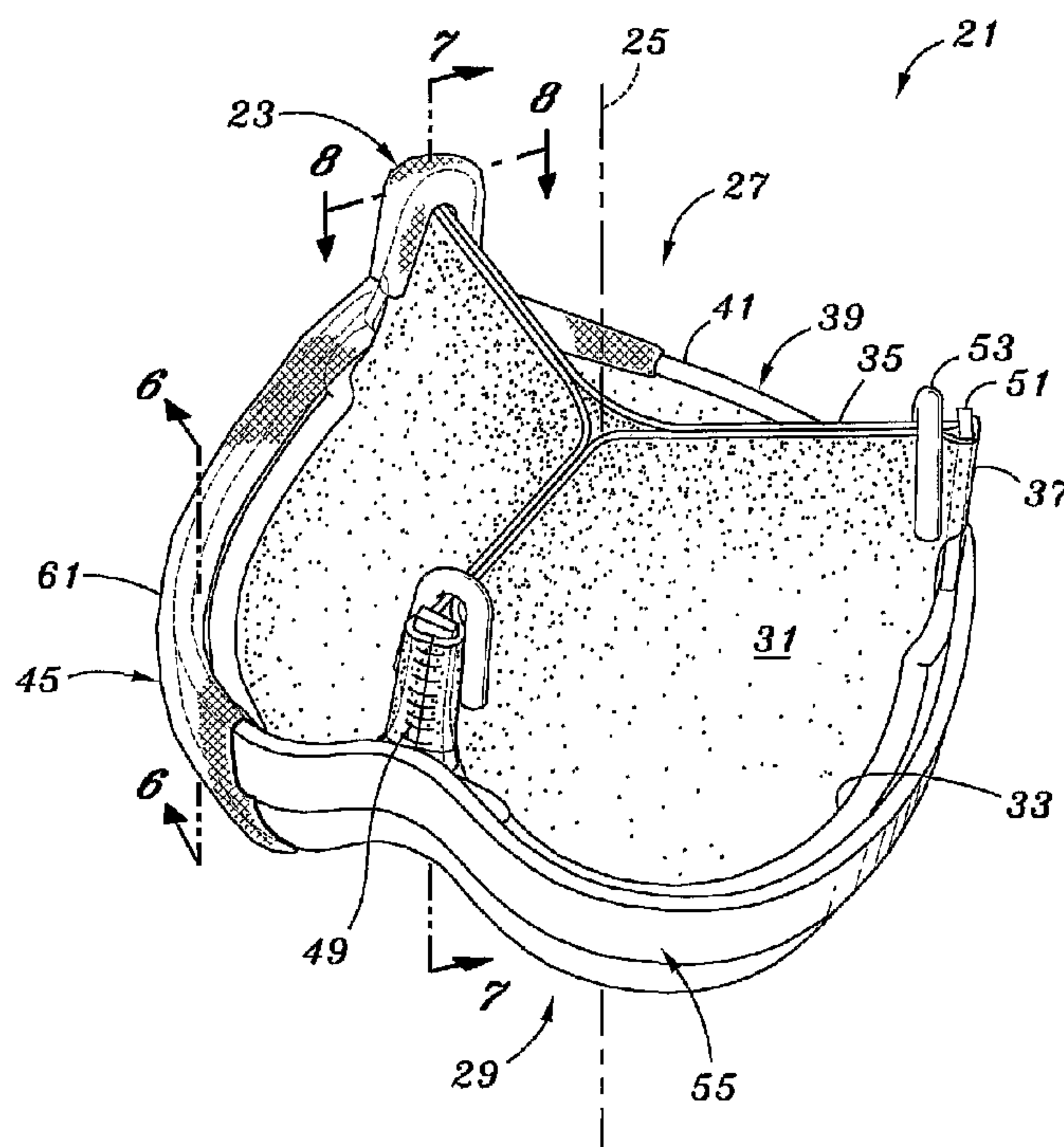




(86) Date de dépôt PCT/PCT Filing Date: 2001/09/14
(87) Date publication PCT/PCT Publication Date: 2002/03/28
(45) Date de délivrance/Issue Date: 2009/12/01
(85) Entrée phase nationale/National Entry: 2003/03/12
(86) N° demande PCT/PCT Application No.: US 2001/028729
(87) N° publication PCT/PCT Publication No.: 2002/024118
(30) Priorité/Priority: 2000/09/22 (US09/668,660)

(51) Cl.Int./Int.Cl. *A61F 2/24* (2006.01)
(72) Inventeur/Inventor:
CAO, DONGBU, US
(73) Propriétaire/Owner:
EDWARDS LIFESCIENCES CORPORATION, US
(74) Agent: BCF LLP

(54) Titre : VALVULE CARDIAQUE SOUPLE DOTE DE COMMISSURES MOBILES
(54) Title: FLEXIBLE HEART VALVE HAVING MOVEABLE COMMISSURES



(57) **Abrégé/Abstract:**

A flexible prosthetic tissue-type heart valve having commissures that are substantially decoupled from a cusp support structure. The valve includes three leaflets having arcuate cusp edges and opposed free edges, with outwardly-directed attachment tabs therebetween. A cusp support structure in either one or more pieces attaches to the leaflet cusp edges. Three commissures are each formed partly with an axially-extending insert member to which two adjacent leaflet tabs attach. An inverted V-shaped clip maintains close contact between the adjacent leaflet tabs and provides a stress-relieving clamping action in conjunction with the insert member. The insert member attaches about its lower end to base sections of the cusp support structure, or to an intermediate sewing ring, so that the commissures may pivot about the cusp support structure. The sewing band is scalloped and enables attachment of the valve along the scalloped aortic root so as to couple the valve to the natural motion of the aorta. Increased vibrational damping results from this biomechanical coupling.

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

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
28 March 2002 (28.03.2002)

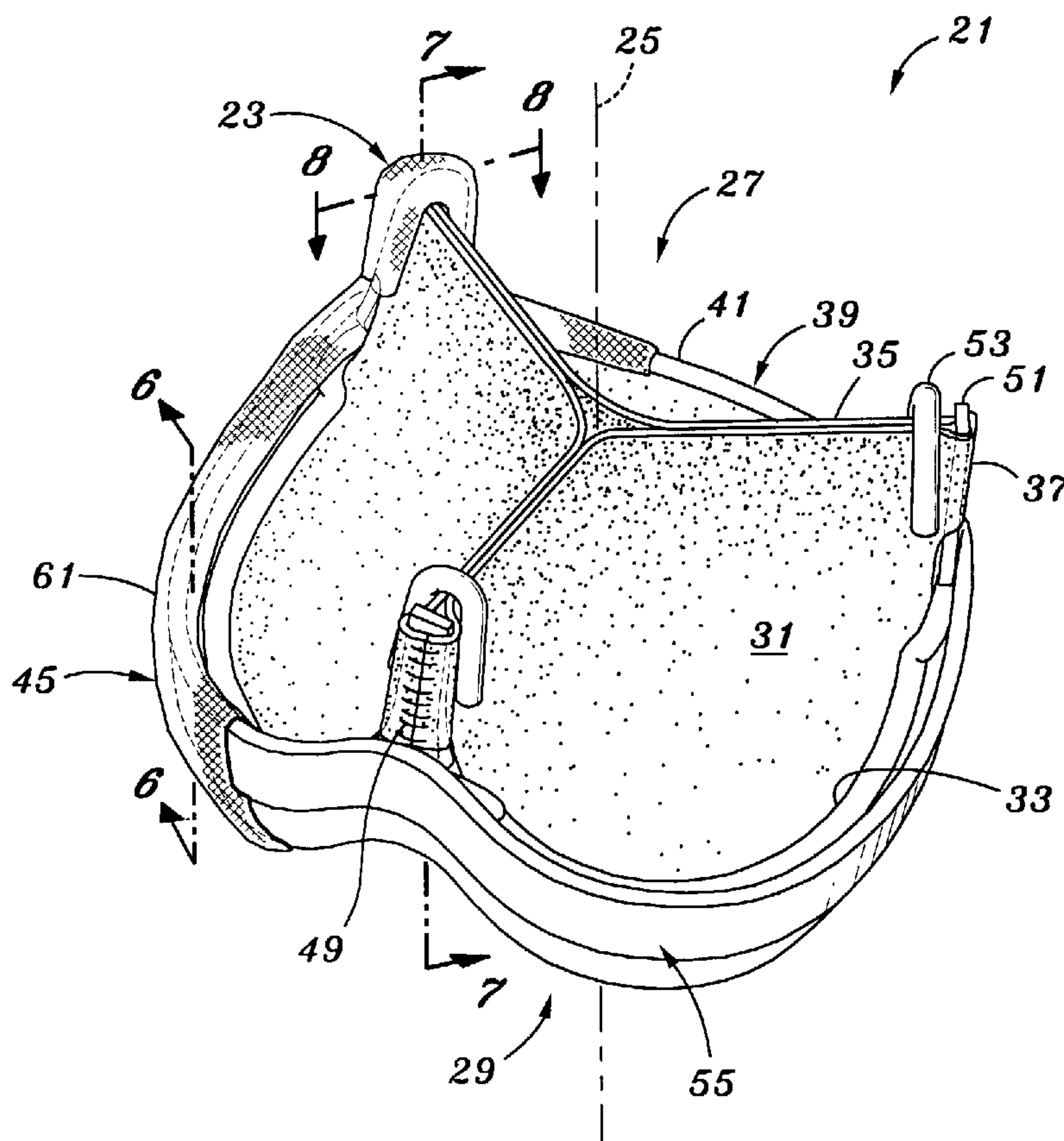
PCT

(10) International Publication Number
WO 02/24118 A1

- (51) International Patent Classification⁷: **A61F 2/24** (72) Inventor: CAO, Dongbu; 11331 Riveredge Drive, Parma, OH 44130 (US).
- (21) International Application Number: PCT/US01/28729 (74) Agents: JAMES, John, Christopher et al.; Edwards Lifesciences LLC, One Edwards Way, Irvine, CA 92614 (US).
- (22) International Filing Date:
14 September 2001 (14.09.2001) (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- (25) Filing Language: English (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
- (26) Publication Language: English
- (30) Priority Data:
09/668,660 22 September 2000 (22.09.2000) US
- (71) Applicant: EDWARDS LIFESCIENCES CORPORATION [US/US]; One Edwards Way, Irvine, CA 92625 (US).

[Continued on next page]

(54) Title: FLEXIBLE HEART VALVE HAVING MOVEABLE COMMISSURES



(57) Abstract: A flexible prosthetic tissue-type heart valve having commissures that are substantially decoupled from a cusp support structure. The valve includes three leaflets having arcuate cusp edges and opposed free edges, with outwardly-directed attachment tabs therebetween. A cusp support structure in either one or more pieces attaches to the leaflet cusp edges. Three commissures are each formed partly with an axially-extending insert member to which two adjacent leaflet tabs attach. An inverted V-shaped clip maintains close contact between the adjacent leaflet tabs and provides a stress-relieving clamping action in conjunction with the insert member. The insert member attaches about its lower end to base sections of the cusp support structure, or to an intermediate sewing ring, so that the commissures may pivot about the cusp support structure. The sewing band is scalloped and enables attachment of the valve along the scalloped aortic root so as to couple the valve to the natural motion of the aorta. Increased vibrational damping results from this biomechanical

WO 02/24118 A1



IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

Published:

— *with international search report*

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

Where replacement of a heart valve is indicated, the dysfunctional valve is typically cut out and replaced with either a mechanical valve, or a tissue valve. Tissue valves are often preferred over mechanical valves because they typically do not require long-term treatment with anticoagulants. The most common tissue valves are constructed with whole porcine (pig) valves, or with separate leaflets cut from bovine (cow) pericardium. Although so-called stentless valves, comprising a section of porcine aorta along with the valve, are available, the most widely used valves include some form of stent or synthetic leaflet support. Typically, a wireform having alternating arcuate cusps and upstanding commissures supports the leaflets within the valve, in combination with an annular stent and a sewing ring. The alternating cusps and commissures mimic the natural contour of leaflet attachment. Importantly, the wireform provides continuous support for each leaflet along the cusp region so as to better simulate the natural support structure.

However, the tissue material tends to calcify after the long term implantation. That is, calcium compound accumulates in the tissue leaflets, eventually making them stiff. The tissue leaflet area along the wireform is especially susceptible to the calcification because of the high bending stresses imposed at that interface.

5 Many prior art stented valves are relatively rigid, typically containing an annular metal or plastic stent ring that provides internal support for an outer sewing ring and the wireform-mounted valve cusps and commissures. This design also provides a basic structure to facilitate valve assembly, which is hand made by highly skilled workers. Although this type of valve has been proven effective,
10 some researchers assert that it excessively occludes the natural orifice area, and thus reduces potential blood flow therethrough. Although stentless valves generally provide greater orifice area, they do not have the advantage of the reliable leaflet support structure of stented valves. Moreover, a stentless valve is more difficult to make, and the implantation of such a device requires much more skill
15 and experience of the cardiac surgeon. Only a few heart centers in the United States are able to perform such a procedure and thus the use of stentless valves is restricted.

More flexible stented valves have been proposed, including U.S. Patent No. 5,549,665 to Vesely, et al. In the Vesely patent, the valve stent commissures may
20 attach to the ascending aorta and may pivot outward for the purpose of reducing localized stresses in the leaflets. The stent commissures are prevented by stops from inward pivoting to ensure proper valve functioning. However, the stent structure appears to be relatively complex, with numerous interior surfaces, thus raising concerns of thromboembolisms and even component failure.

