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Block et al.

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[54] **INFLATABLE PROSTHETIC CARDIOVASCULAR VALVE FOR PERCUTANEOUS TRANSLUMINAL IMPLANTATION OF SAME**

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[22] Filed: **Jul. 18, 1994**

[51] **Int. Cl.**[6] **A61F 2/24**

[52] **U.S. Cl.** **623/2**; 623/12; 623/900; 606/195

[58] **Field of Search** 623/2, 12, 900; 606/195

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,671,979	6/1972	Moulopoulos .	
4,056,854	11/1977	Boretos et al. .	
4,183,102	1/1980	Guiset	623/12
4,592,340	6/1986	Boyles .	
4,727,873	3/1988	Mobin-Uddin .	
4,817,600	4/1989	Herms et al. .	
4,960,424	10/1990	Grooters .	
4,994,077	2/1991	Dobben .	
5,163,897	11/1992	Persky	623/12
5,163,953	11/1992	Vince .	
5,207,695	5/1993	Trout, III .	
5,360,444	11/1994	Kusuhara	623/2
5,370,691	12/1994	Samson	623/12
5,397,351	3/1995	Povcnik et al.	623/2

FOREIGN PATENT DOCUMENTS

2700531	7/1977	Germany .
91/17720	11/1991	WIPO .
93/01768	2/1993	WIPO .

Primary Examiner—Paul B. Prebilic
Attorney, Agent, or Firm—Stetina Brunda Buyan; Raymond Sun

[57] **ABSTRACT**

An inflatable prosthetic cardiovascular valve which is constructed so as to be initially deployable in a deflated "collapsed" configuration wherein the valve may be passed through the lumen of a cardiovascular catheter and subsequently inflated to an "operative" configuration so as to perform its intended valving function at its intended site of implantation within the cardiovascular system. The inflated valve may be held in place by mechanical means (e.g., hooks, projections), by chemical adhesive or through biological assimilation by the heart tissue.

17 Claims, 3 Drawing Sheets

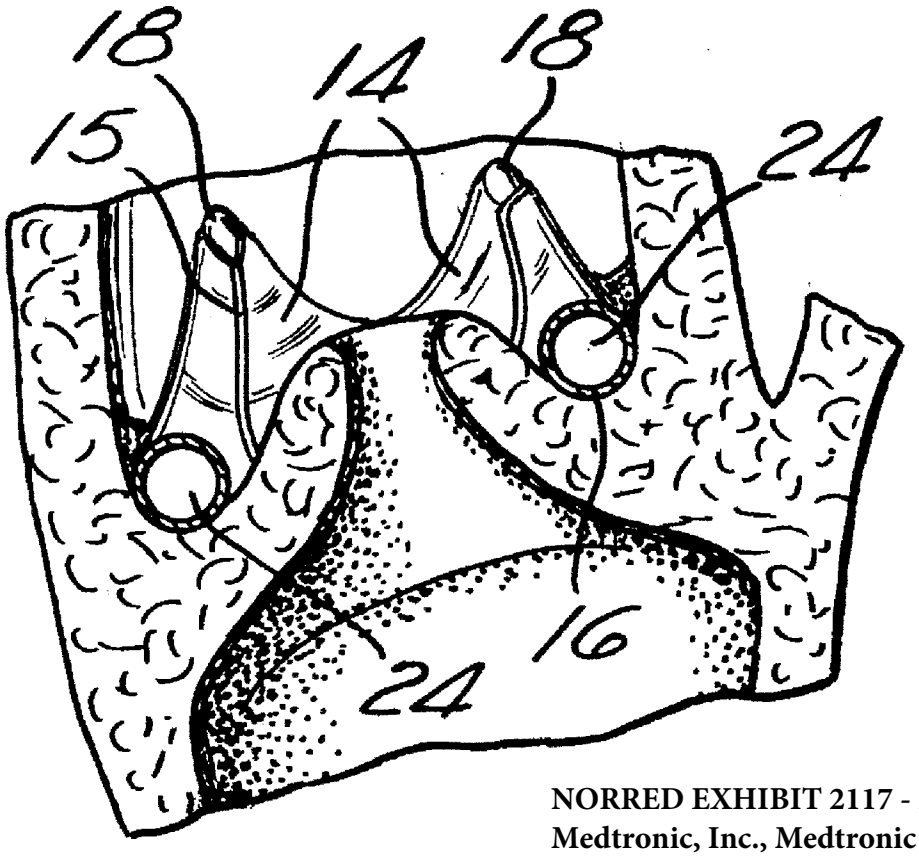
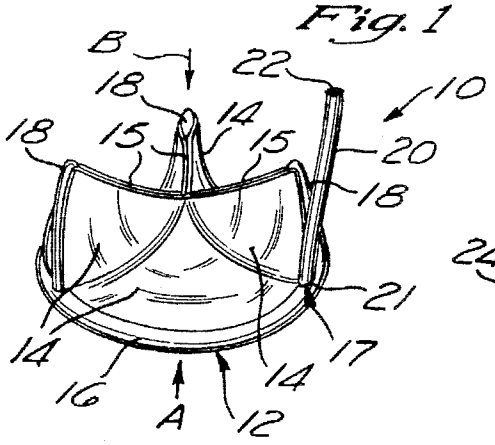


