United States Patent [19]

Fenton, Jr.

[11] **Patent Number: 6,059,827**

[45] **Date of Patent: May 9, 2000**

[54] **SUTURELESS CARDIAC VALVE PROSTHESIS, AND DEVICES AND METHODS FOR IMPLANTING THEM**

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[21] Appl. No.: **09/072,524**

[22] Filed: **May 4, 1998**

[51] **Int. Cl.**^{7} **A61F 2/24**; A61F 2/02

[52] **U.S. Cl.** **623/2**; 623/900

[58] **Field of Search** 623/2, 11, 900, 623/66, 1

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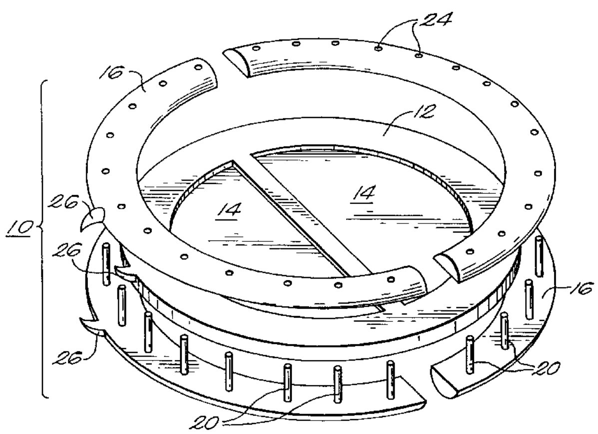
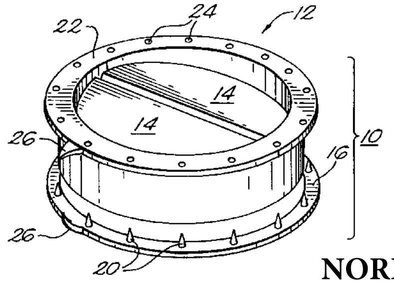
Primary Examiner—David H. Willse
Assistant Examiner—Choon P. Koh
Attorney, Agent, or Firm—McDermott, Will & Emery

[57] **ABSTRACT**

A prosthetic cardiac valve assembly for sutureless implantation in a patient. The assembly includes a generally disk-shaped valve annulus element and one or more generally disk-shaped retainer elements. The elements are adapted for mutual engagement and for engagement with a host tissue region so as to fix a portion of the host tissue between them in a sutureless bond. Ultrasonic or thermal energy is applied to one or more of the elements to bond them together. Either the valve annulus element or the retainer element includes a plurality of projections, and the corresponding element includes a corresponding plurality of apertures for receiving the projections, thus providing for mutual physical engagement. The valve annulus element can include a plurality of valve leaflets which open and close in response to fluid pressure differentials across them. Various insertion devices for the assembly are designed to facilitate insertion of the elements in the heart through a relatively small incision. The elements can be implanted, assembled and bonded together in situ around the host tissue.