25 In view of the foregoing, it is evident that an improved flexible valve that addresses the apparent deficiencies in existing heart valves is necessary and desired. In particular, there is a need for a bioprosthetic valve that provides a large orifice opening and has a dimensionally stable stent to facilitate the valve assembly and implantation.

Summary of the Invention

This invention details a partially stented valve design. The stent is to be completed by the natural aortic root when the valve is implanted. The final valve
5 conforms to the movement of the natural aortic root and therefore provides a larger orifice area like a stentless valve. The valve, however, includes a stent structure that will facilitate the valve assembly and implantation procedures. The movement of the stent structure and leaflet shape also helps to reduce stress concentration in the valve leaflet.

10 In one embodiment, the present invention provides a heart valve for implantation in an annulus of a heart having commissures on an outflow end adapted to move in conformity with an anatomical wall structure adjacent the annulus. The heart valve comprises three leaflets made of a biocompatible and compliant material, each leaflet having a rounded cusp edge opposite a free edge,
15 and a pair of generally oppositely-directed tabs separating the cusp edge and free edge. A cusp support structure generally defines a ring and a valve axis and has three rounded sections each adapted to conform to the cusp edge of the leaflets. The cusp edge of each leaflet is attached to a different rounded section of the cusp support structure so that the three leaflets are arranged generally evenly about the
20 valve axis, the attached leaflet cusp edges and rounded sections together defining valve cusps curving toward an inflow end of the valve. Three valve commissure posts disposed between the valve cusps project generally axially toward an outflow end of the valve. The commissure posts are defined by two adjacent leaflet tabs, a generally axially extending insert member, and an inverted V-shaped clip
25 positioned radially inward from the insert member. The adjacent leaflet tabs are juxtaposed to extend radially outward with respect to the axis through the inverted V-shaped clip and are wrapped around and secured to the insert member, an inflow end of each commissure post is generally pivotally coupled with respect to the cusp support structure so as to permit both radially inward and outward movement

thereof, the valve commissure posts being attachable to the anatomical wall structure. Finally, a sewing band shaped to follow the valve cusps and being attached therealong provides a platform for implanting the heart valve such that the valve cusps are attachable adjacent the annulus or in the supraannular position (i.e., just above the annulus).

In another aspect of the invention, an aortic heart valve adapted to have reduced vibration related strain is provided, comprising three leaflets each having arcuate cusp edges on their inflow ends, free edges on the outflow ends, and two side tabs. Three cusp supports each attach to the cusp edge of one of the leaflets to define valve cusps, the cusps being disposed generally in a circle about a valve axis at an inflow end of the valve. Three generally axially extending commissure posts are disposed in between the valve cusps around the circle and extend toward an outflow end of the valve. The commissure posts are defined by an insert (e.g. a relatively rigid insert) and adjacent tabs of two leaflets attached thereto. The inserts are structurally separate from the three cusp supports but coupled thereto at an end closest to the cusp supports to enable radial pivoting of the outflow end of the commissure posts relative to the cusp supports. Finally, a sewing band shaped to follow the valve cusps and attached therealong is provided. The sewing band and inserts providing a platform for implanting the aortic heart valve such that the valve cusps are attachable adjacent the annulus, and the inserts are attachable to the ascending aorta. In this manner, the commissure posts are freely moveable with respect to the valve cusps so as to generally pivot radially in and out in conjunction with movement of the ascending aorta during the repetitive cycles of systole and diastole such that the heart valve is dynamically coupled to the damping characteristics of the ascending aorta.

In a further aspect of the invention, a tissue-type heart valve adapted to have reduced stress risers in the leaflets, comprises three leaflets each having arcuate cusp edges on their inflow ends, free edges on the outflow ends, and two side tabs, the free edges extending between the side tabs in a concave fashion. The valve may include commissure posts to which adjacent leaflet tabs attach, each post.

including an insert around which the leaflet tabs wrap. The valve further may include a cusp support structure attached to the cusps of each leaflet, wherein the insert is pivotally coupled to the cusp support structure. Desirably, a sewing band for attachment to a valve annulus that surrounds the cusp support structure and is truncated in the region of the inserts to permit direct attachment of the commissure posts to an anatomical wall structure adjacent the annulus. Each leaflet free edge further may include a region that is above a line extending between the middle of the free edge and the side tabs so that the region is not placed in direct tension during closure of the valve. The region is preferably generally triangular and culminates in an apex, and a concave file may exist between the apex and the side tab.

A further understanding of the nature advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

15

Brief Description of the Drawings

Figure 1 is an assembled perspective view of the flexible heart valve of the present invention;

Figure 2 is an exploded perspective view of the heart valve of Figure 1;

20 Figure 2A is a sectional view through a cusp support structure of the heart valve of Figure 1, taken through line 2A-2A of Figure 2;

Figure 3 is a perspective view of components of the three commissures of the heart valve of Figure 1 positioned with respect to the cusp support structure shown in phantom;

25 Figure 4A is an elevational view of an inverted V-shaped clip forming a portion of each of the valve commissures;

Figure 4B is a perspective view of the inverted V-shaped clip of Figure 4A showing a fabric-covering thereon;

Figures 5A and 5B are front and side elevational views, respectively, of an

insert member that forms another portion of each of the valve commissures;

Figure 6 is a vertical sectional view through a valve cusp taken along line 6-6 of Figure 1;

Figure 7 is a vertical sectional view through a valve commissure taken
5 along line 7-7 of Figure 1;

Figure 8 is a horizontal sectional view through a valve commissure taken along line 8-8 of Figure 1;

Figure 9 is a perspective view of an alternative three-piece cusp support structure for the flexible valve of the present invention, also showing the
10 positioning of valve commissure components;

Figure 10 is an elevational view of the alternative cusp support structure and valve commissure components of Figure 9, further illustrating a sewing band in phantom;

Figure 11 is a top plan view of the alternative three-piece cusp support
15 structure of Figure 9;

Figure 12 is a plan view of a valve leaflet of the prior art;

Figure 13A is a plan view of a first embodiment of a valve leaflet for use in the flexible valve of the present invention;

Figure 13B is a plan view of a second embodiment of a valve leaflet for use
20 in the flexible valve of the present invention;

Figure 14 is a perspective view of a cusp support structure as seen in Figure 2, and alternative commissure components for use in a flexible valve of the present invention;

Figure 15 is an elevational view of the assembly of Figure 14, further
25 illustrating a sewing band in phantom; and

Figures 16A and 16B are front and side elevational views, respectively, of an insert member of the valve of Figure 14 coupled to a cusp support structure.

Description of the Preferred Embodiments

The following detailed description, and the figures to which it refers, are
5 provided for the purpose of describing examples and specific embodiments of the invention only and are not intended to exhaustively describe all possible examples and embodiments of the invention. Identical elements and features are given the same reference number as appropriate for purposes of describing the various embodiments of the present invention.

10 Referring now to Figures 1 and 2, a replacement tissue type heart valve 21 of the present invention for implantation in an annulus of a heart is constructed about a valve axis 25 that defines an outflow end 27 and an inflow end 29. The valve includes commissures 23 directed to the outflow end and adapted to move in conformity with an anatomical wall structure adjacent the annulus of the heart.
15 Although the valve 21 of the present invention is particularly suitable for implantation at the aortic valve position, it may also function adequately in other valve positions. The valve has three leaflets 31 made of a biocompatible compliant material, each of which has a rounded cusp edge 33 opposite a free edge 35 and a pair of generally oppositely-directed tabs 37 separating the cusp edge and the free
20 edge. The specific shapes of alternative embodiments of the leaflets 31 of the present invention are shown in Figures 13A and 13B, and will be described in more detail below.

A valve cusp support structure 39 is provided, generally defining a ring comprised of three rounded sections 41 connected by commissure base sections 43.
25 The entire support structure 39, including the rounded sections 41 and base sections 43, is covered with a fabric sleeve 44. Each of the rounded sections 41 conforms and attaches to a rounded cusp edge 33 of a leaflet via the fabric sleeve 44. As seen in the cross-section of Figure 2A, the fabric sleeve 44 exhibits a flap 47 formed by juxtaposed free ends of the fabric material to which the cusp edge 33

of each leaflet 31 attaches, such as with sutures (not shown). The cusp edge 33 of each leaflet 31 is attached to a different rounded section 41 of the cusp support structure 39 so that the three leaflets 31 are arranged generally evenly distributed 120° apart about the valve axis 25. The attached leaflet cusp edges 33 and rounded sections 41 together define valve cusps 45 concavely curved toward the inflow end 29 of the valve.

The three valve commissure posts 23 are disposed between the valve cusps 45 and project generally axially toward the outflow end 27 of the valve. The commissure posts 23 include a generally axially extending insert member 51 attached to two adjoining leaflet tabs 37, here shown sutured together at butt joint 49. Alternatively, as will be described below with respect to Figure 8, the leaflet tabs 37 may overlap and can be mutually attached via stitching through holes in the insert member 51. The leaflet free edges 35 coapt in the middle of the valve and the free edges of each two adjacent leaflets are juxtaposed so that the tabs 37 extend radially outwardly from the valve axis 25 through an inverted V-shaped clip 53 positioned radially inward from the insert member 51. Each insert member 51 is sutured to the cover fabric of the commissure base section 43 so as to permit both radially inward and outward movement of the outflow end of the commissure posts. This generally pivoting attachment (shown by arrow 54 in Figure 7) may be accomplished in a number of ways, several of which are disclosed herein, and to some extent decouples the radial movement of the valve commissures 23 from its cusps 45.

A sewing band 55 shaped to follow the valve cusps 45 and to an extent the valve commissures 23 provides a platform for attaching the heart valve to vestigial heart tissue, such as the aortic annulus or aortic root tissue. As partially seen in Figure 1, the sewing band 55 is encompassed within a fabric cover 61 (shown partially cutaway). The valve cusps 45 are attachable adjacent the annulus with the valve commissures 23 attachable to the adjacent anatomical wall structure itself. Consequently, when implanted, structural support for each valve commissure 23 is

provided by the native aorta, through the V-shaped clip 53 and insert member 51. In the preferred embodiment, the valve 21 is attached to the root tissue that comprised part of the native aortic heart valve. Attachment in this manner allows the replacement valve to more freely move and thus exhibit greater flexibility to match the blood flow capacity of the native aortic heart valve. Moreover, this biomechanical coupling provides natural tissue damping to help suppress excessive vibrations within the valve 21 during its rapid closing.

Referring to the exploded view of Figure 2, the component parts of the invention will be described in more detail. As mentioned, the three tissue leaflets 31 have a tab section 37, a rounded cusp edge 33 and a free edge 35. The insert members 51 rest on the relatively rigid fabric-covered commissure base sections 43 (in this embodiment a rod-like element), and are attached thereto. For instance, sutures are passed through each insert member 51 and around the associated commissure base section to allow the insert member to move both radially inwardly and radially outwardly. This allows the finished commissure posts (Figures 7 and 8) to move both radially inwardly and radially outwardly. V-clips 53 and sewing band 55 are shown in their relative orientation in Figure 2 without connecting structure, to be described below.

Figure 3 shows the relative orientation of the V-shaped clip 53 (shown isolated in figures 4A and 4B), and the insert member 51 on the cusp support structure 39 (shown in phantom) when they are assembled. The cusp support structure 39 may be formed in a generally annular or ring like shape. The V-shaped clips 53, seen in Figures 4A and 4B, cinch the tissue leaflet free edges 35 to the commissure posts, as indicated in Figure 8. In a preferred embodiment, a shroud-like fabric cover 56 is provided around each V-shaped clip 53 to facilitate attachment to the adjacent valve components. Figures 5A and 5B show front and side views of the insert member 51 having a series of through holes 52.

Figure 6 is a sectional view taken along the 6-6 line of Figure 1, showing the attachment of the rounded cusp edge 33 of the tissue leaflet, the rounded

section 41 of the cusp support structure 39 and the sewing band 55. The three pieces are sutured or otherwise attached together in this manner at least along the valve cusps 45 shown in Figure 1.

Figure 7 illustrates one embodiment of the attachment of the insert member 51 to the commissure base section 43 of the cusp support structure utilizing a suture 59 looped through holes 52 in the insert member and then around the base section. The insert 51 is thereby freely attached to the commissure base section 43 to allow its outflow end to move radially inwardly and outwardly, as indicated by arrow 54. The sewing band 55 is not connected to the insert member 51 but instead receives each commissure base section 43 in a groove portion 60. An outflow flange 62 stops short of the insert members 51 and the V-shaped clip 53. That is, the flange 62 of the sewing band 55 is axially truncated so as not to extend fully up each commissure 23. In this arrangement, the valve commissures 23 are exposed to the aortic wall so that they can be sutured directly thereto.

In an alternative embodiment, the commissure base sections 43 of the cusp support structure 39 are omitted to result in three separate cusp supports that attach to the sewing ring 55, such as seen in Figure 6. In such an alternative, each insert member 51 will rest directly on the sewing ring, and its inflow end may be sutured to the sewing ring.