Fig. 1



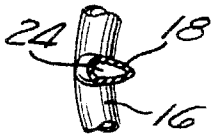
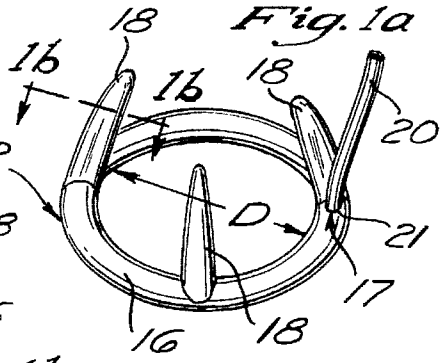


Fig. 1b

Fig. 1a



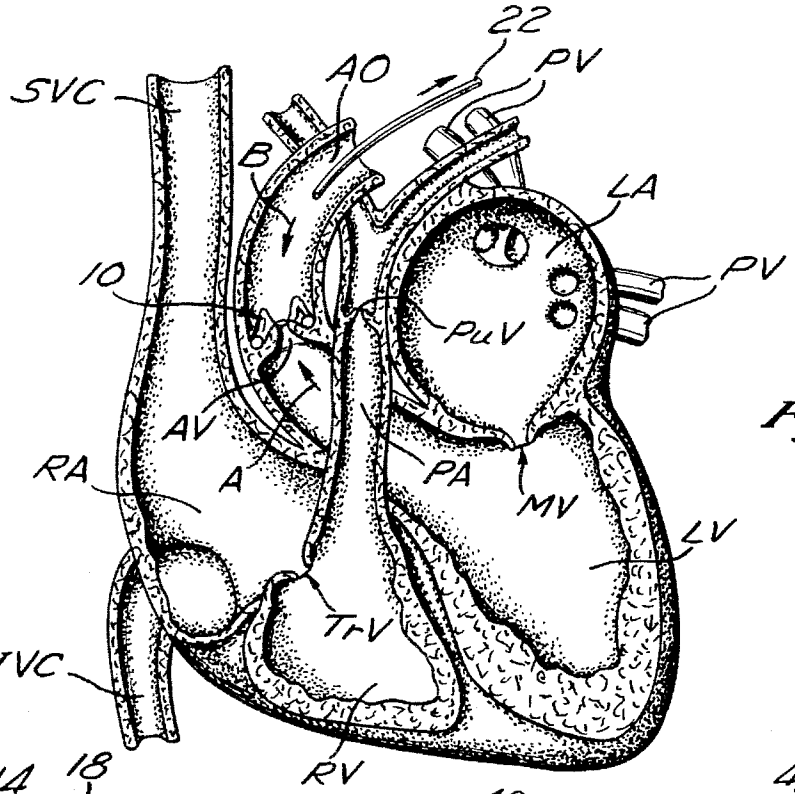


Fig. 3

