Trifecta™

Valve with Glide™ Technology (GT)

Indications
The valve is intended as a replacement for a diseased, damaged or malfunctioning aortic heart valve. The valve may also be used as a replacement for a previously implanted aortic prosthetic heart valve.

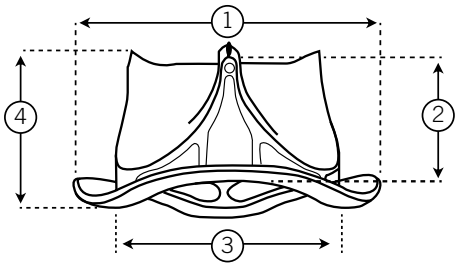
Specifications
- The Trifecta™ GT valve is designed to:
  - Provide excellent hemodynamic performance[1]
  - Provide excellent durability with the pericardial covered stent for tissue-to-tissue contact to prevent the risk of abrasion[2]
  - Address valve calcification with Linx™ AC treatment*[3-9]
  - Maintain structural integrity with a high-strength, fatigue-resistant, titanium alloy stent[2]
  - Provide easier access to the aortic annulus specifically for young surgeons and in minimally invasive approach

General Product Information
- MRI Safety Information: Nonclinical testing has demonstrated the Trifecta™ Valve with Glide™ Technology (GT) is MR Conditional.
- A patient with this device can be safely scanned in an MR system meeting the following conditions:
  - Static magnetic field of 1.5 tesla (1.5T) or 3.0 tesla (3.0T)
  - Maximum spatial gradient magnetic field of less than or equal to 30T/m.
- Normal Operating Mode: Maximum whole-body specific absorption rate (SAR) of:
  - 2.0 W/kg for 15 minutes of scanning in normal operating mode at 1.5T.
  - 2.0 W/kg for 15 minutes of scanning in normal operating mode at 3.0T.
- **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
- **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)
TFGT-19A	19	24	15	12
TFGT-21A	21	26	16	13
TFGT-23A	23	28	17	13
TFGT-25A	25	31	18	14
TFGT-27A	27	33	19	15
TFGT-29A	29	35	20	16



1. Cuff outer diameter
2. Aortic protrusion**
3. Tissue annulus diameter
4. Total height

Ordering Information

Model/Reorder Number	Description
Trifecta™ Valve Series Sizer Set	
TF2000-2	Autoclavable tray with cover, rigid holder handle (screw-in) T2002-R and six double-ended aortic sizers (19 mm–29 mm) with a valve replica end and a cylindrical annular sizing end. UT2000-R rigid holder handle (click-in) is included in TF 2000-2 set for the Trifecta Valve.
Handles	
T2002-R	Trifecta GT rigid holder handle. Made of stainless steel to provide more rigidity than the T2002. May be used in place of T2002.
T2002	Trifecta GT flexible holder handle. Made with nitinol to provide flexibility during implantation. May be used in place of T2002-R.
EX2000-R	Rigid extension handle. Made of stainless steel to provide additional length when used with a holder handle.
EX-05	Flexible extension handle. Made of nitinol to provide additional length when used with a holder handle.

Trifecta™ Valve Series Sizer Set
TF2000-2

Rigid Holder Handle
T2002-R

Double-Ended Aortic Sizers

Rigid Holder Handle
T2002-R

Flexible Holder Handle
T2002

Rigid Extension Handle
EX2000-R

*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.

References

1. Bavaria J. E., Desai, N. D., Cheung, A., Petracek, M. R., Groh, M. A., Borger, M. A., & Schaff, H .V. (2014). The St Jude Medical Trifecta aortic pericardial valve: Results from a global, multicenter, prospective clinical study. *The Journal of Thoracic and Cardiovascular Surgery, 147*(2), 590-7. doi: 10.1016/j.jtcvs.2012.12.087
2. Data on File. St. Jude Medical Technical Report, 90166169
3. Frater, R. W. M., Seifter, E., & Liao, K., (1997). *Advances in anticalcific and antidegenerative treatment of heart valve bioprostheses.* Edited by Gabbay S, and Wheatley D, First Edition, Silent Partners, Inc., 8, 05-13.
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5. Vyavahare, N., Hirsch, D., Lerner, E., Baskin, J. Z., Schoen, F. J., Bianco, R. . . . Levy, R. J. (1997). Prevention of bioprosthetic heart valve calcification by ethanol preincubation: Efficacy and mechanisms. *Circulation, 95*(2), 479-88. http://www.ncbi.nlm.nih.gov/pubmed/9008467
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9. Data on File. St. Jude Medical Technical Report, 871988.

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

Product referenced is CE Mark and FDA approved. Device depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country.

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