** to allow the pivoting to take place. Thus the opposite ends **8**L and **8**R that are distal to the grasping handles comprise heads that are connected to each elongated handle so that each head moves reciprocatingly relative to the other. When handles **6**L and **6**R are drawn together as shown in FIG. **2**, the distal ends or heads **8**L and **8**R are spread apart. A key to the utility of this particular design is the presence of a locking means to lock the heads at a preset distance from each other. The means shown in this case is a ratchet segment **14** having teeth **16** along the arcuate member **15** interconnecting handles **4**L and **4**R. Working in concert with the ratchet segment **14** and its corresponding teeth **16** is a corresponding pawl member **18** which is pivotally mounted at pivot **19**, not shown, working in concert so that the teeth **20** on pawl **18** (as shown in FIG. **2**) are complementary to the teeth **16** and provide a means for locking the heads at a preset distance from each other. Because of the numerous teeth **16** along ratchet member **14** the distance between head members **8**L and **8**R can vary significantly and in small incremental amounts. When pawl member **18** is disengaged from the ratchet segment **14** by not having the teeth in contact, tensioning means **12** tends to keep the handles **6**L and **6**R apart. Thus if the teeth are not engaged, the handles will tend to be spread apart by the tensioning means so that the heads **8**L and **8**R are generally in contact and ready for insertion prior to a surgical operation.

Each head means (which is shown as being unitary with the handle) has a connector means suitable for connecting a connector blade **22** to the corresponding heads **8**L and **8**R of elongated handles **4**L and **4**R. A blade **22** is connected to the head member of the elongated handle **4** by a connector means not shown, with each blade **22** having a width, depth and thickness dimensions that define the blade. The width, for purposes of this invention, is said to extend substantially parallel to the length of the head or handle. The top of the blade as seen as **23** in FIG. **1** such that while in use, the blade would be inserted into the surgical incision and the top edge **23** would remain outside the patient's surgical opening. The depth of the blade would extend downward from the top **23** of the blade into the surgical incision. Thus by looking at the side view of FIG. **1**A, the bottom of the blade **22** would be shown as **24**. The thickness of the blade is shown in FIG. **1** by the approximate extension dotted line at the head of the retractor device. The bottom of blades **24**, when taken together at the position of closest proximity to each other as shown in FIG. **1**, are of a size suitable to be inserted into a surgical incision in a patient undergoing a surgical procedure. Once inserted, the blades are then spread apart as shown in FIG. **2** to form an elongated access opening through which a medical instrument may be inserted to perform exploratory or surgical procedures as discussed hereinafter. The view of FIG. **1**A of the surgical retractor of this device is a side view along lines **1**A to **1**A' in FIG. **1**A while an end view along lines **1**B to **1**B' is shown in FIG. **1**B. The numbers in each of FIGS. **1**, **1**A, **1**B and **2** all designate similar parts of the device.

Turning now to FIG. **3**, one can see an alternative configuration for the surgical retractor of this invention. In FIG. **3**, the same numerals that are used in FIG. **1** are used as well. The only difference here is that the grasping handle **6**L and **6**R has a slightly modified design that allows the surgeon using the retractor to insert a thumb and other digit to grasp the handle at **7**L and **7**R of the proximal end **6**L and **6**R. Otherwise the operation of the retractor is the same as that shown in FIG. **1** and FIG. **2**. FIG. **4** is a side view of the surgical retractor along lines **4**F and **4**F' showing the inserted edge **24** of blade **22** of the retractor. FIG. **3**A shows the surgical retractor in the open position where the blades are spread apart.