15 Claims, 3 Drawing Sheets





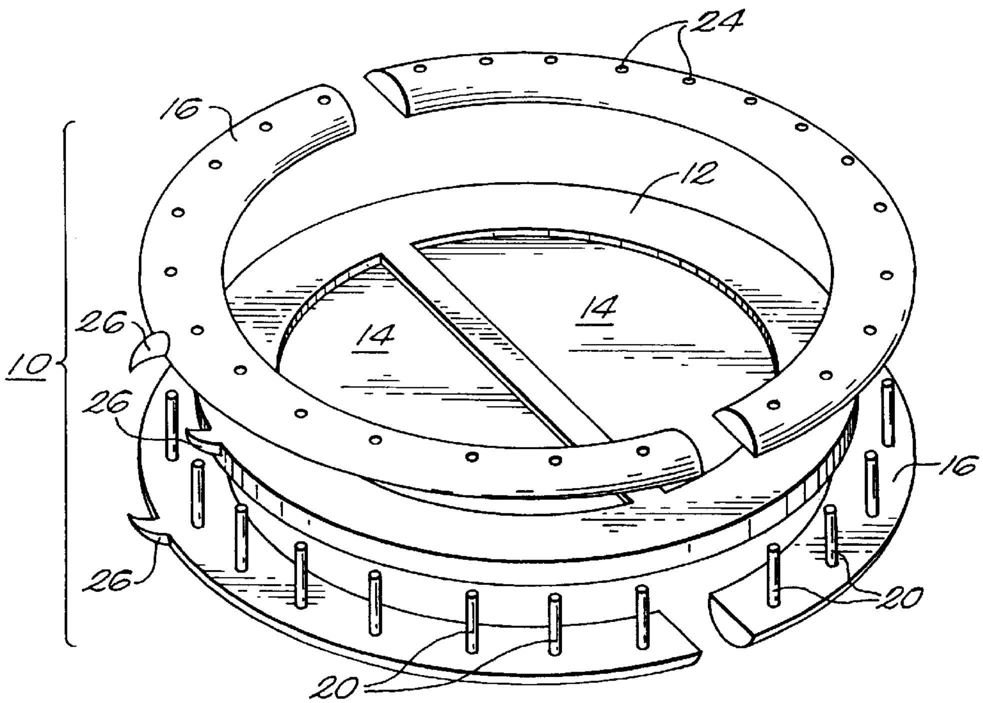


FIG. 1

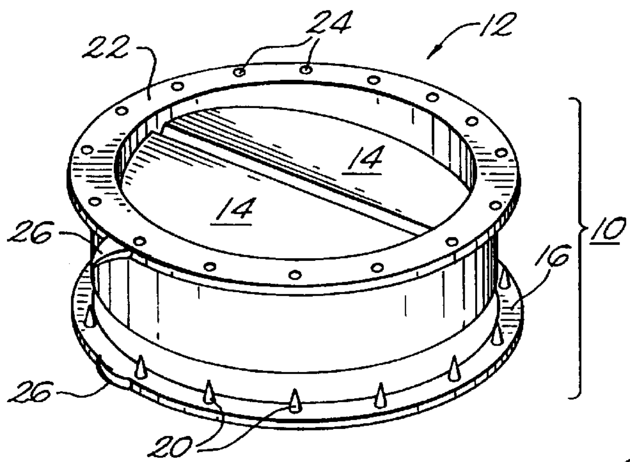


FIG. 2

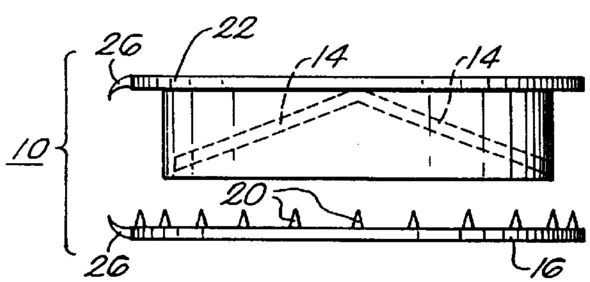


FIG. 3

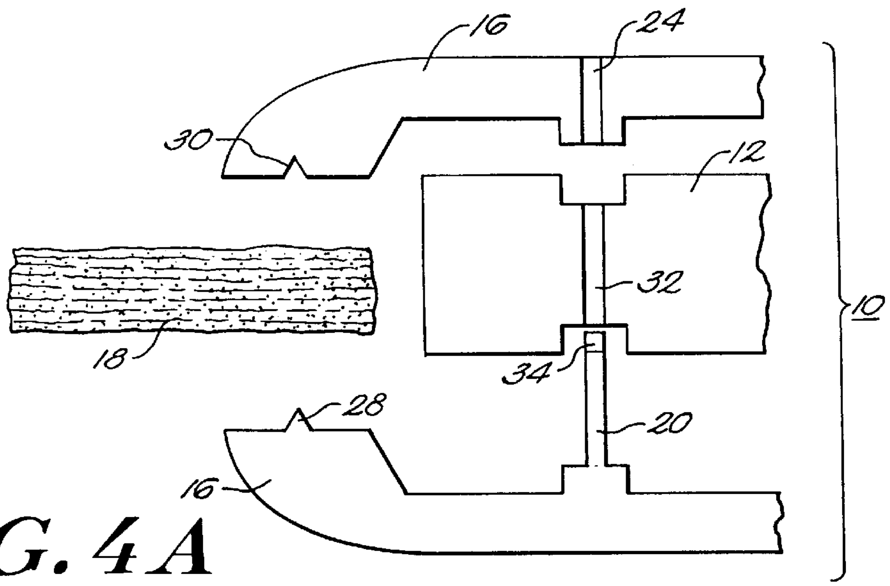


FIG. 4A

