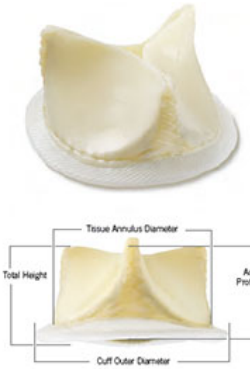
Trifecta™ Stented Tissue Valve with Linx™ AC Technology



Product Highlights

- Exceptional hemodynamic performance[1]
- Exterior-mounted pericardial leaflets with unique suture attachment allows for maximum leaflet excursion and larger EOAs[2]
- Designed to provide excellent durability with the pericardial-covered stent for tissue-to-tissue contact to reduce the risk of abrasion
- Includes Linx™ AC Technology, which is designed to improve long-term performance and valve durability*
- Designed to maintain structural integrity with a high-strength, fatigue-resistant, titanium alloy stent[2]
- Short 2 x 10-second rinse time

Ordering Information

Contents: Aortic Supra-Annular Stented Tissue Valve (1 unit per box)

Reorder Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Cuff Outer Diameter (mm)	Aortic Protrusion (mm)	Total Height (mm)
TF-19A	19	19	24	12	15
TF-21A	21	21	26	13	16
TF-23A	23	23	28	13	17
TF-25A	25	25	31	14	18
TF-27A	27	27	33	15	19
TF-29A	29	29	35	16	20

* There is no clinical data currently available that evaluates the long-term impact of anticalcification tissue treatment in humans.

1. St. Jude Medical. Trifecta Valve, Pre-Market Approval Application Summary of Safety and Effectiveness Data, P100029, 2011.
2. St. Jude Medical. Data on File.

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 orpositioning, 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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Customer Support: 855-478-5833

Last Updated: April 19, 2013