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ISSUE CLASSIFICATION	
Class	Subclass
623	2.17

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PATENT NUMBER

6482228

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U.S. UTILITY Patent Application

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APPLICATION NO.	CONT/PRIOR	CLASS	SUBCLASS	ART UNIT	EXAMINER
09/712121		623	~~2.18~~ 2.17	3738	~~MILANO~~ Matthews

APPLICANTS: Troy Norred

TITLE: Percutaneous aortic valve replacement

PTO-2040 12/99

ISSUING CLASSIFICATION

ORIGINAL		CROSS REFERENCE(S)					
CLASS	SUBCLASS	CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
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A61F	2/06						

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☐ TERMINAL DISCLAIMER	DRAWINGS			CLAIMS ALLOWED	
	Sheets Drwg.	Figs. Drwg.	Print Fig.	Total Claims	Print Claim for O.G.
	9	19	4	~~35~~ 24	1
☐ The term of this patent subsequent to ______ (date) has been disclaimed.	Will H Matt (Assistant Examiner) 3/26/02 (Date)			NOTICE OF ALLOWANCE MAILED 4/2/02	
☐ The term of this patent shall not extend beyond the expiration date of U.S Patent. No. ______	Corrine M McDermott CORRINE McDERMOTT SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700 (Primary Examiner) 4/2/02 (Date)			ISSUE FEE Amount Due: 640; Date Paid: 07/02/02	
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USC 119 (a-d) conditions et	☐ yes ☑ no ☐ Met after Allowance				
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ITLE
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PATENT APPLICATION

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(12) **United States Patent**
Norred

(10) **Patent No.: US 6,482,228 B1**
(45) **Date of Patent: Nov. 19, 2002**

(54) **PERCUTANEOUS AORTIC VALVE REPLACEMENT**

(76) Inventor: **Troy R. Norred**, 4511 Royal Lythem, Columbia, MO (US) 65203

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(22) Filed: **Nov. 14, 2000**

(51) **Int. Cl.**[7] **A61F 2/06**

(52) **U.S. Cl.** **623/2.17**; 623/1.24

(58) **Field of Search** 623/2.1, 2.12, 623/2.13, 2.14, 2.18, 2.2, 2.22, 2.17

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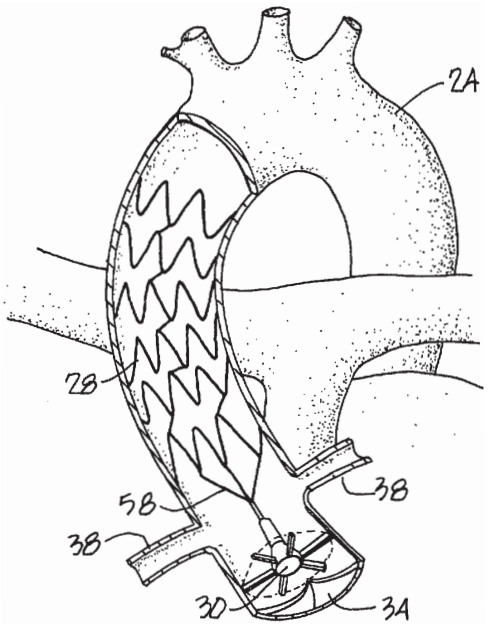
Primary Examiner—Corrine McDermott
Assistant Examiner—William H Matthews
(74) *Attorney, Agent, or Firm*—Chase Law Firm, L.C.

(57) **ABSTRACT**

An aortic heart valve which is adapted to be placed percutaneously without the need for open-heart surgery is placed by a catheter and held in place with a stent system. The stent system is expanded in the ascending aorta to anchor the valve in the aortic channel above the native aortic valve.

24 Claims, 7 Drawing Sheets



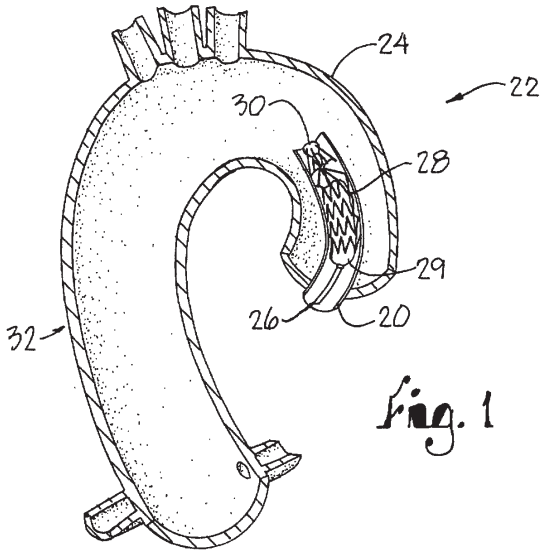


Fig. 1

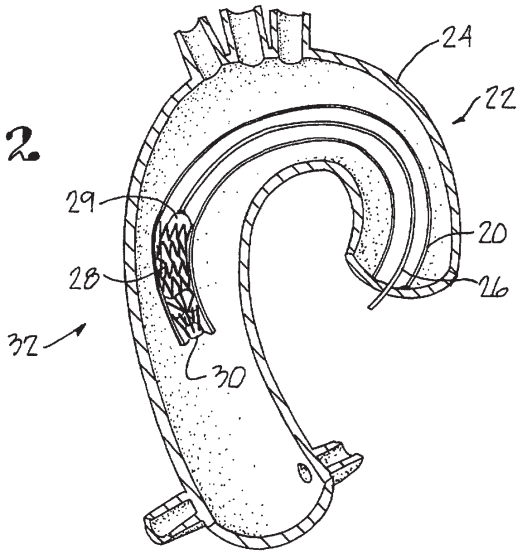


Fig. 2

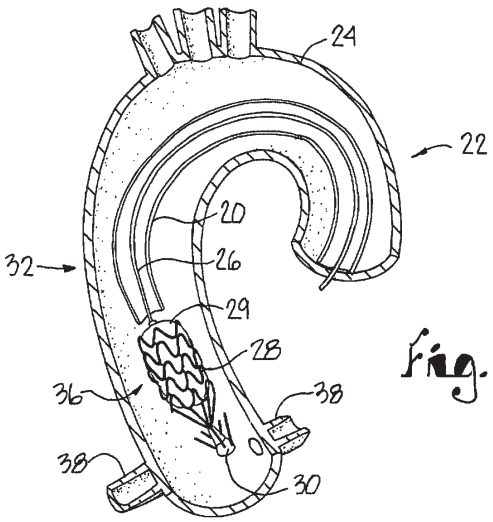
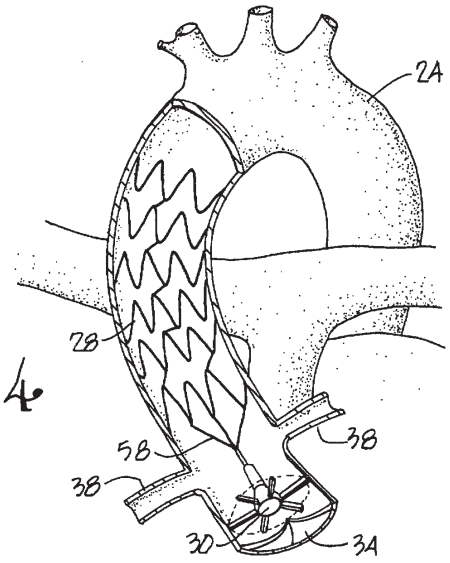


Fig. 3



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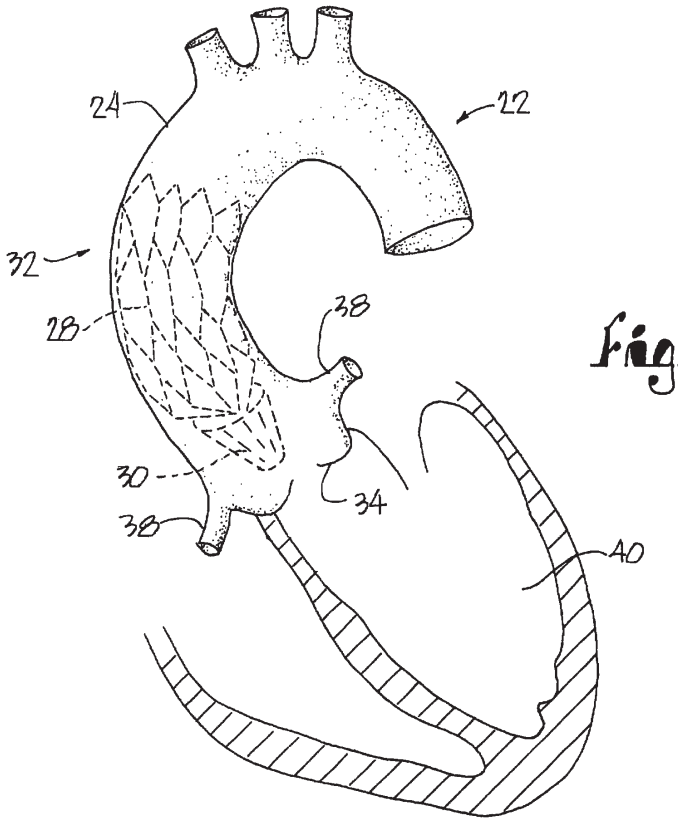

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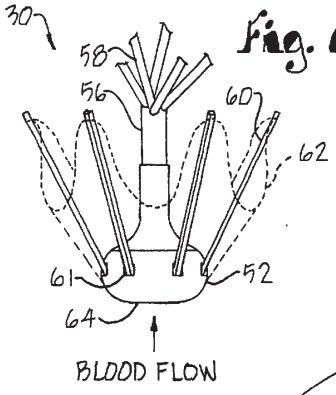

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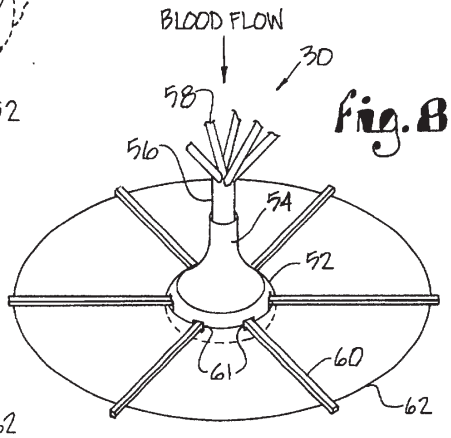

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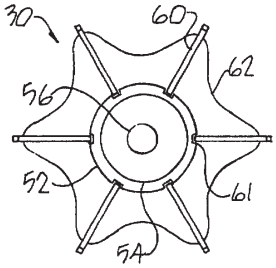

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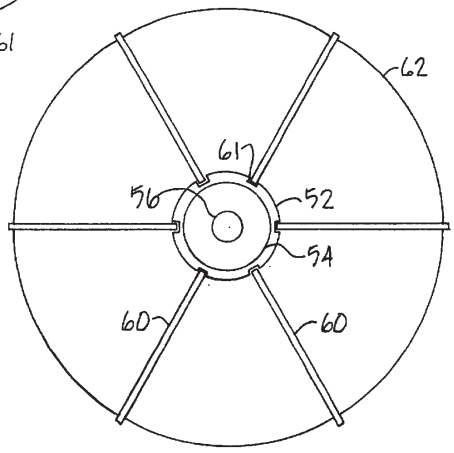

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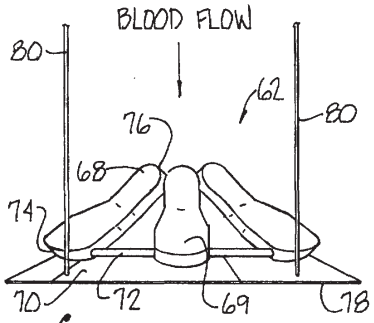

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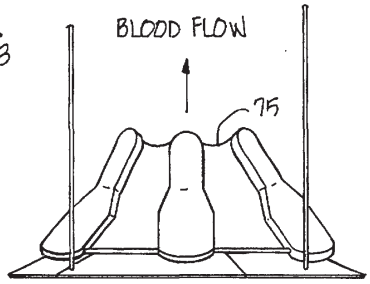

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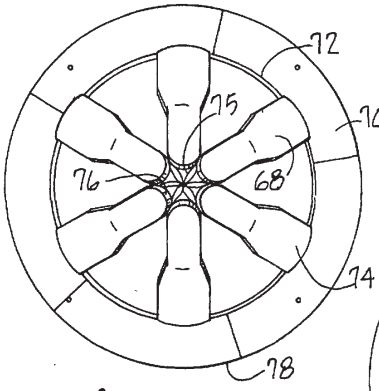

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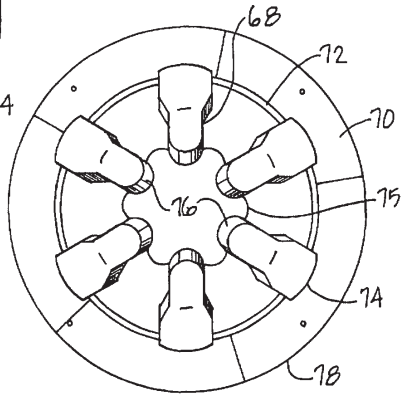
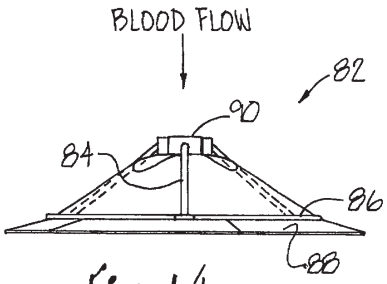


Fig. 13



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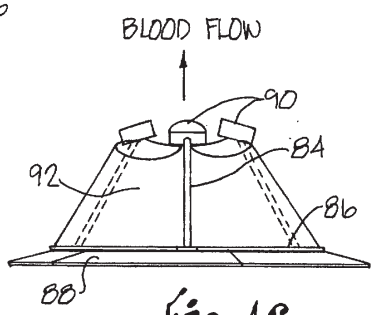

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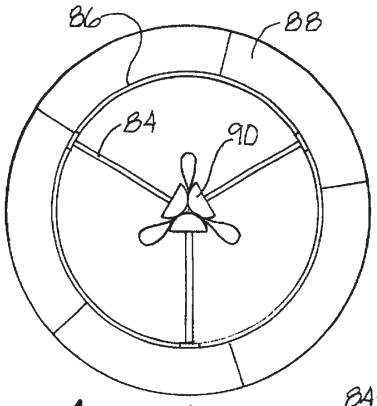

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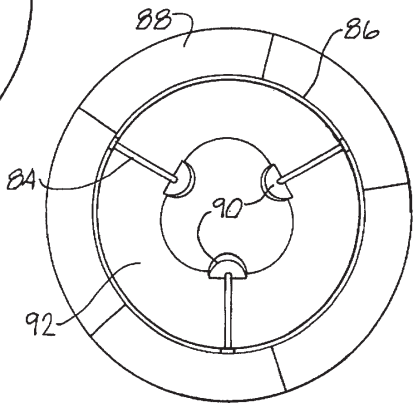

Fig. 17

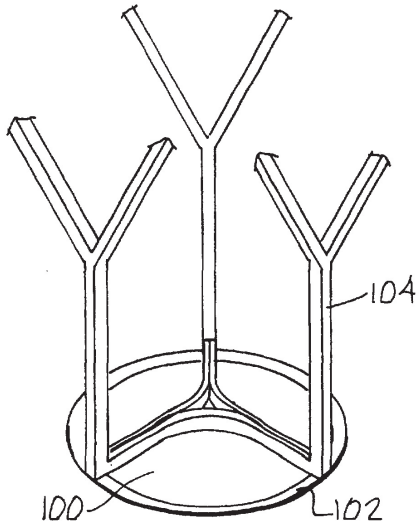

Fig. 18

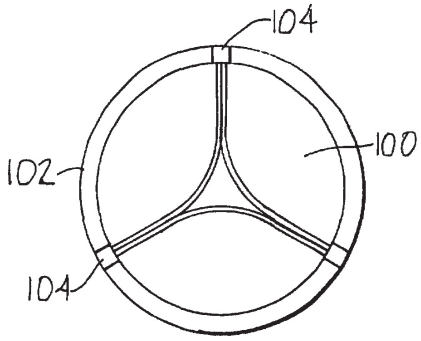

Fig. 19

PERCUTANEOUS AORTIC VALVE REPLACEMENT

BACKGROUND OF THE INVENTION

This invention relates to aortic heart valves and, in particular, to a percutaneous aortic heart valve that is placed by a catheter or other means and held in place with a stent system without the need for surgery.

The aortic valve undergoes a series of changes based upon the initial structure at birth and the normal dynamic daily stresses. The trileaflet aortic valve normally will not become stenotic until the seventh decade of a person's life unless infectious processes are introduced earlier. The incidence of aortic stenosis can reach between two and nine percent of the people in this age range. The average mortality rate at all ages is nine percent a year which also increases as a population ages. Coupled with these facts is the likelihood that as a person ages and becomes symptomatic with aortic stenosis, he is less likely to be an operative candidate due to being physically unable to withstand the stresses of surgery. The mortality of octogenarians has been reported as high as 20% for aortic valve replacement which can preclude a reasonable attempt at the therapy of choice, e.g., surgical replacement of the aortic valve using the traditional method of open heart surgery.

It is therefore the primary object of the present invention to provide an aortic valve that can be placed nonsurgically.

Another object of the present invention as aforesaid is to provide an aortic valve which may be anchored in the ascending aorta by a stent system.

Yet another important object of the present invention is to provide an aortic valve as aforesaid which may be placed percutaneously.

Still another object of the present invention is to provide an aortic valve as aforesaid which functions without removal of the native aortic valve.

Another important object of the present invention is to provide an aortic valve as aforesaid which reduces regurgitation of a native aortic valve.

Yet another important object of the present invention is to provide an aortic valve as aforesaid which increases the effective aortic valve orifice area while minimizing the resultant aortic regurgitation.

Still another important object of the present invention is to provide an aortic valve as aforesaid which reduces left ventricle energy expenditure from aortic regurgitation.

Yet another important object of the present invention is to provide an aortic valve as aforesaid which reduces long-term ventricular and aortic sequelae from pressure overload caused by aortic regurgitation.

Another important object of the present invention is to provide an aortic valve as aforesaid which can be placed nonsurgically so as to minimize the health risk to a patient during the procedure.

