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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 October 2009 (08.10.2009)

PCT

(10) International Publication Number
WO 2009/122412 A1

(51) International Patent Classification:
A61F 2/24 (2006.01)

(21) International Application Number:
PCT/IL2009/000363

(22) International Filing Date:
5 April 2009 (05.04.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/064,856 31 March 2008 (31.03.2008) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) **Title**: DEVICE AND METHOD FOR REMODELING A HEART VALVE LEAFLET

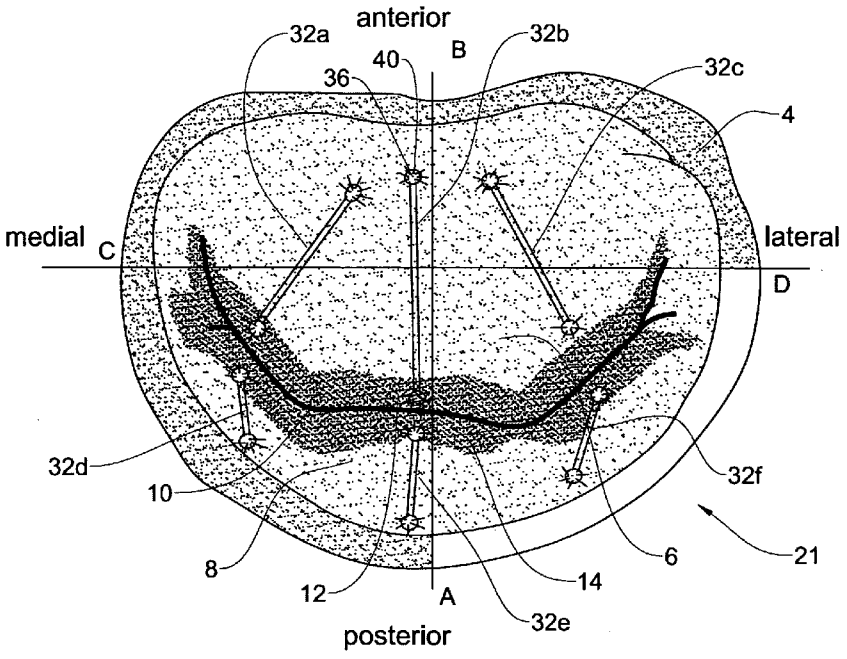

FIG. 4

(57) **Abstract**: The invention provides a device for remodeling a heart valve leaflet such as a mitral valve leaflet or a tricuspid valve in the treatment of valve regurgitation. The device has a slender portion (34) adapted to be affixed to the leaflet. In one embodiment, the device is provided with one or more eyelets for affixing to the leaflet by suturing. The slender portion may be straight or curved, rigid or elastic. The invention also provides a catheter for deploying a device of the invention

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DEVICE AND METHOD FOR REMODELING A HEART VALVE LEAFLET

FIELD OF THE INVENTION

This invention relates to medical devices and methods, and more particular to such devices and methods for treating a heart valve.

BACKGROUND OF THE INVENTION

Fig. 1 shows the structure of a normal mitral valve **2.** The valve **2** has a mitral annulus **4** made of fibrous tissue that surrounds the valve that is generally saddle shaped having a major axis **CD** extending from medial to lateral aspects of the valve, and an anterior-posterior minor axis **AB**. The mitral annulus which is a saddle shaped elliptical region with the anterior leaflet **6** and the posterior leaflet **8** oriented in a medial to lateral direction, and the orifice **10** between the leaflets **6** and **8** is substantially parallel to the major axis **CD** of the annulus.

The anterior leaflet is larger than the posterior leaflet. The combined area of both leaflets is 2.5 times the annulus area and when the leaflets coapt the zone of leaflet apposition results in leaflet overlap. Thus, when a heart valve functions properly, the valve prevents regurgitation of blood from the ventricle into the atrium when the ventricle contracts. In order to withstand the substantial backpressure and prevent regurgitation of blood into the left atrium during the ventricular contraction, the cordae tendinae hold the anterior and posterior leaflets in place across the opening of the annulus ring. The cordae tendinae are fibrous cords that anchor the leaflets to the muscular wall of the heart and thus control the movement of the leaflets.

A heart valve may become defective or damaged from degeneration caused by congenital malformation, disease, aging, etc. One common problem associated with a degenerating heart valve is an enlargement. If the annulus of the mitral valve enlarges or

dilates to a point where the leaflets are unable to fully close the opening (malcoaptation), the leaflets fail to overlap during systole to effectively stop blood flow, a condition known as *"valve regurgitation"*. Furthermore, valve prolapse, or the forcing of the valve annulus and leaflets into the left atrium by backpressure during ventricle contraction, may occur.

Fig. 2 shows a regurgitant heart valve **21** in which the leaflets **6** and **8** fail to overlap during systole due to furling and sagging of the leaflets. Furling of the leaflets **6** and **8** has occurred in a region **20** and **22**, respectively located near the edge of the leaflets. Sagging of the leaflets **6** and **8** has occurred in a region **24** and **26**, respectively, of the leaflets. Due to the furling and sagging, the leaflets fail to overlap during systole so that a gap **23** is present between the leaflets at systole through which valve regurgitation occurs.

Adverse clinical symptoms, such as chest pain, cardiac arrhythmias, dyspnea, may manifest in response to regurgitation or valve prolapse. As a result, surgical correction, either by valve repair procedures or by valve replacement, may be required. Surgical reconstruction or repair procedures may include plication, chordal shortening, or chordal replacement. Another common repair procedure relates to remodelling of the valve annulus (e.g., annuloplasty), which may be accomplished by implantation of a prosthetic ring to help stabilize the annulus and to correct or help prevent valve insufficiency which may result from a defect or dysfunction of the valve annulus. Properly sizing and implanting an annuloplasty ring may substantially restore the valve annulus to its normal, undilated, circumference.