Figures 7 and 8 illustrate the complete structure of the commissures 23 wherein adjacent leaflet tabs 37 wrapped around the insert member 51 and are sutured together on the radially outward side of the insert member. Fabric-covered V-shaped clip 53 is placed over adjoining leaflet tabs 37 and the fabric cover 56 includes a shroud long enough to wrap around the insert member 51. After the V-shaped clip 53 is placed over the leaflets at the commissure 23, the shroud of the fabric cover 56 is pulled down to cover the outward side of the insert member 51 and the leaflet tabs 37, and the free ends thereof are wrapped around the insert member 51 and sutured together (using sutures, not shown). Also, the fabric cover 56 may be sutured to the insert member 51 and leaflet tabs 37 through the aligned

holes at the insert member 51 for additional support, such as by using a stitch 57. The V-shaped clips 53 are desirably formed of a flexible material that flexes apart during an opening cycle of the valve wherein fluid flow through the valve causes the free edges 35 of adjacent leaflet tabs 37 to separate.

5 In this manner the leaflet tabs 37 are anchored to the commissures 23 by the clamping action between the insert 51 and the V-shaped clip 53. That is, each leaflet 31 experiences radially inward forces upon closing of the valve 21, which also tends to pull the insert member 51 inwardly. Because the fabric cover 56 attaches to the surrounding native aorta, and thus the V-shaped clip 53 is retained
10 thereby, this radially inward movement of the insert member 51 clamps the leaflet tabs 37 between the insert member and the clip. This anchoring prevents the sutures, such as suture 57, from being directly stressed and pulled apart through the leaflet material when the valve closes by blood flow during diastole. Further, this anchoring prevents any tissue stitches from being exposing to direct hemodynamic
15 loading and thus prevent stress concentration.

 Figures 9-11 show an alternative embodiment of the invention wherein a cusp support structure 39' comprises three separate rounded sections 65 each respectively supporting the rounded cusp edge 33 of a leaflet. Adjacent rounded sections may be interconnected with separate connector sections 67 and
20 intermediate V-shaped clips 53. The connector sections 67 may be made of a highly compliant material, for example a fabric, silicone or other elastomer to allow the rounded sections to move with respect to one another and more flexibly accommodate static or dynamic distortions in the shape of the native heart tissue. As before, insert 51 and V-shaped clips 53 are shown in the relative orientation as
25 before to form the valve commissures to which the leaflet tabs (not shown) attach.

 The three separate rounded sections 65 may be relatively rigid rod-like elements made of biocompatible metals or polymers. Alternatively, the rounded sections 65 may be made of a pre-formed biocompatible fabric having a radially outward tab to which the cusp edge of a leaflet attaches. In the latter case, the

rounded sections 65 are less rigid than a metal or polymer material, but provide sufficient stiffness to facilitate fabrication and implantation.

Figure 10 shows the use of the scalloped-shaped cusp support structure of Figure 9 with a corresponding scalloped shaped sewing band 55. As is known, this
5 scalloped shape more readily accommodates use of the sewing band as a platform to suture the sewing band to aortic root tissue, which is likewise scalloped. In this embodiment the sewing band is sutured directly to the valve annulus, with the commissure posts attached to the aortic wall to allow the leaflets to fluctuate radially inwardly and outwardly in a more natural manner. The inserts 51 are
10 desirably directly sutured to the sewing band 55, and thus there is no direct connection between the inserts 51 and the cusp support structure 39', and the valve commissures remain free to move inwardly and outwardly.

Figure 12 shows a leaflet of prior art tissue-type replacement heart valves. The free edge 71 of prior art leaflets generally extends straight across between the
15 opposed tabs 73.

For the present invention, the tissue leaflets should be configured as shown in either Figures 13A or 13B for reduced stress in the highly flexible valves. Leaflet free edge 35 between the tabs 37 is concave with either one or more curvatures (i.e., simple or complex curves). The outline of the free edge 71 of a
20 prior art leaflet is shown in phantom superimposed over the new leaflets. As can be seen, extra material 75 is provided at the leaflet tabs 37 to accommodate the additional stresses imposed upon the leaflets from the increased radially inward and outward movement of the valve commissures. That is, the leaflet tabs 37 are axially higher than the middle portions of the free edges. In the embodiment of
25 Figures 13A, the leaflet tabs 37 continue outward a straight edge 77 from the concave free edge 35. In the embodiment of Figure 13B, a concave transition filet 79 is provided from an apex 81 of the free edge 35 to reduce the height of the tabs at the valve commissures from that shown in Figure 13A. The triangular region near the apex 81 is not placed in direct tension from valve closure forces, and helps

reduce stress concentrations in the integrally connected regions that are in direct tension.

Referring now to Figure 14, in an alternative embodiment, the lower end of each insert member 51' bifurcates to straddle the commissure base section 43. The lower end of the insert member 51 thus straddles the base section 43 to facilitate radially inward and outward pivoting and reduces the tendency to slip off of the commissure base section. The bifurcation ends 83 seen in Figures 16A and 16B are disposed on either side of the commissure base section 43 and are secured thereto using a suture 85.

Figure 14 shows the relative orientation of the three valve commissure posts, each including a V-shaped clip 53, an insert member 51' and the cusp support structure 39, when they are assembled. Figure 15 shows the embodiment of Figure 14 further including the sewing band 55 in phantom.

In the various valves of the present invention, structural support from the cusp supports is provided to facilitate fabrication and implantation. The commissures remain flexibly coupled to the rest of the valve to enable aortic wall mounting, and dynamic coupling with the natural tissue. A concave free edge of the leaflet, preferably with an apex region that is not placed in direct tension, further prevents stress risers in the leaflets, and contributes to durability.

While the foregoing is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Moreover, it will be obvious that certain other modifications may be practiced within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A heart valve for implantation in an annulus of a heart having commissures on an outflow end adapted to move in conformity with an anatomical wall structure adjacent the annulus, the heart valve comprising:

5 three leaflets made of a biocompatible and compliant material, each leaflet having a rounded cusp edge opposite a free edge, and a pair of generally oppositely-directed tabs separating the cusp edge and free edge;

a cusp support structure generally defining a ring and a valve axis and having three rounded sections each adapted to conform to the cusp
10 edge of the leaflets, the cusp edge of each leaflet being attached to a different rounded section of the cusp support structure so that the three leaflets are arranged generally evenly about the valve axis, the attached leaflet cusp edges and rounded sections together defining valve cusps curving toward an inflow end of the valve;

15 three valve commissure posts disposed between the valve cusps and projecting generally axially toward an outflow end of the valve, the commissure posts being defined by two adjacent leaflet tabs, a generally axially extending insert member, and an inverted V-shaped clip positioned radially inward from the insert member, the adjacent leaflet tabs being
20 juxtaposed to extend radially outward with respect to the axis through the inverted V-shaped clip and being wrapped around and secured to the insert member, an inflow end of each commissure post being generally pivotally coupled with respect to the cusp support structure so as to permit both radially inward and outward movement thereof, the valve commissure posts
25 being attachable to the anatomical wall structure; and

a sewing band shaped to follow the valve cusps and being attached therealong, the sewing band providing a platform for implanting the heart valve such that the valve cusps are attachable adjacent the annulus.

2. The heart valve of claim 1, wherein the valve is sized for implantation in an aortic annulus, wherein the anatomical wall structure is the aorta.
3. The heart valve of claim 1, wherein the cusp support structure comprises a one-piece ring.
4. The heart valve of claim 3, wherein the cusp support structure comprises the rounded sections curved toward the inflow end of the valve and connected by commissure base sections about which the valve commissure posts pivot.
5. The heart valve of claim 4, wherein the cusp support structure comprises a relatively rigid rod-like element having a fabric covering, the valve commissure posts being attached to the cusp support structure using sutures through the fabric covering.
6. The heart valve of claim 4, wherein the inflow end of the insert member of each commissure post is bifurcated into divergent legs and straddles the associated commissure base section.
7. The heart valve of claim 6, wherein each commissure base section is circular in cross-section, and wherein the divergent legs of the bifurcated inflow end of the associated insert member are sutured together to capture the commissure base section therebetween.
8. The heart valve of claim 1, wherein the cusp support structure comprises three separate pieces arranged generally evenly about the valve axis to define the ring.

9. The heart valve of claim 8, wherein each piece of the cusp support structure comprises a relatively rigid rod-like element having a fabric covering, the sewing band attaching to the valve cusps using sutures through the fabric covering of each piece of the cusp support structure, and wherein the inflow end of each commissure post is pivotally attached to a portion of the sewing band that bridges one of three gaps defined between the three separate pieces of the cusp support structure.

10. The heart valve of claim 8, wherein each piece of the cusp support structure is made of a pre-formed biocompatible fabric having a radially outward tab to which the cusp edge of a leaflet attaches.

11. The heart valve of claim 8, wherein the three separate pieces of the cusp support structure are coupled by six highly compliant connector sections attached between adjacent ends of the rounded sections and V-shaped clips.

12. The heart valve of claim 11, wherein the connector sections are made of fabric.

13. The heart valve of claim 11, wherein the connector sections are made of an elastomer.

14. The heart valve of claim 1, wherein each V-shaped clip is formed of a flexible material adapted to flex apart during an open cycle of the valve wherein fluid flow through the valve causes the free edges of adjacent leaflet tabs to separate.

15. The heart valve of claim 14, further including a fabric covering

around each V-shaped clip that extends around the associated insert member and permits suture attachment of the clip to the insert.

16. The heart valve of claim 1, wherein the three leaflets each have a concave free edge.

17. An aortic heart valve adapted to have reduced vibration-related strain, comprising:
three leaflets each having arcuate cusp edges on their inflow ends, free edges on the outflow ends, and two side tabs;

three cusp supports each attached to the cusp edge of one of the leaflets to define valve cusps, the valve cusps being disposed generally in a circle about a valve axis at an inflow end of the valve;

three generally axially extending commissure posts disposed in between the valve cusps around the circle and extending toward an outflow end of the valve, the commissure posts each being defined by an insert and adjacent tabs of two leaflets attached thereto, wherein the inserts are structurally separate from the three cusp supports but coupled thereto at an end closest to the cusp supports to enable radial pivoting of the outflow end of the commissure posts relative to the cusp supports; and

a sewing band shaped to follow the valve cusps and being attached therealong, the sewing band and inserts providing a platform for implanting the aortic heart valve such that the valve cusps are attachable adjacent the annulus, and the inserts are attachable to the ascending aorta, the commissure posts therefore being freely moveable with respect to the valve cusps so as to generally pivot radially in and out in conjunction with movement of the ascending aorta during the repetitive cycles of systole and diastole such that the heart valve is dynamically coupled to the damping characteristics of the ascending aorta.

18. The heart valve of claim 17, wherein the three cusp supports together define a one-piece ring-shaped cusp support structure.

5 19. The heart valve of claim 18, wherein the cusp support structure comprises the three cusp supports that are curved toward the inflow end of the valve and are connected by three commissure base sections about which the commissure posts pivot.

10 20. The heart valve of claim 19, wherein the cusp support structure comprises a relatively rigid rod-like element having a fabric covering, the commissure posts being attached to the commissure base sections of the cusp support structure using sutures through the fabric covering.

15 21. The heart valve of claim 19, wherein the inflow end of the insert member of each commissure post is bifurcated and straddles the associated commissure base section.

20 22. The heart valve of claim 17, wherein the three cusp supports are separate elements coupled together by mutual attachment to the sewing band.

23. The heart valve of claim 22, wherein each cusp support comprises a relatively rigid rod-like element having a fabric covering, the sewing band attaching to the cusp supports using sutures through the fabric covering of each
25 cusp support, and wherein the inflow end of each commissure post is pivotally attached to a portion of the sewing band that bridges one of three gaps defined between the three separate cusp supports.

24. The heart valve of claim 22, wherein each cusp support is made of a

pre-formed biocompatible fabric having a radially outward tab to which the cusp edge of a leaflet attaches.

25. The heart valve of claim 17, wherein each of the commissure posts
5 further includes an inverted V-shaped clip positioned radially inward from the insert, the adjacent leaflet tabs being juxtaposed to extend radially outward with respect to the axis through the inverted V-shaped clip and being wrapped around and secured to the insert.

10 26. The heart valve of claim 25, wherein each V-shaped clip is formed of a flexible material adapted to flex apart during an open cycle of the valve wherein fluid flow through the valve causes the free edges of adjacent leaflet tabs to separate.

15 27. The heart valve of claim 25, further including a fabric covering around each V-shaped clip that extends around the associated insert and permits suture attachment of the clip to the insert.

20 28. The heart valve of claim 25, wherein the three cusp supports are separate elements coupled together by six compliant connector sections attached between adjacent ends of the cusp supports and V-shaped clips.

29. The heart valve of claim 17, wherein the three leaflets each have a concave free edge.

25

30. A tissue-type heart valve adapted to have reduced stress risers in the leaflets, comprising:

three leaflets each having arcuate cusp edges on their inflow ends, free edges on the outflow ends, and two side tabs, the free edges extending

between the side tabs in a concave fashion.

31. The heart valve of claim 30, further including commissure posts to which adjacent leaflet tabs attach, each post including an insert around which the leaflet tabs wrap, the valve further including a cusp support structure attached to the cusps of each leaflet, wherein the insert is pivotally coupled to the cusp support structure.

32. The heart valve of claim 31, further a sewing band for attachment to a valve annulus that surrounds the cusp support structure and is truncated in the region of the inserts to permit direct attachment of the commissure posts to an anatomical wall structure adjacent the annulus.