Referring again to FIGS. **1**, **1**A, **1**B and **2**, one can see certain preferred aspects of the invention. Each blade for the retractor has an inside face and an outside face. The outside face can be seen in FIGS. **1**A and **1**B. The outside face of the blade is designed to minimize the trauma to the patient's body at the incision when the head means and the blade are spread apart and to further stabilize the blade in the incision. To minimize the trauma and stabilize the blade, it is preferred that the outside surface of the blade be of a finish that is slightly irregular and preferably is of a texture that is less traumatizing than a smooth, hard texture. In general the blades are made of a material which is strong enough to withstand the pressure of opening the retractor in the manner in which it is to be used. For example, if an incision is made in between the fourth and fifth ribs in the intercostal area, the ribs will have to be spread apart and the blades will have to be strong enough to withstand the pressure of gently spreading apart the ribs. Thus material for the blades may be of any material which is biocompatible with the patient's body and using it in the incision. The materials that can be used are stainless steel, plastic such as polyvinyl chloride (PVC), polyethylene, polyesters of various sorts, polycarbonate, teflon coated metal and the like. In addition to, or as an alternative to, the irregular surface of the outside face of the blade, the outside face may be padded or resilient to a certain extent to minimize the trauma to the surrounding tissue as it is spread open. Thus the blade may be of a laminated construction which has a stronger material on the interface with the outerface having a spongier or padded characteristic.

Preferably, the surgical retractor blade will be designed so that the upper edge **22** of each blade when spread apart has

a concavely smooth surface corresponding to a concave surface of the interface which will be suitable for resting a surgical instrument against. This allows for much better movement of the instruments, e.g. in dissection of an internal mammary artery (IMA) and suturing of vessels. This can be seen in FIGS. **1** and **2**, particularly in FIG. **2** where the concave surface is shown as number **25** for each blade connected to head **8**L and **8**R. Preferably there will be a lip at both the top edge **23** and the bottom edge **24** as shown in FIG. **1**B. A slightly rolled edge is important for maintaining the blade in place so that the heads are spread open as shown in FIG. **2**. In some instances it is preferred that the blade is of a flexible material such as a plastic with the outer face having a slightly irregular surface to stabilize the blade in the incision. In that case, the blades, when inserted onto the heads of the retractor, can be essentially parallel to each other but as the blades are spread apart, the ends would tend to bend towards each other forming the concavity shown in FIG. **2**.

Alternatively, the blades may be preformed so that they have a lip or ridge on both the top **23** and the bottom **24** and have a preformed concavity that forms as the two interfaces rest against each other. This can be seen at FIGS. **8**A, **8**B, **10**A and **10**B. In this manner where each blade is rigid and the inner face of each is concave relative to the other where the outwardly protruding lip or ridge **23** on the upper and lower edge **24** of each blade, the blades are maintained in the incision when the head and the blades are spread apart after insertion into the patient's surgical incision. Where a patient's abdominal region is being accessed the lower lip will have to extend more than if the thoracic region is being accessed through the rib cage. Generally the lip at the top edge **23** shown in FIG. **10**B will extend out about ⅜" with the bottom lip **24** extending about ⅛" when entering intercostally. If abdominal access is desired the lower lip **24** will have to extend out further. The dimensions shown in FIG. **8**B will vary with individual patients. However, a particularly useful size for X is about 1.5 inches, for Y is about ⅜ inch and for Z is about ⅛ inch. A preferable aspect to the surgical retractor of this invention is that the blades are removable. The surgeon can select a blade having the desired width and depth to create exactly the size opening he or she wants, depending on a patient's size, shape, age, anatomy, etc., and the type of operation to be performed, e.g. lifting the left IMA for dissection. This is a particularly attractive aspect of the invention because the handles and the rest of the mechanism can be made of a durable, sterilizable material such as stainless steel. The blades can be made of a material that is re-sterilizable, and may be reusable or disposable, thus making the device easier and cheaper for the surgeon to use the device. For example, at the present time the commercially available devices through U.S. Surgical and CTS are very expensive and can be used only once because they have numerous parts and they all cannot be resterilized. By having removable blades **22** that can be disposed of, the surgical retractor **2** can be used multiple times by simply sterilizing then adding new disposable blades.

Preferably, the connector means on the head member of the surgical retractor that is suitable for connecting the blade is simply a male pivot pin as shown in FIGS. **6**A–**6**F. Here the pivot pin, which is at the distal end of the surgical retractor, is shown as **26**L and **26**R. The surgical retractor blade which is removable has a reciprocal female receiving port **27** into which the pivot pin will slip. The pivot pin may be designed to lock the blade in place or to allow the blade to rotate as shown in FIG. **6**E–**6**F. When the surgical retractor's handles are extended outwardly as shown in FIG. **6**A, the blades would be together as shown in FIG. **6**E where the male pivot pin seated in the female receiving port **27** as shown. As the proximal ends **6**L and **6**R are pulled together through grasping means **7**L and **7**R, the blades are pulled apart and can swivel slightly to adjust to the tension in the process of spreading apart the ribs.

