United States Patent [19]

Ionescu et al.

[11] **4,084,268**

[45] **Apr. 18, 1978**

[54] **PROSTHETIC TISSUE HEART VALVE**

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[73] Assignee: **Shiley Laboratories, Incorporated**, Santa Ana, Calif.

[21] Appl. No.: **679,406**

[22] Filed: **Apr. 22, 1976**

[51] **Int. Cl.**[2] **A61F 1/22**

[52] **U.S. Cl.** **3/1.5**

[58] **Field of Search** 3/1.5, 1

[56] **References Cited**

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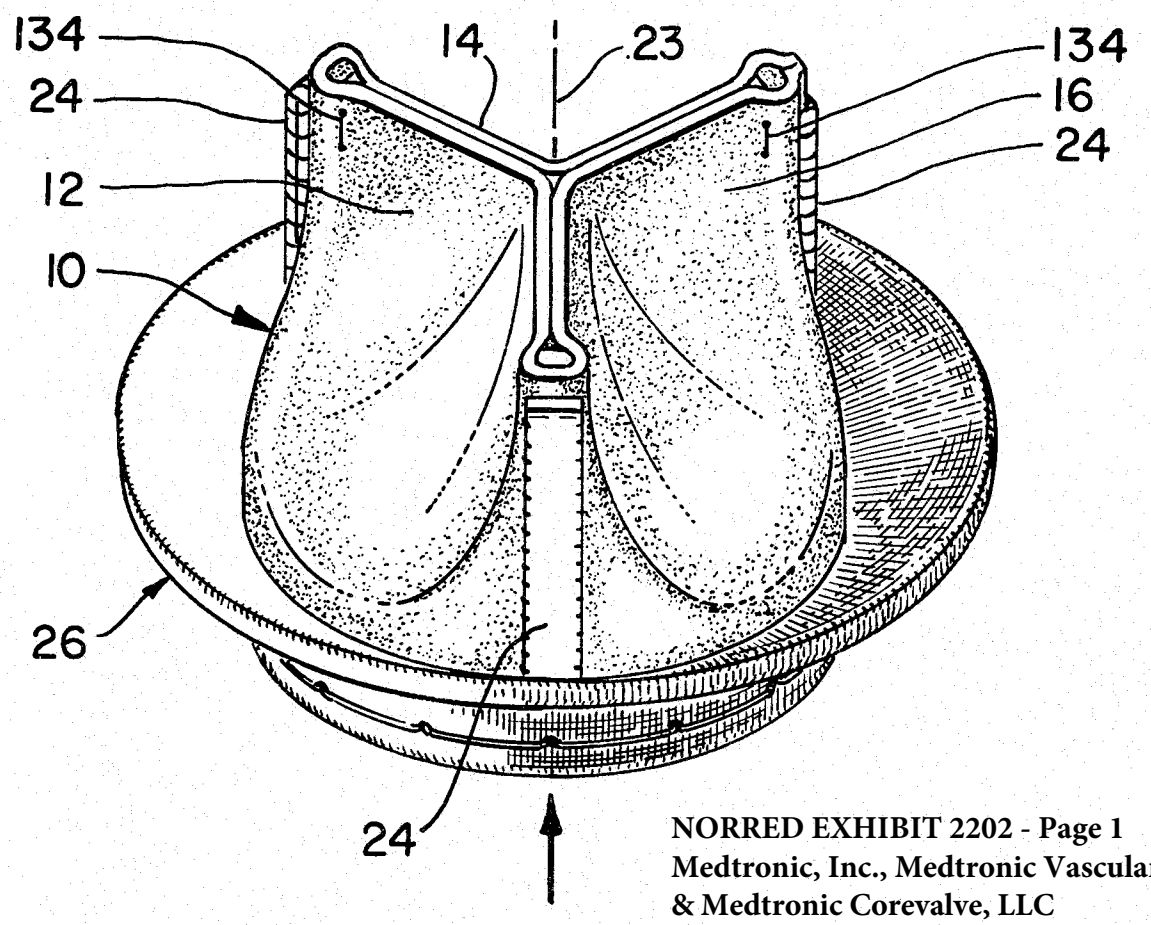
Primary Examiner—Ronald L. Frinks

Attorney, Agent, or Firm—Knobbe, Martens, Olson, Hubbard & Bear

[57] **ABSTRACT**

A tissue heart valve has a cloth-covered stent which provides several layers of padding over the stent edges and an integral sewing ring while maximizing the internal valve diameter for a given size heart annulus. No edges of the cloth are exposed. A continuation of the pledget covers all knots of the stitches connecting the tissue to the stent.