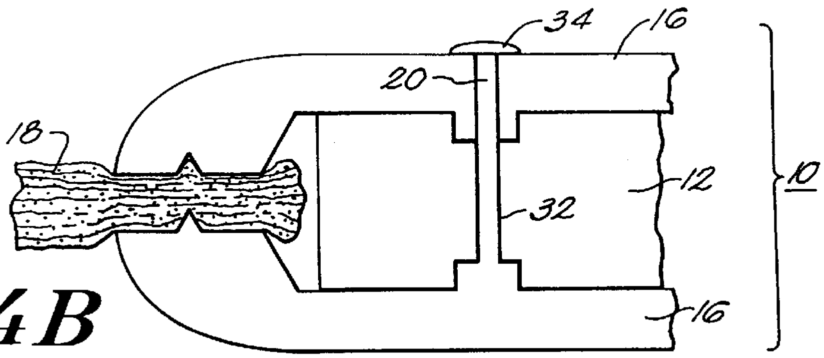


FIG. 4B

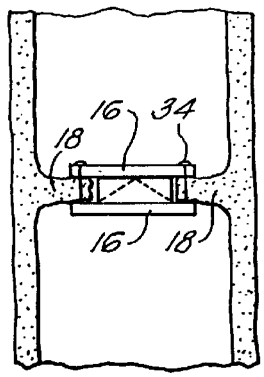


FIG. 5

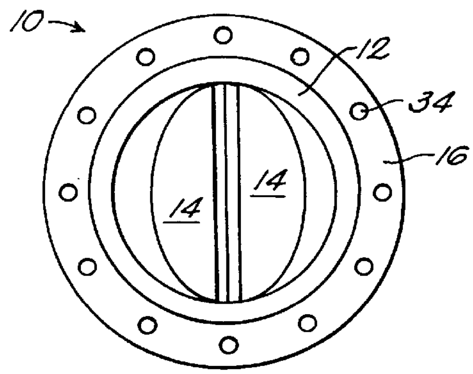


FIG. 6

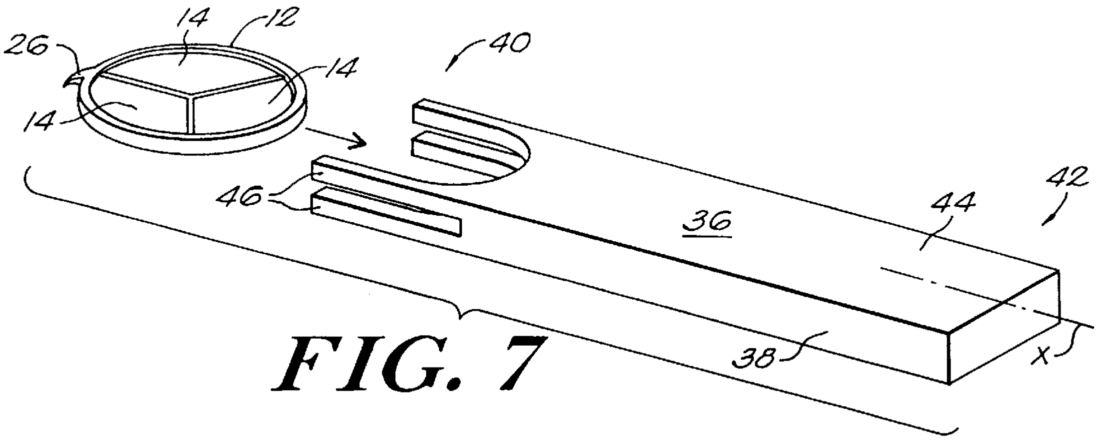
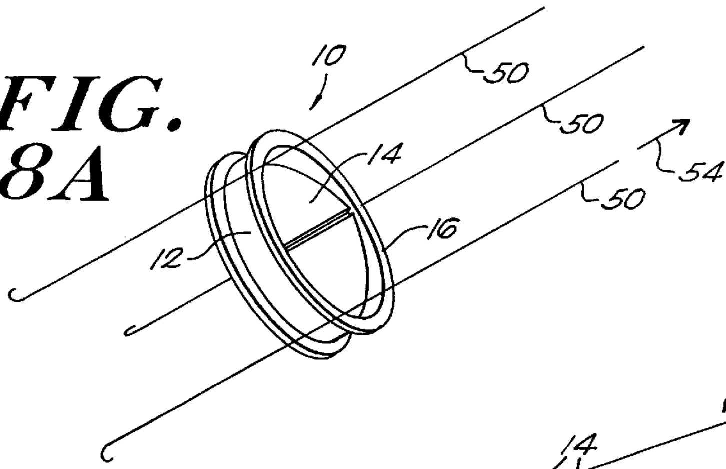


