Clinical Highlights

A publication delivering concise clinical data

Single Center Four Year Results from the FDA Pivotal Trial of the St. Jude Medical Trifecta Pericardial Aortic Valve Bioprosthesis

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OBJECTIVE
To assess mid-term hemodynamics with the St. Jude Medical Trifecta valve, which has a sewing ring specifically designed for supra-annular placement.

METHODS
One hundred Trifecta valves were implanted consecutively between August 2007 and October 2009 during an IDE study. Perioperative variables were collected on a prospective basis. Clinical follow-up was performed at discharge, 6, 12, 24, 36 and 48 months. Echocardiography was obtained at each time point and evaluated by a core lab.

RESULTS
30% of patients had a bicuspid aortic valve and 24% had previous cardiac surgery. There was one early perioperative mortality and four early perioperative RIND with 0 permanent thromboembolic CVA. Through four years and 300 patient years follow-up, two patients had moderate aortic insufficiency. Three patients had mild aortic insufficiency and all other patients had none or trivial aortic insufficiency. There were no instances of serious adverse events for structural valve deterioration, minor or major paravalvular leak, or valve-related death through the fourth year. There were two valve explants: one due to compromise of an aberrant intramural left coronary artery and the other due to endocarditis.

As seen in Figure 1, the hemodynamic performance of the Trifecta valve in patients was exemplary with an overall mean gradient 7.2±3.7 mmHg, 6.6±3.1 mmHg, 7.1±3.4 mmHg, 7.4±3.9 mmHg, 8.6±4.3 mmHg, 6.5±2.7 mmHg at discharge, 6 months, 1, year, 2 year, 3 year, and 4 year postoperatively, respectively. PPM (Effective Orifice Area Index < 0.65) was only 5% at 2 years.

CONCLUSION
The St. Jude Medical Trifecta valve provides excellent hemodynamic performance, very low PPM rates, and remains clinically stable with no instance of SVD through four years.

Figure 1: Hemodynamic Performance through 4 Years
REFERENCE


Product referenced is approved for CE Mark.

Rx Only

Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: The Trifecta Valve is indicated as a replacement for a diseased, damaged, or malfunctioning native or prosthetic aortic heart valve. Adverse events potentially associated with the use of bioprosthetic heart valves include: angina, cardiac arrhythmias, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, leak (transvalvular or perivalvular), myocardial infarction, nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other), prosthesis regurgitation, stroke, structural deterioration (calcification, leaflet tear, perforation, or other), thromboembolism and valve thrombosis. It is possible that these complications could lead to reoperation, explantation, permanent disability or death. Long-term low dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves. Long-term anticoagulant therapy, unless contraindicated, is recommended for all patients with bioprosthetic valves who have risk factors for thromboembolism. Please see the Instructions for Use (IFU) for a full description of indications, contraindications, side effects, precautions, warnings and Instructions for Use.

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C-00025