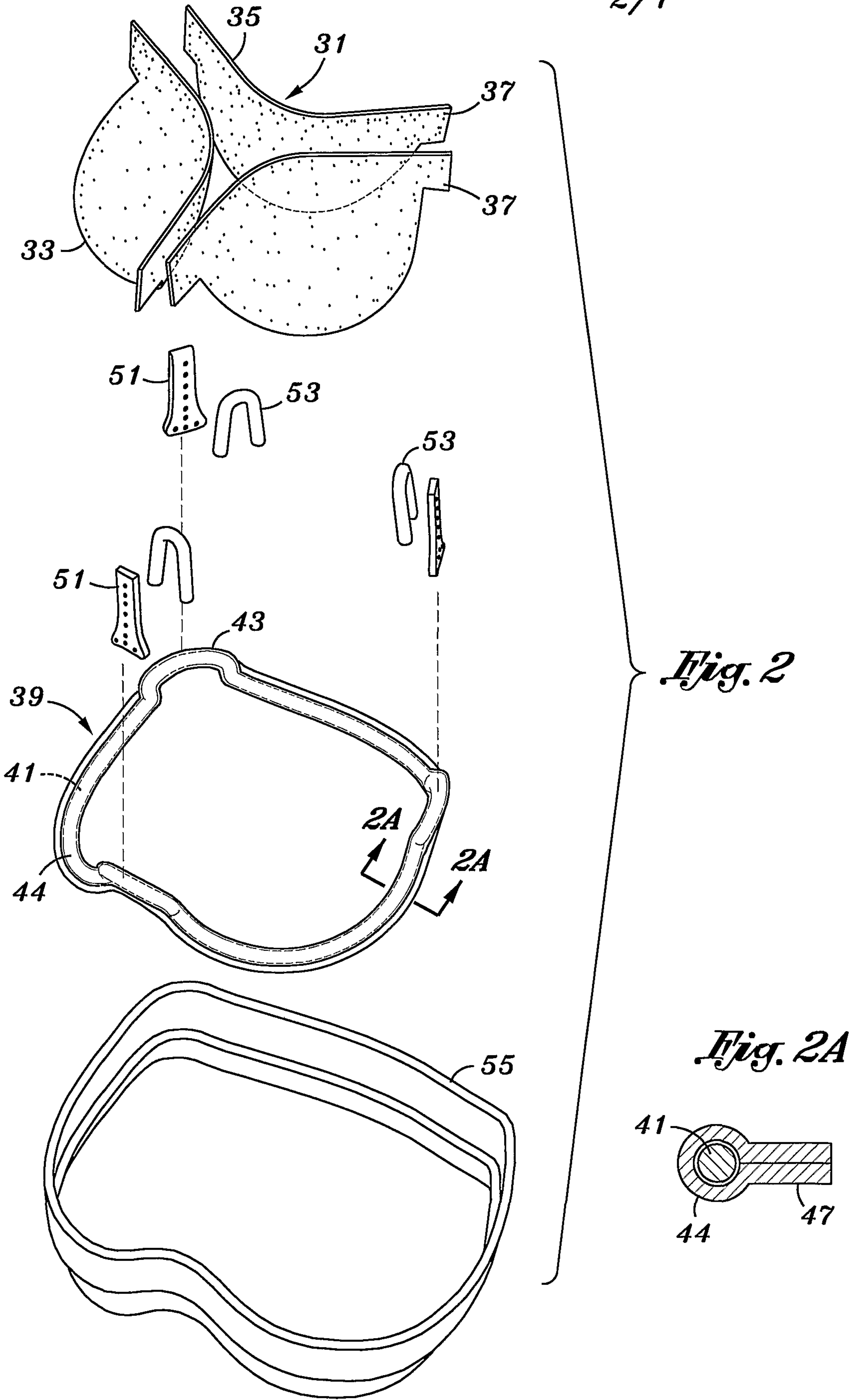
33. The heart valve of claim 30, wherein each leaflet free edge further includes a region that is above a line extending between the middle of the free edge and the side tabs so that the region is not placed in direct tension during closure of the valve.

34. The heart valve of claim 33, wherein the region is generally triangular and culminates in an apex.

35. The heart valve of claim 34, wherein a concave filet exists between the apex and the side tab.

36. The heart valve of any one of claims 17 to 29 wherein the commissure posts are each being defined by a relatively rigid insert and adjacent tabs of two leaflets attached thereto.