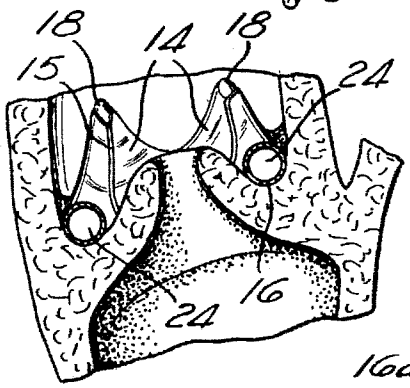


Fig. 3a

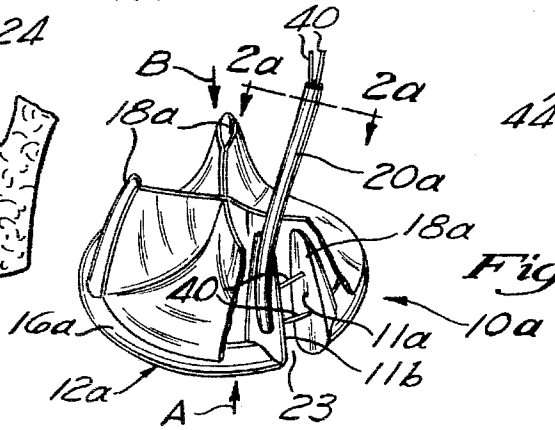


Fig. 2

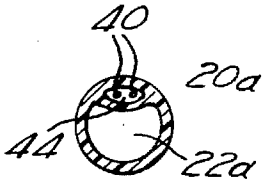
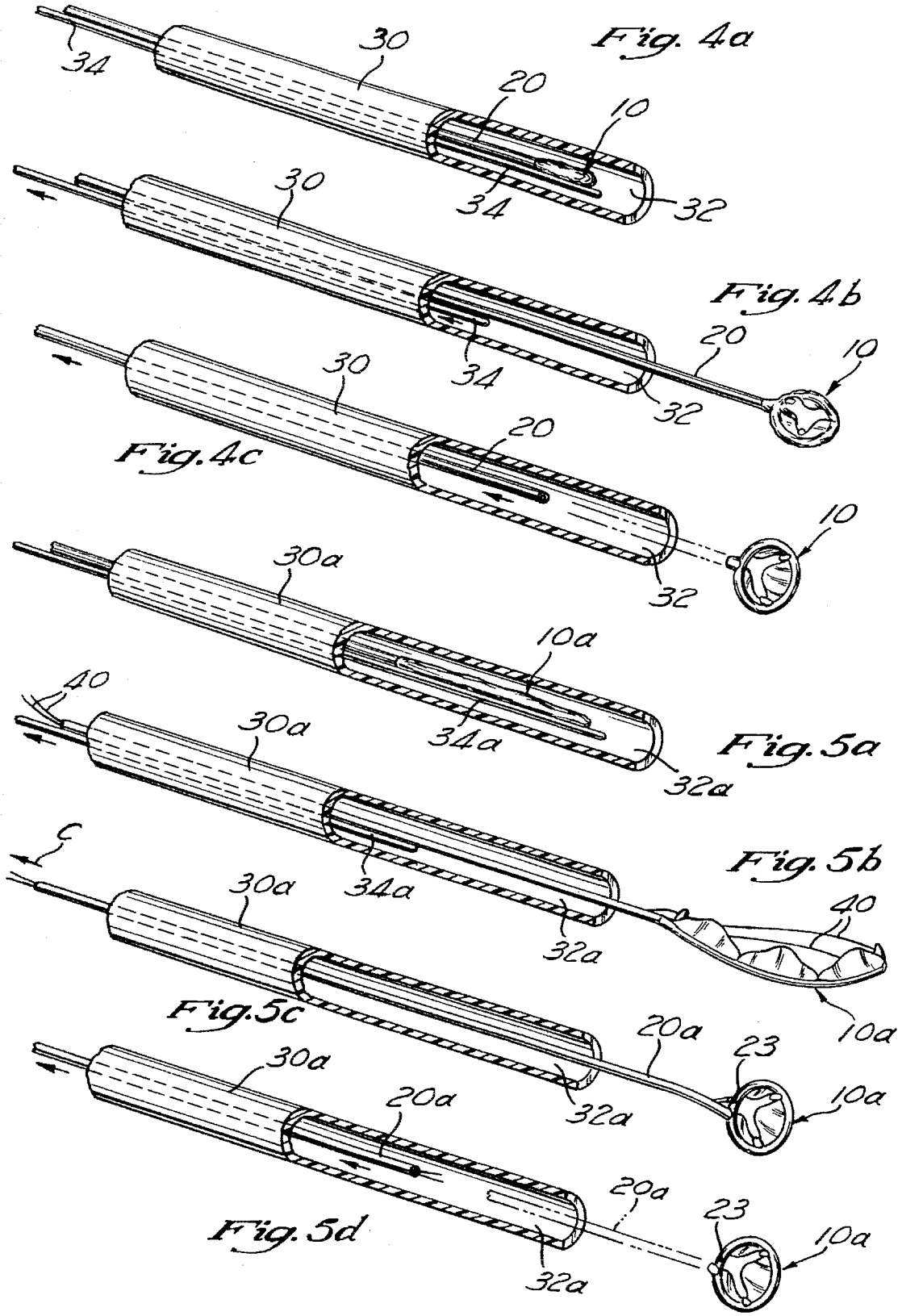