In one type of valve deformation, the annulus is deformed so that the length of the minor axis AB has increased from its normal length shown in Fig. 1. This lengthening of the minor axis increases the separation between the two leaflets, so that the two leaflets fail to overlap during systole. A variety of repair techniques have been developed for tutoring a deformed annulus to decrease the minor axis so as to bring the leaflet edges closer together. The Alfieri technique, involves suturing the anterior and posterior leaflets together in the central section of the leaflets. Other methods include mitral valve repair with left ventricle remodeling and reshaping techniques to re-orient the papillary muscles and the chordae and leaflets such that the approximation of the edges improves and closure of the valve is obtained.

US Patent Publication discloses a valve shield comprising a shaped sheet of material adapted to be affixed to the annulus of a valve and adapted to extend over at least a portion of at least one leaflet of the valve so as to assist or replace the closing function of that valve leaflet.

US Patent publication 20050004665 discloses implantable devices for the repair of a defective cardiac valve having an annuloplasty ring and a restraining or support structure or mechanism. The annuloplasty ring functions to reestablish the normal size and shape of the annulus bringing the leaflet in proximity to each other. The restraining structure functions to restrain the abnormal motion of at least a portion of the valve being repaired. The restraining structure may include at least one restraining member across the interior of the circumference of the ring in a configuration consisting of a primary member to which secondary members are attached or one where all members traverse the ring.

US Patent Publication 20050075727 discloses a mitral valve prosthesis comprising flexible leaflet-like elements with curved coapting surfaces and means for maintaining continuity of the valve when inserted into the mitral annulus.

US Patent No. 7,160,322 discloses a device having a buttress extending from a base portion. The buttress permits flow of blood when the valve leaflets are not engaging the buttress.

SUMMARY OF THE INVENTION

In its first aspect, the present invention provides a device and method for treating a regurgitant heart valve that may be a mitral valve or a tricuspid valve. The device of the invention comprises one or more slender portions. The device of the invention is adapted to be affixed to one of the leaflets of a heart valve. As explained below, affixing the device of the invention onto to a valve leaflet tends to decrease or eliminate a gap between the leaflet edges due to furling or sagging of the leaflets, and thus tends to prevent or reduce prolapse of the leaflet.

Thus, in its first aspect, the invention provides a device for remodeling a heart valve leaflet comprising a slender portion and being adapted to be affixed to the leaflet.

In another of its aspects, the invention provides use of the device of the invention for the treatment of valve regurgitation.

The invention further provides a catheter having a proximal end and a distal end configured for deploying a device of the invention.

Also provided by the invention is a method for remodeling a heart valve leaflet comprising affixing to the leaflet a device of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, embodiments will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1 shows a normal mitral valve;

Fig. 2 shows a regurgitant heart valve;

Fig. 3 shows a device for treating a regurgitant heart valve in accordance with one embodiment of the invention;

Fig. 4 shows a heart valve after deployment of several devices of the invention;

Fig. 5 shows a device for treating a regurgitant heart valve in accordance with another embodiment of the invention;

Fig. 6 shows a device for treating a regurgitant heart valve having an unstrained configuration (**Fig. 6a**) and a strained configuration (**Fig. 6b**) in accordance with yet another embodiment of the invention;

Fig. 7 shows the device of Fig. 6 after deployment in a heart valve;

Fig. 8 shows a catheter for delivering and deploying a device of the invention;

Fig. 9 shows the catheter of Fig. 8 with a device of the invention mounted on the distal end of the catheter;

Fig. 10 shows a device for treating a regurgitant heart valve in accordance with another embodiment of the invention having an unstrained configuration (**Fig. 10a**) and a strained configuration (**Fig. 10b**); and

Fig. 11 shows the device of Fig. 10 after deployment in a heart valve.

DETAILED DESCRIPTION OF EMBODIMENTS

Fig. 3 shows a device **32** for treating a regurgitant heart valve in accordance with one embodiment of the invention. The device **32** comprises a slender portion **34**, which

may be straight, as shown in Fig. 3. Alternatively, the slender portion may be curved or looped, as shown below. The slender portion **34** may be rigid or elastic, as required in any application. At each end of the shaft is an eyelet **36** that serves for suturing the device **32** to a valve leaflet, as explained below. The device **32** is made from a biocompatible rigid material, such as metal, plastic, Nitinol or synthetic collagen. The device **32** is deployed using a suturing catheter having a distal end adapted to mounting a device of the invention. The device **32** may be provided with angiographically visible markers **33** for assistance in positioning the device during deployment. During deployment of the device of the invention, mitral regurgitation can be monitored by echocardiography, transesophageal echo-cardiography or Doppler cardiography.

The device of the invention may be deployed in any heart valve such as a mitral valve or a tricuspid valve. Fig. 4 shows the heart valve **21** after deploying several devices **32** of the invention. Three devices **32a**, **32b**, and **32c** have been affixed to the leaflet **6** and three devices **32d**, **32e**, and **32f** have been affixed to the leaflet **8.** The devices **32** have been affixed to the leaflets **6** and **8** in an orientation that is substantially perpendicular to the edge of the leaflets adjacent to the orifice **10** of the valve **21**. Attachment of the devices **32** to the leaflets tends to reduce or eliminate furling and sagging of the leaflets. Any number of the devices **32** may be deployed on each leaflet as required in any application to reduce or eliminate furling and sagging of the leaflets. The devices **32** have been sutured to the leaflet by sutures **40** at each eyelet **36**. Affixing the devices **32** to the leaflets has reduced or eliminated furling and sagging of the leaflets, thereby returning to the leaflets their original conformation as shown in Fig. 1. In this conformation, the edges of the leaflets **6** and **8** are brought closer together so as to reduce or eliminate the gap **23** (Fig. 2). In this conformation, valve regurgitation is reduced or eliminated.

Fig. 5 shows a device **50** in accordance with another embodiment of the invention. The device **50** has an elongated first section **52** and an elongated second section **54**. At the end of the section **52** and **54** is an eyelet **56** for suturing the device **50** to a valve leaflet, as explained above with reference to Fig. 4. The second section **54** has a lumen **58** dimensioned to receive the first section **52**. The length of the device **50** may thus be selected as required in any application. After adjusting the device **50** to a desired length with two rows of diametrically apposed apertures **60** on the first section **52** aligned with two rows of diametrically apposed apertures **63** on the second section **54**,

the length of the device is fixed by suturing though the aligned apertures **58** and **60**. The device **50** is made from a biocompatible rigid material, such as metal, plastic, Nitinol or synthetic collagen.