The blades which are useful in the surgical retractor of this device are of a width, depth and thickness which will allow the surgeon access to the internal organs of the patient once an incision is made. Generally, the width of each blade may vary between about 1 inch to about 4 inches preferably 1 inch to about 3 inches. The depth will be of a sufficient depth to be adequately retained within the surgical incision when the head of the retractor are spread apart. Generally this depth will be about 1 inch to about 3 inches depending on the size and weight of the patient. The thickness, of course, will be of sufficient thickness to withstand the pressures of spreading apart the ribs of the patient if that's how the retractor is to be used. The thickness will depend on the strength and flexibility of the material used in making the blade. Generally, the thickness will be about one-eighth inch to about three-quarters of an inch.

When the blades are flexible, it is preferable that the male pivot pin receiving means is designed to frictionally receive the blade and retain it without pivoting. If, however, the material is of a metallic nature such as stainless steel and is inflexible, then it's preferable that the pivot pin would allow the inflexible blade to pivot freely on the post. Thus if blades of the approximate dimensions mentioned above are used it can be seen that the surgical opening could have a length of about 1 inch to about 4 inches and a width of about one-quarter inch to about two inches.

Turning now to FIG. **7**A–**7**E one sees a variation on the design of the retractor of this invention. Here, the same numbers designate the same parts as in the previous FIGS. **1** through **6**F. The difference between the design in FIG. **1** and FIG. **7**A is simply that the handles **4**L and **4**R have notches designated at SL and **5**R to provide a better grasp for the surgeon using the retractor. These can be seen in both FIGS. **7**A and **7**B, **7**B being the side view along lines **7**B and **7**B'. In addition, the handles **6**R and **6**L may have an additional notch designated as **28** for receiving a stabilizing bar which the surgeon can use to connect two surgical retractors of this invention. This is discussed hereinafter in greater detail. The cross-sectional end view of the device along lines **7**C, **7**C' shows a cross-section of the blade having the top edge **23** slightly expanded and curved outwardly to form a lip at the top edge. At the bottom edge **24** similarly the blade is curved outwardly to form a smaller lip. By having these lips, the retractor when used will tend to stay in place to a greater extent than in the absence of the lips. By -viewing FIG. **7**D, which is an end-on view, along lines **7**D, **7**D', one can see the end view showing the outer side **21** of the blade **22** having a resilient material attached thereto to minimize the trauma and to maximize the friction to assist in maintaining the blade in place when in use. FIG. **7**A shows the retractor with the heads closed while FIG. **7**E shows the retractor with the head and the blades in an open position spread apart. Of course, the locking mechanism for maintaining the retractor in a spread, open position operates in the same manner as explained for FIGS. **1** through **6**.

Turning now to FIG. **8**A, one can see a close-up of a blade having the concave inner surface and convex outer surface along with a top lip **23** which is more exaggerated than the bottom lip **24**. In general, the top lip might be anywhere from a quarter to a three-quarters of an inch, generally about

three-sixteenths of an inch at the widest point with the bottom lip generally being somewhat less than that amount, about an eighth of an inch, to about a half an inch, generally about an eighth of an inch. These dimensions are further shown in FIG. 8B.

Turning now to FIGS. 9A through 9F, one can see a perspective view the designs of the pairs of blades that would be used in the retractor of this invention. These blades are designed to be disposable and may be made of any materials that would be appropriate for the construction shown. In FIG. 9A, one sees a set of blades that have a top edge 23 and a bottom edge 24 along with a distal edge 29 and a proximal edge 30. Here, both the distal and proximal edges are shown as being rounded. The inside face 25 of the two blades is shown to be essentially straight, although it can be designed to be slightly convex as shown in FIG. 9B, if desired. A blade when attached to the connector means of the head member of the surgical retractor and expanded against the ribs when the retractor is in use will generally provide a convex outer surface 21 and a concave inner surface when the blade is of a flexible material. This is thought to be due to the fact that the female receiving port 27 in the blade 22 would receive the male pivot pin which would be the strongest portion of the blade and which would provide the outward stress to spread the ribs. Thus, the central portion of the blade would tend to spread out further than the distal and proximal edges, 29 and 30 respectively.