Fig. 2a



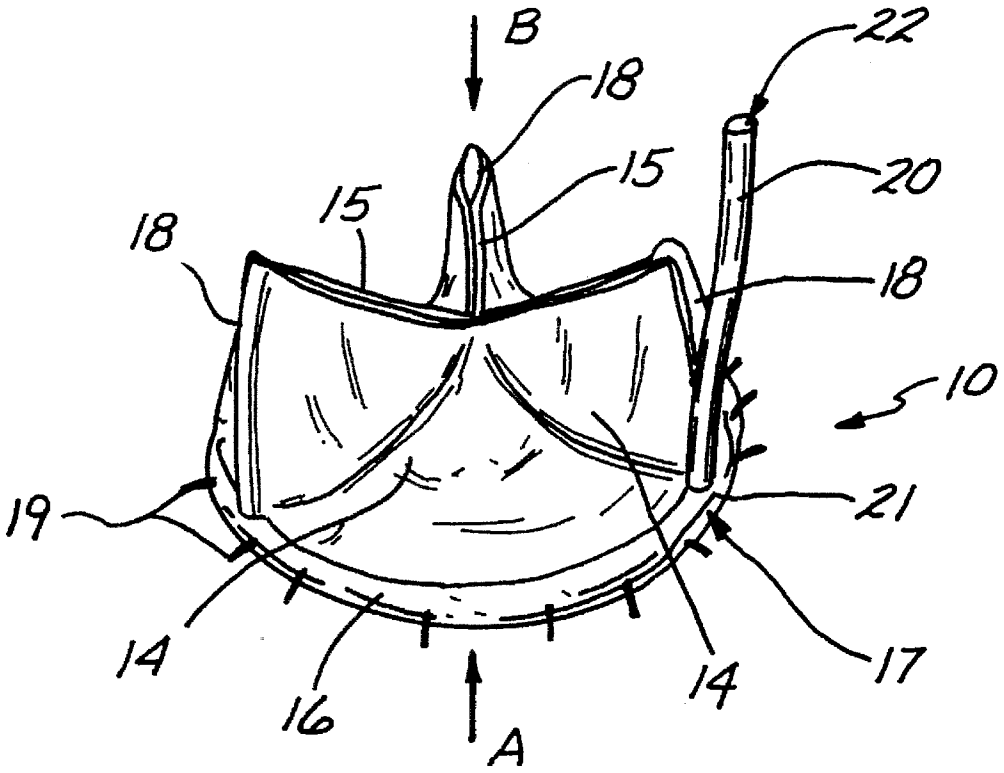


Fig. 1C

INFLATABLE PROSTHETIC CARDIOVASCULAR VALVE FOR PERCUTANEOUS TRANSLUMINAL IMPLANTATION OF SAME

FIELD OF THE INVENTION

The present invention pertains generally to medical equipment, and more particularly a catheter-introducible prosthetic valve which may be implanted into a mammalian heart or elsewhere in the cardiovascular system to augment or replace a malfunctioning endogenous valve.

BACKGROUND OF THE INVENTION

The prior art has included numerous surgically implantable prosthetic valves which may be utilized to replace malfunctioning heart valves, such as the aortic valve and the mitral valve. Some of the prosthetic heart valves of the prior art are "mechanical" valves of non-biological origin. Others are "biological" valves wherein all or a portion of the valve consists of harvested mammalian (e.g., porcine) tissue which has been preserved by way of a chemical fixation process.

Although surgically implantable prosthetic heart valves have become widely used in clinical practice, their implantation involves a major cardiothoracic surgical procedure wherein the patient must be placed on full cardiopulmonary bypass for a significant period of time. As a result, patients who have severe complications of their valvular disease or who are otherwise severely ill or elderly may be unable to undergo the rigors of such major cardiothoracic surgical procedure and are, thus, unable to receive the benefits of a surgically implanted prosthetic cardiovascular valve.