These and other objects and advantages of this invention are achieved by an artificial biomechanical aortic valve integrated with a stent system, which may be placed nonsurgically so as to minimize the risk to the patient during the procedure. The aortic valve is anchored in the ascending aorta with further support supplied in branch vessels or descending aorta as necessary due to the stress forces placed on the artificial valve by the normal hemodynamic pressures in the aorta. The valve is connected to the stent system by serially connected rods. Because of the relatively large surface area of the stent system, this design displaces the forces placed upon the artificial valve across this large surface area. Placing the device nonsurgically eliminates the need for a bypass pump or sternotomy and the associated postoperative risks.

These and other objects and advantages of this invention will become apparent from the following description taken in connection with the accompanying drawings, wherein is set forth by way of illustration and example, a now preferred embodiment of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a diagrammatic sectional view of a catheter containing aortic valve and stents of the present invention in the descending portion of an aorta.

FIG. **2** is a diagrammatic view of FIG. **1** with the catheter advanced to the ascending portion of the aorta.

FIG. **3** is a diagrammatic view of FIG. **2** with the aortic valve and stents being deployed into the aorta and the stents being expanded by inflation of a balloon.

FIG. **4** is a diagrammatic view of FIG. **3** with the stents expended and in place and the catheter removed.

FIG. **5** is a diagrammatic view of FIG. **4** showing the relationship between the placement of the stent system and valve to the aortic valve and left ventricle.

FIG. **6** is an umbrella aortic valve in a closed position.

FIG. **7** is a plan view of the umbrella aortic valve of FIG. **5**.

FIG. **8** is the umbrella aortic valve of FIG. **5** in an open position.

FIG. **9** is a plan view of the umbrella aortic valve of FIG. **7**.

FIG. **10** is a diagrammatic view of a cone-shaped aortic valve in a closed position.

FIG. **11** is a plan view of the cone-shaped valve of FIG. **10**.

FIG. **12** is the cone-shaped valve of FIG. **10** in an open position.

FIG. **13** is a plan view of the cone-shaped valve of FIG. **12**.

FIG. **14** is a diagrammatic view of another cone-shaped aortic valve in a closed position.

FIG. **15** is a plan view of the cone-shaped valve of FIG. **14**.

FIG. **16** is the cone-shaped aortic valve of FIG. **14** in an open position.

FIG. **17** is a plan view of the cone-shaped valve of FIG. **16**.

FIG. **18** is a diagrammatic view of a cadaver/porcine incorporated valve and stent system.

FIG. **19** is a plan view of the cadaver/porcine valve of FIG. **18**.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Turning more particularly to the drawings, FIG. **1** illustrates a sectional diagrammatic view of a cannular catheter **20** in the descending portion **22** of aorta **24**. Cannular catheter **20** contains a balloon catheter **26** which is surrounded by a wire mesh tube or stent system **28** connected to artificial valve **30**.

The stent system **28** is made up of a small slotted stainless steel tube or series of interconnected rods which form an expandable cylindrical lattice or scaffolding. The stent system **28** is initially collapsed to a small diameter around an angioplasty balloon **29** so that it and valve **30** may be guided into place using an antegrade approach through the fermoral artery (not shown) to the ascending aorta **32** (FIG. **2**).

Once cannular catheter **20** is located in ascending aorta **32** above native aortic valve **34**, the balloon catheter **26** is deployed (FIG. **3**) to place the valve/stent combination **36** in the correct anatomical position so that valve **30** is above aortic valve **34** (FIG. **4**) and below coronary arteries **38** so that the openings to coronary arteries **38** are unobstructed. When the valve/stent combination **36** is correctly placed, the balloon **29** is inflated to expand the stent scaffolding **28** and force the stent system **28** against the inner walls of ascending aorta **32** to anchor valve **30** in place. After balloon **29** is deflated and balloon catheter **26** is removed, the stent **28** remains locked in place. The stent lattice **28** may extend into descending aorta **32** or branch vessels (not shown) to further support and secure valve **30** in place.

Once the valve and stent combination **36** is in place, the balloon **29** is deflated and balloon catheter **26** is retracted into cannular catheter **20**. Both catheters **26** and **20** are removed from aorta **24** through the fermoral artery (not shown).

Simultaneously with placement of the valve/stent combination **36**, the fermoral vein would be accessed and cannulated to guide a balloon catheter into the left ventricle using a retrograde approach to perform a valvoplasty by inflating the balloon within the aortic valve. The purpose of the valvoplasty is to force the aortic valve open to relieve the pressure gradient between the left ventricle **40** (FIG. **5**) and aorta **24**. Visualization to place the catheters within the aorta **24** and left ventricle **40** would be accomplished using continuous roentgenogram and ultrasound techniques, such as intracardiac echocardiography (ICE) or fluoroscopy, which are known in the art.

Use of this valve/stent combination **36** precludes removal of the native aortic valve **34**. The focus would instead be upon debulking of the native aortic valve **34**. The main purpose is abolition of the resting gradient. The techniques employed would attempt to achieve a large effective aortic valve area regardless of the functioning of the native aortic valve **34** post-procedure because an artificial aortic valve **30** designed to prevent aortic regurgitation would be in place. Aortic valve **30** is designed not to hinder the ejection of blood from the left ventricle, and to minimize the aortic regurgitant volume. The techniques used to debulk the native aortic valve may include positioning of an Er-YSGG percutaneous laser to decalcify the valve and repeat balloon aortic valvuloplasty. If this is not effective then high frequency ultrasound percutaneously applied to the aortic valve may be necessary.

These techniques have been shown to be highly effective at producing debulking and preventing restenosis and increasing the effective aortic valve orifice area. However, they produce tremendous aortic regurgitation. This would not be a problem for the unattached valve **30** which would work as disclosed below for aortic regurgitation.

If these techniques do not produce the desired result of increasing the effective aortic valve orifice area then a host of options are still available. For example, two rings may be guided onto both the aortic and ventricular sides of the native aortic valve and pneumatically sealed together. Then expandable and retractable biotomes may be percutaneously placed for controlled dissection of the native aortic valve. The biotomes may be used for primary resection without stabilizing rings, but there would need to be a stabilization mechanism for the native aortic valve. Another such mechanism could employ the use of a micro screw into the native valve, which would act as an anchor to guide a biotome onto the native valve. Then the biotomes would take small snips in a controlled fashion off of the native valve. This would gradually increase the effective orifice area. Because the artificial valve is not anchored or dependent upon the native valve for its function, this technique could be easily reapplied, if the native valve were to restenose, without comprising the artificial valve. A tremendous advantage of this procedure would be its independence from a need for a percutaneous bypass pump.

Referring to FIGS. **6–9**, an inverted generally umbrella-shaped valve **30** is shown. Umbrella valve **30** has a generally pear or bulb-shaped main body **52** and a neck **54** which extends from the body. Extending from neck **54** is connecting rod **56** which secures stent struts **58** to umbrella valve **30**. Frame members or ribs **60** extend radially from and are hingedly attached to body **52**. Hinges **61** permit ribs **60** to move between a folded position (FIGS. **6–7**) where the ribs extend generally parallel to neck **54**, and an unfolded position (FIGS. **8–9**) where the ribs extend generally radially from an perpendicular to body **52**. Hinges **61** prevent ribs **60** from overextending when unfolded. A generally circular canopy **62** is secured to the lower sides of each of the frame members **60** and the lower side **64** of body **52**. Canopy **62** may be made of a biocompatible, flexible material such as an elastomeric sheet or a Dacron® reinforced polymer, for example. Frame members **60** may be made of stainless steel or a plastic polymer that is able to withstand the shear stresses during folding of valve **30**.

In FIGS. **6–9** frame members **60** are shown generally straight. However, frame members **60** may be curved inwardly toward neck **54** when valve **30** is in the folded or collapsed position (FIG. **6**) and generally tangentially to the inner wall of the aorta and toward the stent system **28** (FIG. **4**) when valve **30** is in the unfolded position (FIG. **8**). Additionally, canopy **62** may extend beyond the ends of frame members **60** to help reduce or eliminate peri-valvular leaks by sealing the valve against the inner wall of the aorta.

The end **64** of valve body **52** is generally hemispherical which permits the desired laminar blood flow characteristics of the native aortic valve in the aorta around valve **30**. Generally, any rounded shape, such as a rounded cone or hemi-ellipse, will produce satisfactory laminar flow.

Generally, umbrella-shaped valve **30** is placed in a position above the native aortic valve and below the openings of the coronary arteries **28** (FIG. **4**). The structure of valve **30** collapses to a folded (FIG. **6**) position wherein the ribs extend along the neck such that the canopy does not traverse the aortic channel. Thus, during systolic contraction of the left ventricle the blood from the left ventricle may be expelled unimpeded into the aorta (FIGS. **6–7**) as the valve is folded. During diastolic filling of the left ventricle, the pressure in the aorta becomes greater than the pressure in the left ventricle and the blood attempts to flow from the aorta into the left ventricle or regurgitate. This backflow is caught in the canopy **62** which causes valve structure **30** to unfold (FIGS. **8–9**) and prevents aortic regurgitation as the opening between the aorta **24** and the left ventricle is sealed. At this position ribs **60** extend radially and generally perpendicular from body **52**.

Referring to FIGS. **10–13** a second embodiment of an artificial aortic valve is shown which may be placed percutaneously. Conical valve **66** consists of two to **32** interconnected plates or fingers **68** and a generally ring-shaped base **70** and a ring **72** secured to the base **70**. The fingers **68** are generally wedge or bowling pin-shaped and are hingedly secured together by ring **72** extending through the base **74** of each finger **68** and interconnected by a biocompatible, durable, flexible generally conically-shaped fabric **75** membrane secured to the inside surfaces **69** of the fingers. The fingers **68** extend generally radially inwardly and away from the base **70**. Fingers **68** may be constructed of stainless steel, plastic or other biocompatible material.

In the closed position (FIGS. **10–11**), the tops **76** of the fingers contact each adjacent fingertip **76** to prevent regurgitation. It should be understood that if the number of fingers

is increased, contact with the adjacent fingers may be along the entire length of the finger **68**. If contact is along the entire side length of each adjacent finger when conical valve **66** is in the closed position, a membrane **75** may not be necessary to prevent regurgitation. To minimize components and to aid in miniaturizing the device for delivery, the number of fingers **68** may be reduced to two to four interconnecting fingers **68**.

During systole valve **66** expands or opens as shown in FIGS. **12–13** to allow blood ejected from the left ventricle to flow through the center of valve **66**. Fingers **68** pivot on ring **72** and tips **76** separate to allow blood to flow through the center of valve **66**. Membrane **75** prevents fingers from overextending to block coronary arteries **38** (FIG. **4**).

Valve **66** and the combined stent **28** is guided into position as shown in FIGS. **1–4**, and placed over the native aortic valve **34**. Base **70** is seated against the root of the aortic valve **34** next to the inner wall of the aorta **24** below coronary arteries **38**. The rim **78** of base **70** is made of a pliable biocompatible material which seals against the root of the native aortic valve **34** to reduce peri-valvular leaks. Valve **66** is anchored along the root of the aortic valve with connecting rods **80** which are connected to the ascending aortic stents **28** (see FIG. **4**). Valve **66** is placed such that rods **80** are positioned between the right and left coronary ostia tangentially along the sinus of valsalva. In this embodiment, there are no intraluminal connecting rods **58** within the ascending aorta as with umbrella valve **30** (see FIG. **4**).

Conical valve **66** centralizes the blood ejection jet from the left ventricle providing improved laminar flow characteristics through the valve **66** and minimizes hematologic sequelae.

Referring to FIGS. **14–17**, a third embodiment of an artificial aortic valve is shown which may be placed percutaneously. Trihedral valve **82** is similar in structure and operation to conical valve **66** (FIGS. **10–13**). Arms **84** are hingedly attached to ring **86** of base **88** and extend upwardly and radially inwardly from base **88** to generally form a trihedron or cone. Each rod **84** has a crescent-shaped pad **90** at its free end. A cone-shaped membrane **92** of fibrous polymer is secured to each arm **84** and base **88** (not shown in FIG. **14**).

During diastole, back flow of blood from the aorta to the left ventricle causes valve **82** to close preventing regurgitation (FIGS. **14–15**). During systole, blood is ejected from the left ventricle to force valve **82** open and allow blood to flow into the ascending aorta through the center of valve **82**. Valve **82** is anchored along the aortic valve root wall with connecting rods (not shown; see connecting rods **80**, FIG. **10**) which are connected to ascending aortic stents **28** (FIG. **4**). Valve **82** is placed so that the connecting rods are positioned between the right and left coronary ostia tangentially along the sinus of valsalva. In this embodiment, as in the conical valve **66**, there are no interluminal connecting rods **58** within the ascending aorta as with umbrella valve **30** (see FIG. **4**).

Base **88** of valve **82** is constructed as disclosed above for base **70** of conical valve **62**. Arms **84** may be constructed of stainless steel or other structural biocompatible material such as plastic. Crescent-shaped pads **90** may be constructed of stainless steel for durability or of softer biocompatible materials to better seal the valve **82** when in the closed position (FIGS. **14–15**), and reduce regurgitation.

Other valvular designs which may prove valuable to this technique include the usage of biological tissue incorporated valves, such as cadaver/porcine valves, placed within a percutaneously stented system the benefits of favorable flow and hematologic characteristics (see FIGS. **18** and **19**). Cadaver/porcine valve **100** is retained in a base ring **102**. Ring **102** is made of a pliable biocompatible material which seals against the root of the native aortic valve **34** (see FIG. **4**) to reduce peri-valvular leaks. Valve **100** is anchored along the root of the aortic valve with connecting rods **104** which are connected to the ascending aortic stents **28** shown in FIG. **4**. Valve **100** is placed such that rods **104** are positioned between the right and left coronary ostia tangentially along the sinus of valsalva.

The central themes involve increasing the effective aortic valve orifice area while minimizing the resultant aortic regurgitation. Thus, the goals in reducing left ventricular energy expenditure and its resultant long-term sequelae of pressure overload would be met with this system of percutaneously delivered aortic valves.

Having thus described the invention, what is claimed as new and desired to be secured by Letters Patent is:

1. An aortic valve for regulating blood flow through a channel of an aorta, the channel surrounded by an aortic wall, upon placement therein, said valve comprising:

a body member having a configuration adapted to fit within a channel of an aorta;

a membrane made of a material impervious to an aortic blood flow, said membrane having a first membrane position precluding a blood flow through the aorta and a second position for allowing a blood flow through the aorta; and

a plurality of frame members with said membrane mounted thereto, each frame member having a first end pivotally secured to said body member and a second end, said frame members pivotally responsive to a condition within the aorta between a first position wherein said membrane at said first frame member position is at said first membrane position and a said second frame member position wherein said membrane is at said second membrane position.

2. An aortic valve as claimed in claim **1** wherein said membrane extends across the aortic channel to block a blood flow at said first membrane position and extends generally along the aortic channel to allow a blood flow through the aorta at said second membrane position.

3. The aortic valve as claimed in claim **1** further comprising means for stopping pivotal movement of said second end of said frame members into contact with the aorta wall.

4. The aortic valve as claimed in claim **1** wherein said condition within the aorta is a change in blood pressure in the aorta.

5. The aortic valve as claimed in claim **1** wherein said frame members and membrane move to said second positions in response to systolic ejection of blood from the left ventricle in which the blood pressure in the left ventricle is higher than the blood pressure in the aorta.

6. The aortic valve as claimed in claim **1** wherein said frame member and membrane move to said first position in response to diastolic filling of the left ventricle and the blood pressure in the aorta is higher than the blood pressure in the left ventricle resulting in a reverse flow of blood from the aorta to the left ventricle which is stopped by said membrane at said first position.

7. An aortic valve as claimed in claim **1** wherein said body member has an exterior configuration to present a space between said body member exterior configuration and the aortic wall to allow blood flow therearound at said membrane second position.

8. The aortic valve as claimed in claim **1** wherein said body member comprises a base presenting an edge adapted to seat about the aortic wall surrounding the aortic channel;

an aperture in said base for blood flow therethrough;

a ring surrounding said aperture, said first end of said frame members pivotally mounted to said ring with

said membrane mounted thereto, said second ends of said frame members being in contact at said first frame member position to cause said membrane to span said base aperture and preclude a blood flow past said second frame member ends and said membrane, said frame members pivotable about said ring to a second position wherein said second frame member ends are displaced one from the other to allow a blood flow through the aperture and past said membrane.

9. The aortic valve as claimed in claim **8** wherein said membrane presents a base opening secured about said aperture and a free end having an aperture therein, said aperture in said free end of said membrane at said second frame and membrane positions is open to allow blood to flow though said membrane between said membrane base opening and said aperture in said free end of said membrane at said membrane second position.

10. The aortic valve as claimed in claim **9** wherein said membrane free end aperture is closed at said first frame membrane and member positions to preclude blood from flowing though said membrane at said membrane first position.

11. The aortic valve as claimed in claim **1** further comprising means for maintaining said body member within the aortic channel.

12. An aortic valve for regulating blood flow through a channel of an aorta upon placement therein, said valve comprising:

a body member having a configuration adapted to fit within a channel of an aorta to allow passage of a blood flow therearound;

a membrane for traversing the aortic channel to preclude blood flow therethrough; and

at least two ribs for attachment of said membrane thereto, each rib having a first end hingedly attached to said body member and a free end extending from said body member, wherein said at least two ribs are responsive to a change in pressure in the aorta for movement between a first position wherein said membrane is unfolded so as to traverse the aortic channel and preclude a blood flow therethrough and a second collapsed position wherein said membrane is positioned relative to the aorta channel to allow a blood flow therearound.

13. The aortic valve as claimed in claim **12** wherein said at least two ribs extend radially from said body so as to traverse the aortic channel at a first rib position, said first rib position corresponding to unfold said membrane at said first position, and wherein said ribs extend generally along said aortic channel at a second rib position to collapse said membrane at said second position.

14. The aortic valve as claimed in claim **13** wherein said membrane presents an edge adapted for contact about a wall of the aortic channel in said first position, said contact seats said membrane edge against the aortic channel wall to reduce a blood flow therearound.

15. The aortic valve as claimed in claim **12** further comprising means for maintaining said body member at a selected position in the aorta.

16. An aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein, said valve comprising:

a ring member having a circumference adapted to seat about an aortic wall surrounding an aortic channel, said ring including an aperture for blood flow therethrough;

a membrane having first and second spaced-apart open ends, said membrane made of a material resistant to a fluid flow therethrough; and

means for mounting said first open end of said membrane about said ring aperture with said second open end displaced therefrom, said means moving said membrane second end between a first open position to allow a blood flow therethrough and a second closed position to preclude a blood flow therethrough.