Fig. 6 shows a device **62** in accordance with yet another embodiment of the invention. The device **62** has an elongated shaft **64**. Along the length of the shaft **64** are two or more eyelets **66** for suturing the device **62** to a valve leaflet. The device **64** is made from an elastic material so that the shaft **64** is elastically deformable from a slightly curved, unstrained, configuration shown in Fig. 6a to strained configuration of higher curvature shown in Fig. 6b.

Fig. 7 shows the device **62** after deployment in the heart valve **21**. The device **62** was strained into the high curvature configuration shown in Fig. 6b and then sutured to the leaflet **6** by sutures **68** at each of the eyelets **66**. The device **62** is thus affixed to the leaflet **6** in a strained configuration in an orientation substantially parallel to the edge of the valve adjacent to the orifice **10** of the valve. In this orientation, the device **62** tends to stretch the leaflet **6** and bring it closer to the leaflet **8** as the device **62** tends to curve back to the slightly curved configuration, as shown in Fig. 7. In this conformation, the edges of the leaflets **6** and **8** are brought closer together so as to reduce or eliminate the gap **23** (Fig. 2). In this conformation, valve regurgitation is reduced or eliminated.

Fig. 10 shows a device **92** in accordance with yet another embodiment of the invention. The device **92** has a closed loop structure. Along the device **92** are two or more eyelets **66** for suturing the device **62** to a valve leaflet. The device **92** is made from an elastic material so that the device **92** is elastically deformable from a slightly curved, unstrained, configuration shown in Fig. 10a to strained configuration of higher curvature shown in Fig. 10b.

Fig. 11 shows the device **92** after deployment in the heart valve **21**. The device **92** was strained into the high curvature configuration shown in Fig. 10b and then sutured to the leaflet **6** by sutures **68** at each of the eyelets **66**. The device **92** is thus affixed to the leaflet **6** in a strained configuration which tends to stretch the leaflet **6** and bring it closer to the leaflet **8** as the device **92** tends to revert to the slightly curved configuration, as shown in Fig. 11. In this conformation, the edges of the leaflets **6** and **8** are brought closer together so as to reduce or eliminate the gap **23** (Fig. 2). In this conformation, valve regurgitation is reduced or eliminated.

Figs. 8 and 9 show a catheter **70** for delivering and deploying a device of the invention in an atrium adjacent to a mitral valve to be treated by the device. The catheter **70** has a slender flexible shaft **72** having a proximal end **74** and a distal end **76**. The distal end **76** is configured to have mounted upon it a device of the invention for treating a mitral valve. Fig. 9 shows the device **50** mounted on the distal end **76** of the catheter **70**. This is by way of example only, and the distal end **76** can be adapted to mount any device of the invention for treating a mitral valve. A control wire **80** extends along the interior of the shaft from the proximal end to the distal end that allows an operator to release the device **50** from the distal end **76** when the device **50** is deployed adjacent to a mitral valve. The distal end is also provided with a suture assembly **78** for suturing the device **50** at the site of deployment of the device. The suture assembly may be used with spring sutures or cords. The distal end **76** of the catheter **70** may be delivered to the mitral valve via a transseptal approach.

CLAIMS:

1. A device for remodeling a heart valve leaflet comprising a slender portion and being adapted to be affixed to the leaflet.

2. The device according to Claim 1 wherein the slender portion is straight.

3. The device according to Claim 2 being dimensioned and configured to be affixed to a valve leaflet in an orientation substantially perpendicular to an edge of the valve adjacent to an orifice of the valve.

4. The device according to any one of the previous claims having one or more eyelets.

5. The device according to any one of the previous claims comprising one or more angiographic markers.

6. The device according to any one of the previous claims adapted for affixing to the leaflet by suturing.

7. The device according to any one of the previous claims wherein the slender portion has an adjustable length.

8. The device according to Claim 7 comprising a first member and a second member, the first member having an interior configured to slidably receive a portion of the second member.

9. The device according to Claim 7 or 8 wherein the length of the device is fixed using one or more sutures.

10. The device according to any one of the previous claims, wherein the slender poriton is rigid.

11. The device according to any one of Claims 1 to 10 wherein the slender portion is elastic.

12. The device according to Claim 11 wherein the slender portion has a curved unstrained shape.

13. The device according to Claim 12 being dimensioned and configured to be affixed to a valve leaflet in an orientation substantially parallel to an edge of the valve adjacent to an orifice of the valve.

14. The device according to Claim 11 wherein the device has a closed loop structure.

15. Use of the device according to any one of the previous claims for the treatment of valve regurgitation.

16. A catheter having a proximal end and a distal end configured for deploying a device according to any one of the previous claims.

17. The catheter according to Claim 16 adapted for mounting a device according to any one of Claims 1 to 11 at the distal end of the catheter.

18. The catheter according to Claim 16 or 17 further comprising a suturing assembly at the distal end of the catheter.

19. A method for remodeling a heart valve leaflet comprising affixing to the leaflet a device according to any one of Claims 1 to 13.