14 Claims, 9 Drawing Figures



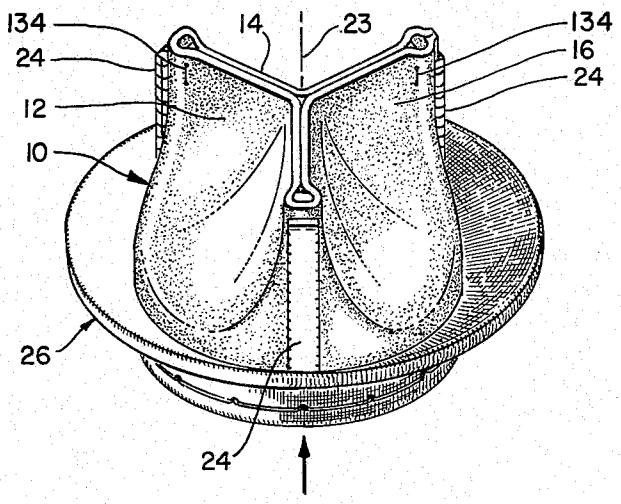


FIG. 1.

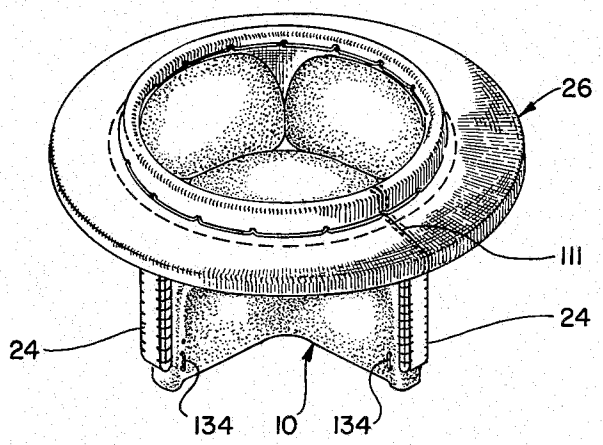


FIG. 2.

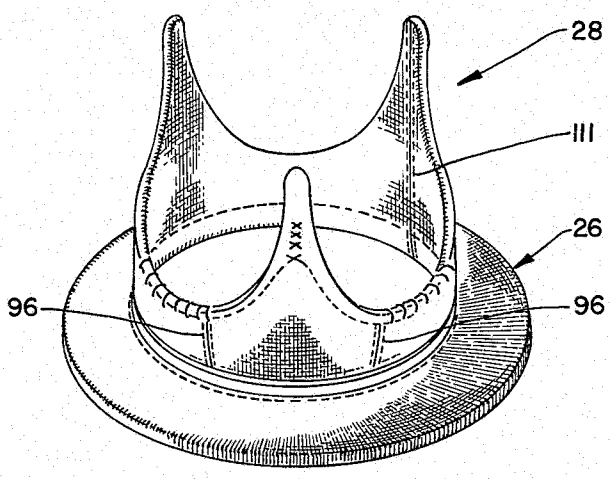


FIG. 3.

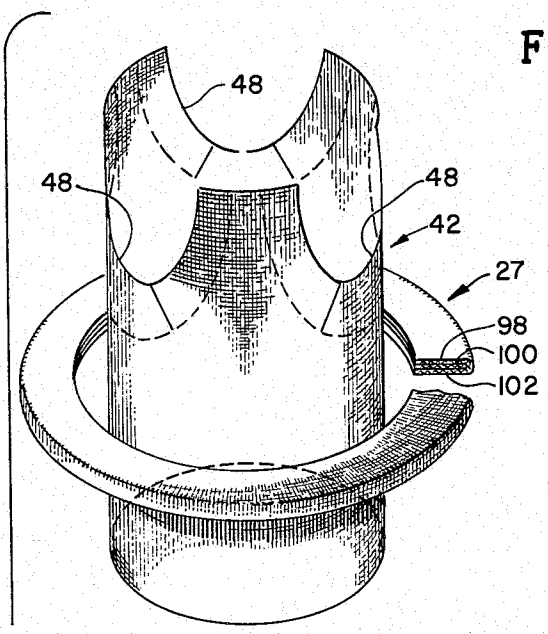


FIG. 5.