In FIG. 9B, one can see that there is a taper from the central portion of blade 22 where the female receiving port 27 is found to the distal edge 29 as well as to the proximal edge 30. Here the blade is somewhat an elongate, ovoid in shape and would take a shape similar to that shown in 9E when used with the surgical retractor in the manner designed. Alternatively, the design shown in 9C in essence shows a crescent shape for each of the blades wherein the opposing faces of the internal sides 25 are essentially parallel while the outside face 21 of each blade is convex. When in use, this too would take the configuration generally shown in FIG. 9E. Still another configuration is shown in FIG. 9F. Here the inner faces 25 are essentially parallel to the outer faces 21 and the edges of the proximal and distal edges 30 and 29, are somewhat blunter than those shown in either FIGS. 9A, 9B or 9C. This blade would take a configuration shown in FIG. 9D. In each of the disposable blades shown in FIGS. 9A through 9F, when viewed along line 9J–9J' as shown in FIG. 9C, the lower edge 24 is slightly tapered to minimize the amount of space needed for the initial insertion of the blades as attached to the surgical device.

Particularly useful configurations of the disposable blades of this invention are shown in FIG. 17A–17C. In the figures the numbers used to designate the part are the same as in FIGS. 9A–9J. Here in FIG. 17A one sees a blade which is thicker in the midsection than at the ends somewhat similar to the configuration in 9B and 9C. The view here is a direct top down view showing distal end 29 and proximal end 30 along with the inside face 25 and outside face 21. The top side is shown as 23 and the female receiving means is shown as 27. When the blade is fitted on to the corresponding male fastening means or post and the blades of the surgical retractor are spread apart the blade to the left in FIG. 17A will take the configuration shown in configuration number 2 as compared to configuration number 1 which shows the blade at rest. The primary spreading force will be at the center of the blade 27 and an elongated oval shaped opening will be formed as a result of the spreading of the blades. Turning now to FIG. 17B one sees a slightly different design wherein an internal channel 62 which aids in the cushioning effect of the blade. Here when the blade is attached to the head means through the male pivot pin which fits into the female receptor 27 and the retractor is spread apart to spread apart tissue and ribs as earlier discussed the blade will flex as shown in II and the cutout channel will straighten as shown in the diagram in the right part of FIG. 17B. The channel 62 has a slightly curved part 63 that will straighten somewhat to form the silhouette shown in II at 17B. Thus the outer wall 21 prevents the blade from flexing too much when expanded and the channel 62 provides a cushioning effect so that the inner face 25 pushes against the outer wall 21 by compressing channel 62 while making a greater opening between the convex surfaces 25 of the blade. Alternatively in FIG. 17C one can see the channel extending from the proximal edge of the blade 29 to the distal edge of the blade 30. Here when the blade is attached to the male connector means which is inserted into the female receptor and the retractor and expanded then the design which has an essentially flat face 35 changes to that silhouette shown in II. Here the outer wall defined by 21 bears the force of the flexion of the blade and prevents the limbs of the blade from flexing too much. The air channel compresses to add some cushioning effect and flexibility against the tissues to reduce the trauma to the tissues.