20. The method according to Claim 19 comprising suturing the device to the leaflet.

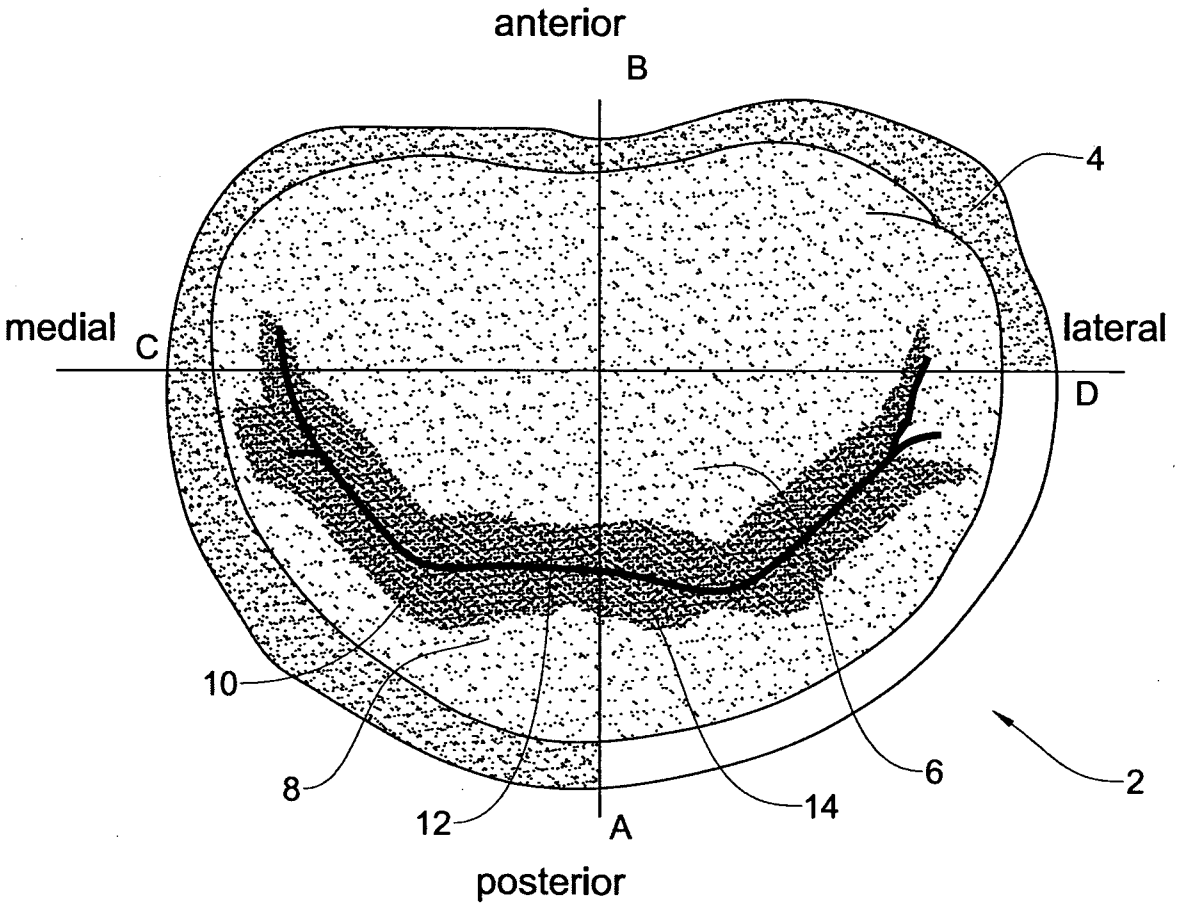


FIG. 1
(PRIOR ART)

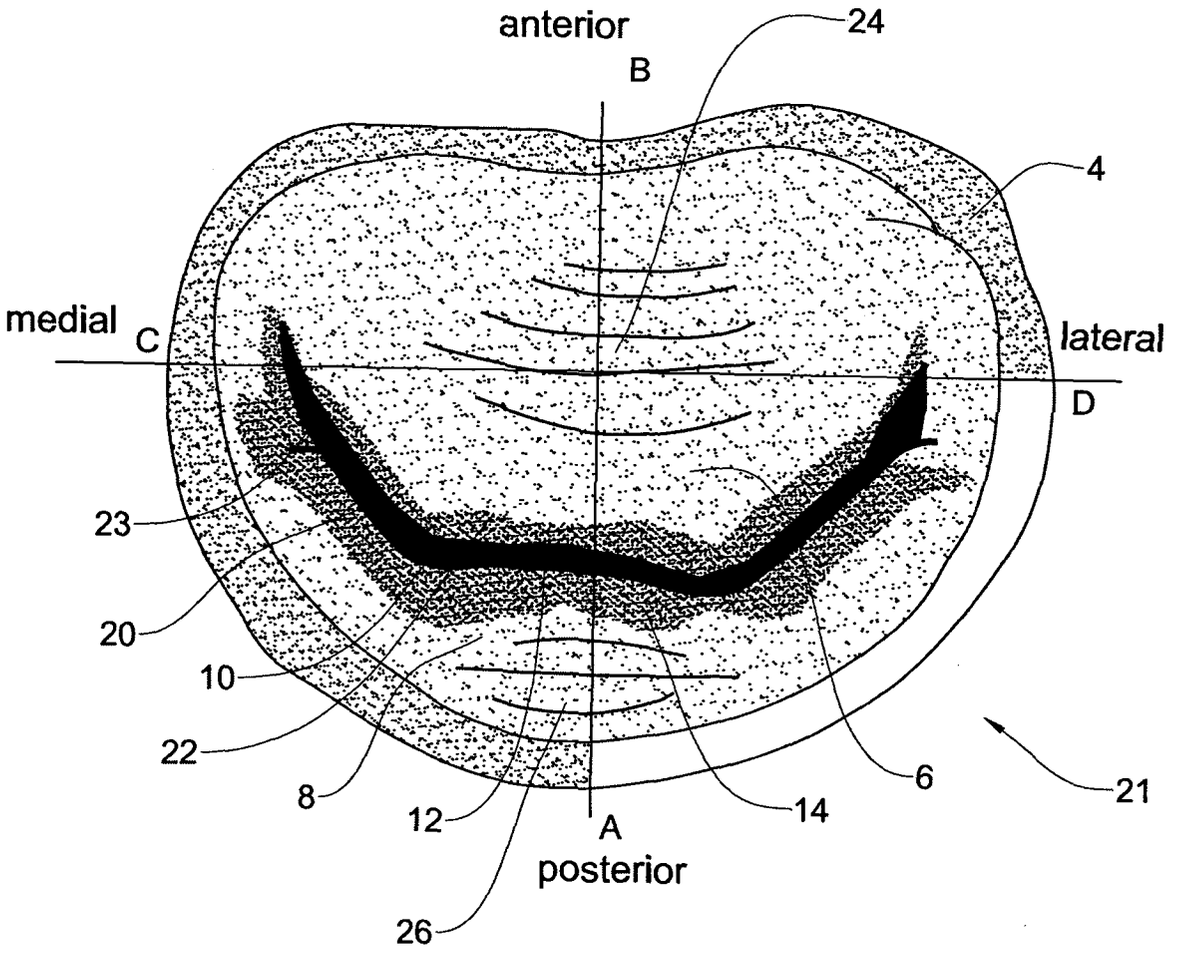


FIG. 2
(PRIOR ART)