17. The aortic valve as claimed in claim **16** wherein said mounting means comprises at least one arm having a first end hingedly secured to said ring member and a free end spaced therefrom, said first end of said at least one arm secured to said first end of said membrane, said free end of said at least one arm secured to said second end of said membrane, said at least one arm responsive to a blood flow within the channel for movement with said membrane between said first open and second closed positions.

18. The aortic valve as claimed in claim **17** wherein said at least one arm extends generally along a path of said blood flow at said first open position, and generally traverses a blood flow path when at said second closed position.

19. The aortic valve as claimed in claim **16** further comprising means for maintaining said ring member in said seat about the aortic wall.

20. An aortic valve for controlling a blood flow through an aortic channel upon placement therein, said valve comprising:

a tissue valve having an interior member made of a tissue material and presenting an opening movable between open and closed positions;

a ring member surrounding said tissue valve, said ring member having an outer circumference adapted to seat said ring member about an aortic wall surrounding an aortic channel;

means for maintaining said ring member in said seated position about the aortic wall,

said tissue valve interior member responsive to changes of conditions within the aorta for movement of said opening between a first closed position and a second open position.

21. The aortic valve as claimed in claim **20** wherein said tissue valve interior member is responsive to changes in blood pressure in the aorta whereby to move said tissue valve between said first and second positions.

22. The aortic valve as claimed in claim **21** wherein said tissue valve interior member moves to said second position in response to systolic ejection of blood from the left ventricle in which the blood pressure in the left ventricle is greater than the blood pressure in the aortic channel.

23. The aortic valve as claimed in claim **21** wherein said tissue valve interior member moves to said first position in response to diastolic filling of the left ventricle whereby the blood pressure in the aortic channel is greater than the blood pressure in the left ventricle.

24. The aortic valve as claimed in claim **20** wherein said ring member contacts the wall of the aortic channel and seals said ring against the aortic channel wall to reduce blood flow therearound.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,482,228 B1
DATED : November 19, 2002
INVENTOR(S) : Troy R. Norred

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 7,
Lines 15 and 21, delete "though" and substitute -- through --.

Signed and Sealed this

Fourth Day of March, 2003

JAMES E. ROGAN
Director of the United States Patent and Trademark Office

11-15-00 A

PTO/SB/05 (08-00)

Please type a plus sign (+) inside ⊞

Approved for use through 10/31/2002. OMB 0651-0032
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	2745
First Inventor	TROY R. NORRED
Title	PERCUTANEOUS AORTIC VALVE REPLACEMENT
Express Mail Label No.	EL659686506US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. [X] Fee Transmittal Form (e.g., PTO/SB/17) *(Submit an original and a duplicate for fee processing)*
2. [X] Applicant claims small entity status. See 37 CFR 1.27.
3. [X] Specification [Total Pages 27] *(preferred arrangement set forth below)*
   - Descriptive title of the invention
   - Cross Reference to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to sequence listing, a table, or a computer program listing appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
4. [X] Drawing(s) *(35 U.S.C. 113)* [Total Sheets 9]
5. Oath or Declaration [Total Pages 2]
   a. [X] Newly executed (original or copy)
   b. [ ] Copy from a prior application (37 CFR 1.63 (d)) *(for continuation/divisional with Box 17 completed)*
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. [ ] Application Data Sheet. See 37 CFR 1.76

ADDRESS TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231

7. [ ] CD-ROM or CD-R in duplicate, large tables or Computer Program *(Appendix)*
8. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   a. [ ] Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. [ ] CD-ROM or CD-R (2 copies); or
      ii. [ ] paper
   c. [ ] Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. [ ] Assignment Papers (cover sheet & document(s))
10. [ ] 37 CFR 3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
11. [ ] English Translation Document *(if applicable)*
12. [X] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
13. [ ] Preliminary Amendment
14. [X] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
15. [ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. [ ] Other: .....

17. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:*

[ ] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No.: _____ / _____

Prior application information: *Examiner* _____ *Group / Art Unit:* _____

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

18. CORRESPONDENCE ADDRESS

[ ] *Customer Number or Bar Code Label* (Insert Customer No. or Attach bar code label here) or [ ] *Correspondence address below*

Name	23618 PATENT TRADEMARK OFFICE
Address	
City	State / Zip Code
Country	Telephone / Fax

Name (Print/Type)	James J. Kernell	Registration No. (Attorney/Agent)	42,720
Signature	James J. Kernell	Date	11/14/00

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I hereby certify that this paper or fee is being deposited with the U.S. Postal Service "Express Mail" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner of Patents, Washington, D.C., 20231.

James J. Kernell, #42,720

jc948 U.S. PTO 11/14/00

09/712121 11/14/00

PTO/SB/17 (08-00)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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FEE TRANSMITTAL for FY 2000

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT ($) 458.00

Complete If Known	
Application Number	
Filing Date	
First Named Inventor	TROY R. NORRED
Examiner Name	
Group Art Unit	
Attorney Docket No.	2745

09/712121 U.S. PTO 11/14/00

METHOD OF PAYMENT (check one)

1. [X] The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:
   - Deposit Account Number: 03-1425
   - Deposit Account Name: Chase & Yakimo
   - [X] Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17
   - [X] Applicant claims small entity status. See 37 CFR 1.27
2. [X] Payment Enclosed: [X] Check [ ] Credit card [ ] Money Order [ ] Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	690	201	345	Utility filing fee	355.00
106	310	206	155	Design filing fee	
107	480	207	240	Plant filing fee	
108	690	208	345	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($) 355.00

2. EXTRA CLAIM FEES

	Extra Claims		Fee from below	Fee Paid
Total Claims	27 -20** =	7	X 9.00	=63.00
Independent Claims	4 - 3** =	1	X 40.00	=40.00
Multiple Dependent				=-0-

**or number previously paid, if greater; For Reissues, see below

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	78	202	39	Independent claims in excess of 3
104	260	204	130	Multiple dependent claim, if not paid
109	78	209	39	** Reissue independent claims over original patent
110	18	210	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 103.00

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for *ex parte* reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	380	216	190	Extension for reply within second month	
117	870	217	435	Extension for reply within third month	
118	1,360	218	680	Extension for reply within fourth month	
128	1,850	228	925	Extension for reply within fifth month	
119	300	219	150	Notice of Appeal	
120	300	220	150	Filing a brief in support of an appeal	
121	260	221	130	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,210	241	605	Petition to revive - unintentional	
142	1,210	242	605	Utility issue fee (or reissue)	
143	430	243	215	Design issue fee	
144	580	244	290	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	690	246	345	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	690	249	345	For each additional invention to be examined (37 CFR § 1.129(b))	
179	690	279	345	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($) -0-

SUBMITTED BY				Complete (if applicable)	
Name (Print/Type)	James J. Kernell	Registration No. (Attorney/Agent)	42,720	Telephone	913-339-9666
Signature	James J. Kernell			Date	11/14/00

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PERCUTANEOUS AORTIC VALVE REPLACEMENT

Background of the Invention

This invention relates to aortic heart valves and, in particular, to a percutaneous aortic heart valve that is placed by a catheter or other means and held in place with a stent system without the need for surgery.

The aortic valve undergoes a series of changes based upon the initial structure at birth and the normal dynamic daily stresses. The trileaflet aortic valve normally will not become stenotic until the seventh decade of a person's life unless infectious processes are introduced earlier. The incidence of aortic stenosis can reach between two and nine percent of the people in this age range. The average mortality rate at all ages is nine percent a year which also increases as a population ages. Coupled with these facts is the likelihood that as a person ages and becomes symptomatic with aortic stenosis, he is less likely to be an operative candidate due to being physically unable to withstand the stresses of surgery. The mortality of octogenarians has been reported as high as 20% for aortic valve replacement which can preclude a reasonable attempt at the therapy of choice, e.g., surgical replacement of the aortic valve using the traditional method of open heart surgery.

(Docket 2745)

It is therefore the primary object of the present invention to provide an aortic valve that can be placed nonsurgically.

Another object of the present invention as aforesaid is to provide an aortic valve which may be anchored in the ascending aorta by a stent system.

Yet another important object of the present invention is to provide an aortic valve as aforesaid which may be placed percutaneously.

Still another object of the present invention is to provide an aortic valve as aforesaid which functions without removal of the native aortic valve.

Another important object of the present invention is to provide an aortic valve as aforesaid which reduces regurgitation of a native aortic valve.

Yet another important object of the present invention is to provide an aortic valve as aforesaid which increases the effective aortic valve orifice area while minimizing the resultant aortic regurgitation.

Still another important object of the present invention is to provide an aortic valve as aforesaid which reduces left ventricle energy expenditure from aortic regurgitation.

Yet another important object of the present invention is to provide an aortic valve as aforesaid which reduces long-term ventricular and aortic sequelae from pressure overload caused by aortic regurgitation.

Another important object of the present invention is to provide an aortic valve as aforesaid which can be placed nonsurgically so as to minimize the health risk to a patient during the procedure.

These and other objects and advantages of this invention are achieved by an artificial biomechanical aortic valve integrated with a stent system, which may be placed nonsurgically so as to minimize the risk to the patient during the procedure. The aortic valve is anchored in the ascending aorta with further support supplied in branch vessels or descending aorta as necessary due to the stress forces placed on the artificial valve by the normal hemodynamic pressures in the aorta. The valve is connected to the stent system by serially connected rods. Because of the relatively large surface area of the stent system, this design displaces the forces placed upon the artificial valve across this large surface area. Placing the device nonsurgically eliminates the need for a bypass pump or sternotomy and the associated postoperative risks.

These and other objects and advantages of this invention will become apparent from the following description

taken in connection with the accompanying drawings, wherein is set forth by way of illustration and example, a now preferred embodiment of this invention.

Brief Description of the Drawings

Fig. 1 is a diagrammatic sectional view of a catheter containing aortic valve and stents of the present invention in the descending portion of an aorta.

Fig. 2 is a diagrammatic view of Fig. 1 with the catheter advanced to the ascending portion of the aorta.

Fig. 3 is a diagrammatic view of Fig. 2 with the aortic valve and stents being deployed into the aorta and the stents being expanded by inflation of a balloon.

Fig. 4 is a diagrammatic view of Fig. 3 with the stents expended and in place and the catheter removed.

Fig. 5 is a diagrammatic view of Fig. 4 showing the relationship between the placement of the stent system and valve to the aortic valve and left ventricle.

Fig. 6 is an umbrella aortic valve in a closed position.

Fig. 7 is a plan view of the umbrella aortic valve of Fig. 5.

Fig. 8 is the umbrella aortic valve of Fig. 5 in an open position.

Fig. 9 is a plan view of the umbrella aortic valve of Fig. 7.

Fig. 10 is a diagrammatic view of a cone-shaped aortic valve in a closed position.

Fig. 11 is a plan view of the cone-shaped valve of Fig. 10.

Fig. 12 is the cone-shaped valve of Fig. 10 in an open position.

Fig. 13 is a plan view of the cone-shaped valve of Fig. 12.

Fig. 14 is a diagrammatic view of another cone-shaped aortic valve in a closed position.

Fig. 15 is a plan view of the cone-shaped valve of Fig. 14.

Fig. 16 is the cone-shaped aortic valve of Fig. 14 in an open position.

Fig. 17 is a plan view of the cone-shaped valve of Fig. 16.

Fig. 18 is a diagrammatic view of a cadaver/porcine incorporated valve and stent system.

Fig. 19 is a plan view of the cadaver/porcine valve of Fig. 18.

Description of the Preferred Embodiment

Turning more particularly to the drawings, Fig. 1 illustrates a sectional diagrammatic view of a cannular catheter 20 in the descending portion 22 of aorta 24. Cannular catheter 20 contains a balloon catheter 26 which is surrounded by a wire mesh tube or stent system 28 connected to artificial valve 30.

The stent system 28 is made up of a small slotted stainless steel tube or series of interconnected rods which form an expandable cylindrical lattice or scaffolding. The stent system 28 is initially collapsed to a small diameter around an angioplasty balloon 29 so that it and valve 30 may be guided into place using an antegrade approach through the fermoral artery (not shown) to the ascending aorta 32 (Fig. 2).

Once cannular catheter 20 is located in ascending aorta 32 above native aortic valve 34, the balloon catheter 26 is deployed (Fig. 3) to place the valve/stent combination 36 in the correct anatomical position so that valve 30 is above aortic valve 34 (Fig. 4) and below coronary arteries 38 so that the openings to coronary arteries 38 are unobstructed. When the valve/stent combination 36 is correctly placed, the balloon 29 is inflated to expand the stent scaffolding 28 and force the stent system 28 against the inner walls of ascending

aorta 32 to anchor valve 30 in place. After balloon 29 is deflated and balloon catheter 26 is removed, the stent 28 remains locked in place. The stent lattice 28 may extend into descending aorta 32 or branch vessels (not shown) to further support and secure valve 30 in place.

Once the valve and stent combination 36 is in place, the balloon 29 is deflated and balloon catheter 26 is retracted into cannular catheter 20. Both catheters 26 and 20 are removed from aorta 24 through the fermoral artery (not shown).

Simultaneously with placement of the valve/stent combination 36, the fermoral vein would be accessed and cannulated to guide a balloon catheter into the left ventricle using a retrograde approach to perform a valvoplasty by inflating the balloon within the aortic valve. The purpose of the valvoplasty is to force the aortic valve open to relieve the pressure gradient between the left ventricle 40 (Fig. 5) and aorta 24. Visualization to place the catheters within the aorta 24 and left ventricle 40 would be accomplished using continuous roentgenogram and ultrasound techniques, such as intracardiac echocardiography (ICE) or fluoroscopy, which are known in the art.

Use of this valve/stent combination 36 precludes removal of the native aortic valve 34. The focus would

aorta 32 to anchor valve 30 in place. After balloon 29 is deflated and balloon catheter 26 is removed, the stent 28 remains locked in place. The stent lattice 28 may extend into descending aorta 32 or branch vessels (not shown) to further support and secure valve 30 in place.

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Use of this valve/stent combination 36 precludes removal of the native aortic valve 34. The focus would

instead be upon debulking of the native aortic valve 34. The main purpose is abolition of the resting gradient. The techniques employed would attempt to achieve a large effective aortic valve area regardless of the functioning of the native aortic valve 34 post-procedure because an artificial aortic valve 30 designed to prevent aortic regurgitation would be in place. Aortic valve 30 is designed not to hinder the ejection of blood from the left ventricle, and to minimize the aortic regurgitant volume. The techniques used to debulk the native aortic valve may include positioning of an Er-YSGG percutaneous laser to decalcify the valve and repeat balloon aortic valvuloplasty. If this is not effective then high frequency ultrasound percutaneously applied to the aortic valve may be necessary.

These techniques have been shown to be highly effective at producing debulking and preventing restenosis and increasing the effective aortic valve orifice area. However, they produce tremendous aortic regurgitation. This would not be a problem for the unattached valve 30 which would work as disclosed below for aortic regurgitation.

If these techniques do not produce the desired result of increasing the effective aortic valve orifice area then a host of options are still available. For example, two rings may be guided onto both the aortic and ventricular sides

of the native aortic valve and pneumatically sealed together. Then expandable and retractable biotomes may be percutaneously placed for controlled dissection of the native aortic valve. The biotomes may be used for primary resection without stabilizing rings, but there would need to be a stabilization mechanism for the native aortic valve. Another such mechanism could employ the use of a micro screw into the native valve, which would act as an anchor to guide a biotome onto the native valve. Then the biotomes would take small snips in a controlled fashion off of the native valve. This would gradually increase the effective orifice area. Because the artificial valve is not anchored or dependent upon the native valve for its function, this technique could be easily reapplied, if the native valve were to restenose, without comprising the artificial valve. A tremendous advantage of this procedure would be its independence from a need for a percutaneous bypass pump.

Referring to Figs. 6-9, an inverted generally umbrella-shaped valve 30 is shown. Umbrella valve 30 has a generally pear or bulb-shaped main body 52 and a neck 54 which extends from the body. Extending from neck 54 is connecting rod 56 which secures stent struts 58 to umbrella valve 30. Frame members or ribs 60 extend radially from and are hingedly attached to body 52. Hinges 61 permit ribs 60 to move between

a folded position (Figs. 6-7) where the ribs extend generally parallel to neck 54, and an unfolded position (Figs. 8-9) where the ribs extend generally radially from an perpendicular to body 52. Hinges 61 ~~permit~~ prevent ribs 60 from overextending when unfolded. A generally circular canopy 62 is secured to the lower sides of each of the frame members 60 and the lower side 64 of body 52. Canopy 62 may be made of a biocompatible, flexible material such as an elastomeric sheet or a Dacron® reinforced polymer, for example. Frame members 60 may be made of stainless steel or a plastic polymer that is able to withstand the shear stresses during folding of valve 30.

In Figs. 6-9 frame members 60 are shown generally straight. However, frame members 60 may be curved inwardly toward neck 54 when valve 30 is in the folded or collapsed position (Fig. 6) and generally tangentially to the inner wall of the aorta and toward the stent system 28 (Fig. 4) when valve 30 is in the unfolded position (Fig. 8). Additionally, canopy 62 may extend beyond the ends of frame members 60 to help reduce or eliminate peri-valvular leaks by sealing the valve against the inner wall of the aorta.

The end 64 of valve body 52 is generally hemispherical which permits the desired laminar blood flow characteristics of the native aortic valve in the aorta around

valve 30. Generally, any rounded shape, such as a rounded cone or hemi-ellipse, will produce satisfactory laminar flow.

Generally, umbrella-shaped valve 30 is placed in a position above the native aortic valve and below the openings of the coronary arteries 28 (Fig. 4). The structure of valve 30 collapses to a folded (Fig. 6) position wherein the ribs extend along the neck such that the canopy does not traverse the aortic channel. Thus, during systolic contraction of the left ventricle the blood from the left ventricle may be expelled unimpeded into the aorta (Figs. 6-7) as the valve is folded. During diastolic filling of the left ventricle, the pressure in the aorta becomes greater than the pressure in the left ventricle and the blood attempts to flow from the aorta into the left ventricle or regurgitate. This backflow is caught in the canopy 62 which causes valve structure 30 to unfold (Figs. 8-9) and prevents aortic regurgitation as the opening between the aorta 24 and the left ventricle is sealed. At this position ribs 60 extend radially and generally perpendicular from body 52.