2/7



3/7

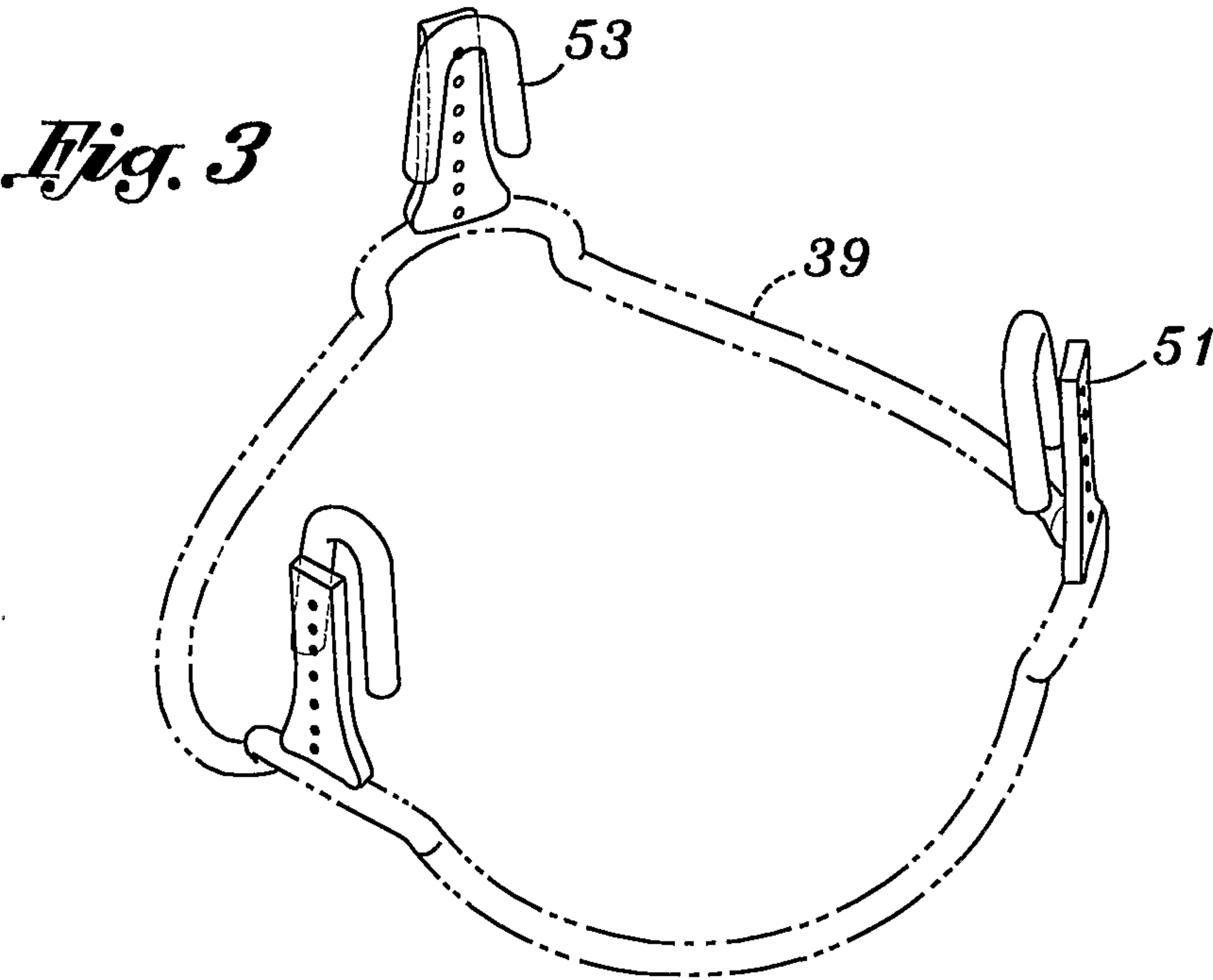


Fig. 4A

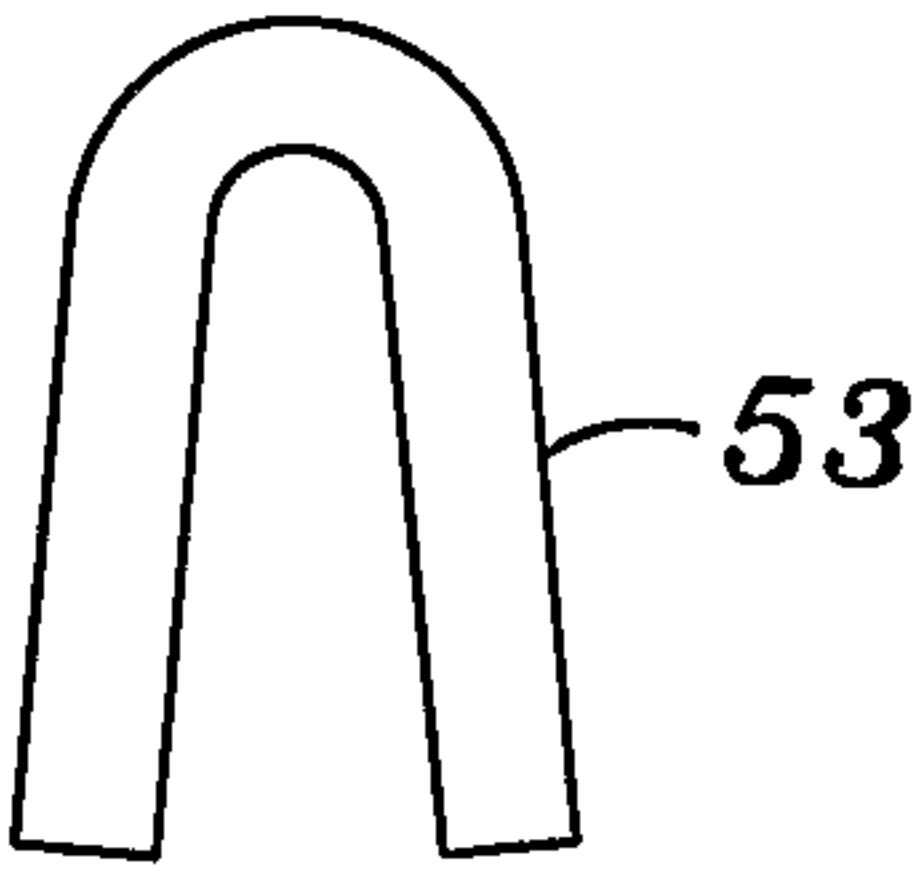


Fig. 4B

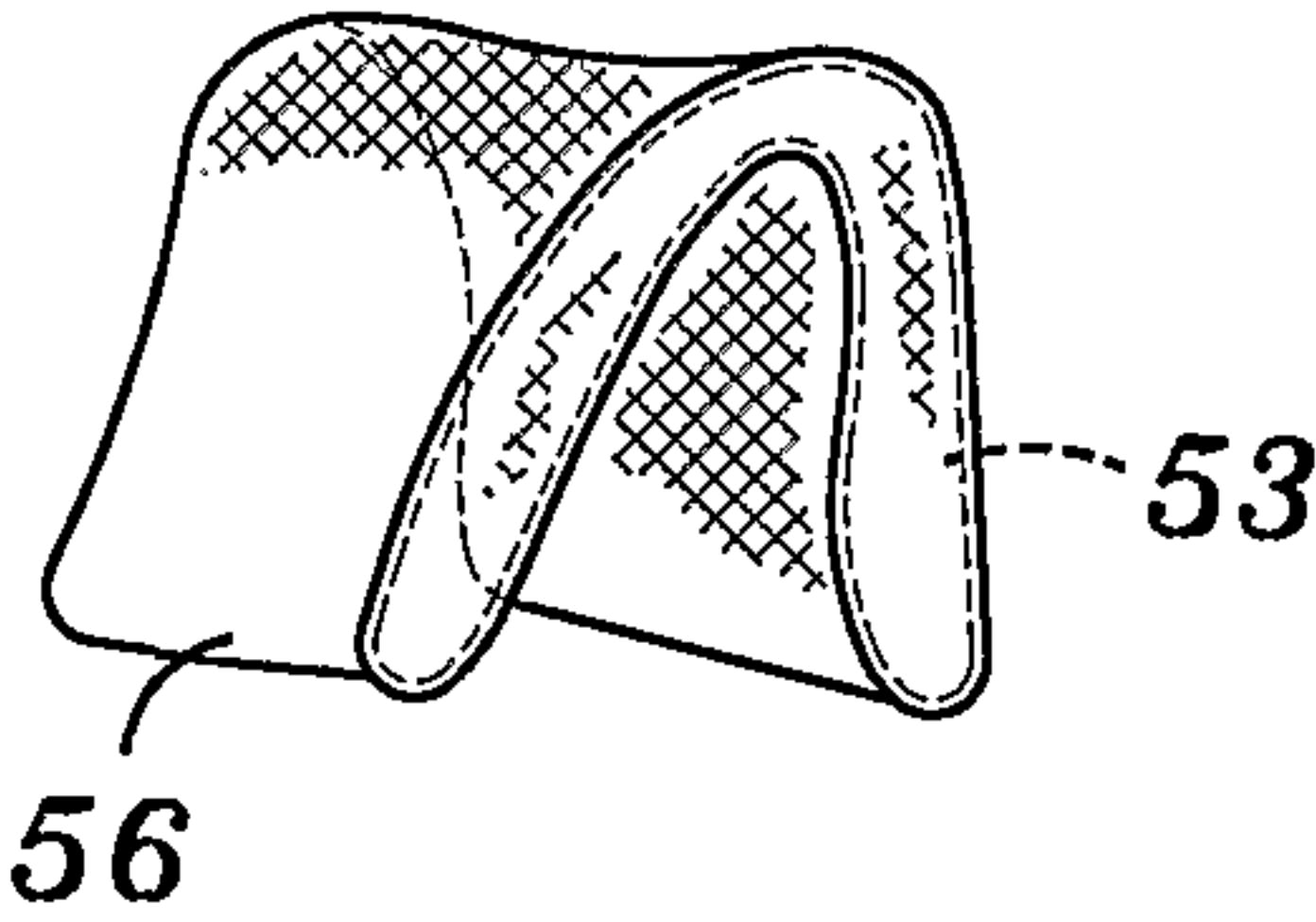


Fig. 5A

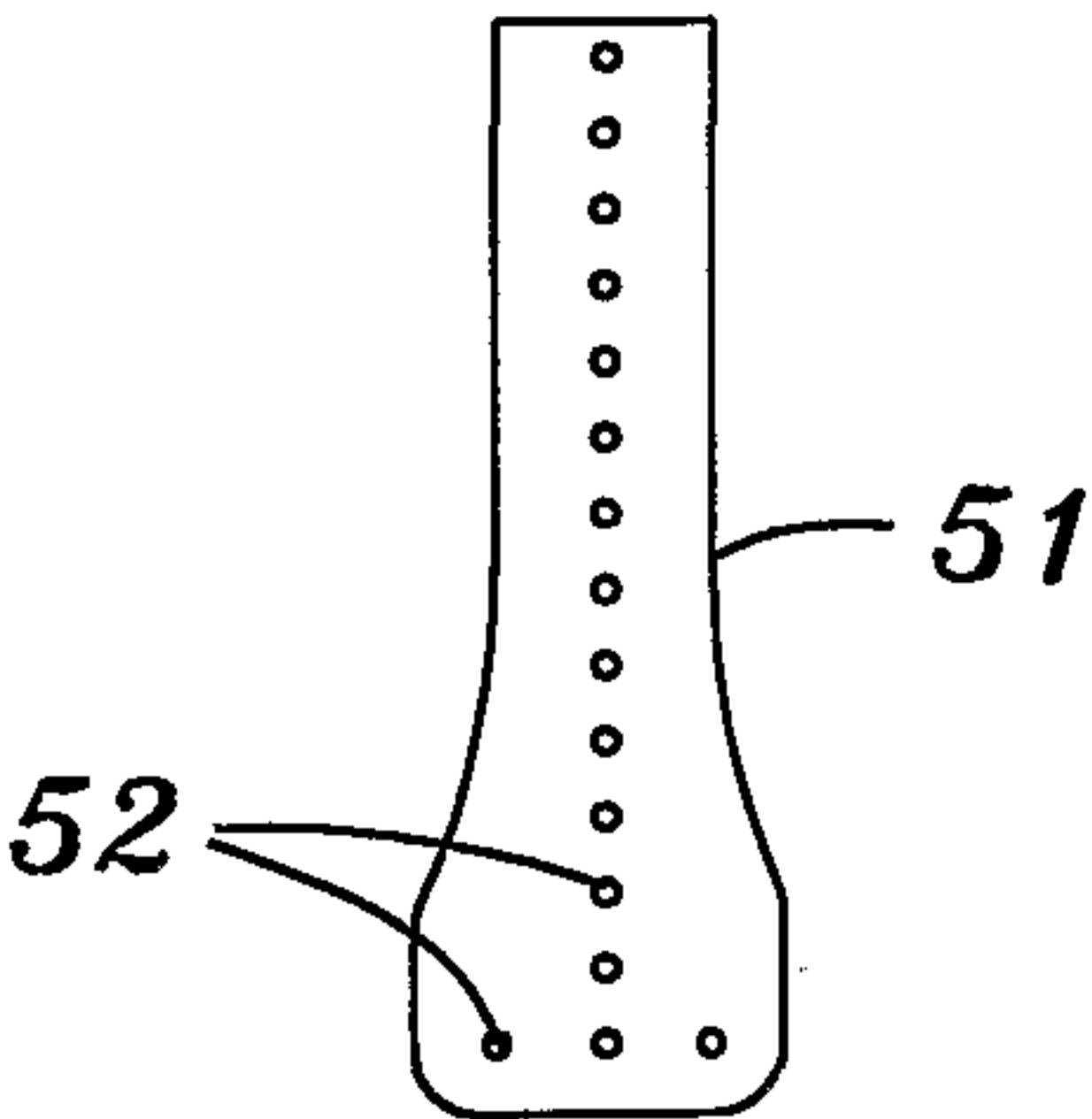
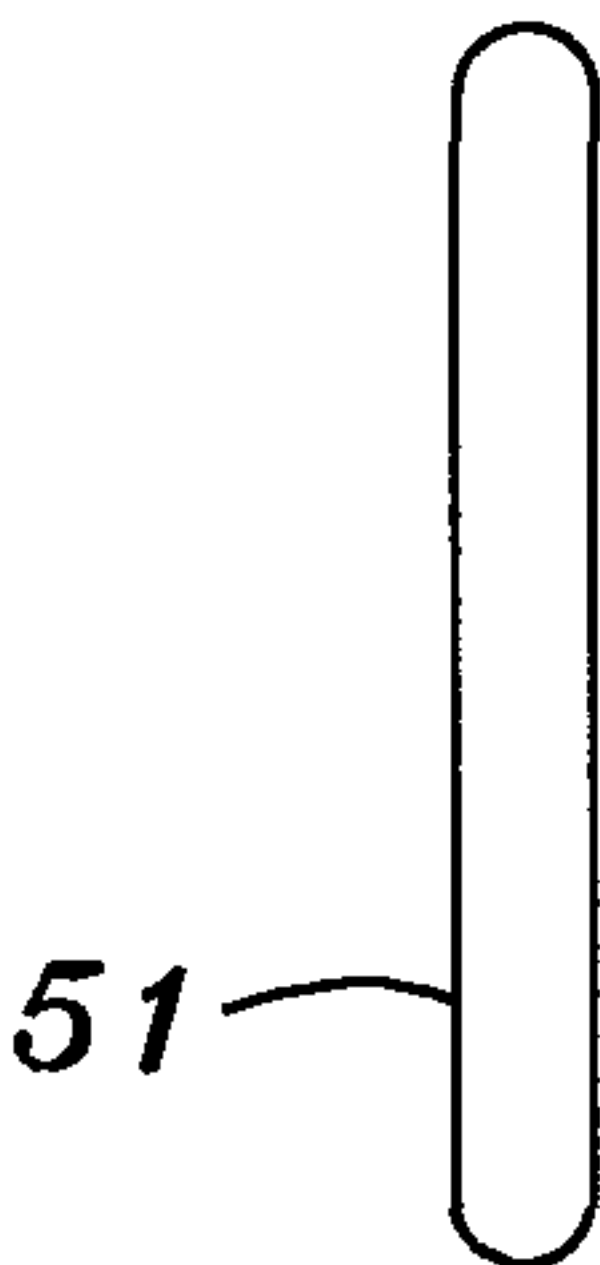