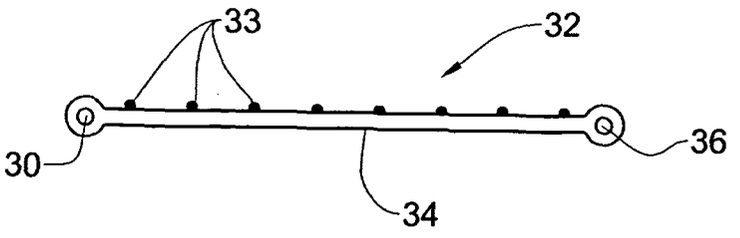


FIG. 3

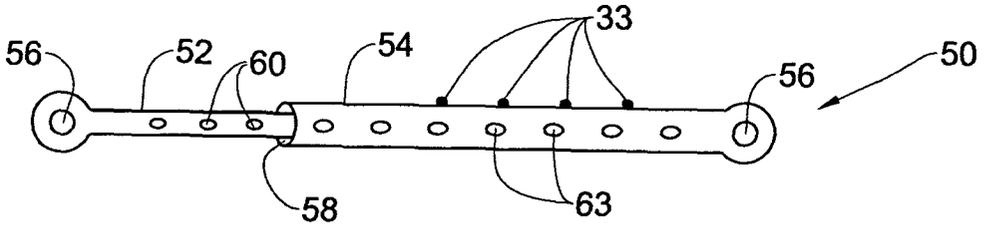


FIG. 5

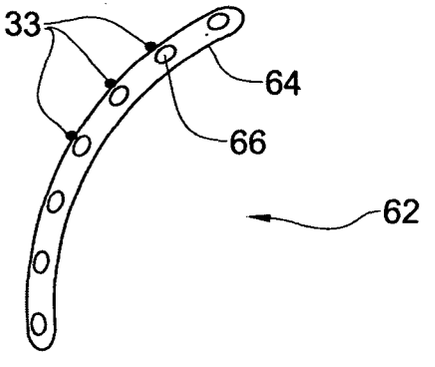


FIG. 6(a)

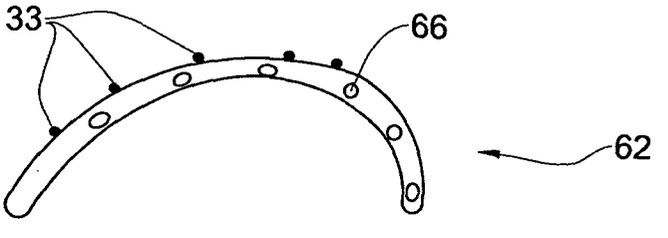
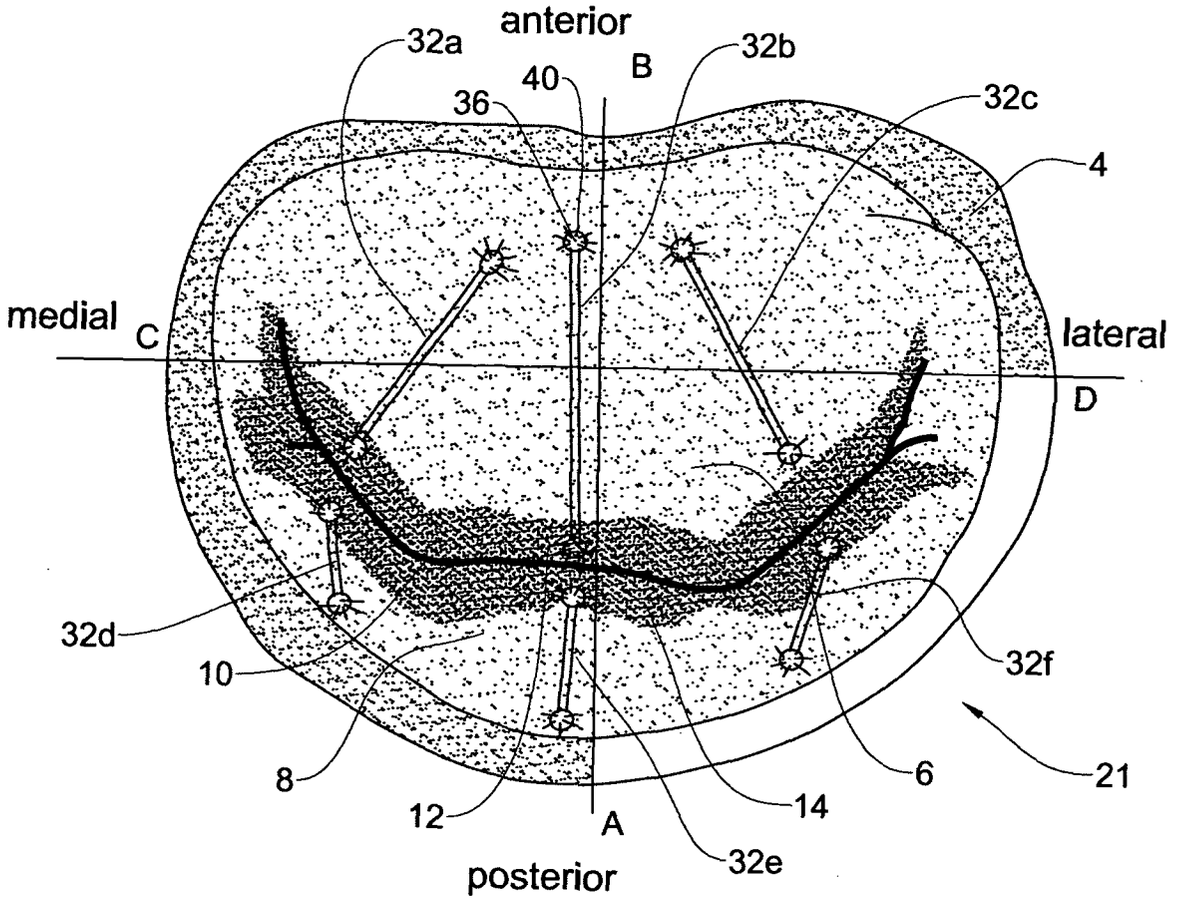