FIG. 7

FIG. 8A



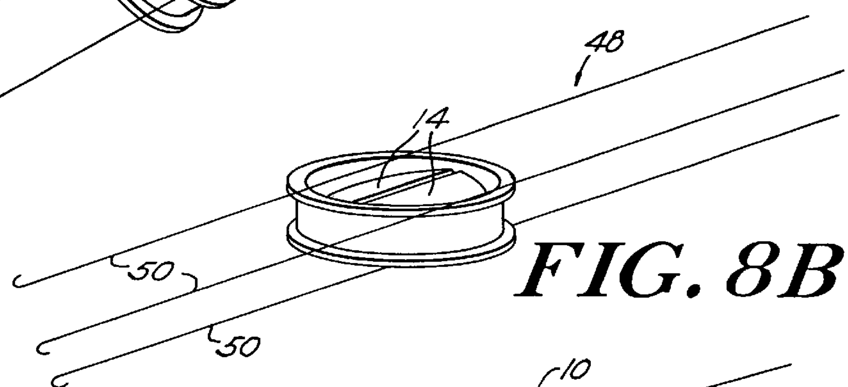


FIG. 8B

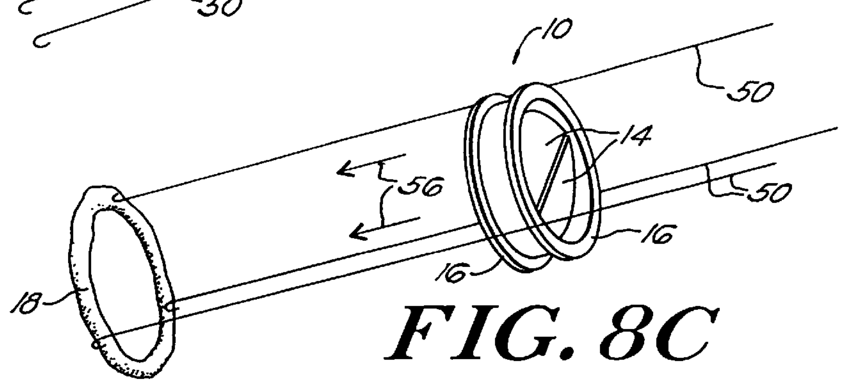


FIG. 8C

SUTURELESS CARDIAC VALVE PROSTHESIS, AND DEVICES AND METHODS FOR IMPLANTING THEM

FIELD OF THE INVENTION

The invention relates to prosthetic cardiac valves, and more particularly to prosthetic cardiac valves which can be implanted in a patient without sutures.

BACKGROUND OF THE INVENTION

Cardiac valve replacement may be required if the valve is prolapsed or otherwise malfunctioning. Replacement of a cardiac valve, such as, for example, the mitral or tricuspid valve, typically involves the resection of at least a portion of the diseased valve, leaving an annulus of host tissue, and the implantation of a prosthetic valve which includes a flexible ring and a plurality of leaflets mounted within the ring which are designed to open and close in response to changes in fluid pressure across them. The leaflets may be rotatable within the ring so that they can be oriented properly after the prosthesis has been implanted in the heart.

Prior art cardiac valve prostheses typically include a titanium ring and either two or three pyrolytic carbon leaflets (two if a mitral valve, three if a tricuspid valve). The ring is typically covered with a fabric cuff which promotes endothelialization of cardiac tissue into the prosthesis.