In use, the surgical retractor of this invention can be employed either in the anterior or lateral position on the chest for thoracic retraction. Preferably, it is employed laterally and in surgery the patient would be positioned to expose the lateral side of the patient to the doctor. This position is shown in FIG. 16 where the arm 31 of the patient is raised to expose the lateral side 32 of the patient to the doctor. The back 33 is positioned as shown. In the semi-cutaway view of FIG. 11 one can see how the retractor of this invention would work. Here the patient would be positioned similar to that shown in FIG. 16 with the arm 31 raised to expose the lateral side of the patient. The ribs shown as numbers 34 through 44 are attached to the spine shown roughly as 45 with intercostal spaces between the ribs. Incisions 46 and 47 are shown as being made between ribs 4 and 5 and 7 and 8. Once the incision is made, the retractors are used in accordance with FIG. 12. Here, the retractors are shown inserted with the head spread open to provide access for the surgeon to enter the thoracic cavity. The retractors may be connected in accordance with the use of connecting rods shown in FIGS. 12B or 12C and connected in accordance with the use of a retractor having a notch in the handle similar to that shown in FIG. 7B. The connecting rod may be of a design shown in FIGS. 12B and 12C as configuration 48 or 50. Once the retractors 2U and 2L are in place, creating the elongated opening or windows, into the thoracic cavity, in intercostal spaces between the fourth and fifth ribs shown as 46 in between the 7th and 8th ribs shown as 47. The positioning for a bar such as that shown in 48 and 50 in FIGS. 12B and 12C respectively, may be accomplished by several ways. In one mechanism, a screw down mechanism is used, shown as 48*a* and 48*b* in FIG. 12C. By using the positioning bars with the retractors, the retractors are secured to enable the retractors to be angled at the appropriate angle toward the heart or other structure to enable a diagnostic or therapeutic procedure is to be carried out. The angles of retractors to 2U and 2L is such that a 5° to 50° angle of the instruments relative to a perpendicular line through the opening is achieved. This provides the surgeon with an angle of access and a range of movement that is similar to that of an open heart surgical procedure. Locking screws 49A and 49B are shown where the solid bar 48 is rigid. While the bar is shown as straight

it may optionally be slightly curved to contour to the shape of the rib cage. In FIG. **12C**, positioning bar **50** is made of interlocking metal pieces with an interior wire that when tightened locks the position of the shape of the bar into place and the securing screws shown as **51***a* and **51***b* are shown protruding from one side of the interlocking metal pieces.

FIG. **13** indicates the difference in the elongated opening or window approach and the port method reported by Sterman, et al. Elongated openings **46** and **47** show greater exposure and flexibility compared with the trocar port in performing the work. Using the trocars generally a port will be located at positions **52**, **53**, **54** and at **46**. Alternatively, if a minimally invasive direct coronary artery bypass MIDCAB incision such as a sternotomy incision is used, it is done at **55**. Whatever is used it is useful to provide a percutaneous opening **56** for a view scope and one or more additional instruments required for traction or manipulation of the thoracic cavity. It should be understood that the invention retractor can also be used for MIDCAB surgery where the entry is made anterially as compared to laterally.

Turning now to FIG. **14**, one can see the greater degree of manipulation that a doctor would have using the surgical retractor of applicant's invention as compared to the trocar. With the surgical retractor one can see that one obtains a wider range of motion for a surgical instrument shown as **58**. The view here is of the cross-section, end-on view that would be similar to that shown in FIG. **7E** along lines 7C–7C' shown in FIG. **7***a*. Here you can see the top **23** of blade **22**.

The bottom of the blade **24** sits inside the thoracic cavity. Ribs **4** and **5** are shown as **37** and **38**. The flexibility of the opening **46** in such a case should be compared with the lack of flexibility in FIG. **15** where a trocar is used to enter the thoracic cavity. This is visualized better by viewing a top-down view of FIG. **14A** that shows the cross-section of elongate opening **46** compared to the cross-section of opening **60** of trocar **59** in FIG. **15A**.

Having described the details of the surgical retractor of this invention, one can now consider another aspect of the invention, namely a method of providing surgical access to a patient. The method comprises making a surgical incision through the skin and soft tissue of the patient, inserting two blades of a surgical retractor perpendicularly through the incision, and spreading the blades of said retractor to provide a relatively symmetrical, elongated channel for internally accessing said patient. The channel is defined by the blades wherein the internal faces of the blades have a concave surface to define a substantially ovoid channel, each blade having a smooth, continuous upper surface. The method of course, is best performed using the surgical retractor described hereinbefore.