Referring to Figs. 10-13 a second embodiment of an artificial aortic valve is shown which may be placed percutaneously. Conical valve 66 consists of two to 32 interconnected plates or fingers 68 and a generally ring-shaped base 70 and a ring 72 secured to the base 70. The

fingers 68 are generally wedge or bowling pin-shaped and are hingedly secured together by ring 72 extending through the base 74 of each finger 68 and interconnected by a biocompatible, durable, flexible generally conically-shaped fabric 75 membrane secured to the inside surfaces 69 of the fingers. The fingers 68 extend generally radially inwardly and away from the base 70. Fingers 68 may be constructed of stainless steel, plastic or other biocompatible material.

In the closed position (Figs. 10-11), the tops 76 of the fingers contact each adjacent fingertip 76 to prevent regurgitation. It should be understood that if the number of fingers is increased, contact with the adjacent fingers may be along the entire length of the finger 68. If contact is along the entire side length of each adjacent finger when conical valve 66 is in the closed position, a membrane 75 may not be necessary to prevent regurgitation. To minimize components and to aid in miniaturizing the device for delivery, the number of fingers 68 may be reduced to two to four interconnecting fingers 68.

During systole valve 66 expands or opens as shown in Figs. 12-13 to allow blood ejected from the left ventricle to flow through the center of valve 66. Fingers 68 pivot on ring 72 and tips 76 separate to allow blood to flow through

the center of valve 66. Membrane 75 prevents fingers from overextending to block coronary arteries 38 (Fig. 4).

Valve 66 and the combined stent 28 is guided into position as shown in Figs. 1-4, and placed over the native aortic valve 34. Base 70 is seated against the root of the aortic valve 34 next to the inner wall of the aorta 24 below coronary arteries 38. The rim 78 of base 70 is made of a pliable biocompatible material which seals against the root of the native aortic valve 34 to reduce peri-valvular leaks. Valve 66 is anchored along the root of the aortic valve with connecting rods 80 which are connected to the ascending aortic stents 28 (see Fig. 4). Valve 66 is placed such that rods 80 are positioned between the right and left coronary ostia tangentially along the sinus of valsalva. In this embodiment, there are no intraluminal connecting rods 58 within the ascending aorta as with umbrella valve 30 (see Fig. 4).

Conical valve 66 centralizes the blood ejection jet from the left ventricle providing improved laminar flow characteristics through the valve 66 and minimizes hematologic sequelae.

Referring to Figs. 14-17, a third embodiment of an artificial aortic valve is shown which may be placed percutaneously. Trihedral valve 82 is similar in structure and operation to conical valve 66 (Figs. 10-13). Arms 84 are

hingedly attached to ring 86 of base 88 and extend upwardly and radially inwardly from base 88 to generally form a trihedron or cone. Each rod 84 has a crescent-shaped pad 90 at its free end. A cone-shaped membrane 92 of fibrous polymer is secured to each arm 84 and base 88 (not shown in Fig. 14).

WHm

During ~~diastole~~ diastole, back flow of blood from the aorta to the left ventricle causes valve 82 to close preventing regurgitation (Figs. 14-15). During systole, blood is ejected from the left ventricle to force valve 82 open and allow blood to flow into the ascending aorta through the center of valve 82. Valve 82 is anchored along the aortic valve root wall with connecting rods (not shown; see connecting rods 80, Fig. 10) which are connected to ascending aortic stents 28 (Fig. 4). Valve 82 is placed so that the connecting rods are positioned between the right and left coronary ostia tangentially along the sinus of valsalva. In this embodiment, as in the conical valve 66, there are no interluminal connecting rods 58 within the ascending aorta as with umbrella valve 30 (see Fig. 4).

Base 88 of valve 82 is constructed as disclosed above for base 70 of conical valve 62. Arms 84 may be constructed of stainless steel or other structural biocompatible material such as plastic. Crescent-shaped pads 90 may be constructed of stainless steel for durability or of

softer biocompatible materials to better seal the valve 82 when in the closed position (Figs. 14-15), and reduce regurgitation.

Other valvular designs which may prove valuable to this technique include the usage of biological tissue incorporated valves, such as cadaver/porcine ~~vales~~ valves, placed within a percutaneously stented system the benefits of favorable flow and hematologic characteristics (see Figs. 18 and 19). Cadaver/porcine valve 100 is retained in a base ring 102. Ring 102 is made of a pliable biocompatible material which seals against the root of the native aortic valve 34 (see Fig. 4) to reduce peri-valvular leaks. Valve 100 is anchored along the root of the aortic valve with connecting rods 104 which are connected to the ascending aortic stents 28 shown in Fig. 4. Valve 100 is placed such that rods 104 are positioned between the right and left coronary ostia tangentially along the sinus of valsalva.

The central themes involve increasing the effective aortic valve orifice area while minimizing the resultant aortic regurgitation. Thus, the goals in reducing left ventricular energy expenditure and its resultant long-term sequelae of pressure overload would be met with this system of percutaneously delivered aortic valves.

Claims

Having thus described the invention, what is claimed as new and desired to be secured by Letters Patent is:

1. An aortic valve for regulating blood flow through a channel of an aorta upon placement therein, said valve comprising:

a body member having a configuration adapted to fit within a channel of an aorta;

a membrane made of a material impervious to an aortic blood flow therethrough; and

means for mounting said membrane relative to said body member between a first position wherein said membrane precludes a blood flow past said body member and a second position wherein said membrane allows a blood flow past said body member.

2. An aortic valve as claimed in claim 1 wherein said membrane extends across the aortic channel at said first membrane position and extends generally along the aortic channel at said second membrane position.

3. The aortic valve as claimed in claim 1 wherein said mounting means comprises a plurality of frame members each having a first end hingedly secured to said body and a free end extending from said body wherein said frame members move with said membrane between said first and second positions.

4. The aortic valve as claimed in claim 3 further comprising a means for stopping said frame members at said first position.

5. The aortic valve as claimed in claim 1 wherein said mounting means is responsive to changes in blood pressure in the aorta whereby to move said membrane between said first and second positions.

6. The aortic valve as claimed in claim 5 wherein said membrane moves to said second position in response to systolic ejection of blood from the left ventricle in which the blood pressure in the left ventricle is higher than the blood pressure in the aorta.

7. The aortic valve as claimed in claim 5 wherein said membrane moves to said first position in response to diastolic filling of the left ventricle and the blood pressure in the aorta is higher than the blood pressure in the left ventricle resulting in a reverse flow of blood from the aorta to the left ventricle which is stopped by said membrane.

8. An aortic valve as claimed in claim 1 wherein said body member has an exterior configuration to present a space between said body member exterior configuration and said aortic wall to allow blood flow therearound at said membrane second position.

9. The aortic valve as claimed in claim 1 wherein said body member is generally ring-shaped having a circumference adapted to seat about an inner circumference of the aortic wall surrounding the aortic channel, said ring having an aperture for blood flow therethrough.

10. The aortic valve as claimed in claim 9 wherein said membrane is generally funnel-shaped having a base opening secured to an inner circumference of said ring-shaped body member and a free end having an aperture therein whereby said aperture in said free end of said membrane is open to allow blood to flow though said membrane from said membrane base opening to said aperture in said free end of said membrane at said membrane second position.

11. The aortic valve as claimed in claim 9 wherein said membrane is generally funnel-shaped having a base opening secured to an inner circumference of said ring-shaped body member and a free end having an aperture therein whereby said aperture in said free end of said membrane is closed to preclude blood from flowing though said membrane from said aperture in said free end of said membrane to said membrane base opening at said membrane first position.

12. The aortic valve as claimed in claim 10 wherein said membrane is generally funnel-shaped having a base opening secured to an inner circumference of said ring-shaped body member and a free end having an aperture therein whereby said aperture in said free end of said membrane is closed to preclude blood from flowing though said membrane from said aperture in said free end of said membrane to said membrane base opening at said membrane first position.

13. The aortic valve as claimed in claim 1 further comprising means for maintaining said body member within the aortic channel.

14. An aortic valve for regulating blood flow through a channel of an aorta upon placement therein, said valve comprising:

a body member having a configuration adapted to fit within a channel of an aorta to allow passage of a blood flow therearound;

a membrane for traversing the aortic channel to preclude blood flow therethrough; and

means for mounting said membrane to said body member between a first position wherein said membrane is unfolded so as to traverse the aortic channel and preclude a blood flow therethrough and a second position wherein said membrane is positioned relative to the body member to allow a blood flow therearound.

15. The aortic valve as claimed in claim 14 wherein said means for mounting comprises at least two ribs each having a first end hingedly secured to said body member and a free end extending from said body wherein said ribs move with said membrane between said first and second positions.

13 ~~14~~ ~~18~~. The aortic valve as claimed in claim ~~14~~ 12 ~~13~~ wherein said at least two ribs extend radially from said body so as to traverse the aortic channel at a first rib position, said first rib position corresponding to unfold said membrane at said first position, and wherein said ribs extend generally along said aortic channel at a second rib position to collapse said membrane at said second position.

17. The aortic valve as claimed in claim 14 wherein said membrane contacts the wall of the aortic channel in said first position and seals said membrane against the aortic channel wall to reduce a blood flow therearound.

18. The aortic valve as claimed in claim 14 further comprising means for maintaining said body member in the aorta.

19. An aortic valve for regulating a blood flow through an aortic channel upon placement therein, said valve comprising:

a ring member having a circumference adapted to seat about an aortic wall surrounding an aortic channel, said ring including an aperture for blood flow therethrough;

a membrane having first and second spaced-apart ends, said membrane made of a material resistant to a fluid flow therethrough; and

means for mounting said first end of said membrane about said ring aperture with said second end displaced therefrom, said means moving said second membrane end between an open position to allow a blood flow therethrough and a second closed position to preclude a blood flow therethrough.

20. The aortic valve as claimed in claim 19 wherein said mounting means comprises at least one arm having a first end hingedly secured to said ring member and a free end spaced therefrom, said first end of said arm secured to said first end of said membrane, said free end of said arm secured to said second end of said membrane, and wherein said arm moves with said membrane between said first and second positions.

21. The aortic valve as claimed in claim 19 wherein said arm extends generally along a path of said blood flow when in said open position, and generally traverse to said blood flow when in said closed position.

22. The aortic valve as claimed in claim 19 further comprising means for maintaining said ring member in said seat about the aortic wall.

23. An aortic valve for controlling a blood flow through an aortic channel upon placement therein, said valve comprising:

a tissue valve having an interior member and circumference;

a ring member secured to said tissue valve along said tissue valve circumference and having an outer circumference adapted to seat said ring member about an aortic wall surrounding an aortic channel;

means for maintaining said ring member in said seated position about the aortic wall; and

means for moving said tissue valve interior member between a first closed position and a second open position.

24. The aortic valve as claimed in claim 23 wherein said tissue valve interior member is responsive to changes in blood pressure in the aorta whereby to move said tissue valve between said first and second positions.

22 25. The aortic valve as claimed in claim 21 wherein said tissue valve interior member moves to said second position in response to systolic ejection of blood from the left ventricle in which the blood pressure in the left ventricle is greater than the blood pressure in the aortic channel.

23 26. The aortic valve as claimed in claim 21 wherein said tissue valve interior member moves to said first position in response to diastolic filling of the left ventricle whereby the blood pressure in the aortic channel is greater than the blood pressure in the left ventricle.

24 27. The aortic valve as claimed in claim 20 wherein said ring member contacts the wall of the aortic channel and seals said ring against the aortic channel wall to reduce blood flow therearound.

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S.N. 09/712121

Abstract of the Disclosure

An aortic heart valve which is adapted to be placed percutaneously without the need for open-heart surgery is placed by a catheter and held in place with a stent system. The stent system is expanded in the ascending aorta to anchor the valve in the aortic channel above the native aortic valve.

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☒ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	2745
First Named Inventor	Troy R. Norred
COMPLETE IF KNOWN	
Application Number	/
Filing Date	
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

PERCUTANEOUS AORTIC VALVE REPLACEMENT

(Title of the Invention)

the specification of which
☒ is attached hereto
OR
☐ was filed on (MM/DD/YYYY) [ ] as United States Application Number or PCT International Application Number [ ] and was amended on (MM/DD/YYYY) [ ] (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
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			☐	☐	☐
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☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

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I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

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Name	Registration Number	Name	Registration Number
D. A. N. Chase	20,682		
Michael Yakimo, Jr.	28,549		
Ginnie C. Derusseau	35,855		
James J. Kernell	42,720		

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

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Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Troy R.	Norred

Inventor's Signature	Troy Norred					Date	11/6/00
Residence: City	Columbia	State	MO	Country	U.S.A.	Citizenship	U.S.A.
Post Office Address	4511 Royal Lytham						
Post Office Address							
City	Columbia	State	MO	ZIP	65203	Country	U.S.A.

☐ Additional inventors are being named on the ___ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto

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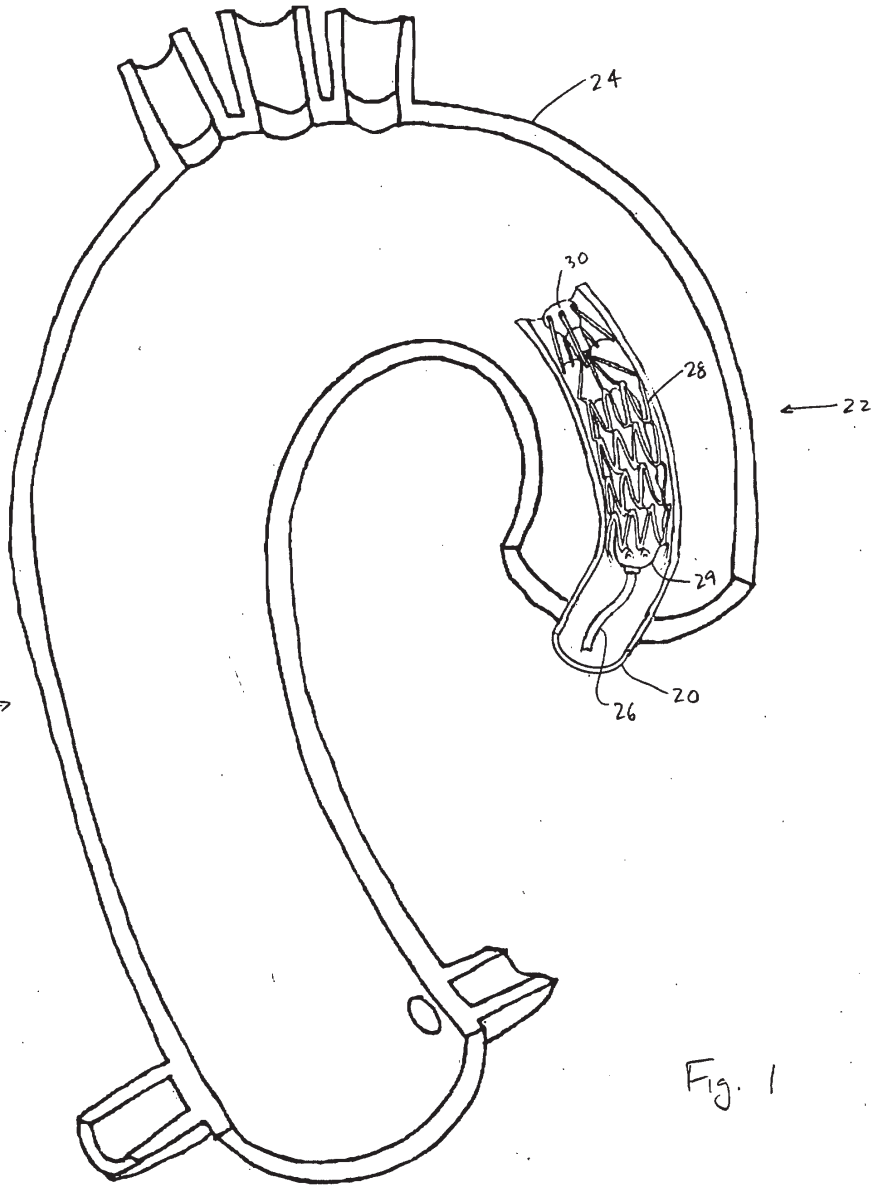

Fig. 1

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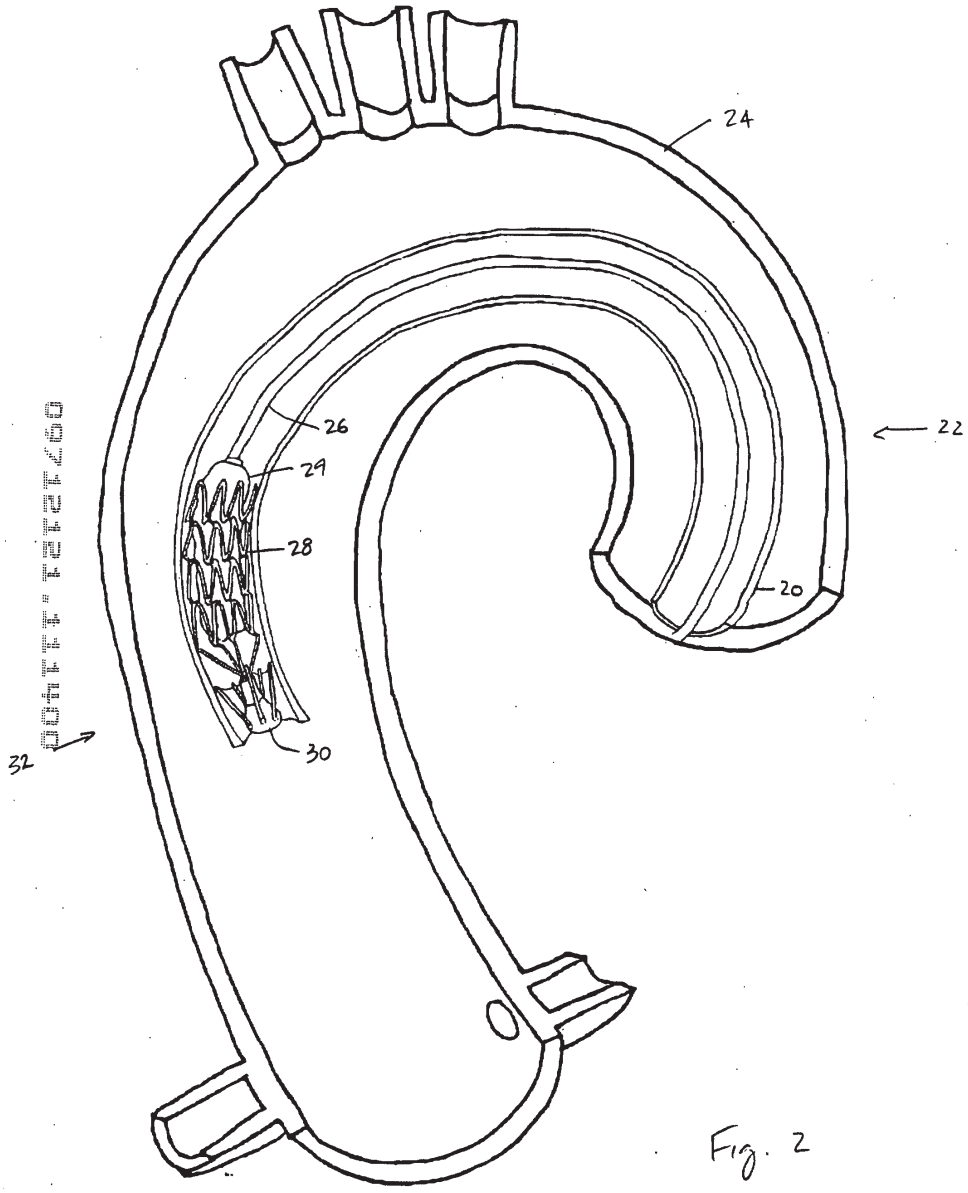