Fig. 5B



4/7

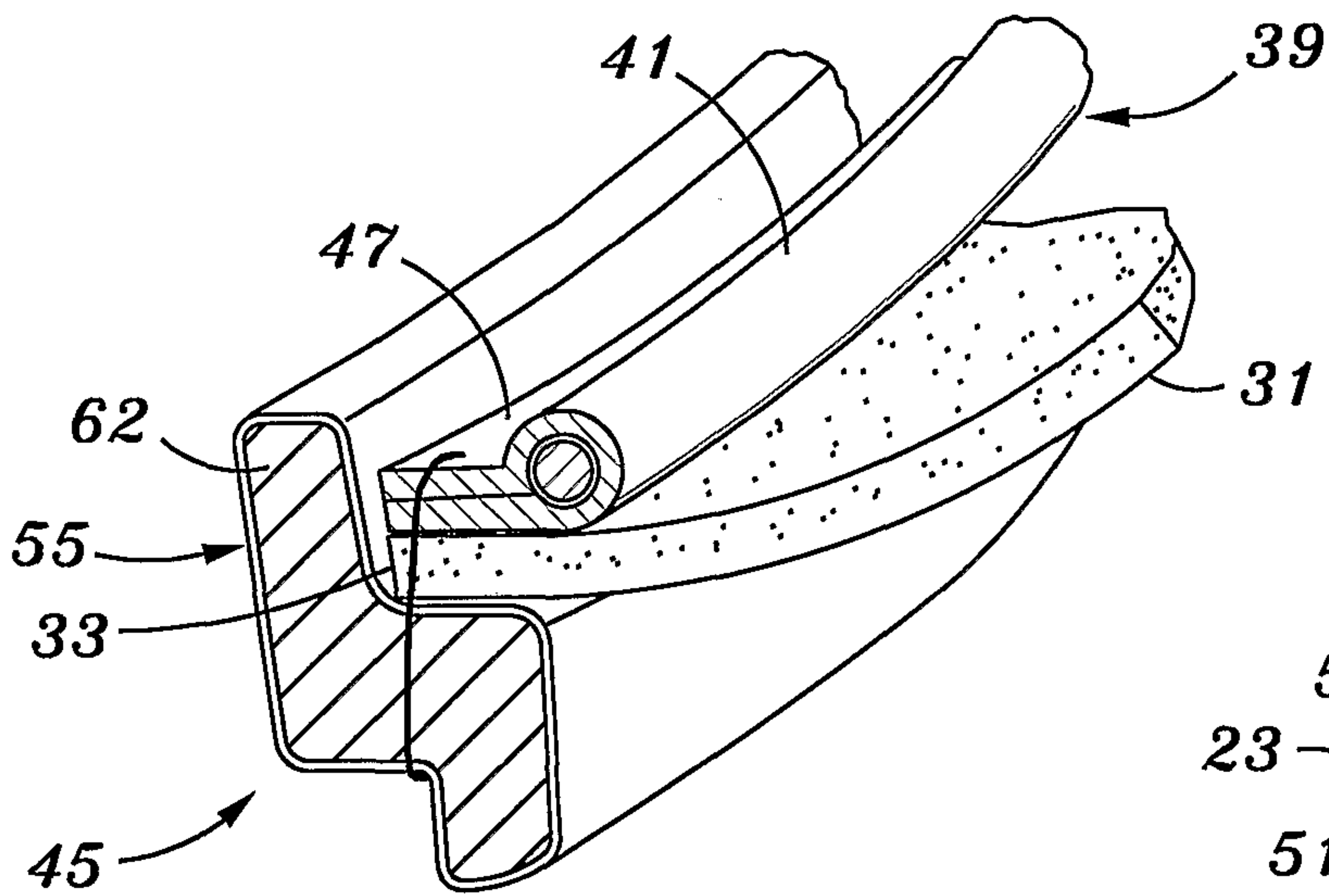


Fig. 6

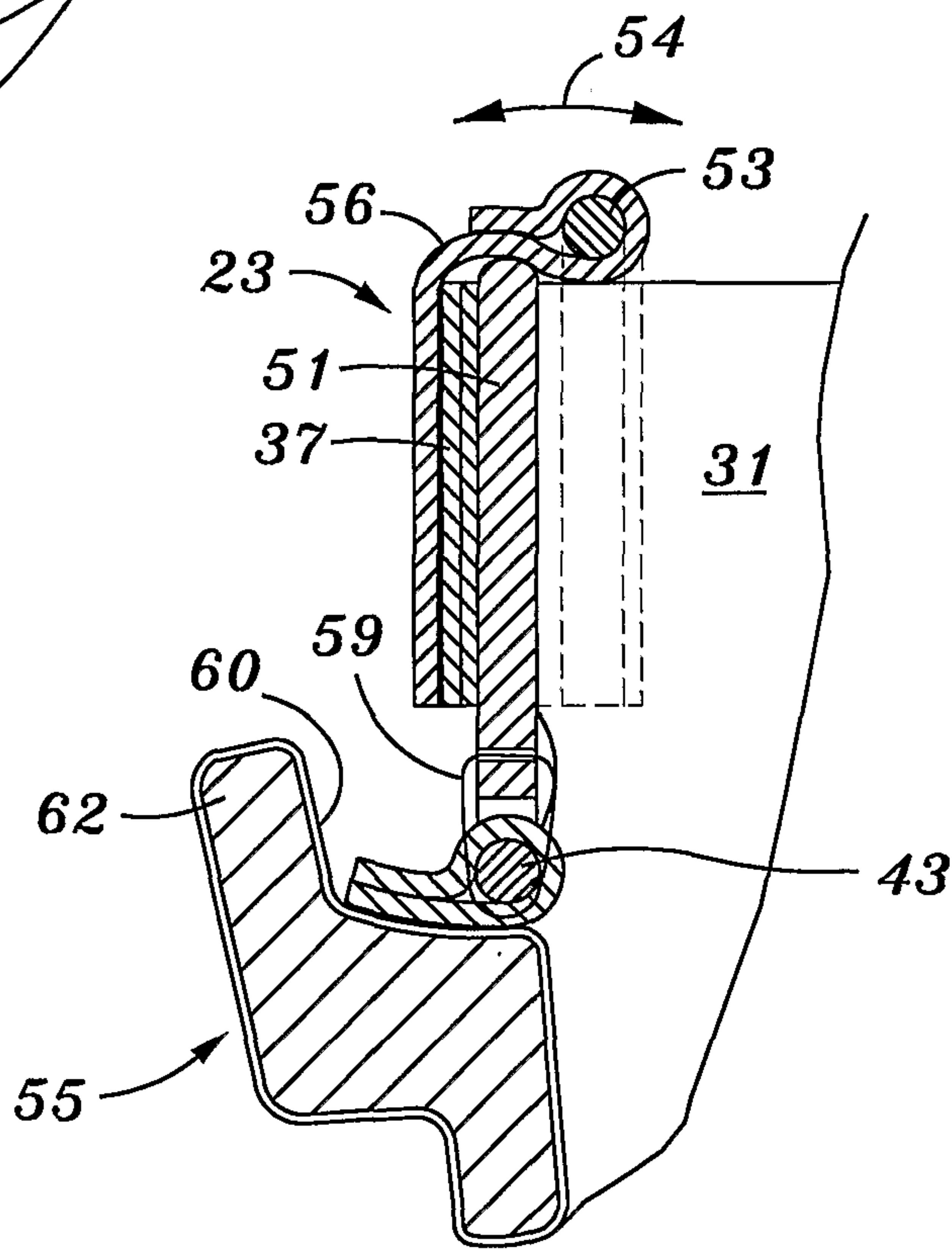


Fig. 7

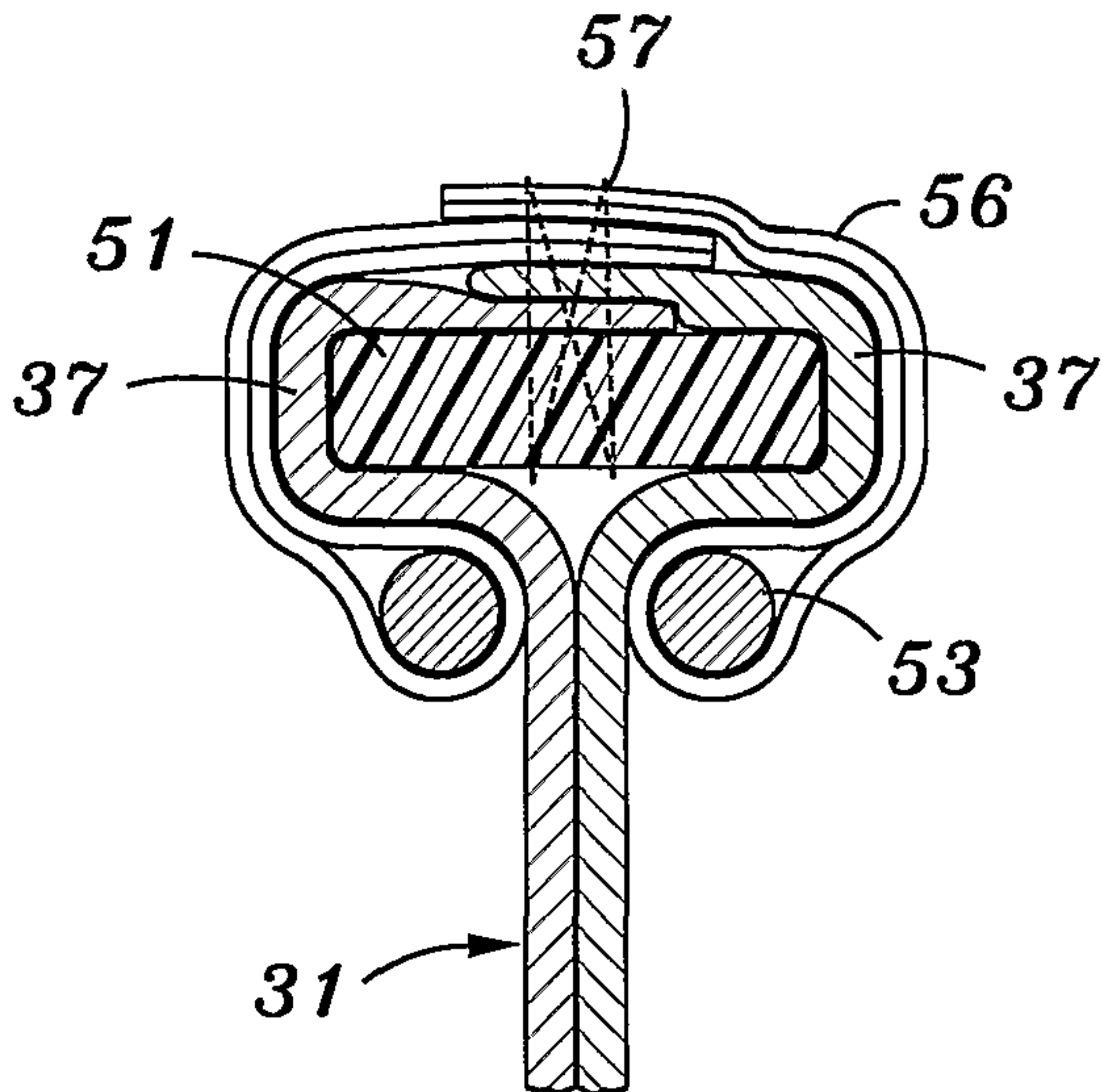


Fig. 8

5/7

Fig. 11

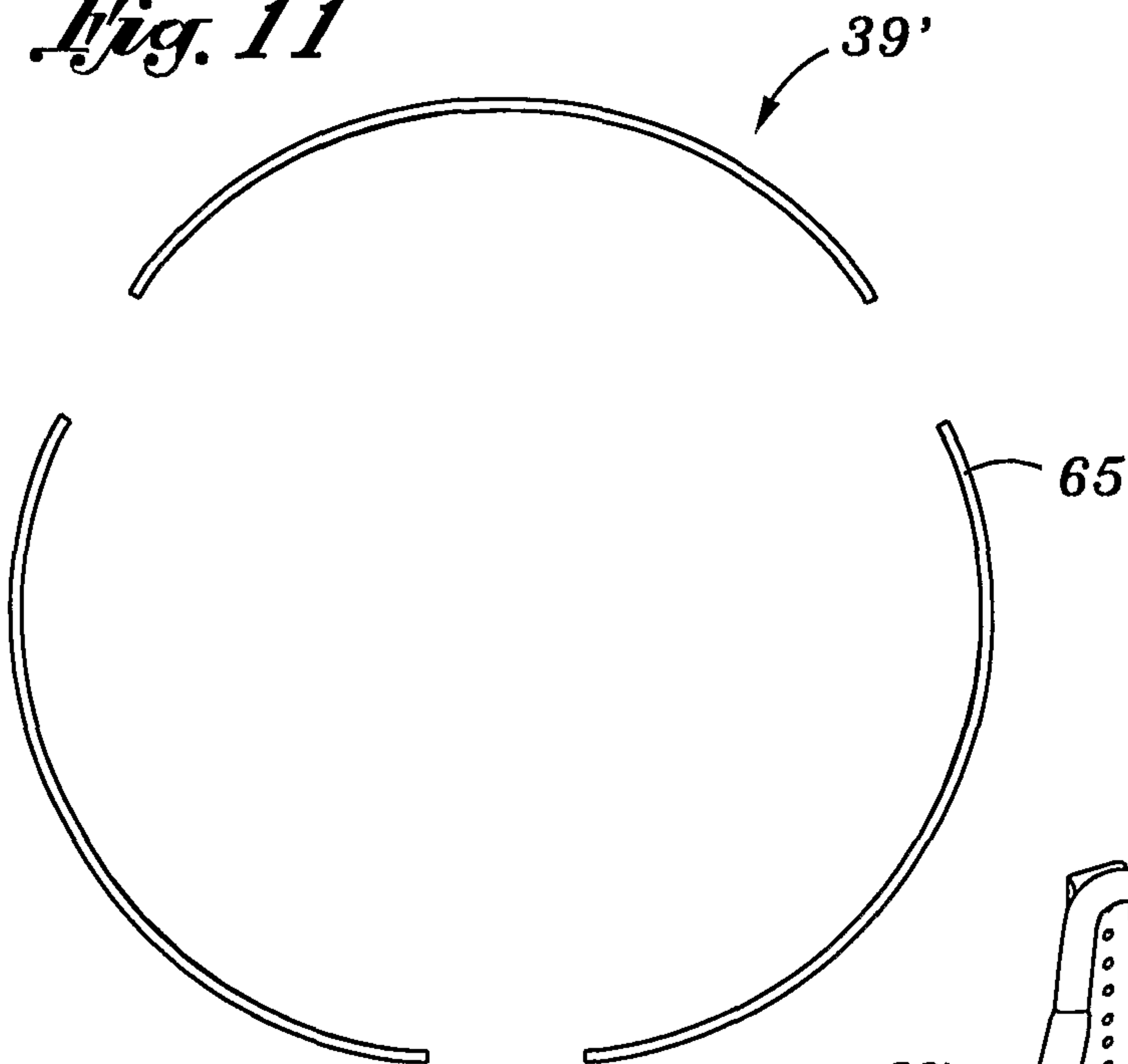


Fig. 9

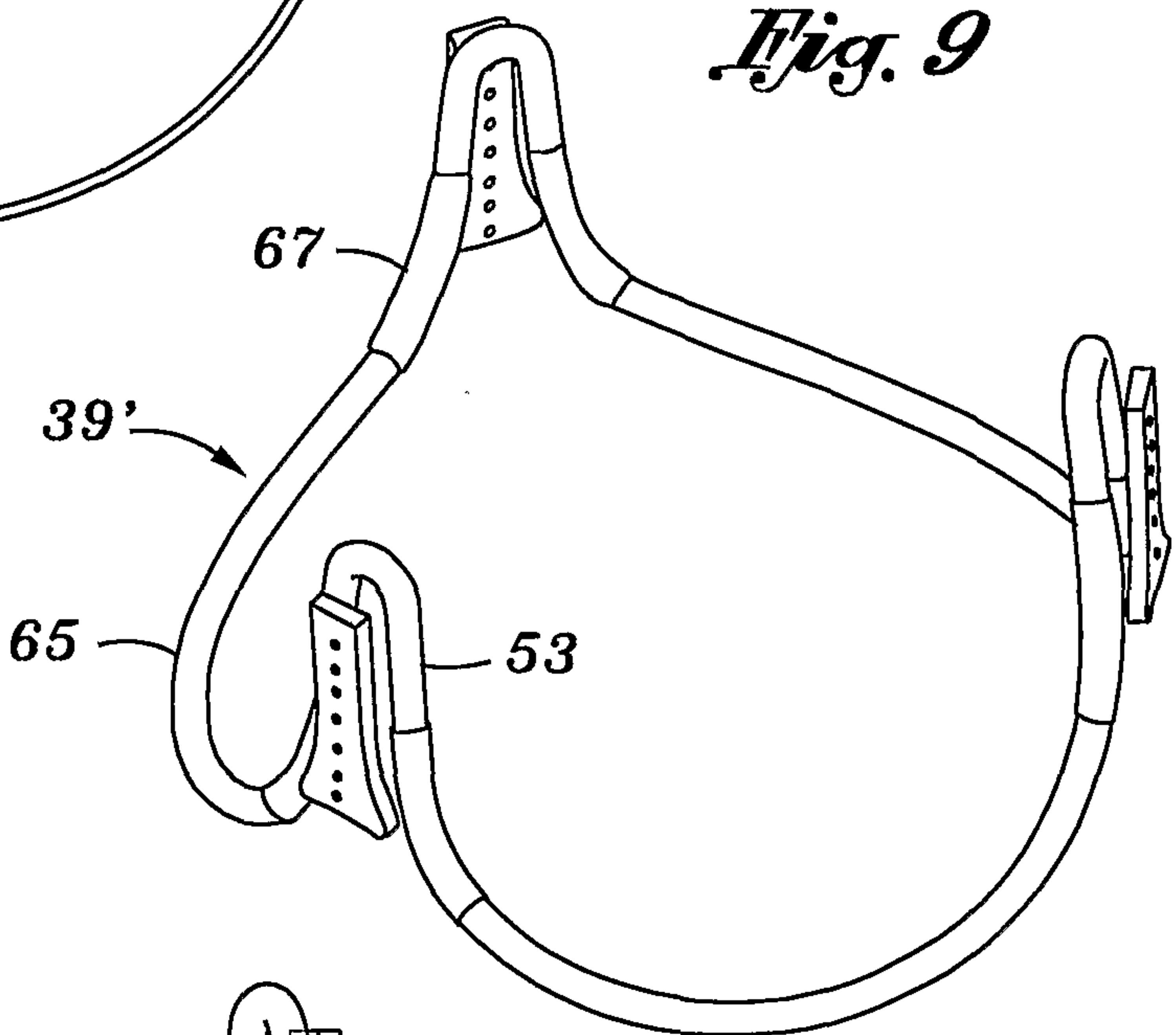
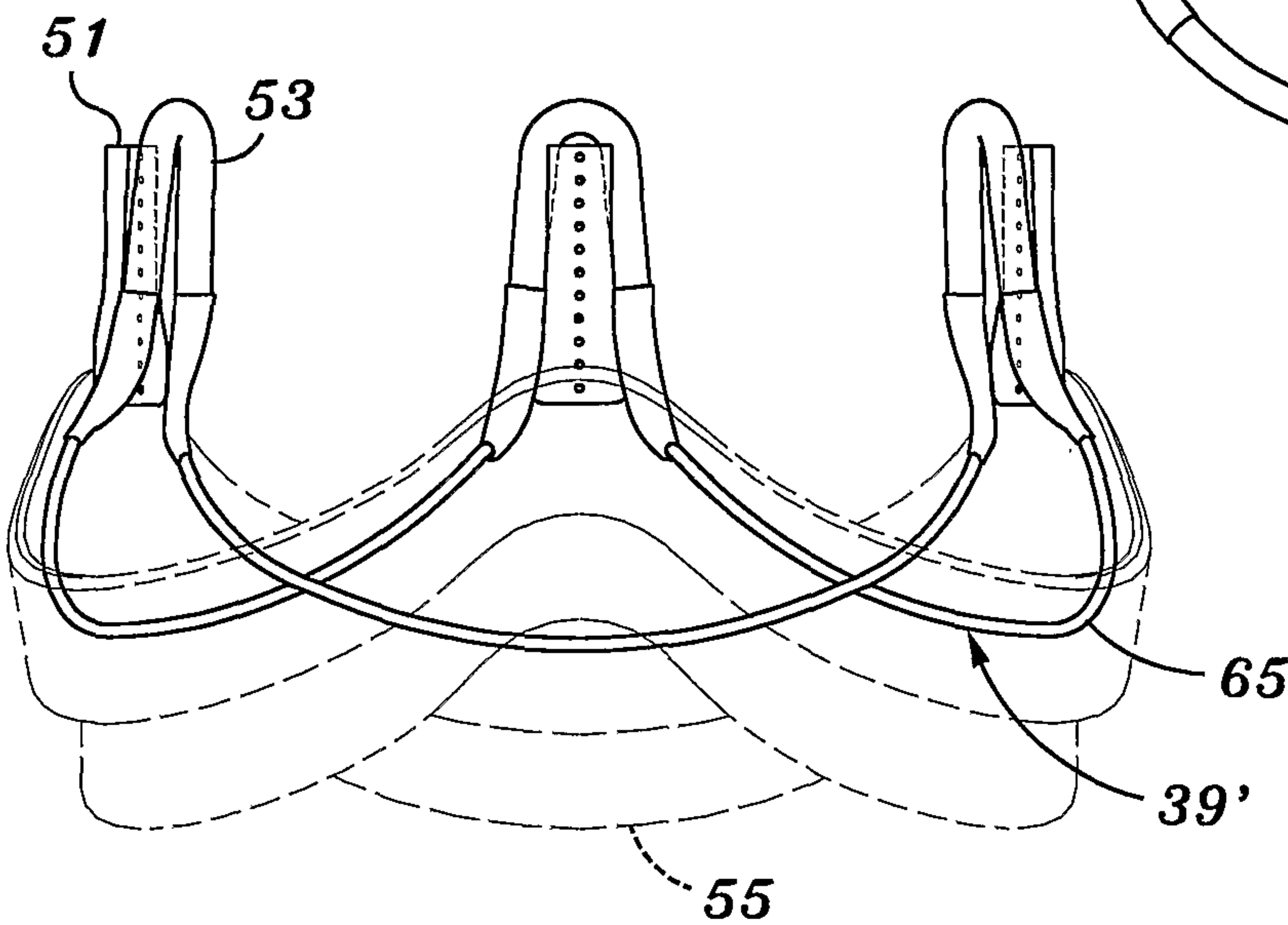