The method is particularly valuable in cardiac surgery where the surgical incision is made intercostally for access to the patient's thoracic region. Generally, at least two surgical incisions are made intercostally and sufficiently spaced apart to allow for the insertion and spreading of the blades of two of said surgical retractors. Each pair of spread blades then provide a relatively symmetrical, elongated channel for accessing the internal thoracic region of the patient. Preferably, two surgical incisions are made laterally on said patient, although the incisions may also be made anteriorly on said patient. As shown in FIG. **12A**, the two surgical retractors may be interconnected by a stabilizing bar to fix their positions relative to the other. To provide viewing access to the patient's thoracic cavity a third incision is made to insert an image transmission means to transmit an image of the patient's internal thoracic region.

Another aspect of this invention is a method of performing minimally-invasive invasive surgery on a patient. The method comprises

making a surgical incision through the skin and soft tissue of the patient,

inserting two blades of a surgical retractor, perpendicularly through the incision, spreading the blades of said retractor to provide a relatively symmetrical, elongated channel for internally accessing said patient (the channel is defined by the blades wherein the internal faces of the blades have a concave surface to define a substantially ovoid channel, each blade having a smooth continuous upper surface),

inserting a surgical instrument through said substantially ovoid channel, and

performing a surgical procedure using the surgical instrument so inserted. The method preferably employs the retractor described herein. The size and shape of the retractor blades are chosen for the exact size opening desired. The smooth continuous upper surface allows the surgeon to carryout the surgical procedures more easily. This method is particularly suited for cardiac surgery when said patient is maintained on a cardiopulmonary by-pass machine and the surgical incision is made intercostally for access to the patient's thoracic region. Preferably at least two surgical incisions (preferably lateral) are made intercostally and sufficiently spaced apart to allow for the inserting and spreading of the blades of two of said surgical retractors, each pair of spread blades providing a relatively symmetrical, elongated channel for accessing the internal thoracic region of the patient.

What is claimed is:

1. An adjustable surgical retractor that comprises

(a) two handles suitable for grasping positioned opposite each other and pivotally connected so that the handles move reciprocatingly relative to each other,

(b) a head connected to each handle so that each head moves reciprocatingly relative to the other,

(c) a means for locking the heads at a preset distance from each other,

(d) each head having a post suitable for connecting a blade, and

(e) a blade connected to each head through a receptacle to frictionally receive the post and swivel thereon, with each blade having a width, depth and thickness so that the width extends substantially parallel to the length of the head and the depth extends downward from the top of the head wherein the blades taken together at the position of closest proximity to each other are of a size suitable to be inserted into a surgical incision in a patient undergoing a surgical procedure then spread apart to form an elongated access opening through which a medical instrument may be inserted to perform exploratory or surgical procedures.

2. The surgical retractor of claim **1** wherein each blade has an inside face and an outside face, said inside face of each blade facing the inside face of the other blade and the outside face of each blade designed to (i) minimize the trauma to the patient's body at the incision when the head and blades are spread apart and (ii) stabilize the blades in the incision.

3. The surgical retractor of claim **1** wherein the upper edge of each blade when spread apart has a concavely smooth surface corresponding to a concave surface of the inner face and is designed to stabilize a surgical instrument when such instrument contacts it.

4. The surgical retractor of claim **3** wherein each blade comprises a flexible material with the outer face having a textured surface to stabilize the blade in the incision.

5. The surgical retractor of claim **4** wherein when the inner faces of the blades are in closest proximity, the length of each blade is parallel to the other.

6. The surgical retractor of claim 3 wherein each blade is a flexible material and the outer surface comprises a resilient material.

7. The surgical retractor of claim 1 wherein each blade is rigid and each inner face is concave relative to the other with an outwardly protruding lip on the upper and lower edge of each blade to assist in maintaining the blades in the incision when the head and blades are spread apart after insertion into the patient's surgical incision.

8. The surgical retractor of claim 1 wherein the blades are disposable.

9. The surgical retractor of claim 1 wherein the width of each blade is about one inch to about four inches, the depth is about one inch to about three inches and the thickness is about one-eighth inch to about three-quarters of an inch.

10. The surgical retractor of claim 1 wherein when the head and blades are spread apart a surgical opening having a length of about one inch to about four inches and a width of about one-quarter inch to about two inches.