Fig. 2

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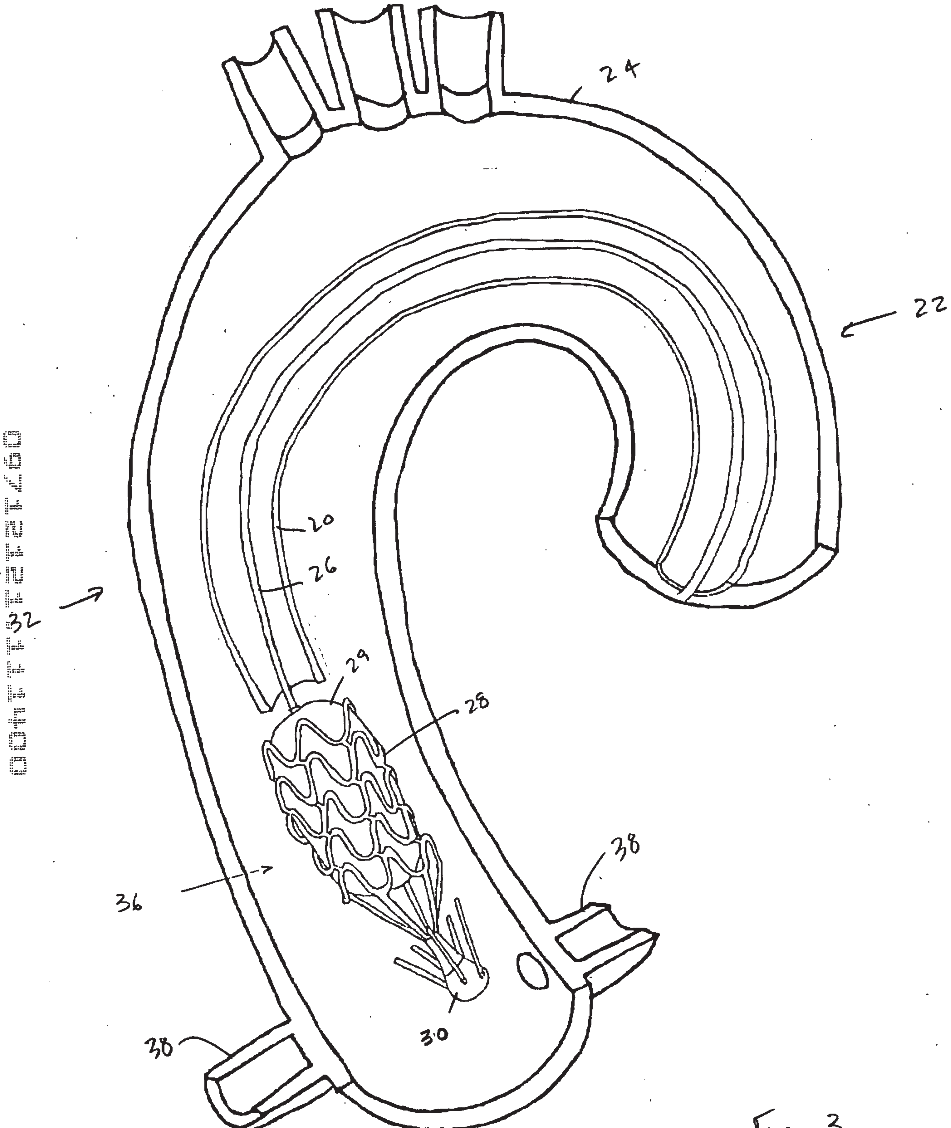

Fig. 3

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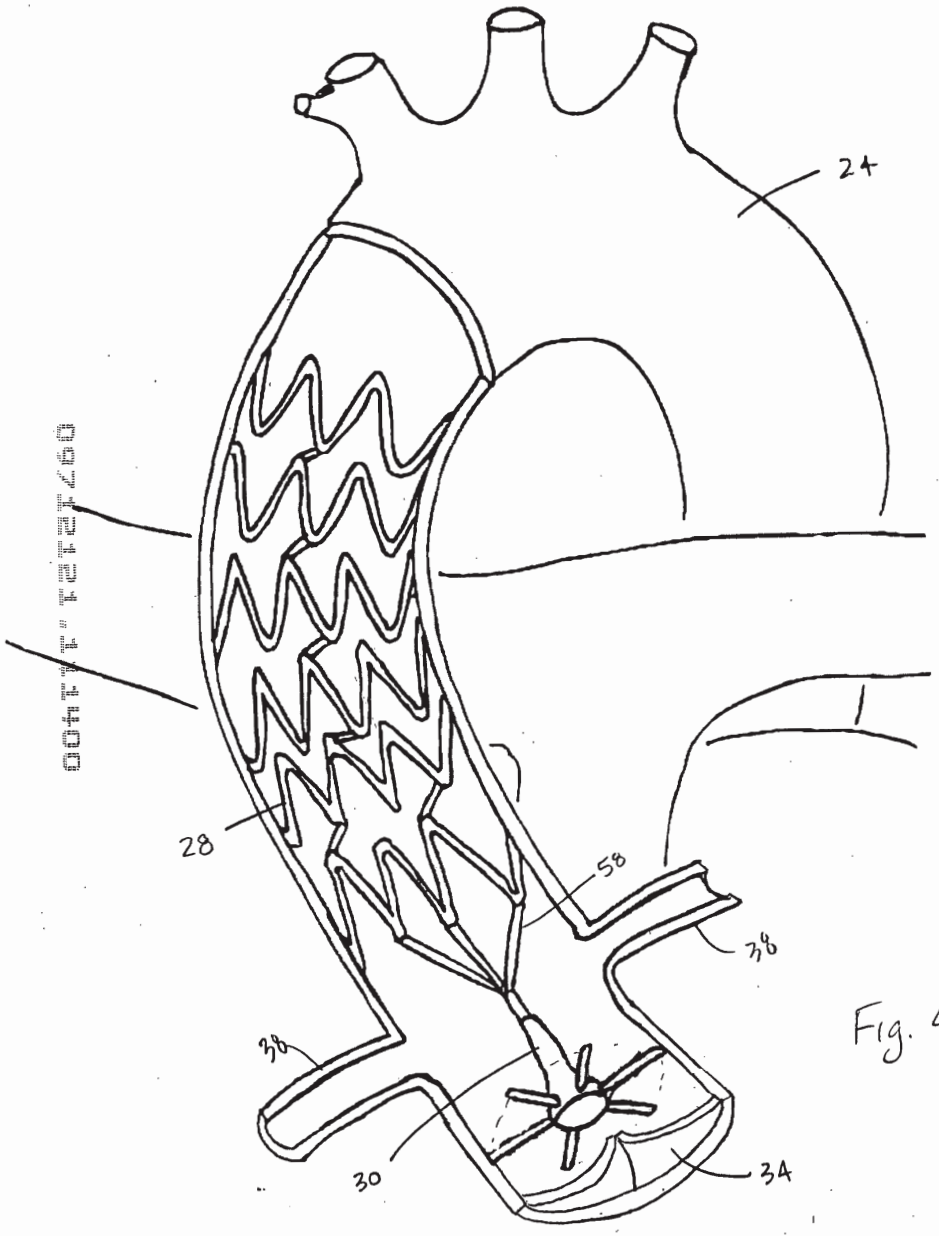

Fig. 4

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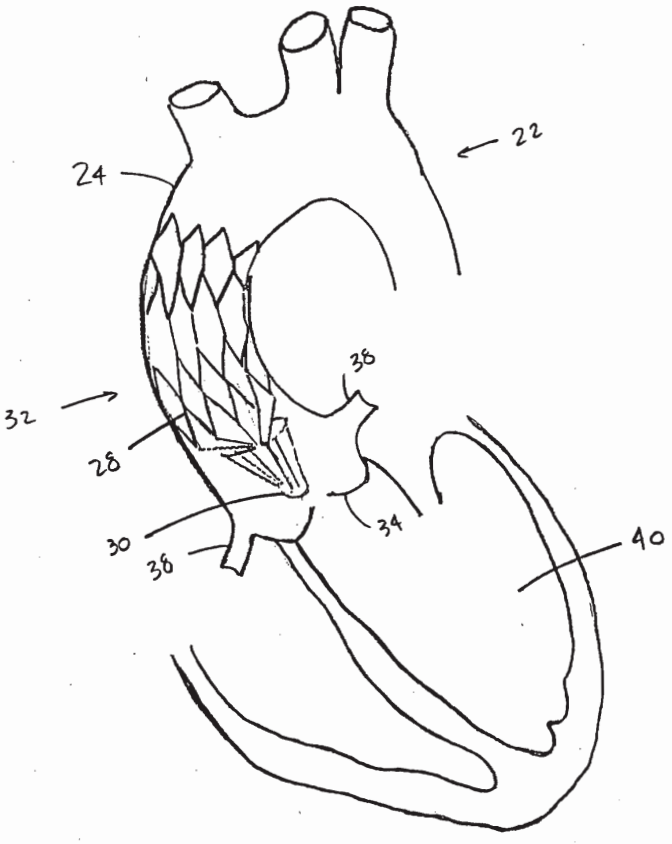

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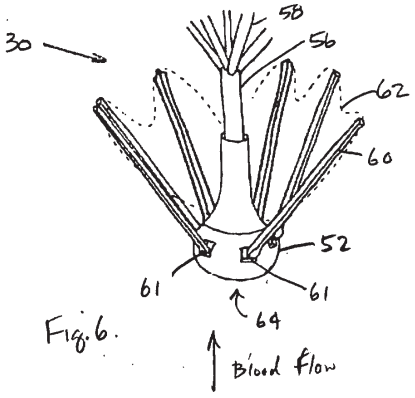

Fig. 6.

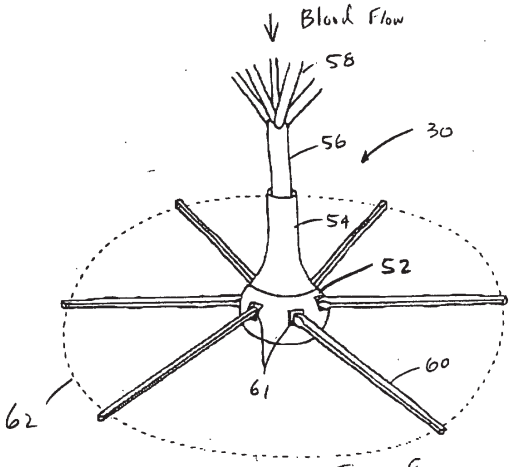

Fig 8

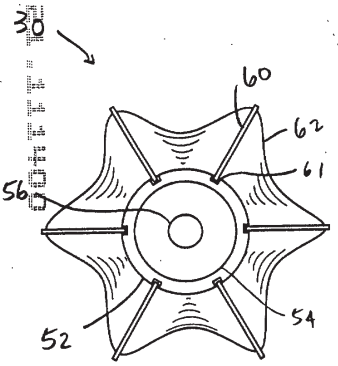

Fig 7

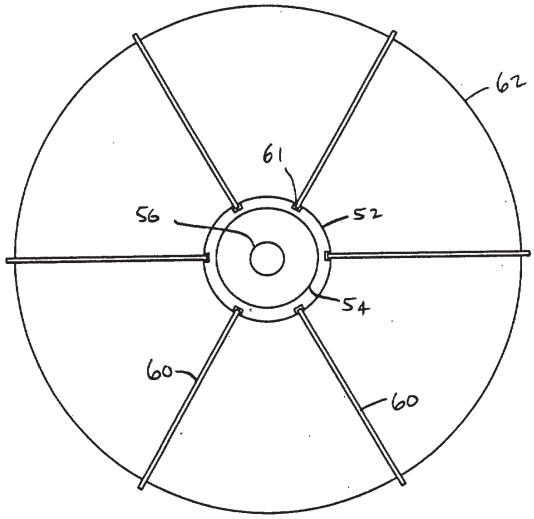

Fig 9

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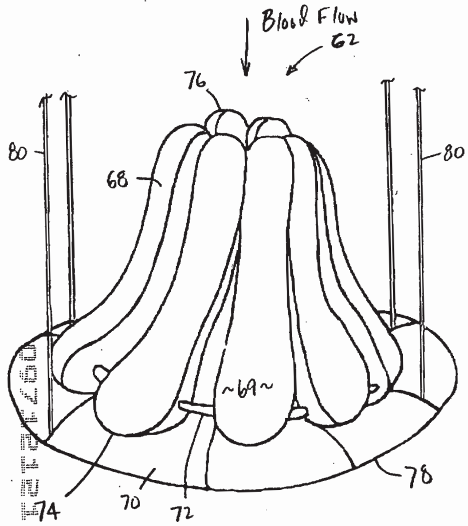

Fig. 10

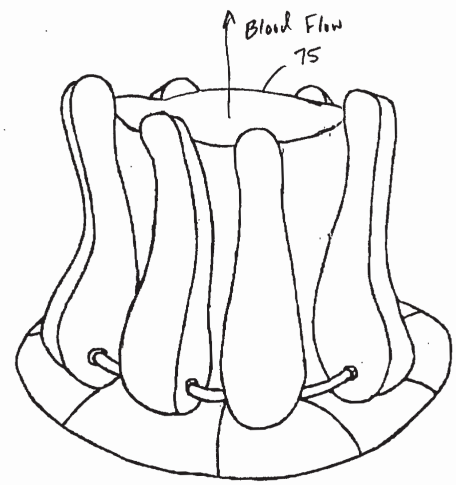

Fig. 12

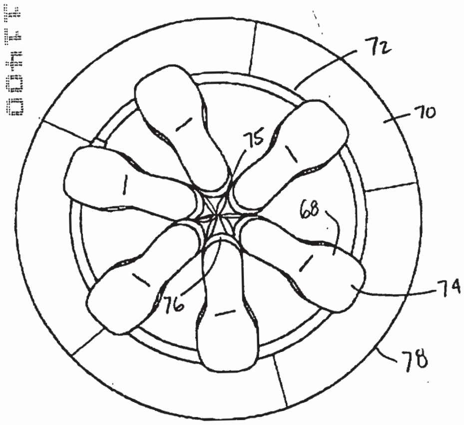

Fig. 11

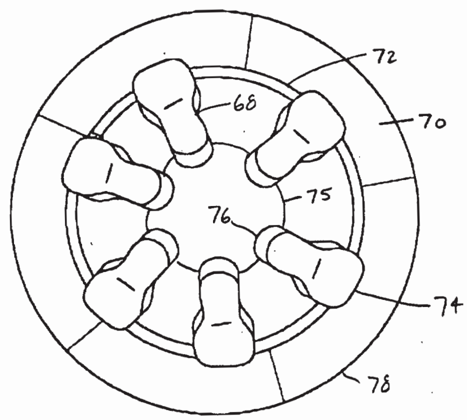

Fig. 13

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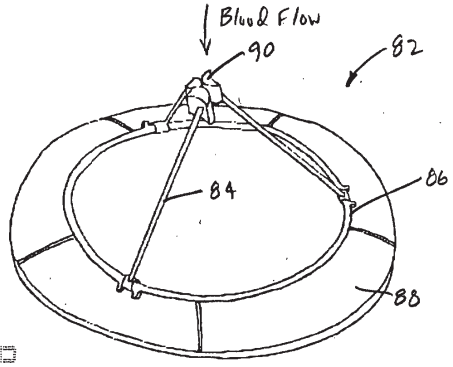

Fig 14

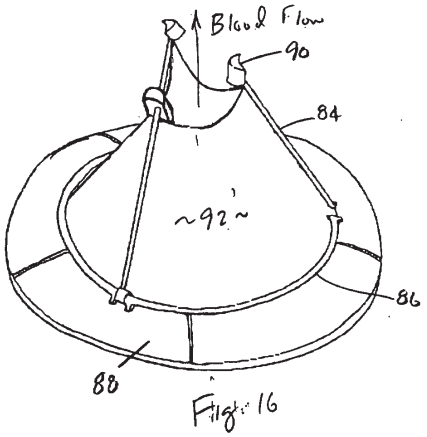

Fig. 16

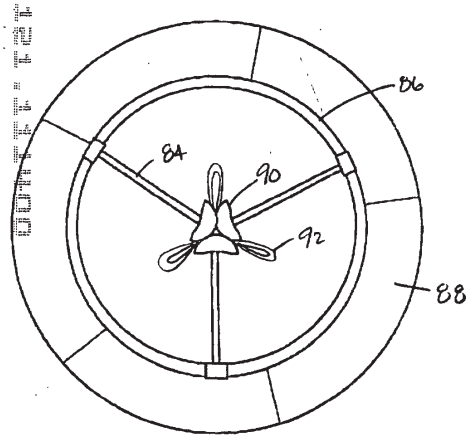

Fig. 15

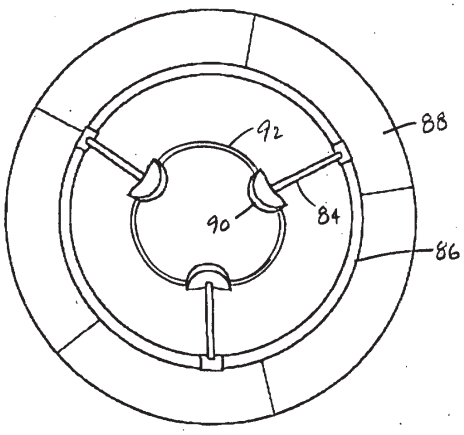

Fig. 17

PRINT OF DRAWINGS
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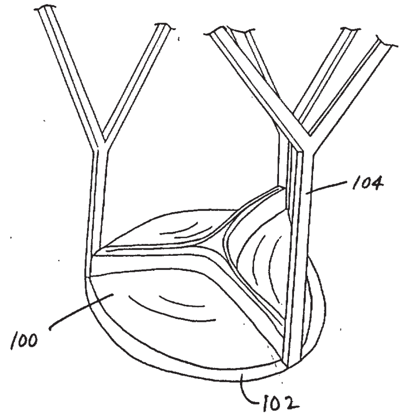

Fig. 18

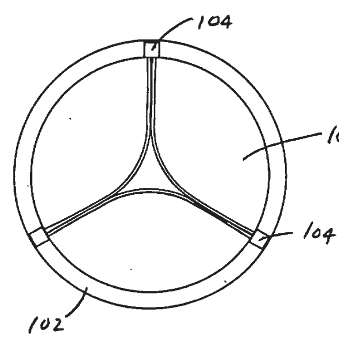

Fig. 19

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of	)	November 14, 2000
	)	
TROY R. NORRED	)	
	)	
For: PERCUTANEOUS AORTIC VALVE REPLACEMENT	)	
	)	

Assistant Commissioner of Patents

Washington, D. C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

Applicant hereby represents that he is unaware of any prior art. No pre-application search has been conducted in the records of the U. S. Patent and Trademark Office. The applicant does not represent that no prior art exists.

