#### PERCUTANEOUS AORTIC VALVE REPLACEMENT

#### Background of the Invention

This invention relates to artificial 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 life unless infectious processes are introduced person's The incidence of aortic stenosis can reach between earlier. 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 to being physically unable operative candidate due 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 A L A R M NORRED EXHIBIT 2044 - Page 1 Medtronic, Inc., Medtronic Vascular, Inc., & Medtronic Corevalve, LLC v. Troy R. Norred, M.D. Case IPR2014-00110

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.

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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 aortic valve is anchored in the ascending the procedure. 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 The valve is connected to the stent system by serially aorta. 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

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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.

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Fig. 8 is the umbrella aortic valve of Fig. 5 in

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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. 9.

Fig. 12 is the cone-shaped valve of Fig. 9 in an open position.

Fig. 13 is a plan view of the cone-shaped valve of Fig. 11.

Fig. 14 is a diagrammatic view of another coneshaped aortic valve in a closed position.

Fig. 15 is a plan view of the cone-shaped valve of Fig. 13.

Fig. 16 is the cone-shaped aortic valve of Fig. 13 in an open position.

Fig. 17 is a plan view of the cone-shaped valve of Fig. 15.

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