

Trifecta™

Valve



 **ST. JUDE MEDICAL™**
MORE CONTROL. LESS RISK.



WHEN THE GOAL IS SUPERIOR HEMODYNAMICS¹ THE VALVE IS TRIFECTA.

Introducing the next-generation pericardial tissue heart valve—and perfect complement—to the line of tissue valves from St. Jude Medical that includes Epic™ and Biocor™. The Trifecta valve is a stented tissue heart valve with *in vivo* single-digit mean gradients across all valve sizes.¹ The unique valve design includes pericardial tissue leaflets attached to the exterior of the valve stent to open more fully and efficiently to perform like a natural heart valve. For more than 30 years, St. Jude Medical has demonstrated a commitment to cardiac surgery, offering patients the gold standard in mechanical heart valve performance and tissue valve durability, and applies this market-leading expertise to the development of the Trifecta valve.

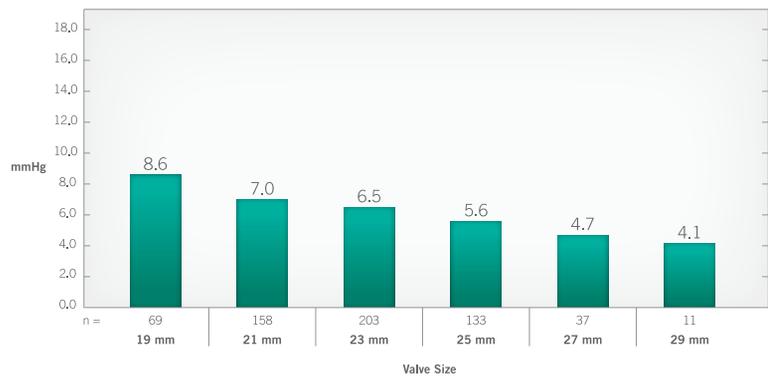


WHEN THE GOAL IS HEMODYNAMICS.

Created exclusively for the aortic position, the Trifecta valve delivers significantly larger EOAs, resulting in single-digit pressure gradients. The Trifecta valve is designed to mimic the flow of a natural, healthy heart valve and offers excellent hemodynamic performance, which may provide patients with an improved quality of life.



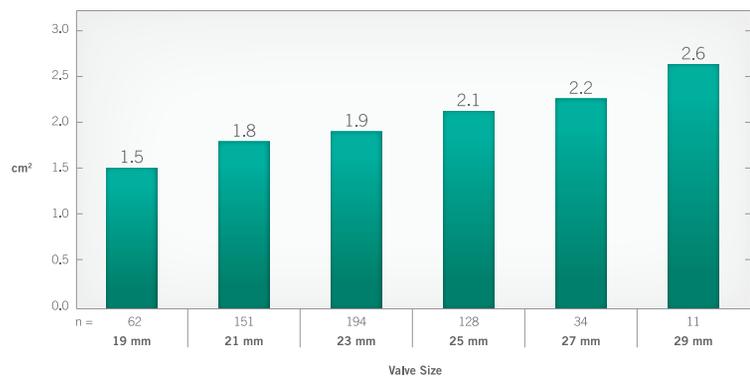
Mean Gradient



- *In vivo* single-digit mean gradients averaged across all valve sizes at six months.¹

Externally mounted tissue allows for leaflets to open more fully, efficiently performing more like a natural heart valve.

Effective Orifice Area (EOA)



- Large EOAs across all valve sizes result in decreased risk of patient-prosthesis mismatch at six months.¹

WHEN THE GOAL IS DURABILITY.

With more than 30 years of market experience, the Trifecta valve was designed for long-term durability and performance. The result is a design that has demonstrated excellent *in vitro* wear testing.²



- 1 Pericardial covered stent for tissue-to-tissue contact reducing the risk of abrasion and structural valve deterioration.¹
- 2 Elimination of tacking suture at top of commissure reduces risk of tearing.
- 3 Proper leaflet shaping and coaptation are achieved through proprietary tissue leaflet fixation.²
- 4 Leaflets from a single pericardial sheet, externally mounted, optimize coaptation and maximize flow.



Fatigue-resistant, high-strength titanium stent designed to reduce stress on leaflets during cardiac cycle.¹

LINX™ AC TECHNOLOGY

Linx AC Technology is a patented proprietary valve treatment that has been demonstrated in animal studies to reduce calcification in both porcine and bovine pericardial tissue.⁷⁻⁸

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

WHEN THE GOAL IS IMPLANTABILITY.

The Trifecta valve offers superior hemodynamic performance¹ with the implantability of a stented valve, accommodating a surgeon's existing implantation technique.

- Contoured silicone insert within a unique polyester cuff is designed to conform to the shape of the native annulus for proper seating and to reduce the risk of PV leak.¹



Cylindrical
intra-annular end



Replica end

Trifecta valve sizers are optimized for true-to-size valve selection.

- Efficient 2 x 10-second rinse.



- Aortic valve holder improves visibility and cuff access for suturing.

- Both the flexible and rigid valve holder handles provide quick, click-in handle attachment and removal to stabilize the valve and minimize the risk of unseating.



OUR COMMITMENT TO CARDIAC SURGERY.

The St. Jude Medical commitment to cardiac surgery continues to grow through our legacy of market-leading heart valves. Adding to our portfolio of highly regarded mechanical heart valves and tissue heart valves Epic and Biocor, the Trifecta valve offers significantly larger EOAs than any stented bioprosthetic heart valve on the market. With outstanding performance in all three key areas of hemodynamics, durability and implantability, the Trifecta valve demonstrates our passion of putting more control into the hands of physicians to offer patients an improved quality of life.



Ordering Information

Aortic

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

Accessories

Model Number	Description
Trifecta Valve Sizer Set	
TF2000	Autoclavable tray with cover, flexible holder handle (UT2000) and six double-ended aortic sizers (19 mm–29 mm) with a valve replica end and a cylindrical annular sizing end.
Handles	
UT2000	Flexible holder handle. Made with Nitinol to provide flexibility during implantation of the Trifecta valve. (The UT2000 is also included in the Trifecta Valve Sizer Set.)
UT2000-R	Rigid holder handle. Made of stainless steel to provide more rigidity than the UT2000. May be used in place of the UT2000.
EX2000-R	Rigid extension handle. Made of stainless steel to provide additional length when used with a holder handle.

References

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4. Kelly SJ, Ogle MF, Carlyle WC, et al. *Biocompatibility and calcification of bioprosthetic heart valves*. Society for Biomaterials, Sixth World Biomaterials Congress Transaction, 2000;13534.
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TISSUE MECHANICAL REPAIR SURGICAL ABLATION

Global Headquarters

One St. Jude Medical Drive
St. Paul, Minnesota 55117
USA
+1 651 756 2000
+1 651 756 3301 Fax

Cardiovascular Division

177 East County Road B
St. Paul, Minnesota 55117
USA
+1 651 756 4470
+1 651 756 4466 Fax

St. Jude Medical

Coordination Center BVBA
The Corporate Village
Avenue Da Vincilaan 11 Box F1
B-1935 Zaventem
Belgium
+32 2 774 68 11
+32 2 772 83 84 Fax

SJMprofessional.com



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