Respectfully submitted,

D. A. N. CHASE
Patent Office Reg. No. 20,682
MICHAEL YAKIMO, JR.
Patent Office Reg. No. 28,549
GINNIE CHASE DERUSSEAU
Patent Office Reg. No. 35,855
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Attorneys for Applicant

(Docket 2745)

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/712,121	11/14/00	NORRED	T 2745

EXAMINER

QM32/0809

MICHAEL YAKIMO, JR.
CHASE & YAKIMO, L. C.
4400 COLLEGE BOULEVARD, SUITE 130
OVERLAND PARK KS 66211

ART UNIT	PAPER NUMBER
3738	3

DATE MAILED: 08/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/712,121	NORRED, TROY R.	
	Examiner	Art Unit	
	Michael J Milano	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-7,9-14 and 16-18* is/are rejected.

7)☒ Claim(s) *3,4,8 and 15* is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 is not understood because "said at least two ribs" lacks antecedent basis in claim 14.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1,2,5-7,13,14 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Quijano, 6110201.

Claims 1,2,5-7,13,14,17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Baykut, 4787901.

Claims 1,2,5-7,9-14 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Leonhardt, 5957949.

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Andersen, 6168614.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J Milano whose telephone number is 703-308-2496. The examiner can normally be reached on M,T,TH,F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corinne McDermott can be reached on 703-308-0858. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Michael J Milano
Primary Examiner
Art Unit 3738

mjm
August 7, 2001

Notice of References Cited	Application/Control No. 09/712,121	Applicant(s)/Patent Under Reexamination NORRED, TROY R.	
	Examiner Michael J Milano	Art Unit 3738	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification	
	A	US-6264700-B1	07-2001	KILCOYNE	623	12.2
	B	US-6254642-B1	07-2001	TAYLOR	623	12.2
	C	US-6168614-B1	01-2001	ANDERSON	623	12.2
	D	US-6110201-A	08-2000	QUIJANO	623	2.1
	E	US-6027525-A	02-2000	SUH	623	2.1
	F	US-5957949-A	09-1999	LEONHARDT	623	2.1
	G	US-5891195-A	04-1999	KLOSTERMEYER	623	2.1
	H	US-5549665-A	08-1996	VESELY	623	2.1
	I	US-5545215-A	08-1996	DURAN	623	2.1
	J	US-5413599-A	05-1995	IMACHI	623	2.1
	K	US-5397351-A	03-1995	PAVCNIK	623	2.1
	L	US-4787901-	11-1988	BAYKUT	623	2.1
	M	US- -				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification	
	N	- -					
	O	- -					
	P	- -					
	Q	- -					
	R	- -					
	S	- -					
	T	- -					

NON-PATENT DOCUMENTS

*		*Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)*
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

06/01/01

Interview Summary	Application No.	Applicant(s)	
	09/712,121	NORRED, TROY R.	
	Examiner	Art Unit	
	Michael J Milano	3731	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Michael J Milano*. (3)_____.

(2) *Michael Yakimo*. (4)_____.

Date of Interview: *30 January 2002* .

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____ .

Claim(s) discussed: *Claims 19-27* .

Identification of prior art discussed: _____ .

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *The status of claims 19-27 was missing from the Office action of 8/9/01. Claims 19-27 should have been stated as allowable in the 8/9/01 action. The 8/9/01 Office action should have stated that claims 1,2,5-7,9-14 and 16-18 were rejected, claims 3,4,8 and 15 were objected to and claims 19-27 were allowed.* .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i)☒ It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

_____
Examiner's signature, if required

ummary of Record of Interview Requireme

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

#5/C
Thomo
3-8-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of	)	February 6, 2002
TROY R. NORRED	)	
Serial No. 09/712,121	)	Group Art Unit 3738
Filed November 14, 2000	)	
For: PERCUTANEOUS AORTIC VALVE REPLACEMENT	)	Examiner: Michael J. Milano (703) 308-2496

Assistant Commissioner of Patents

Washington, D. C. 20231

Sir:

RESPONSE

In response to the office action dated August 9, 2001, please amend the above-identified application as set forth below.

In the claims:

1. (Amended) An aortic valve for regulating blood flow through a channel of an aorta, the channel surrounded by an aortic wall, upon placement therein, said valve comprising:

a body member having a configuration adapted to fit within a channel of an aorta;

a membrane made of a material impervious to an aortic blood flow [therethrough], said membrane having a first position precluding a blood flow through the aorta and a second position for allowing a blood flow through the aorta; and

(Docket 2745)

03/04/2002 MAHMED1 00000176 09712121
01 FC:217 460.00 OP

I hereby certify that this paper is being deposited with the U.S. Postal Service with sufficient postage as first class mail addressed to the Assistant Commissioner of Patents, Washington, D. C. 20231 on February 6, 2002.

Michael Yakimo, Jr., P.O. Reg. No. 28,549

[means for mounting said membrane relative to said body member between] a plurality of frame members with said membrane mounted thereto, each frame member having a first end pivotally secured to said body member and a second end, said frame members pivotally responsive to a condition within the aorta between [to] a first position wherein said membrane at said first frame member position is at said first membrane position [precludes a blood flow past said body member] and a said second frame member position wherein said membrane [allows a blood flow past said body member.] is at said second membrane position.

2. (Amended) An aortic valve as claimed in claim 1 wherein said membrane extends across the aortic channel to block a blood flow at said first membrane position and extends generally along the aortic channel to allow a blood flow through the aorta at said second membrane position.

Please cancel claim 3.

4. (Amended) The aortic valve as claimed in claim [3] 1 further comprising [a] means for stopping pivotal movement of said second end of said frame members [at said first position.] into contact with the aorta wall.

5. (Amended) The aortic valve as claimed in claim 1 wherein [said mounting means is responsive to] said condition within the aorta is a change[s] in blood pressure in the aorta, [whereby to move said membrane between said first and second positions.]

6. (Amended) The aortic valve as claimed in claim [5] 1 wherein said frame members and membrane move[s] to said second positions in response to systolic ejection of blood from the left ventricle in which the blood pressure in the left ventricle is higher than the blood pressure in the aorta.

7. (Amended) The aortic valve as claimed in claim [5] 1 wherein said frame member and membrane move[s] to said first position in response to diastolic filling of the left ventricle and the blood pressure in the aorta is higher than the blood pressure in the left ventricle resulting in a reverse flow of blood from the aorta to the left ventricle which is stopped by said membrane at said first position.

8. (Amended) An aortic valve as claimed in claim 1 wherein said body member has an exterior configuration to present a space between said body member exterior configuration and [said] the aortic wall to allow blood flow therearound at said membrane second position.

9. (Amended) The aortic valve as claimed in claim 1 wherein said body member [is generally ring-shaped having] comprises a [circumference] base presenting an edge adapted to seat about [an inner circumference of] the aortic wall surrounding the aortic channel; [, said ring having]

an aperture in said base for blood flow therethrough;[.]

a ring surrounding said aperture, said first end of said frame members [rotatably] pivotally mounted to said ring with said membrane mounted thereto, said second ends of said frame members being in contact at said first frame member position to cause said membrane to span said base aperture and preclude a blood flow past said second frame member ends and [through] said [aperture] membrane, said frame members [rotatable] pivotable about said ring to a second position wherein said second frame member ends are displaced one from the other to allow a blood flow [thereby] through the aperture and past said membrane.

10. (Amended) The aortic valve as claimed in claim 9 wherein said membrane [is generally funnel-shaped having] presents a base opening secured [to an inner circumference of said ring-shaped body member] about said aperture and a free end having an aperture therein, [whereby] said aperture in said free end of said membrane at said second frame and membrane positions is open to allow blood to flow though said membrane [from] between said membrane base opening [to] and said aperture in said free end of said membrane at said membrane second position.

11. (Amended) The aortic valve as claimed in claim 9 wherein said membrane [is generally funnel-shaped having a base opening secured to an inner circumference of said ring-shaped body member and a] free end [having an] aperture [therein whereby said aperture in said free end of said membrane] is closed at said first frame member and membrane positions to preclude blood from flowing though said membrane [from said aperture in said free end of said membrane to said membrane base opening] at said membrane first position.

12. (Amended) The aortic valve as claimed in claim 10 wherein said membrane [is generally funnel-shaped having a base opening secured to an inner circumference of said ring-shaped body member and a] free end [having an] aperture [therein whereby said aperture in said free end of said membrane] is closed at said first frame membrane and member positions to preclude blood from flowing though said membrane [from said aperture in said free end of said membrane to said membrane base opening] at said membrane first position.

14. (Amended) An aortic valve for regulating blood flow through a channel of an aorta upon placement therein, said valve comprising:

a body member having a configuration adapted to fit within a channel of an aorta to allow passage of a blood flow therearound;

a membrane for traversing the aortic channel to preclude blood flow therethrough; and

[means for mounting said membrane] at least two ribs for attachment of said membrane thereto, each rib having a first end hingedly attached to said body member and a free end extending from said body member, wherein said at least two ribs are responsive to a change in pressure in the aorta for movement between a first position wherein said membrane is unfolded so as to traverse the aortic channel and preclude a blood flow therethrough and a second collapsed position wherein said membrane is positioned relative to the [body member] aorta channel to allow a blood flow therearound.

Please cancel claim 15.

17. (Amended) The aortic valve as claimed in claim 14 wherein said membrane presents an edge adapted for contact[s the] about a wall of the aortic channel in said first position [and seals], said contact seats said membrane edge against the aortic channel wall to reduce a blood flow therearound.

18. (Amended) The aortic valve as claimed in claim 14 further comprising means for maintaining said body member at a selected position in the aorta.

19. (Amended) An aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein, said valve comprising:

a ring member having a circumference adapted to seat about an aortic wall surrounding an aortic channel, said ring including an aperture for blood flow therethrough;

a membrane having first and second spaced-apart open ends, said membrane made of a material resistant to a fluid flow therethrough; and

means for mounting said first open end of said membrane about said ring aperture with said second open end displaced therefrom, said means moving said [second] membrane second end between a[n] first open position to allow a blood flow therethrough and a second closed position to preclude a blood flow therethrough.

20. (Amended) The aortic valve as claimed in claim 19 wherein said mounting means comprises at least one arm having a first end hingedly secured to said ring member and a free end spaced therefrom, said first end of said at least one arm secured to said first end of said membrane, said free end of said at least one arm secured to said second end of said membrane, [and wherein] said at least one arm responsive to a blood flow within the channel for movement [moves] with said membrane between said first open and second closed positions.

21. (Amended) The aortic valve as claimed in claim 19 wherein said at least one arm extends generally along a path of said blood flow [when in] at said first open position, and generally traverses [to said] a blood flow path when [in] at said second closed position.

23. (Amended) An aortic valve for controlling a blood flow through an aortic channel upon placement therein, said valve comprising:

a tissue valve having an interior member [and circumference;] made of a tissue material and presenting an opening movable between open and closed positions;

a ring member [secured to] surrounding said tissue valve, [along said tissue valve circumference and] said ring member having an outer circumference adapted to seat said ring member about an aortic wall surrounding an aortic channel;

means for maintaining said ring member in said seated position about the aortic wall,[; and]

[means for moving] said tissue valve interior member responsive to changes of conditions within the aorta for movement of said opening between a first closed position and a second open position.

24. (Amended) The aortic valve as claimed in claim 23 wherein said tissue valve interior member is responsive to changes in blood pressure in the aorta whereby to move said tissue valve between said first and second positions.

REMARKS

Claims 1, 2, 4-14, 16-27 are now in this application.

Claim 14 has been amended to address the examiner's 35 U.S.C. § 112 objection to claim 16.

Applicant has incorporated the objected to claims 3 and 15 into the respective independent claims 1 and 14. Thus, these claims and their dependent claims should now stand allowed.

Claim 9 has been amended to reflect the use of a base, ring and frame members pivotally mounted thereto. No such structure is shown in the prior art. Thus, claims 9-14 should now stand allowed.

Applicant has also amended all the claims, including the allowed claims 19-27, to improve the language therein. No substantive changes have been made by these grammatical amendments.

Accordingly, reconsideration and allowance of the now pending claims 1, 2, 4-14, 16-19 is requested, along with the previously allowed claims.

A $460 check for the three-month extension fee is also enclosed.

Respectfully submitted,

D. A. N. CHASE, Reg. #20,682
MICHAEL YAKIMO, JR., Reg. #28,549
GINNIE C. DERUSSEAU, Reg. #35,855
JAMES J. KERNELL, Reg. #42,720
SEAN T. BRADLEY, Reg. #46,572
CHASE LAW FIRM, L.C.
4400 College Boulevard
Suite 130
Overland Park, Kansas 66211
Telephone: (913) 339-9666

Attorneys for Applicant

1. (Amended) An aortic valve for regulating blood flow through a channel of an aorta, the channel surrounded by an aortic wall, upon placement therein, said valve comprising:

a body member having a configuration adapted to fit within a channel of an aorta;

a membrane made of a material impervious to an aortic blood flow, said membrane having a first membrane position precluding a blood flow through the aorta and a second position for allowing a blood flow through the aorta; and

a plurality of frame members with said membrane mounted thereto, each frame member having a first end pivotally secured to said body member and a second end, said frame members pivotally responsive to a condition within the aorta between a first position wherein said membrane at said first frame member position is at said first membrane position and a said second frame member position wherein said membrane is at said second membrane position.

2. (Amended) An aortic valve as claimed in claim 1 wherein said membrane extends across the aortic channel to block a blood flow at said first membrane position and extends generally along the aortic channel to allow a blood flow through the aorta at said second membrane position.

3 4. (Amended) The aortic valve as claimed in claim 1 further comprising means for stopping pivotal movement of said second end of said frame members into contact with the aorta wall.

4 5. (Amended) The aortic valve as claimed in claim 1 wherein said condition within the aorta is a change in blood pressure in the aorta.

5 6. (Amended) The aortic valve as claimed in claim 1 wherein said frame members and membrane move to said second positions in response to systolic ejection of blood from the left ventricle in which the blood pressure in the left ventricle is higher than the blood pressure in the aorta.

6 7. (Amended) The aortic valve as claimed in claim 1 wherein said frame member and membrane move to said first position in response to diastolic filling of the left ventricle and the blood pressure in the aorta is higher than the blood pressure in the left ventricle resulting in a reverse flow of blood from the aorta to the left ventricle which is stopped by said membrane at said first position.

1 8. (Amended) An aortic valve as claimed in claim 1 wherein said body member has an exterior configuration to present a space between said body member exterior configuration and the aortic wall to allow blood flow therearound at said membrane second position.

23

8. (Amended) The aortic valve as claimed in claim 1 wherein said body member comprises a base presenting an edge adapted to seat about the aortic wall surrounding the aortic channel;

an aperture in said base for blood flow therethrough;

a ring surrounding said aperture, said first end of said frame members pivotally mounted to said ring with said membrane mounted thereto, said second ends of said frame members being in contact at said first frame member position to cause said membrane to span said base aperture and preclude a blood flow past said second frame member ends and said membrane, said frame members pivotable about said ring to a second position wherein said second frame member ends are displaced one from the other to allow a blood flow through the aperture and past said membrane.

10. (Amended) The aortic valve as claimed in claim 8 wherein said membrane presents a base opening secured about said aperture and a free end having an aperture therein, said aperture in said free end of said membrane at said second frame and membrane positions is open to allow blood to flow though said membrane between said membrane base opening and said aperture in said free end of said membrane at said membrane second position.

11. (Amended) The aortic valve as claimed in claim 9 wherein said membrane free end aperture is closed at said first frame member and membrane positions to preclude blood from flowing though said membrane at said membrane first position.

12. (Amended) The aortic valve as claimed in claim 10 wherein said membrane free end aperture is closed at said first frame membrane and member positions to preclude blood from flowing though said membrane at said membrane first position.

14. (Amended) An aortic valve for regulating blood flow through a channel of an aorta upon placement therein, said valve comprising:

a body member having a configuration adapted to fit within a channel of an aorta to allow passage of a blood flow therearound;

a membrane for traversing the aortic channel to preclude blood flow therethrough; and

at least two ribs for attachment of said membrane thereto, each rib having a first end hingedly attached to said body member and a free end extending from said body member, wherein said at least two ribs are responsive to a change in pressure in the aorta for movement between a first position wherein said membrane is unfolded so as to traverse the aortic channel and preclude a blood flow therethrough and a second collapsed position wherein said membrane is positioned relative to the aorta channel to allow a blood flow therearound.

17. (Amended) The aortic valve as claimed in claim 14 wherein said membrane presents an edge adapted for contact about a wall of the aortic channel in said first position, said contact seats said membrane edge against the aortic channel wall to reduce a blood flow therearound.

18. (Amended) The aortic valve as claimed in claim 14 further comprising means for maintaining said body member at a selected position in the aorta.

19. (Amended) An aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein, said valve comprising:

a ring member having a circumference adapted to seat about an aortic wall surrounding an aortic channel, said ring including an aperture for blood flow therethrough;

a membrane having first and second spaced-apart open ends, said membrane made of a material resistant to a fluid flow therethrough; and

means for mounting said first open end of said membrane about said ring aperture with said second open end displaced therefrom, said means moving said membrane second end between a first open position to allow a blood flow therethrough and a second closed position to preclude a blood flow therethrough.