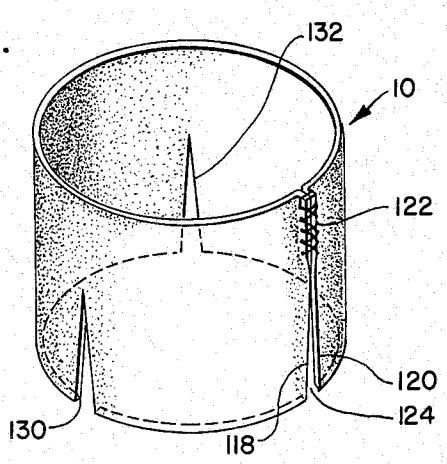
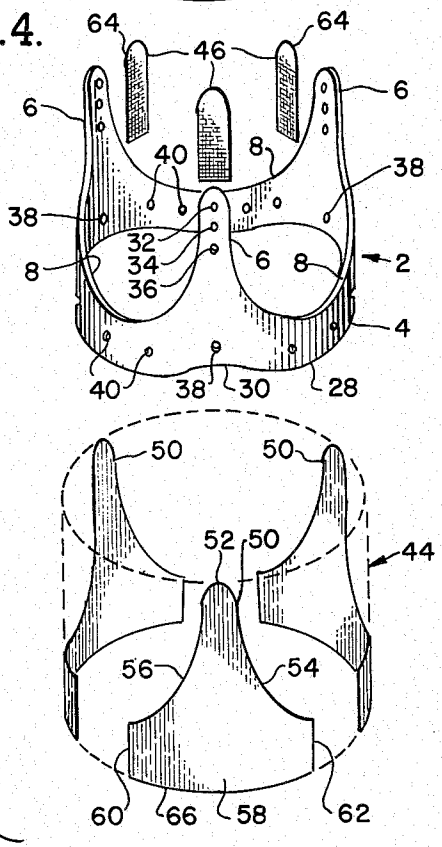


FIG. 4.



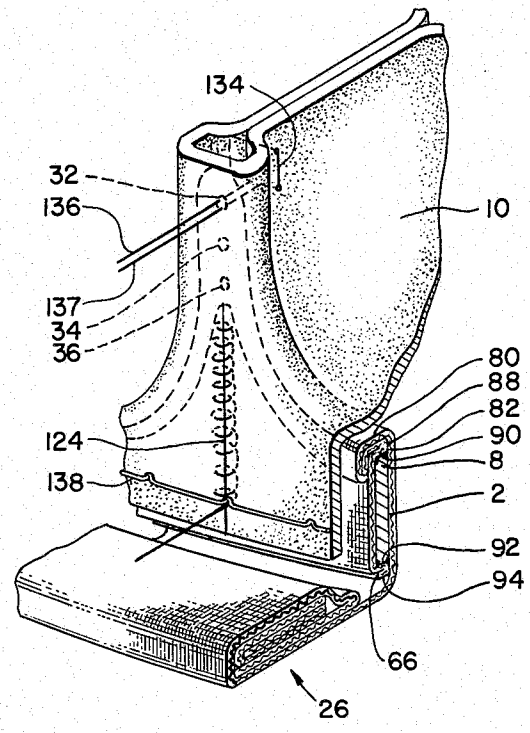


FIG. 6.

FIG. 7.