FIG. 6(b)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32a
40
B
32b
36
32c
4
medial
C
lateral
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10
32f
8
6
21
12
A
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32e
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FIG. 4

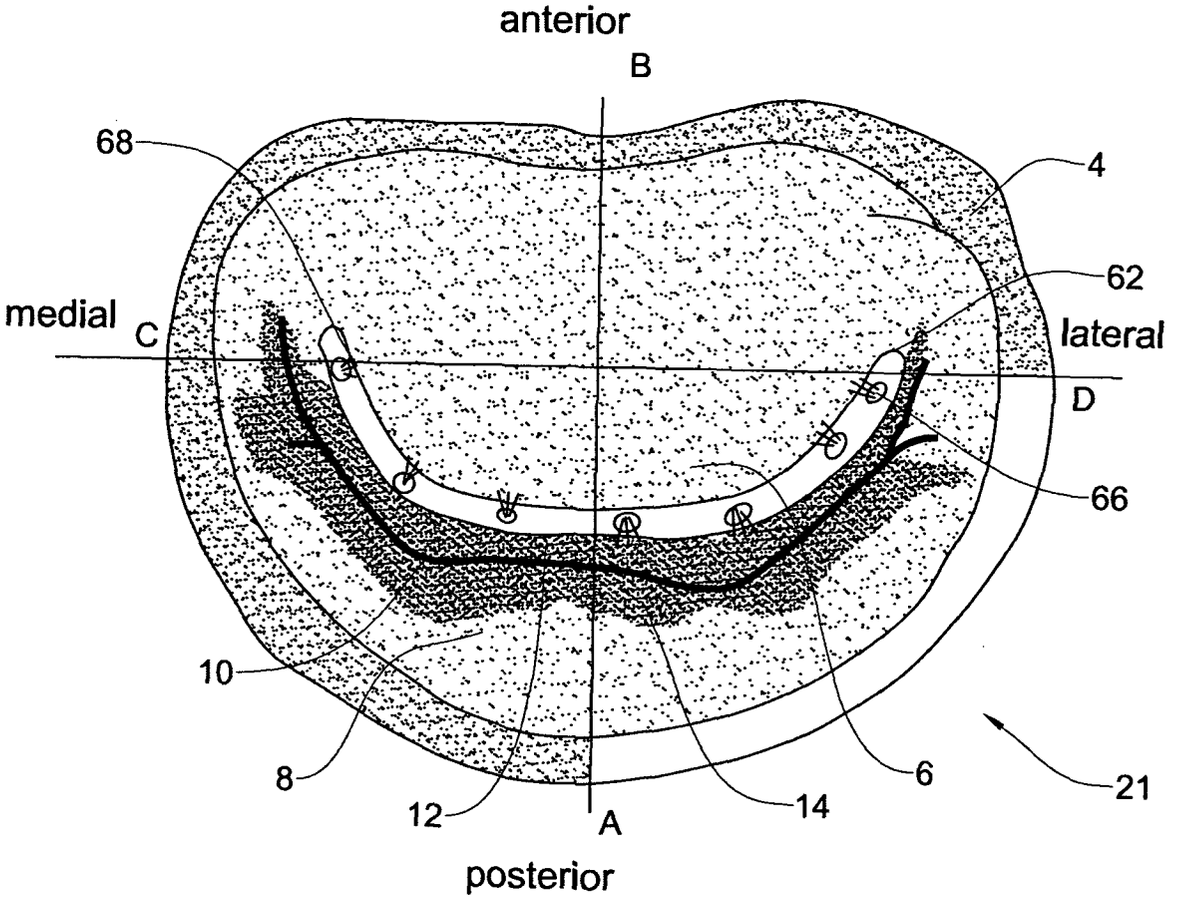
anterior
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FIG. 7