Fig. 10



6/7

Fig. 12
(PRIOR ART)

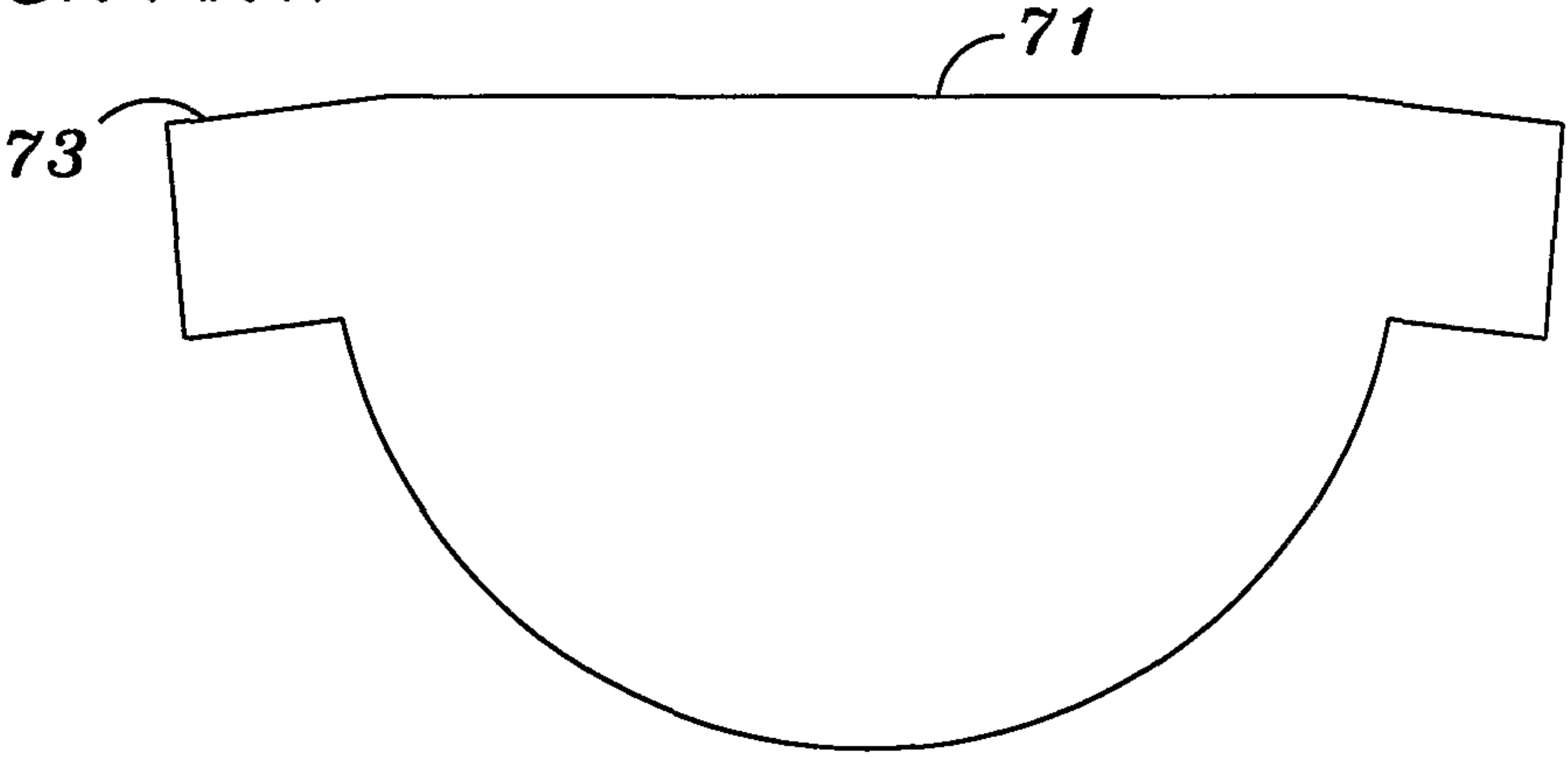


Fig. 13A

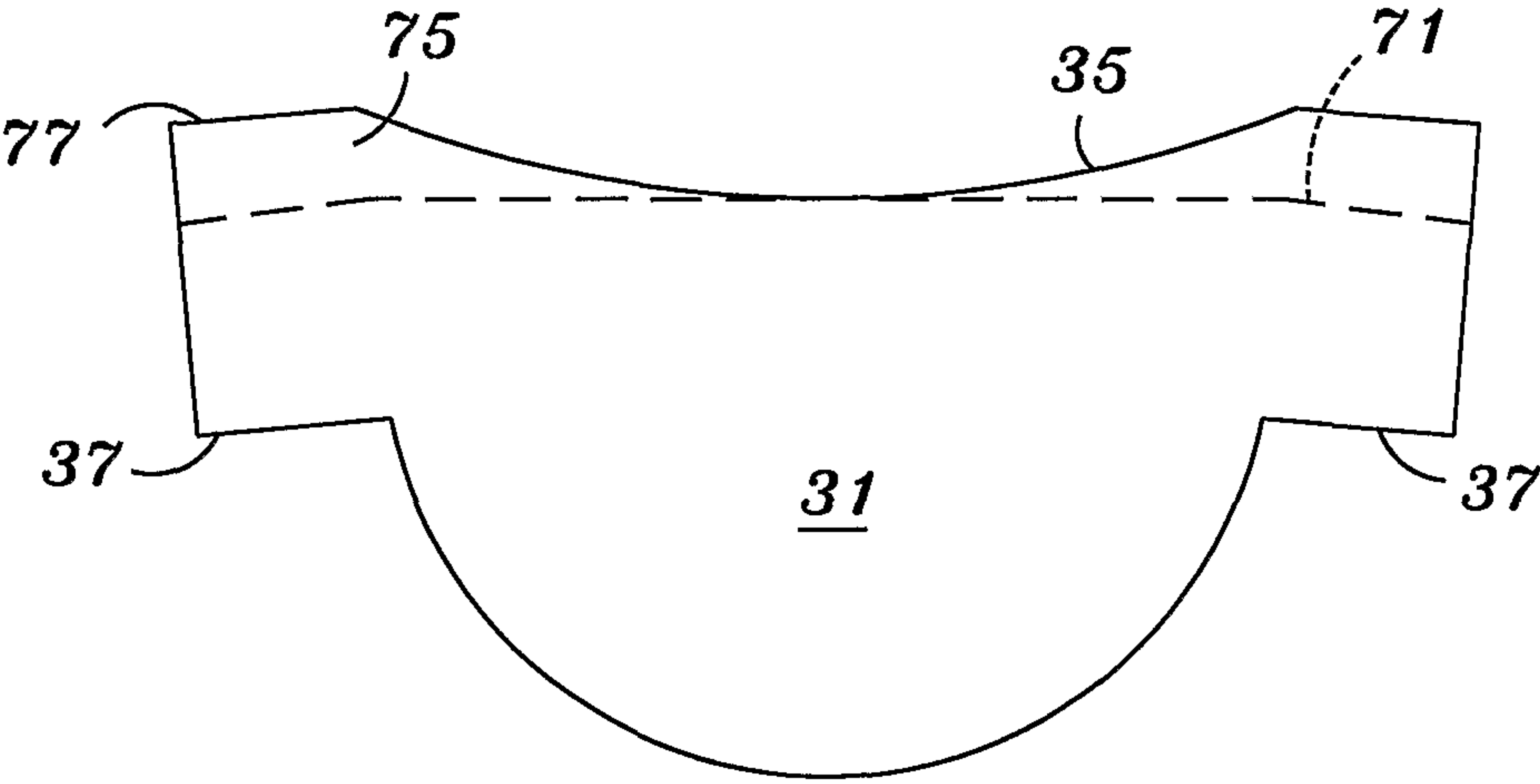
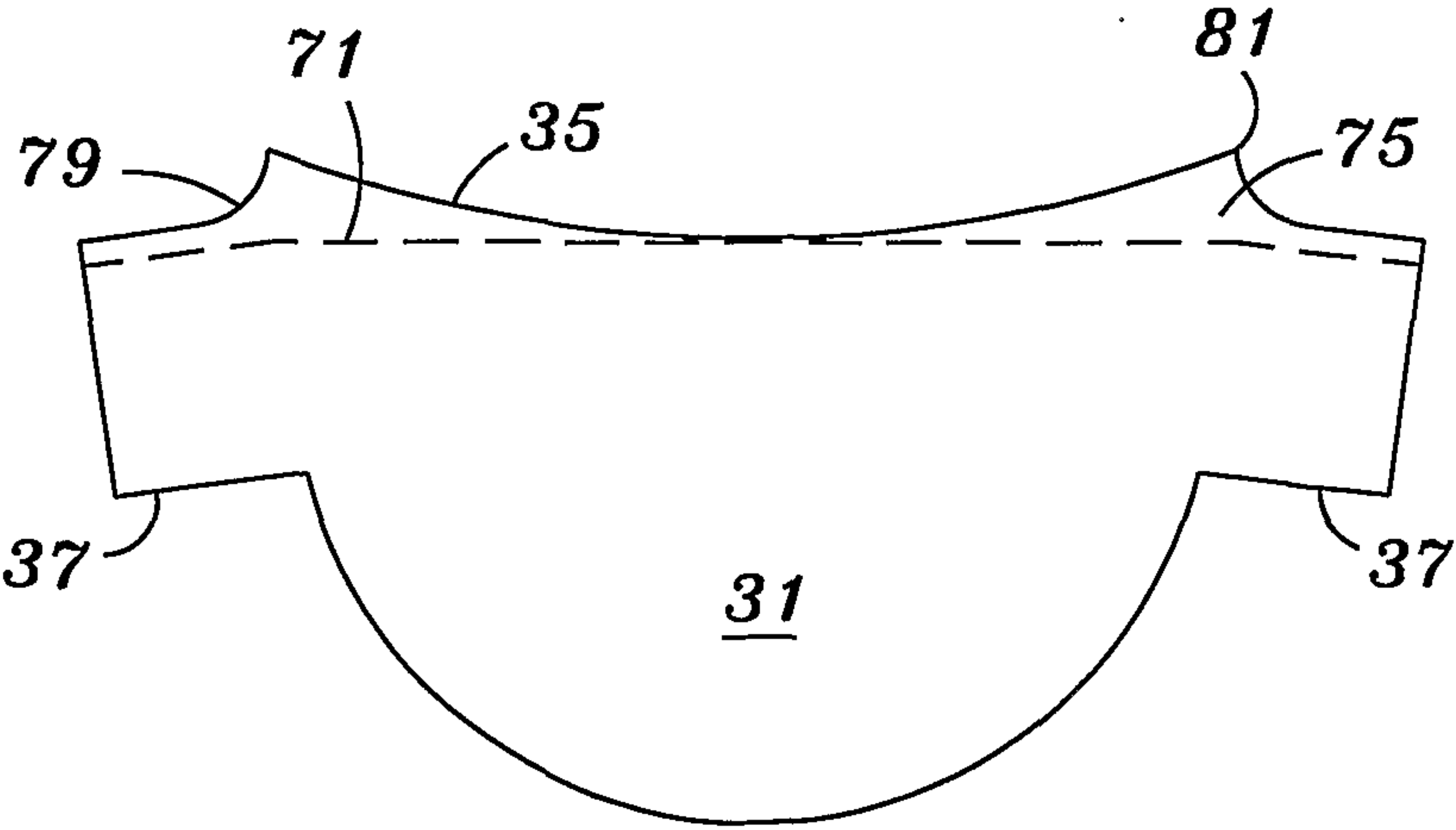