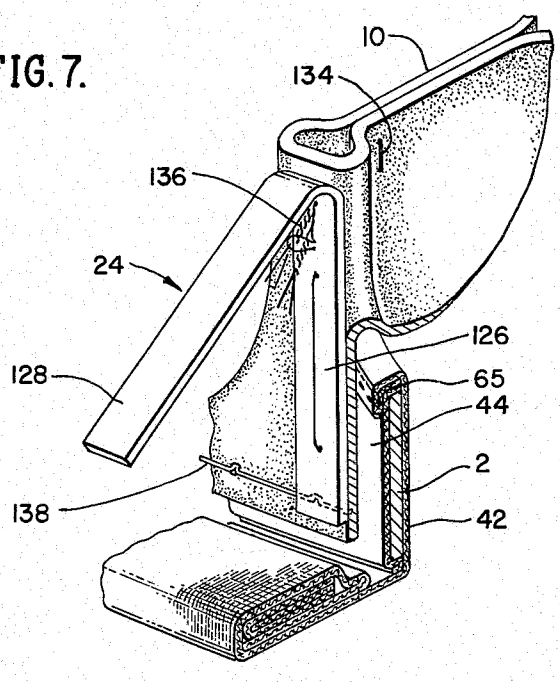


FIG. 8.

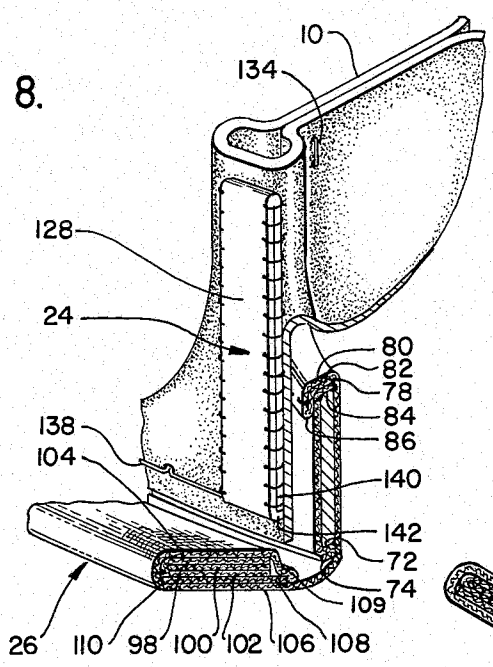
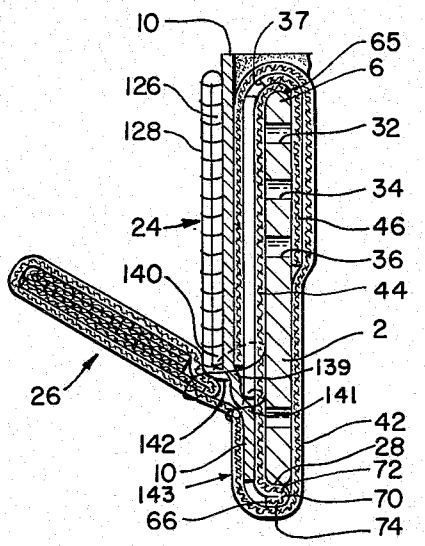


FIG. 9.



PROSTHETIC TISSUE HEART VALVE

BACKGROUND

This invention relates to frame mounted, prosthetic tissue heart valves, and particularly to improvements in the construction of such valves.

Frame-mounted fascia lata heart valves were used clinically by Dr. Marian I. Ionescu and Dr. D. N. Ross in 1969. Since that time hundreds of tissue valves made of autologous or homologous fascia lata, dura mater, or of heterologous pericardium have been implanted. A construction of bovine pericardial valves is reported in *Frame-mounted Tissue Heart Valves: Technique of Construction,* Bartels, Holden and Ionescu, Thorax (1974) 29, 51. As reported in that article, an important factor on which the long-term function of these valves depends is their construction before insertion. This invention is an improved construction over that described in the cited article.

SUMMARY OF INVENTION

This invention is directed to an improved construction principally in the cloth covering for the valve frame or stent by which raw fabric or tissue edges are not exposed to the blood stream, particularly at the valve inlet, added protection is obtained against the frame or stitches tearing through the covering cloth, risk of the sewing ring separating from the valve is eliminated, the stitches attaching the tissue to the stent are covered by cloth, and the thickness of material at the annulus is reduced to increase the ratio of valve internal diameter to external valve diameter, and therefore to internal diameter of the heart annulus receiving the valve.