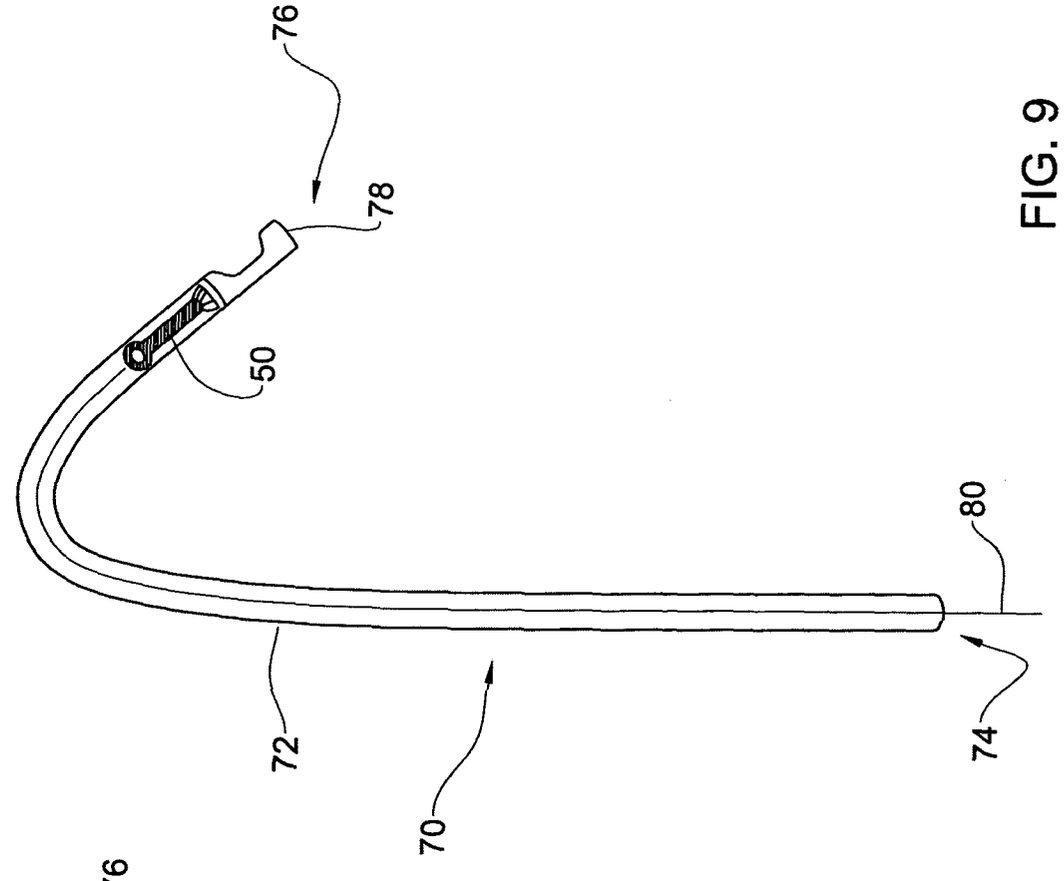


FIG. 9

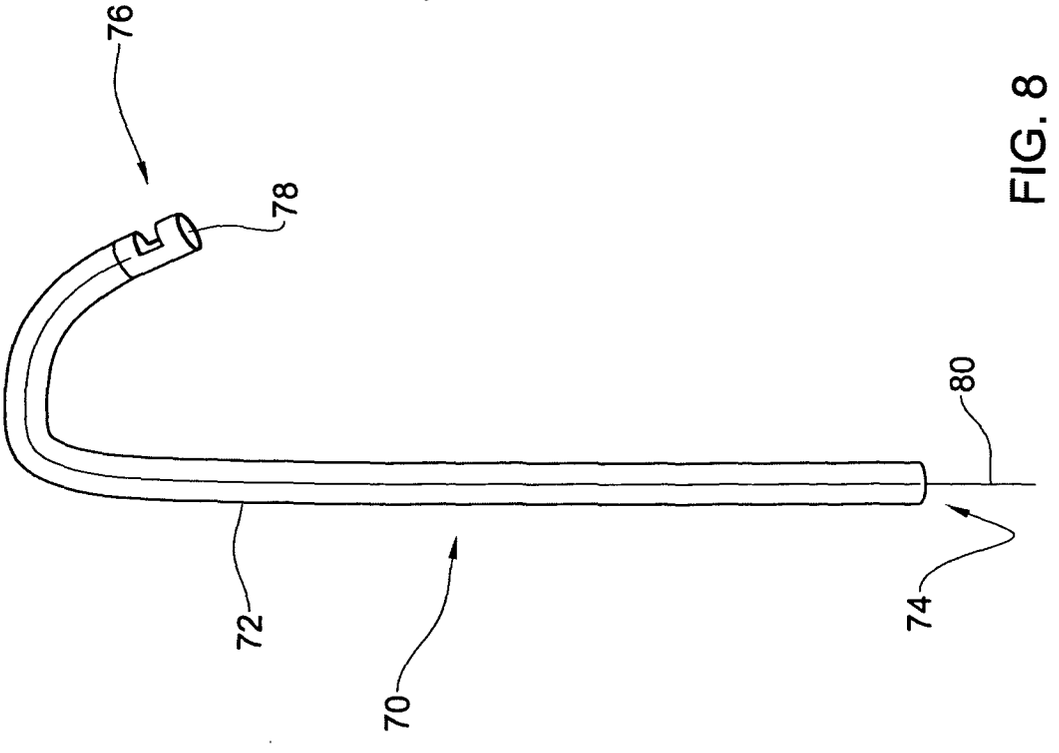


FIG. 8

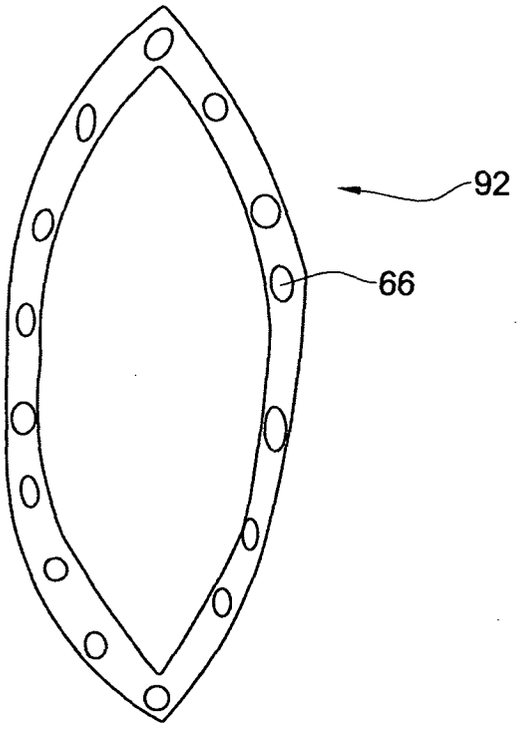


FIG. 10(a)