A number of prior investigators have proposed various "collapsible" cardiovascular valves and other cardiovascular apparatus (e.g., embolus traps) which may be collapsed and inserted into the mammalian vasculature through the lumen of a tubular catheter or introducer. Examples of collapsible cardiovascular valves and related apparatus are found in U.S. Pat. Nos. 3,671,979; 4,056,854; 4,592,340; 4,727,873; 4,817,600; 4,960,424; 4,994,077; 5,163,953; and 5,207,695, as well as the following foreign patents and/or patent publications WO91/17720; DT 2700-531 and WO93/01768.

Although various collapsible, catheter deployable, heart valves and/or other cardiovascular apparatus may have been proposed in the prior art, there remains a need for further refinement and development of such devices so as to arrive at a clinically useful prosthetic cardiovascular valve which may be implanted, through the lumen of a cardiovascular catheter, without the need for major cardiothoracic surgery.

SUMMARY OF THE INVENTION

Broadly stated, the present invention comprises an inflatable prosthetic cardiovascular valve which, when in a deflated state, is sufficiently collapsible to be passed through the lumen of a tubular cardiovascular catheter and which, when subsequently inflated, will assume a fully functional operative cardiovascular valve configuration.

In accordance with a first integral or annular embodiment of the invention, there is provided a collapsible prosthetic cardiovascular valve comprising an annular inflatable toroidal valve body and one or more occluder members (e.g., pliable leaflets) affixed thereto. A plurality of legs or strut members may extend from one side of the toroidal valve body to facilitate attachment of, and/or to maintain operative positioning of, the valve leaflets.

In accordance with a second split or linear embodiment of the invention, there is provided a collapsible prosthetic cardiovascular valve comprising an inflatable valve body having a split or separation formed therein and one or more occluder members (e.g., pliable leaflets) affixed thereto. When deflated, the valve body may be separated at its split or separation and extended into an elongate linear deflated configuration. When inflated, the valve body assumes a function annular or circular configuration. The inflatable valve body may be inherently biased to assume said annular or circular configuration upon inflation thereof, or may be provided with one or more tether lines or other guide members useable to guide or pull the valve body into the desired annular configuration as inflation of the valve body is accomplished.

Although the prosthetic cardiovascular valves of the present invention may incorporate various numbers of individual valve leaflets, a preferred embodiment of the valve incorporates three (3) valve leaflets, each having three (3) inboard edges which meet along a tre-foil margin within the annular central passageway of the inflatable valve body.

Although the collapsible cardiovascular valves of the present invention may be inflated by various means, one preferred embodiment of the invention employs a detachable inflation tube which is initially connected to the valve, and which may be subsequently severed from the valve and removed following inflation thereof.

The inflatable cardiovascular valves of the present invention may be inflated with any suitable inflation fluid. In some embodiments, the valve may be initially inflated with material(s) which will react or otherwise undergo gelation or solidification within the valve body, thereby resulting in a gel-filled or solid-filled valve.

The collapsible cardiovascular valves of the present invention may be specifically sized and configured for implantation at various sites or locations within the cardiovascular anatomy. In particular, collapsible valves of the present invention may be sized or configured to replace or augment any natural heart valve, including the mitral and aortic valves of the human heart. Similarly, collapsible cardiovascular valves of the present invention may be sized and configured for implantation in veins of the extremities to replace or augment absent or malfunctioning venous valves. In instances when the valves of the present invention are utilized to replace or augment the aortic valve of the heart, the positioning and location of the prosthetic valve of the present invention will be such that the prosthetic valve does not interfere with blood flow into the coronary circulation.

Further in accordance with the invention, there are provided apparatus and methods for percutaneous transluminal insertion and utilization of the collapsible/inflatable cardiovascular valves of the above-described character.

Further objects and advantages of the invention will become apparent to those skilled in the art upon reading and understanding of the following detailed description and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a catheter-introducible cardiovascular valve of the present invention having an inflatable toroidal support structure.

FIG. **1***a* is a perspective view of the inflatable toroidal support structure portion of the catheter-introducible cardiovascular valve of FIG. **1**.

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