20. (Amended) The aortic valve as claimed in claim 19 wherein said mounting means comprises at least one arm having a first end hingedly secured to said ring member and a free end spaced therefrom, said first end of said at least one arm secured to said first end of said membrane, said free end of said at least one arm secured to said second end of said membrane, said at least one arm responsive to a blood flow within the channel for movement with said membrane between said first open and second closed positions.

21. (Amended) The aortic valve as claimed in claim 19 wherein said at least one arm extends generally along a path of said blood flow at said first open position, and generally traverses a blood flow path when at said second closed position.

20 ~~21~~ ~~23~~. (Amended) An aortic valve for controlling a blood flow through an aortic channel upon placement therein, said valve comprising:

a tissue valve having an interior member made of a tissue material and presenting an opening movable between open and closed positions;

a ring member surrounding said tissue valve, said ring member having an outer circumference adapted to seat said ring member about an aortic wall surrounding an aortic channel;

means for maintaining said ring member in said seated position about the aortic wall,

said tissue valve interior member responsive to changes of conditions within the aorta for movement of said opening between a first closed position and a second open position.

21 ~~24~~. (Amended) The aortic valve as claimed in claim ~~23~~ 20 wherein said tissue valve interior member is responsive to changes in blood pressure in the aorta whereby to move said tissue valve between said first and second positions.

GP/3738

PTO/SB/17 (10-01)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2002

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT ($) 460.00

Complete if Known	
Application Number	09/712,121
Filing Date	November 14, 2000
First Named Inventor	Troy R. Norred
Examiner Name	Michael J. Milano
Group Art Unit	3738
Attorney Docket No.	2745

METHOD OF PAYMENT

1. ☑ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:
   - Deposit Account Number: 03-1425
   - Deposit Account Name: Chase & Yakimo
   - ☑ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17
   - ☑ Applicant claims small entity status. See 37 CFR 1.27
2. ☑ **Payment Enclosed:** ☑ Check ☐ Credit card ☐ Money Order ☐ Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	740	201	370	Utility filing fee	
106	330	206	165	Design filing fee	
107	510	207	255	Plant filing fee	
108	740	208	370	Reissue filing fee	
114	160	214	80	Provisional filing fee	

SUBTOTAL (1) ($) -0-

2. EXTRA CLAIM FEES

	Extra Claims		Fee from below	Fee Paid
Total Claims		-20** =	X	=
Independent Claims		- 3** =	X	=
Multiple Dependent				=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	84	202	42	Independent claims in excess of 3
104	280	204	140	Multiple dependent claim, if not paid
109	84	209	42	** Reissue independent claims over original patent
110	18	210	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) -0-

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for *ex parte* reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	400	216	200	Extension for reply within second month	
117	920	217	460	Extension for reply within third month	460.00
118	1,440	218	720	Extension for reply within fourth month	
128	1,960	228	980	Extension for reply within fifth month	
119	320	219	160	Notice of Appeal	
120	320	220	160	Filing a brief in support of an appeal	
121	280	221	140	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,280	241	640	Petition to revive - unintentional	
142	1,280	242	640	Utility issue fee (or reissue)	
143	460	243	230	Design issue fee	
144	620	244	310	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Processing fee under 37 CFR 1.17(q)	
126	180	126	180	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	740	246	370	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	740	249	370	For each additional invention to be examined (37 CFR § 1.129(b))	
179	740	279	370	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 460.00

TC 3700 MAIL ROOM

SUBMITTED BY				Complete (if applicable)	
Name (Print/Type)	Michael Yakimo, Jr.	Registration No. (Attorney/Agent)	28,549	Telephone	913-339-9666
Signature	Michael Yakimo			Date	2/6/2002

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

10

Notice of Allowability	Application No.	Applicant(s)
	09/712,121	NORRED, TROY R.
	Examiner	Art Unit
	William H. Matthews (Howie)	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Amendment filed 2-26-02*.
2. ☒ The allowed claim(s) is/are *1,2,4-14,16-27 (renumbered as claims 1-25)*.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☒ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____.
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

8. ☒ CORRECTED DRAWINGS must be submitted.
   (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☒ hereto or 2) ☐ to Paper No. ____.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1☐ Notice of References Cited (PTO-892)
2☐ Notice of Informal Patent Application (PTO-152)
3☒ Notice of Draftperson's Patent Drawing Review (PTO-948)
4☐ Interview Summary (PTO-413), Paper No.____.
5☐ Information Disclosure Statements (PTO-1449), Paper No. ____.
6☒ Examiner's Amendment/Comment
7☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
8☐ Examiner's Statement of Reasons for Allowance
9☐ Other

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michael Yakimo on March 26, 2002.

The application has been amended as follows:

In the claims,

On line 6 of claim 1, ----membrane---- was inserted between "first" and "position".

On line 6 of claim 2, ----membrane---- was inserted between "second" and "position".

On lines 2 and 3 of claim 27, "ring" was replaced with ----ring member----.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

WHM
March 27, 2002

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Form PTO 948 (Rev. 03/01) U.S. DEPARTMENT OF COMMERCE - Patent and Trademark Office Application No. 7/2/21

NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW

The drawing(s) filed (insert date) 11/14/00 are:

A. ☐ approved by the Draftsperson under 37 CFR 1.84 or 1.152.

B. ☒ objected to by the Draftsperson under 37 CFR 1.84 or 1.152 for the reasons indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawing must be sumitted according to the instructions on the back of this notice.

1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings:
Black ink. Color.
___ Color drawings are not acceptable until petiton is granted.
Fig(s) _____
___ Pencil and non black ink not permitted. Fig(s) _____

2. PHOTOGRAPHS. 37 CFR 1.84(b)
___ Photographs may not be mounted. 37 CFR 1.84(e)
___ Poor quality (half-tone). Fig(s) _____

3. TYPE OF PAPER. 37 CFR 1.84(e)
___ Paper not flexible, strong, white, and durable.
Fig(s) _____
___ Erasures, alterations, overwritings, interlineations, folds, copy machine marks not accepted. Fig(s) _____
___ Mylar, velum paper is not acceptable (too thin).
Fig(s) _____

4. SIZE OF PAPER. 37 CFR 1.84(f): Acceptable sizes:
___ 21.0 cm by 29.7 cm (DIN size A4)
___ 21.6 cm by 27.9 cm (8 1/2 x 11 inches)
___ All drawing sheets not the same size.
Sheet(s) _____
___ Drawings sheets not an acceptable size. Fig(s) _____

5. MARGINS. 37 CFR 1.84(g): Acceptable margins:
Top 2.5 cm Left 2.5cm Right 1.5 cm Bottom 1.0 cm
SIZE: A4 Size
Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm
SIZE: 8 1/2 x 11
Margins not acceptable. Fig(s) _____
_____ Top (T) _____ Left (L)
_____ Right (R) _____ Bottom (B)

6. VIEWS. 37 CFR 1.84(h)
REMINDER: Specification may require revision to correspond to drawing changes.
Partial views. 37 CFR 1.84(h)(2)
___ Brackets needed to show figure as one entity.
Fig(s) _____
___ Views not labeled separately or properly.
Fig(s) _____
___ Enlarged view not labeled separetely or properly.
Fig(s) _____

7. SECTIONAL VIEWS. 37 CFR 1.84 (h)(3)
___ Hatching not indicated for sectional portions of an object.
Fig(s) _____
___ Sectional designation should be noted with Arabic or Roman numbers. Fig(s) _____

8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)
___ Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s) _____

9. SCALE. 37 CFR 1.84(k)
___ Scale not large enough to show mechanism without crowding when drawing is reduced in size to two-thirds in reproduction.
Fig(s) _____

10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(l)
☒ Lines, numbers & letters not uniformly thick and well defined, clean, durable, and black (poor line quality).
Fig(s) 1 – 19

11. SHADING. 37 CFR 1.84(m)
___ Solid black areas pale. Fig(s) _____
___ Solid black shading not permitted. Fig(s) _____
___ Shade lines, pale, rough and blurred. Fig(s) _____

12. NUMBERS, LETTERS, & REFERENCE CHARACTERS. 37 CFR 1.84(p)
___ Numbers and reference characters not plain and legible.
Fig(s) _____
___ Figure legends are poor. Fig(s) _____
___ Numbers and reference characters not oriented in the same direction as the view. 37 CFR 1.84(p)(1)
Fig(s) _____
___ English alphabet not used. 37 CFR 1.84(p)(2)
Figs. _____
___ Numbers, letters and reference characters must be at least .32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3)
Fig(s) _____

13. LEAD LINES. 37 CFR 1.84(q)
___ Lead lines cross each other. Fig(s) _____
___ Lead lines missing. Fig(s) _____

14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(t)
___ Sheets not numbered consecutively, and in Arabic numerals beginning with number 1. Sheet(s) _____

15. NUMBERING OF VIEWS. 37 CFR 1.84(u)
___ Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s) _____

16. CORRECTIONS. 37 CFR 1.84(w)
___ Corrections not made from prior PTO-948 dated _____

17. DESIGN DRAWINGS. 37 CFR 1.152
___ Surface shading shown not appropriate. Fig(s) _____
___ Solid black shading not used for color contrast.
Fig(s) _____

COMMENTS

REVIEWER _____ DATE 3/24/02 TELEPHONE NO. _____

ATTACHMENT TO PAPER NO. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 04/02/2002

Michael Yakimo, Jr.
Chase & Yakimo, L. C.
4400 College Boulevard, Suite 130
Overland Park, KS 66211

EXAMINER
MATTHEWS, WILLIAM H

ART UNIT	CLASS-SUBCLASS
3738	623-002180

DATE MAILED: 04/02/2002

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,121	11/14/2000	Troy R. Norred	2745	9253

TITLE OF INVENTION: PERCUTANEOUS AORTIC VALVE REPLACEMENT

TOTAL CLAIMS	APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
25	nonprovisional	YES	$640	$0	$640	07/02/2002

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above. If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

B. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (REV. 07-01) Approved for use through 01/31/2004.

PART B - FEE(S) TRANSMITTAL

Complete and mail this form, together with applicable fee(s), to:

Box ISSUE FEE
Assistant Commissioner for Patents
Washington, D.C. 20231

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

7590 04/02/2002

Michael Yakimo, Jr.
Chase & Yakimo, L. C.
4400 College Boulevard, Suite 130
Overland Park, KS 66211

Note: The certificate of mailing below can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

Certificate of Mailing

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(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,121	11/14/2000	Troy R. Norred	2745	9253

TITLE OF INVENTION: PERCUTANEOUS AORTIC VALVE REPLACEMENT

TOTAL CLAIMS	APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
25	nonprovisional	YES	$640	$0	$640	07/02/2002

EXAMINER	ART UNIT	CLASS-SUBCLASS
MATTHEWS, WILLIAM H	3738	623-002180

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Use of PTO form(s) and Customer Number are recommended, but not required.

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47) attached.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

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3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) ❑ individual ❑ corporation or other private group entity ❑ government

4a. The following fee(s) are enclosed:

❑ Issue Fee

❑ Publication Fee

❑ Advance Order - # of Copies _____

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❑ A check in the amount of the fee(s) is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

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(Authorized Signature) (Date)

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,121	11/14/2000	Troy R. Norred	2745	9253

7590 04/02/2002

Michael Yakimo, Jr.
Chase & Yakimo, L. C.
4400 College Boulevard, Suite 130
Overland Park, KS 66211

EXAMINER	
MATTHEWS, WILLIAM H	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 04/02/2002

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The patent term adjustment to date is 0 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 0 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (http://pair.uspto.gov)

PTOL-85 (REV. 07-01) Approved for use through 01/31/2004.

3
09/712,121

B2
#7
Amdt b (Rule 312) N.E.
S. Bruce 8/12/02

OIPE JC
JUL 10 2002
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of	)	July 2, 2002
TROY R. NORRED	)	
	)	Group Art 3738
Serial No. 09/712,121	)	Notice of Allowance: April 2, 2002
Filed November 14, 2000	)	
For: PERCUTANEOUS AORTIC VALVE REPLACEMENT	)	Examiner: William H. Matthews
	)	(703) 305-0316

Match & Return

Assistant Commissioner of Patents
Washington, D. C. 20231

Sir:

37 C.F.R. §1.312 AMENDMENT AFTER ALLOWANCE

In response to the Notice of Allowability of April 2, 2002, please amend the above-identified application as set out below.

Entered
APP
9-12-02

In the claims:

Please cancel claim 11.

B1

18 ~~17~~ 21. (Amended) The aortic valve as claimed in claim ~~20~~ 17 wherein said at least one arm extends generally along a path of said blood flow at said first open position, and generally traverses a blood flow path when at said second closed position.

(Docket 2745)

I hereby certify that this paper is being deposited with the U.S. Postal Service with sufficient postage as first class mail addressed to the Assistant Commissioner of Patents, Washington, D. C. 20231 on July 2, 2002.

James J. Kennell, P. O. Reg. No. 42,720

REMARKS

Claims 1, 2, 4-10, 12-14 and 16-27 are now in this application.

Claim 11 has been cancelled as it mistakenly depended from claim 9 instead of claim 10. Claim 12 recites this dependency.

Claim 21 has been amended to properly depend from claim 20 instead of claim 19.

Entry of these amendments is respectfully requested. No new search is required.

Respectfully submitted,

D. A. N. CHASE, Reg. #20,682
MICHAEL YAKIMO, JR., Reg. #28,549
GINNIE C. DERUSSEAU, Reg. #35,855
JAMES J. KERNELL, Reg. #42,720
SEAN T. BRADLEY, Reg. #46,572
CHASE LAW FIRM, L.C.
4400 College Boulevard
Suite 130
Overland Park, Kansas 66211
Telephone: (913) 339-9666

Attorneys for Applicant

VERSION WITH MARKINGS TO SHOW CHANGES MADE

21. (Amended) The aortic valve as claimed in claim [19] 20 wherein said at least one arm extends generally along a path of said blood flow at said first open position, and generally traverses a blood flow path when at said second closed position.

K.A #10 JG B #8 Draftsman Letter S. Boyce 8/12/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of	July 2, 2002
TROY R. NORRED	
Serial No. 09/712,121	Group Art 3738 Notice of Allowance: April 2, 2002
Filed November 14, 2000	
For: PERCUTANEOUS AORTIC VALVE REPLACEMENT	Examiner: William H. Matthews (703) 305-0316

Assistant Commissioner of Patents
Washington, D. C. 20231

Sir:

LETTER TO THE OFFICIAL DRAFTSMAN

This application was filed with informal drawings. In accordance with the Examiner's request filed as an attachment to the Notice of Allowance, applicant hereby submits seven (7) sheets of formal drawings.

Respectfully submitted,

D. A. N. CHASE
Patent Office Reg. No. 20,682
MICHAEL YAKIMO, JR.
Patent Office Reg. No. 28,549
GINNIE CHASE DERUSSEAU
Patent Office Reg. No. 35,855
JAMES J. KERNELL
Patent Office Reg. No. 42,720
SEAN T. BRADLEY
Patent Office Reg. No. 46,572
CHASE LAW FIRM, L.C.
4400 College Boulevard, #130
Overland Park, Kansas 66211
Telephone: (913) 339-9666

Attorneys for Applicant

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James J. Kernell, P.O. Reg. No. 42,720

(Docket 2745)

04/02

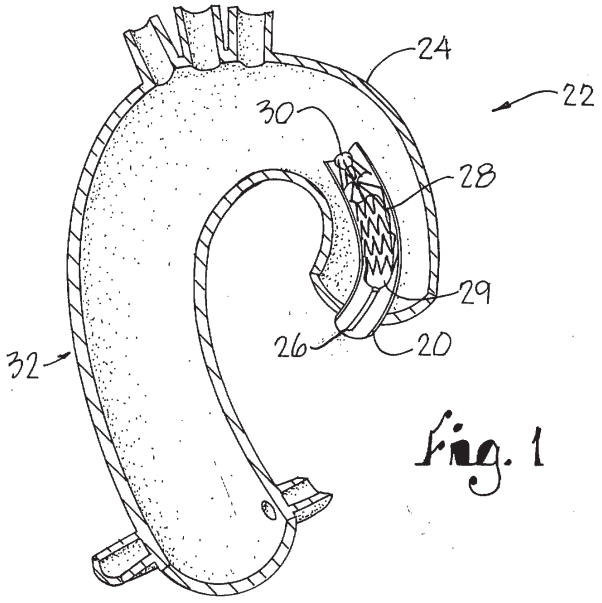

Fig. 1

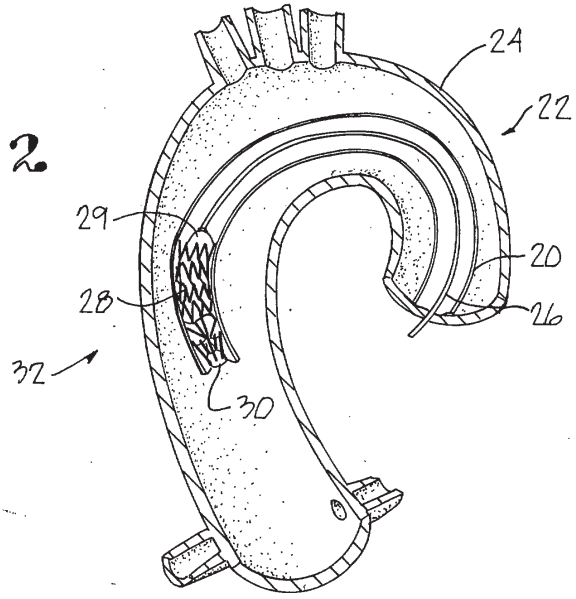

Fig. 2

Sheet 2 of 11
Group Art Unit 3738
Filed 11/14/00 - S/N 09/712,121
Notice of Allow.: 4/2/02

