

Trifecta™

Valve



INDICATIONS

- The Trifecta valve is indicated as a replacement for a diseased, damaged, or malfunctioning native or prosthetic aortic heart valve.

SPECIFICATIONS

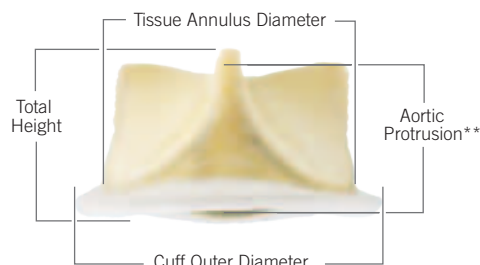
- The Trifecta valve is designed to:
 - Provide excellent hemodynamic performance¹
 - Provide excellent durability with the pericardial-covered stent for tissue-to-tissue contact to reduce the risk of abrasion²
 - Address valve calcification with Linx™ AC technology*^{3,4,5}
 - Maintain structural integrity with a high-strength, fatigue-resistant, titanium alloy stent²

GENERAL PRODUCT INFORMATION⁶

- **MRI Safety Information:** Nonclinical testing has demonstrated that the Trifecta valve is MR conditional. It can be scanned safely under the following conditions:
 - Static magnetic field of 3 Tesla or less
 - Spatial gradient of 525 Gauss/cm or less
 - Maximum whole-body-averaged specific absorption rate (SAR) of 2.0-W/kg for 15 minutes of scanning
- **Sterilization:** Liquid chemical sterilization
- **Storage Solution:** Formaldehyde, 0.5%
- **Storage Temperature:** 5 °C – 25 °C
- **Shelf-Life:** Two years
- **Rinse:** 500 ml (sterile isotonic solution) x 2 x 10 seconds

MATERIALS LIST

- **Valve Leaflets:** Bovine pericardium
- **Stent:** Titanium (radiopaque)
- **Fabric Stent Covering:** Polyester
- **Valve Sewing Cuff:** Polyester with silicone insert
- **Tissue Stent Covering:** Porcine pericardium
- **Latex-free**



REFERENCE DIMENSIONS AND ORDERING INFORMATION

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

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

** Aortic protrusion correlates with ISO 5840, 3.37 outflow tract profile height.



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