Fig. 13B



7/7

Fig. 14

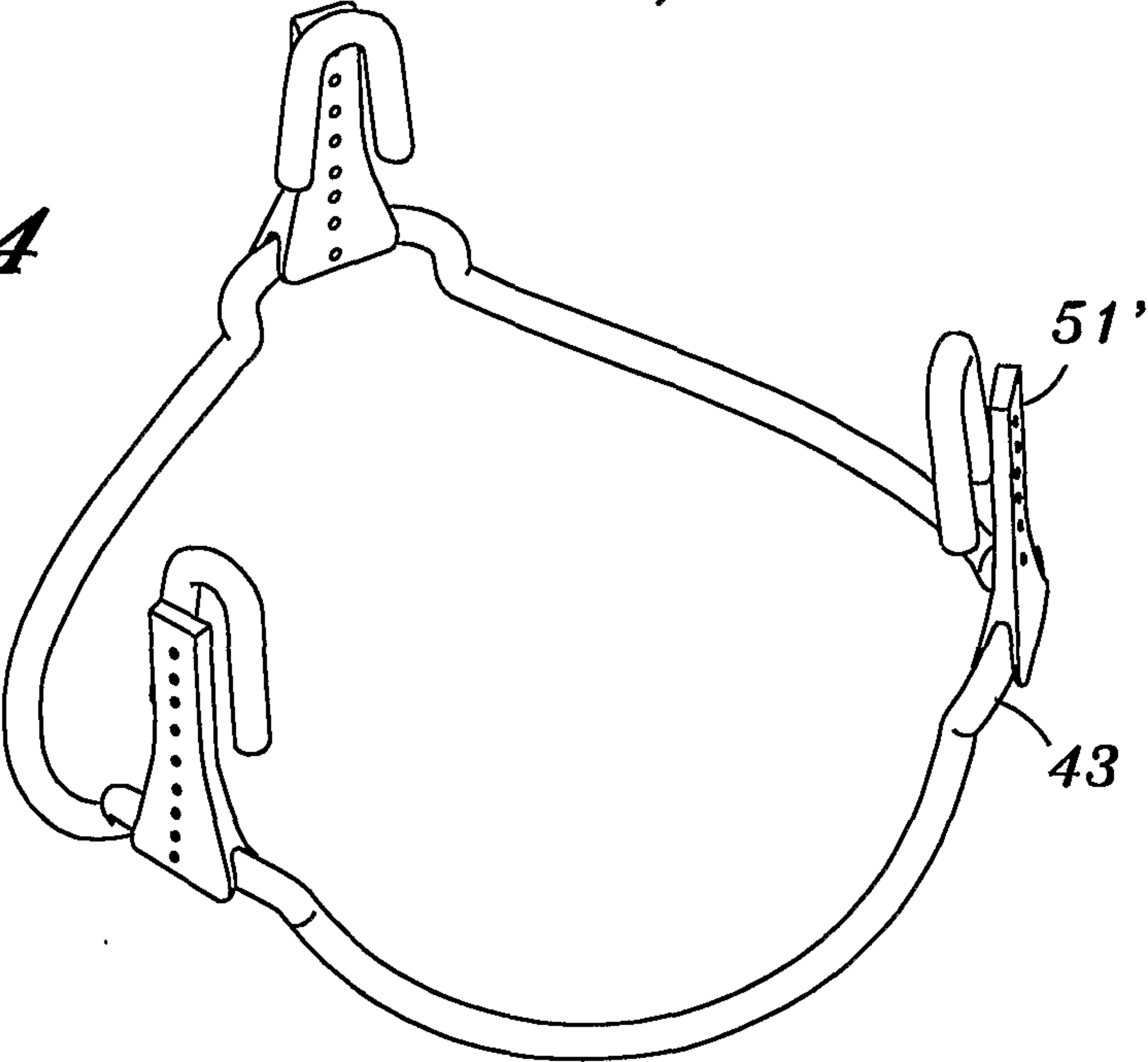


Fig. 15

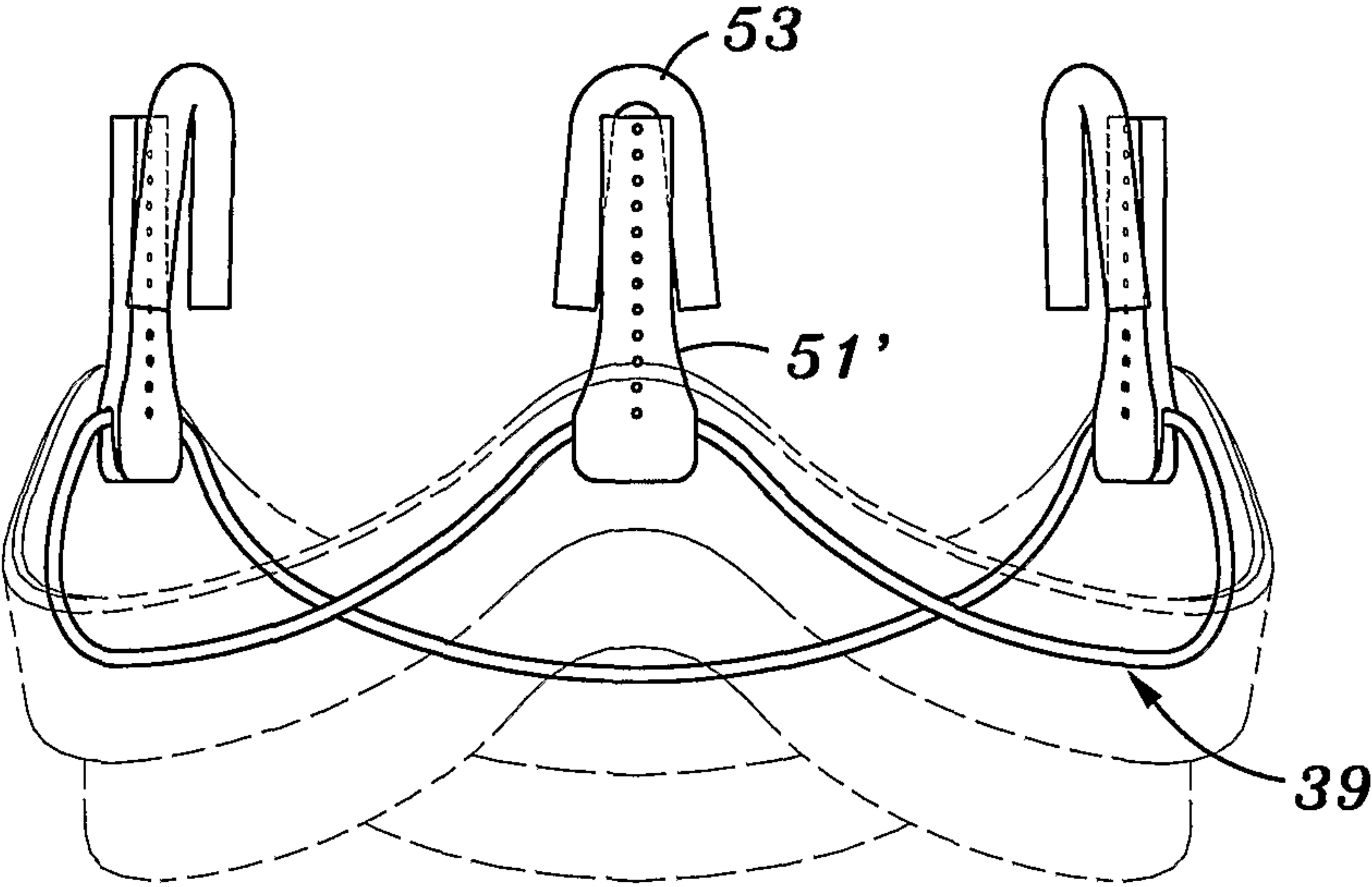


Fig. 16A

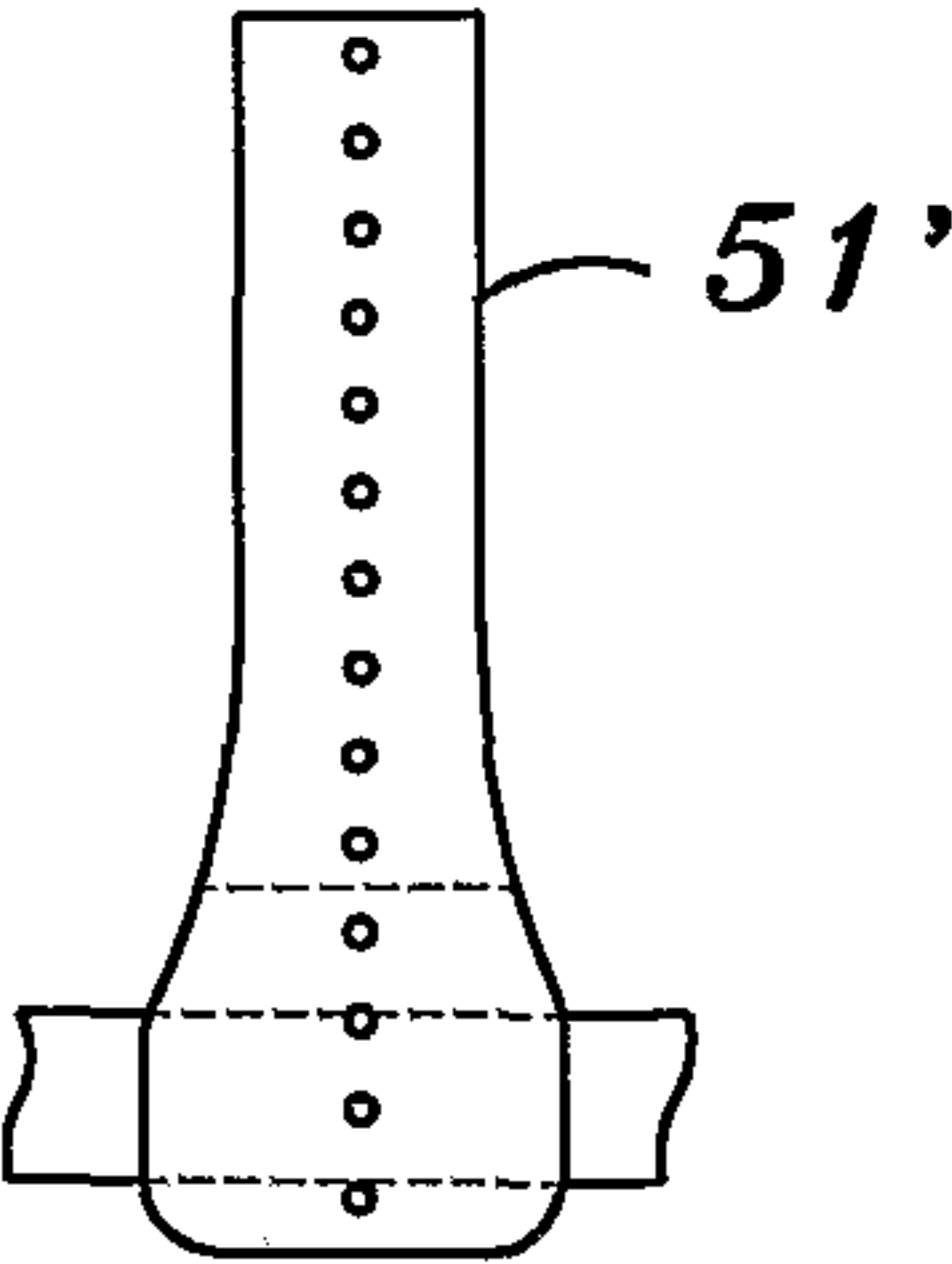


Fig. 16B