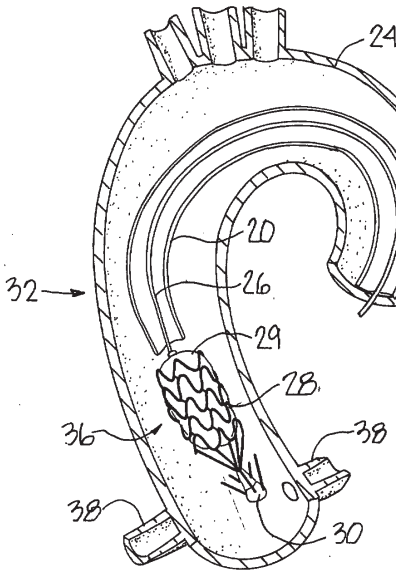

Fig. 3

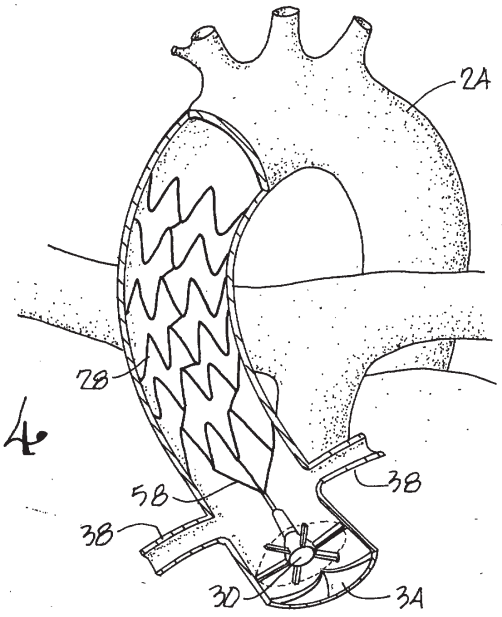

Fig. 4

Sheet 5 of 11
Group Art Unit 3738
Filed 11/14/00 - S/N 09/712,121
Notice of Allowance 4/2/02

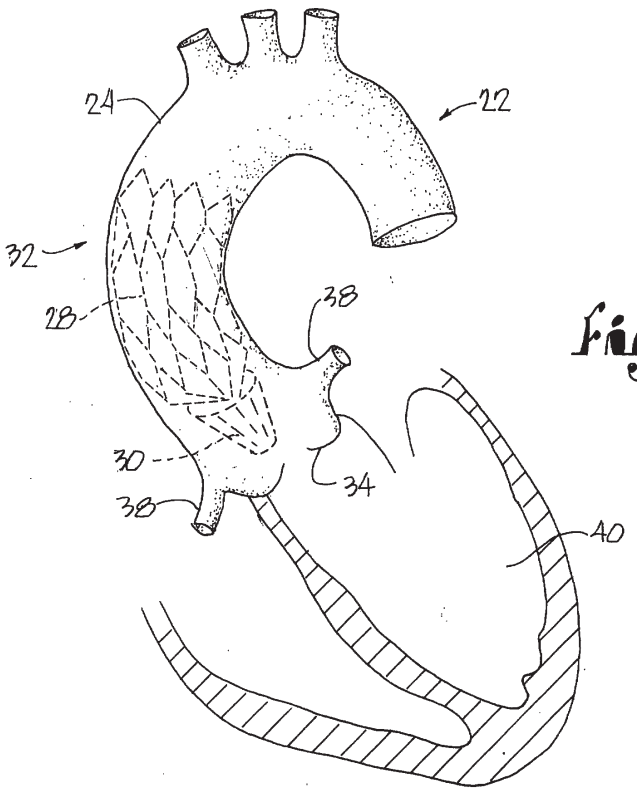

Fig. 5

Sheet 4 of 7
Group Art Unit 3732
Filed 11/14/00 - S/N 09/712,121
Notice of Allowance 4/2/03

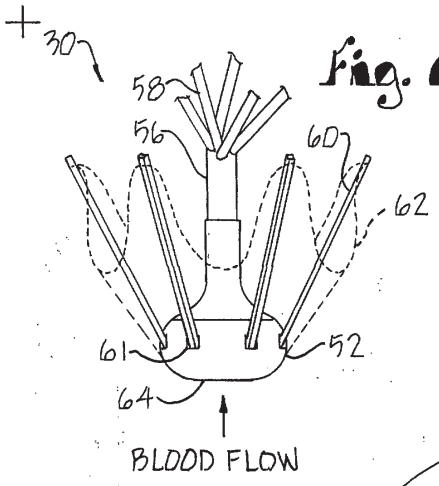

Fig. 6

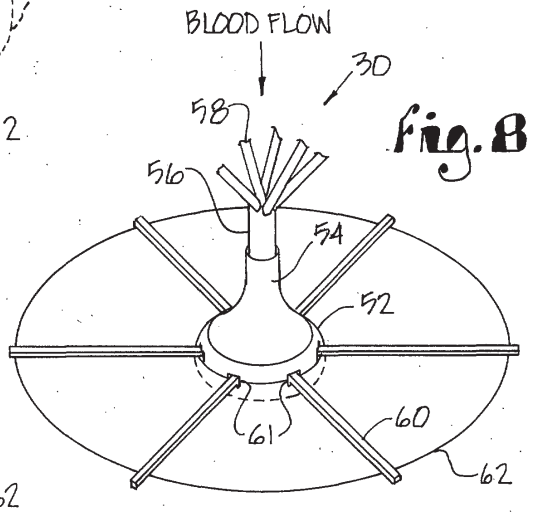

Fig. 8

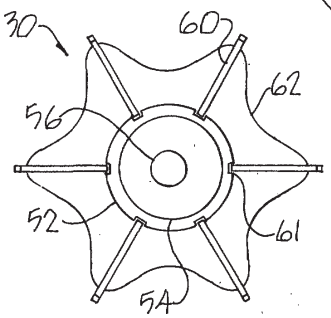

Fig. 7

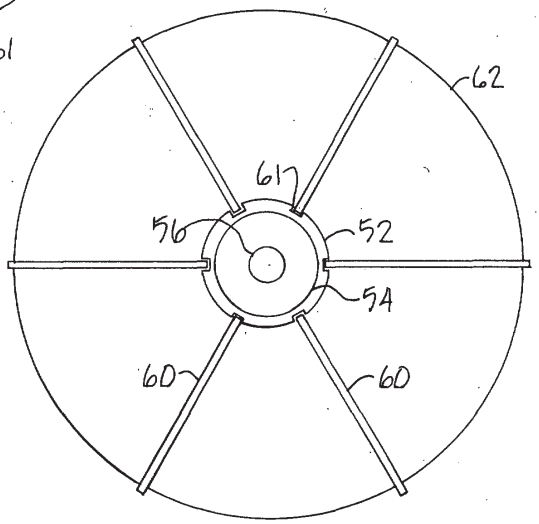

Fig. 9

Sheet 5 of 7
Group Art Unit 3738
Filed 11/14/00 - S/N 09/712,121
Notice of Allow: 4/2/02

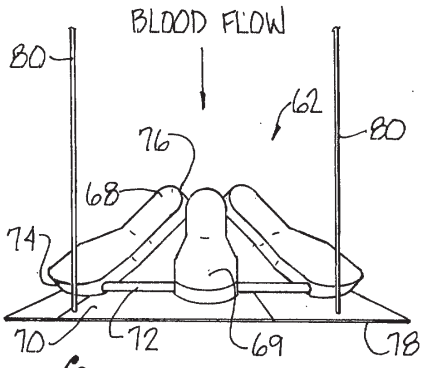

Fig. 10

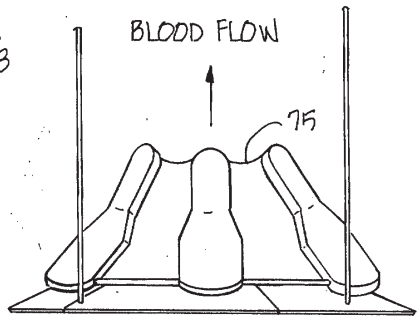

Fig. 12

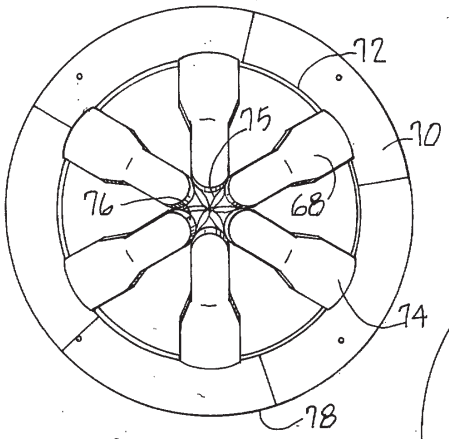

Fig. 11

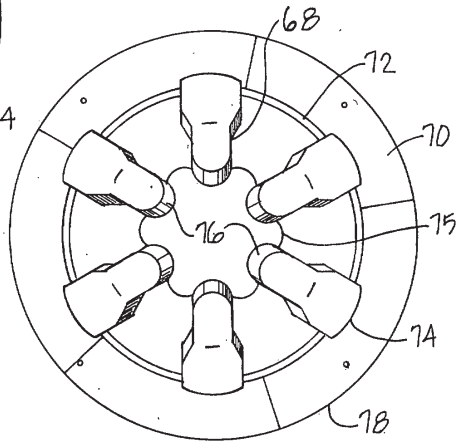

Fig. 13

Sheet 6 of 7
Group Art Unit 3732
Filed 11/14/00 - S/N 09/712,121
Notice of Allowance 11/2/02

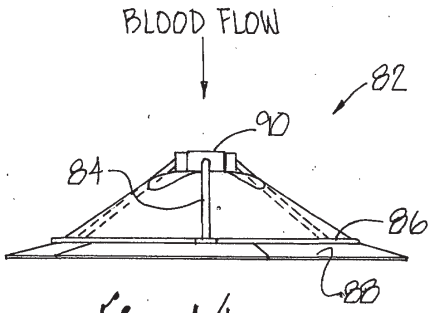

Fig. 14

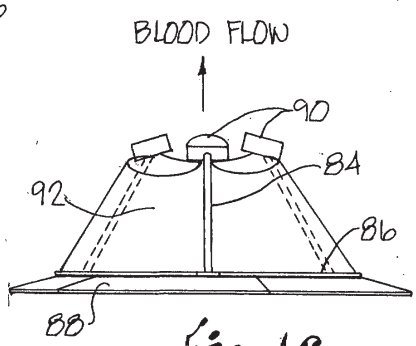

Fig. 16

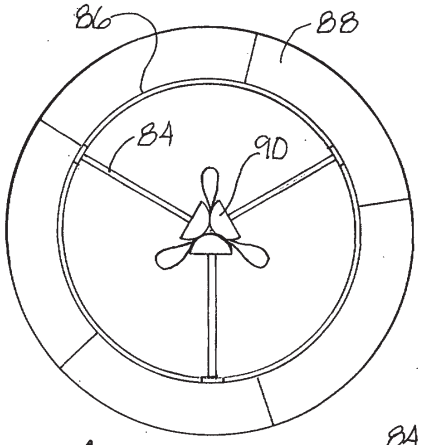

Fig. 15

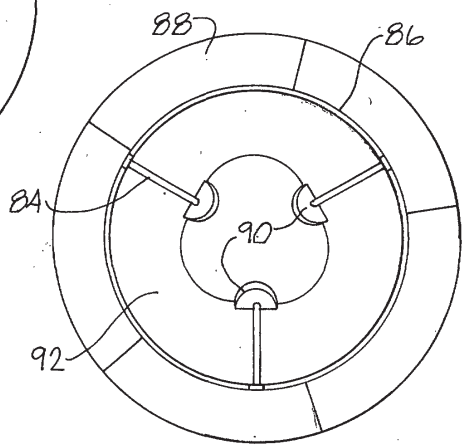

Fig. 17

Sheet 7 of 7
Group Art Unit 3738
Filed w/Amdt. Ser. 09/903,121
Notice of Allowance 4/12/02

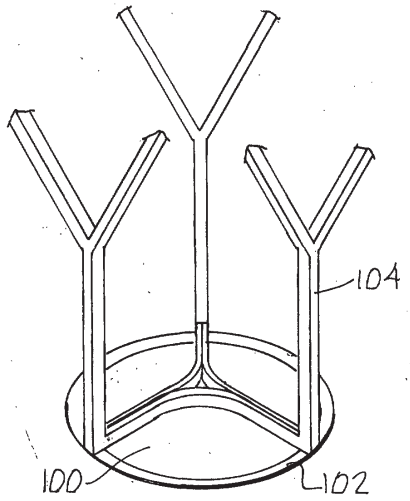

Fig. 18

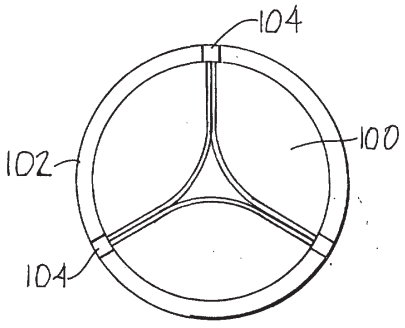

Fig. 19

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7590 04/02/2002

Michael Yakimo, Jr.
Chase & Yakimo, L. C.
4400 College Boulevard, Suite 130
Overland Park, KS 66211

09/712121

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James J. Kernell	(Depositor's name)
	(Signature)
July 2, 2002	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,121	11/14/2000	Troy R. Norred	2745	9253

TITLE OF INVENTION: PERCUTANEOUS AORTIC VALVE REPLACEMENT

TOTAL CLAIMS	APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
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EXAMINER	ART UNIT	CLASS-SUBCLASS
MATTHEWS, WILLIAM H	3738	623-002180

1. **Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Use** of PTO form(s) and Customer Number are recommended, **but not required.**

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1 Chase Law Firm, L.C.
2
3

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(Authorized Signature) James J. Kernell (Date) 7/2/2002

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01 FC:1242 640.00 OP

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UNITED STATES DEPARTMENT OF COMMERCE
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09/712,121	11/14/2000	Troy R. Norred	2745	9253

7590 09/12/2002

Michael Yakimo, Jr.
Chase & Yakimo, L. C.
4400 College Boulevard, Suite 130
Overland Park, KS 66211

EXAMINER
MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 09/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Response to Rule 312 Communication	Application No.	Applicant(s)	
	09/712,121	NORRED, TROY R.	
	Examiner	Art Unit	
	William H. Matthews (Howie)	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☒ The amendment filed on *10 July 2002* under 37 CFR 1.312 has been considered, and has been:

a) ☒ entered.

b) ☐ entered as directed to matters of form not affecting the scope of the invention.

c) ☐ disapproved because the amendment was filed after the payment of the issue fee.
Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

d) ☐ disapproved. See explanation below.

e) ☐ entered in part. See explanation below.

Paul B. Prebilic
Primary Examiner

#11 9A-POC

QUERY CONTROL FORM				RTIS USE ONLY	
Serial No.	09712121	Prepared by	TW	Tracking Number	77295
Examiner-GAU	McDermott-3738	Date	9-30-02	Week Date	4-8-02
		No. of queries	1		

10/1 10

JACKET			
a. Serial No.	f. Foreign Priority	k. Print Claim(s)	p. PTO-1449
b. Applicant(s)	g. Disclaimer	l. Print Fig.	q. PTOL-85b
c. Continuing Data	h. Microfiche Appendix	m. Searched Column	r. Abstract
d. PCT	i. Title	n. PTO-270/328	s. Sheets/Figs
e. Domestic Priority	j. Claims Allowed	o. PTO-892	t. Other

SPECIFICATION

a. Page Missing
b. Text Continuity
c. Holes through Data
d. Other Missing Text
e. Illegible Text
f. Duplicate Text
g. Brief Description
h. Sequence Listing
i. Appendix
j. Amendments
k. Other

CLAIMS

a. Claim(s) Missing
b. Improper Dependency
c. Duplicate Numbers
d. Incorrect Numbering
e. Index Disagrees
f. Punctuation
(g) Amendments
h. Bracketing
i. Missing Text
j. Duplicate Text
k. Other

MESSAGE

Claim 11 is crossed out by the "B" amendment but according to the claim index ~~and Specification~~ it is still allowed. Claim may need to be renumbered.

Please verify.

Thank You

initials TW

RESPONSE Corrected dlf

E-5 (Rev. 02/08/99)

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

11/17/2000 DTESSEM1 00000087 09712121

01	FC:201	355.00 OP
02	FC:203	63.00 OP
03	FC:202	40.00 OP

PTO-1556
(5/87)

*U.S. GPO: 1999-459-082/19144

PATENT APPLICATION FEE DETERMINATION RECORD
Effective October 1, 2000

Application or Docket Number

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS		
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	27 minus 20=	* 7
INDEPENDENT CLAIMS	4 minus 3 =	* 1
MULTIPLE DEPENDENT CLAIM PRESENT		☐

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
RATE	FEE		RATE	FEE
BASIC FEE	355.00	OR	BASIC FEE	710.00
X$ 9=	63.00	OR	X$18=	
X40=	40.00	OR	X80=	
+135=		OR	+270=	
TOTAL		OR	TOTAL	

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X40=		OR	X80=	
+135=		OR	+270=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X40=		OR	X80=	
+135=		OR	+270=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X40=		OR	X80=	
+135=		OR	+270=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
***If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-875
(Rev. 8/00)

Patent and Trademark Office, U.S. DEPARTMENT OF COMMER

ISSUE SLIP STAPLE AREA (for additional cross references)

POSITION	INITIALS	ID NO.	DATE
FEE DETERMINATION			
O.I.P.E. CLASSIFIER		8	12-600
FORMALITY REVIEW	VJ	875	03/22/01
RESPONSE FORMALITY REVIEW			

INDEX OF CLAIMS

✔ ..... Rejected
= ..... Allowed
— (Through numeral)... Canceled
÷ ..... Restricted
N ..... Non-elected
I ..... Interference
A ..... Appeal
O ..... Objected

Claim Final	Claim Original	Date
1	1	✔
2	2	✔
	3	O
3	4	O
4	5	✔
5	6	✔
6	7	✔
7	8	O
8	9	✔
9	10	
	11	
10	12	=
11	13	=
12	14	✔
	15	O
13	16	✔
14	17	✔
15	18	✔
16	19	✔
17	20	
18	21	
19	22	=
20	23	+
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Claim Final	Claim Original	Date
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Claim Final	Claim Original	Date
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If more than 150 claims or 10 actions staple additional sheet here

(LEFT INSIDE)

H.S. 3.23.01

[redacted]

SEARCHED

Class	Sub.	Date	Exmr.
623	2.1 2.12 2.13 2.14 2.18 2.2 2.22	3/6/01	WTM
Updated Above Search		3/25/02	WTM
623	2.17	3/26/02	WTM

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
623	2.1 2.12-2.14 2.18 2.2 2.22	3/26/02	WTM
623	2.17	2/26/02	WTM

SEARCH NOTES (INCLUDING SEARCH STRATEGY)

	Date	Exmr.
Consulted Examiner Mike Milano AU 3721	3/20/02	WTM
Consulted Examiner Dave Wilse AU 3738	3/25/02	WTM

(RIGHT OUTSIDE)