The prosthesis is generally secured to the annulus of native tissue at the valve site within the heart with a relatively large number of sutures which must be precisely placed and oriented so that the prosthesis does not rotate and the movement of the leaflets is not impeded when the prosthesis is in place. In practice, the prosthetic valve is secured to the host tissue using sutures attached to the fabric cuff surrounding the ring. Generally, relatively long sutures are passed through the tissue at the intended valve site and carefully laid out to extend through the incision in patient's chest, to points outside the incision. Then, the distal ends of the sutures are coupled to the cuff, and finally the valve and cuff arc "parachuted", or slid down the sutures, into place with the orientation of the valve maintained. The sutures anchoring the cuff of the prosthesis to the host tissue are then tied off.

Open-heart surgery is complicated, delicate, and confined. Minimally invasive surgical technologies and techniques are favored to minimize patient trauma; however, such procedures require a high degree of surgical skill. The implantation of a prosthetic valve with large numbers of sutures that cannot be crossed or otherwise twisted or misplaced is painstaking and difficult and prolongs the surgical procedure, thereby increasing patient trauma and the risk of infection. It would be an advancement in the art of cardiac valve replacement surgery to provide a valve which can be implanted without sutures.

SUMMARY OF THE INVENTION

According to one aspect of the invention, there is provided a prosthetic cardiac valve assembly for sutureless implantation in a living patient. The assembly comprises a valve annulus element and at least one retainer element which are adapted for mutual engagement and engagement with one or more sections of host tissue. The valve annulus element and retainer element are made of a biocompatible material and can be bonded together around the section or sections of host tissue upon application of energy to one or more of the elements, thereby fixing the host tissue between

them without sutures. Preferably, the material is a thermoplastic material which is suitable for bonding using ultrasonic or thermal welding techniques.

The valve annulus element can, but need not, include a plurality of valve leaflets which are pivotably mounted in the valve annulus element for controlling fluid flow through the assembly in response to fluid pressure differentials across the leaflets. In one embodiment, the prosthetic cardiac valve assembly is suitable for use as a mitral valve, and the valve annulus element includes a pair of valve leaflets. In another embodiment, the assembly is suitable for use as a tricuspid valve, and the valve annulus element includes three valve leaflets. The valve leaflets can be made of living tissue, such as porcine tissue, or from a synthetic material. In another embodiment, the valve annulus element contains no leaflets and is suitable for use in annuloplastic surgery.

Either or both of the retainer element and the annulus preferably include a plurality of projecting members, and the mating part includes a corresponding plurality of apertures adapted to receive the projecting members. In this embodiment, the valve annulus element is held to the retainer element by mechanical engagement of the projecting members in corresponding apertures on the mating part.

In one embodiment, the retainer element is in the form of a single-piece, continuous ring; in another embodiment the retainer is a multi-piece ring. In still another embodiment the assembly includes a pair of retainer elements, the first retainer element including a plurality of projecting members, and the second retainer element including a corresponding plurality of apertures adapted to snugly receive the projecting members of the first retainer element. In this embodiment, the valve annulus element is held frictionally between the first and second retainer elements.

At least one of the valve annulus element and the retainer element includes a tissue anchor for penetrating the host tissue and facilitating and maintaining the placement of the assembly.

The tissue-contacting surfaces of the valve annulus element and retainer element are preferably adapted to promote endothelialization of the host tissue into and around the supporting ring-like portion of the valve assembly.

The valve annulus element and the retainer element are preferably adapted to be bonded together upon application of ultrasonic or thermal energy to one or both of the elements.

According to another aspect of the invention, there is provided an insertion device for sutureless implantation of a generally disk-shaped cardiac valve prosthesis in a living patient. The device comprises a flat elongated member extending along a principal axis between distal and proximal ends. The proximal end of the device includes a handle, and the distal end includes a plurality of fingers that extend at least partially in the direction of the principal axis. The fingers are adapted to receive and hold a generally disk-shaped cardiac valve prosthesis in an orientation having its principal plane substantially parallel to the principal axis of the device during implantation of the prosthesis.

According to still another aspect of the invention, there is provided a different insertion device for sutureless implantation of a generally disk-shaped cardiac valve prosthesis in a living patient. The device comprises a plurality of rigid wires, each wire including a tissue anchor at a distal end thereof for penetrating host tissue. In use the wires are disposed parallel to each other, and each wire is engageable with a portion of the circumference of the prosthesis so that the prosthesis is supported by the wires and is maneuverable

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