Accordingly, this invention provides a prosthetic tissue heart valve in which a continuation of the pledget covers the knots of the threads used to stitch the tissue to the stent. This invention also provides a construction wherein the interior fabric cover is integral with the sewing ring or cuff. Further in accordance with this invention several layers of padding are provided along the edges of the stent where tearing is most likely and cushioning is desirable, yet only three layers of cloth add to the thickness of the stent at the bottom portion which fits in the heart annulus. Moreover, this invention provides a novel construction wherein no edges of the cloth fabric covering the stent are exposed to the bloodstream.

DESCRIPTION OF DRAWINGS

FIG. **1** is a perspective view of a completed valve;

FIG. **2** is a perspective view of the same completed valve inverted;

FIG. **3** is a perspective view of the stent covered with cloth and ready to receive the tissue, with the sewing ring turned down to show certain construction details;

FIG. **4** is an exploded perspective view of the elements used in constructing the cloth covered stent;

FIG. **5** is a perspective view of the tissue ready to be placed on the cloth covered stent of FIG. **3**;

FIG. **6** is a perspective view, partially in section, of the valve with portions removed;

FIG. **7** is a perspective view, partially in section, of a portion of a partially assembled valve;

FIG. **8** is a perspective view, partially in section, of a portion of a partially completed valve; and

FIG. **9** is a sectional view, through the valve at a post of a completed valve.

Referring to FIG. **4**, the valve includes a thin-walled stent **2** having an annular base **4** and three equally spaced upright posts **6** with scalloped upper edges **8** on the stent between posts **6**. Throughout this application the term upper will be used for convenience to refer to the outflow end of the valve and lower will be used to refer to the inflow side, recognizing that the valve may not be upright where installed. Also, the term upper edge of the stent is used to include the side edges of the posts **6**. Referring now to FIG. **1** the stent supports a tissue valve element **10** which surrounds the stent and has three cusps **12**, **14**, and **16** meeting along their upper edge portions in the closed position. The cusps are free to separate when the pressure below the valve exceeds that above to pass blood through the valve in a known manner. The flow of blood is from bottom to top in FIG. **1** along the axis **23** of the valve. Applicants refer to the article cited above in the application for a more complete description of the tissue and its assembly and operation.

A pledget and cover **24** extends down the outside of the tissue at each post, and a sewing ring or cuff **26** is provided for grafting the prosthetic valve into the heart valve annulus using well known surgical procedures.

Referring again to FIG. **4**, the stent may be constructed of any of the known materials, suitable for cloth covered prosthetic heart valves, titanium or nickel-cobalt alloy or Teflon or Delvon plastic being among the alternatives available. Its bottom edge **28** preferably is slightly scalloped having its high points **30** beneath the posts **6**. Each post **6** has sewing holes, **32**, **34**, and **36** three in the illustrated embodiment, spaced vertically near its upper end. Additional sewing holes **38**, and **40** are spaced around the circumference of the base. In the illustrated embodiment the base **4** has one sewing hole **38** at the base of each post and five **40** between adjacent posts, but that number can be varied, as can the number on the posts.

The cloth covering preferably is of Dacron velour and includes an inner sleeve **42**, a three piece outer sleeve **44**, and three interior post sewing pads **46**. The inner sleeve originally is of a cylindrical shape with scallops **48** removed as shown in FIG. **4**, corresponding generally with the scallops **8** on the upper edge of the stent. The outside diameter of the inner sleeve is about the same as the inside diameter of the stent base **4**. The outer sleeve pieces **44** can advantageously be cut from a cylinder of cloth to the shape shown, such that each has a post portion **50** with a rounded top **52** and two scalloped side edges **54**, **56** and a base portion **58** with straight side edges **60**, **62**. The interior post pads **46** are each a short length of fabric of the same width as the posts **6** and having a rounded top **64**.

Referring to FIGS. **8** and **9**, three outer sleeve pieces **44** are each located on the outside of a respective stent post **6** and folded over the scalloped edges **8** and top of the stent post terminating at **78** flush with the inside surface of the stent. The three outer cloth pieces **44** do not cover the outside of the stent base **4** between the regions of the posts **6** as is evident from the spaces shown in FIG. **4**, but extend to the seams **96** shown in FIG. **3**. As best shown in FIG. **9**, the bottom edge **66** of each outer sleeve piece is folded over the bottom edge **28** of the stent and then folded back at **70** to form a two layer **72**, **74** pad at the bottom edge **28** and terminates at **66** about flush with the outer surface of the stent.

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