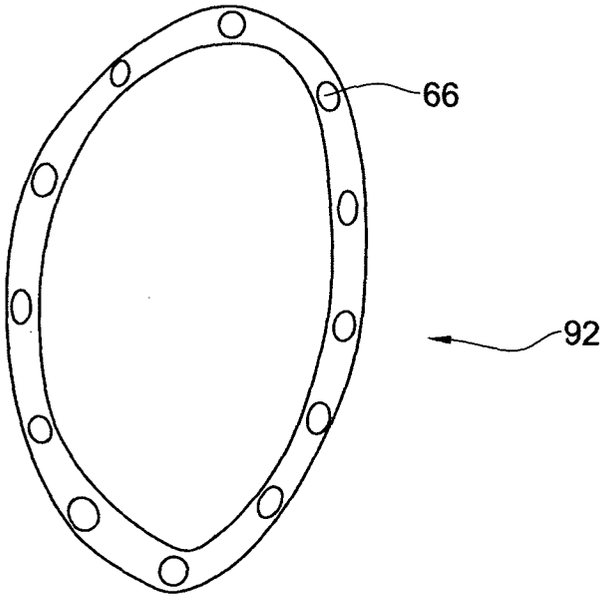
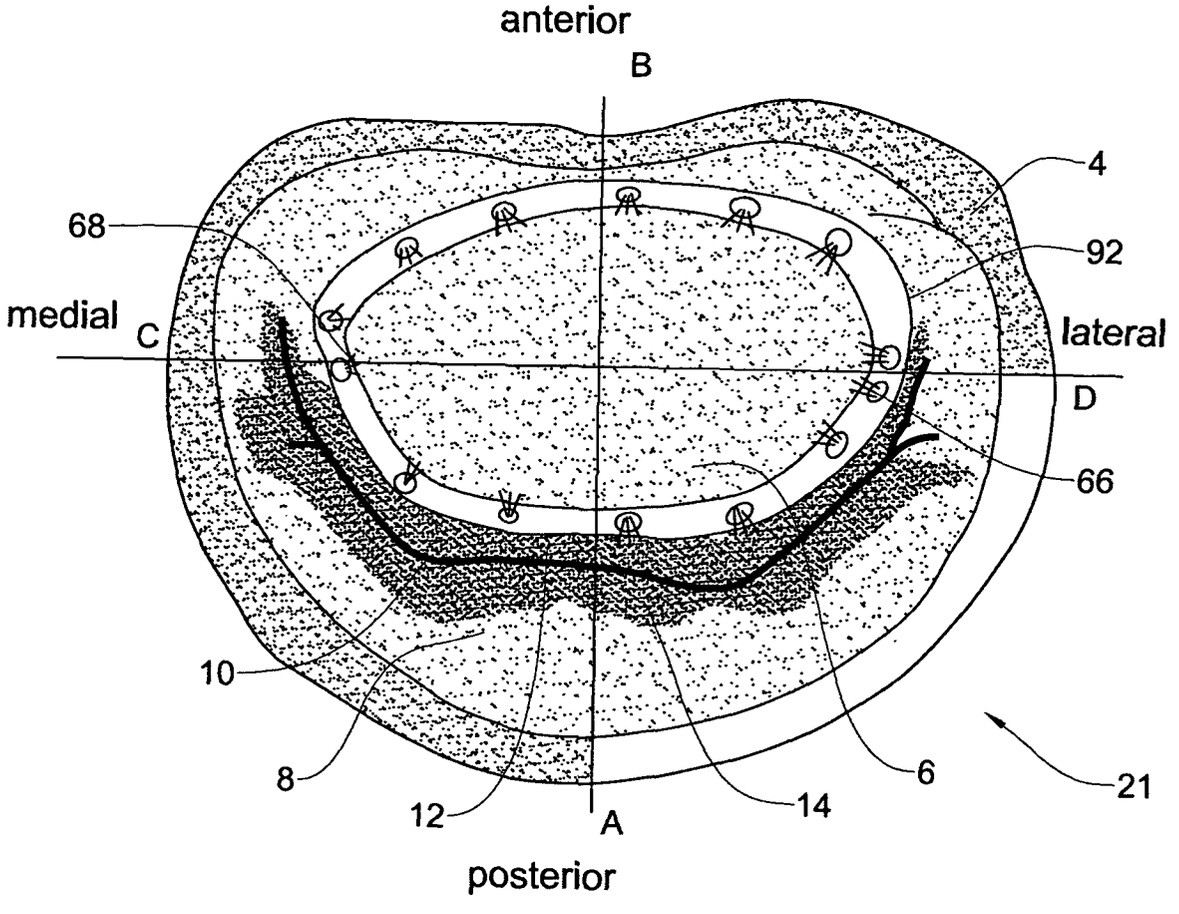


FIG. 10(b)


anterior
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21
posterior

FIG. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2009/000363

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 709 695 A (NORTHRUP III WILLIAM F [US]) 20 January 1998 (1998-01-20)	1
Y	column 4, line 29 - column 7, line 54; claims; figures	2-14, 16-18
X	WO 2005/069875 A (SINAI SCHOOL MEDICINE [US]; FILSOUFI FARZAN [US] ITY MOUNT SINAI SCHOO) 4 August 2005 (2005-08-04)	1
Y	the whole document	2-14, 16-18
X	US 6 524 338 B1 (GUNDRY STEVEN R [US]) 25 February 2003 (2003-02-25)	1
Y	column 3, line 31 - column 4, line 50; claims; figures	2-14, 16-18

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
25 June 2009	02/07/2009

Name and mailing address of the ISA/	Authorized officer
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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2009/000363

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/042621 A1 (LIDDICOAT JOHN R [US] ET AL LIDDICOAT JOHN R [US] ET AL) 11 April 2002 (2002-04-11)	1
Y	paragraph [0074] - paragraph [0101]	2-14, 16-18
X	US 2003/120340 A1 (LISKA JAN [SE] ET AL) 26 June 2003 (2003-06-26)	1
Y	paragraph [0025] - paragraph [0040]	2-14, 16-18
X	US 2002/065554 A1 (STREETER RICHARD B [US]) 30 May 2002 (2002-05-30)	1
Y	the whole document	2-14, 16-18
P,X	WO 2008/081450 A (MEDICAL RES FUND AT THE TEL AV [IL]; KEREN GAD [IL]) 10 July 2008 (2008-07-10) the whole document	1-14, 16-18

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 15, 19, 20

The subject-matter of claims 19 and 20, discloses a method for remodelling a heart valve comprising the step of affixing a device to a leaflet.
The International preliminary searching authority is not required to establish an opinion with regard to novelty, inventive step and industrial applicability on methods for treatment of the human body by surgery or therapy (Rule 39.1(iv)PCT). The same objection applies for claim 15.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2009/000363

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 15, 19, 20
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IL2009/000363

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