11. A method of providing surgical access to the internal thoracic region of a patient, which method comprises making an intercostal, surgical incision through the skin and soft tissue of the patient, wherein the incision is sufficiently sized to allow for the insertion of a surgical retractor in the incision;

inserting two blades of a surgical retractor perpendicularly through the incision; and

spreading the blades of said retractor to provide a relatively symmetrical, elongated channel for accessing the internal thoracic region of the patient, said channel being defined by said blades wherein the internal faces of the blades have a concave surface to define a substantially ovoid channel, each blade having a smooth, continuous upper surface.

12. The method of claim 11, wherein each said retractor comprises

(a) two handles suitable for grasping positioned opposite each other and pivotally connected so that the handles move reciprocatingly relative to each other;

(b) a head connected to each handle so that each head moves reciprocatingly relative to the other;

(c) a means for locking each head at a preset distance from the other;

(d) each head having a connector means suitable for connecting a blade, and

(e) a blade connected to each head through the connector means with each blade having a width, depth and thickness so that the width extends substantially parallel to the length of the head and the depth extending downward from the top of the head.

13. The method of claim 11, wherein at least two surgical incisions are made intercostally and sufficiently spaced apart to allow for the insertion and spreading of the blades of two of said surgical retractors, each pair of spread blades providing a relatively symmetrical, elongated channel for accessing the internal thoracic region of the patient.

14. The method of claim 11, wherein said two surgical incisions are made laterally on said patient.

15. The method of claim 11, wherein said two surgical incisions are made anteriorly on said patient.

16. The method of claim 11, wherein said two surgical retractors are interconnected by a stabilizing bar to fix their positions relative to the other.

17. The method of claim 11, wherein a third incision is made to provide access to the patient's thoracic cavity sufficient to insert an image transmission means to transmit an image of the patient's internal thoracic region.

18. A method of performing minimally-invasive cardiac surgery on a patient, which method comprises

making an intercostal surgical incision through the skin and soft tissue of the patient, wherein the incision is sufficiently sized to allow for the inserting and spreading of the blades of a surgical retractor,

inserting two blades of a surgical retractor, perpendicularly through the incision,

spreading the blades of said retractor to provide a relatively symmetrical, elongated channel for accessing the internal thoracic region of said patient, said channel being defined by said blades wherein the internal faces of the blades have a concave surface to define a substantially ovoid channel, each blade having a smooth continuous upper surface,

inserting a surgical instrument through said substantially ovoid channel, and

performing a surgical procedure using the surgical instrument so inserted.

19. The method of claim 18, wherein said retractor comprises

(a) two handles suitable for grasping positioned opposite each other and pivotally connected so that the handles move reciprocatingly relative to each other,

(b) a head connected to each handle so that each head means moves reciprocatingly relative to the other,

(c) a means for locking each head at a preset distance from the other,

(d) each head having a connector means suitable for connecting a blade, and

(e) a blade connected to each head through the connector means with each blade having a width, depth and thickness so that the width extends substantially parallel to the length of the head and the depth extending downward from the top of the head.

20. The method of claim 18, wherein said surgery is cardiac surgery and said patient is maintained on a cardiopulmonary by-pass machine.

21. The method of claim 20, wherein at least two surgical incisions are made intercostally and sufficiently spaced apart to allow for the inserting and spreading of the blades of two of said surgical retractors, each pair of spread blades providing a relatively symmetrical, elongated channel for accessing the internal thoracic region of the patient.

22. The method of claim 18, wherein said two surgical incisions are made laterally on said patient.

23. The method of claim 18, wherein said two surgical incisions are made anteriorly on said patient.

24. The method of claim 18, wherein said two surgical retractors are interconnected by a stabilizing bar to fix their positions relative to the other.

25. The method of claim 18, wherein a third incision is made to provide access to the patient's thoracic cavity sufficient to insert an image transmission means to transmit an image of the patient's internal thoracic region.

26. The method of claim 25, wherein the surgery is performed by the surgeon by manipulating the instruments viewing the image surgery so transmitted by the transmission means.

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