Avalus™
Bioprosthesis

PROVEN PLUS.

Introducing the Avalus™ Aortic Valve by Medtronic.

With more than 40 years of heart valve innovations, we took proven valve design concepts and adapted them for excellent implantability for you and performance for your patients.

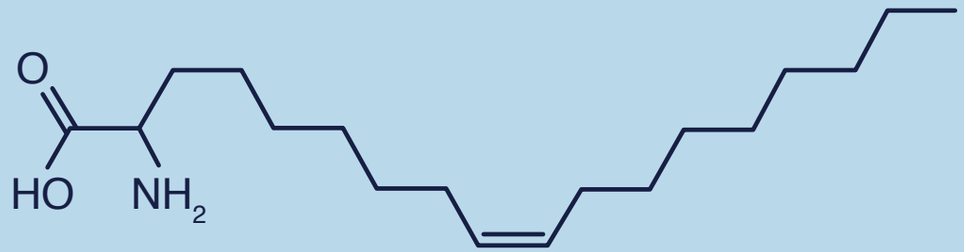
Medtronic
Further, Together

YOU WANT THE VERY BEST FOR YOUR PATIENTS. SO DO WE.

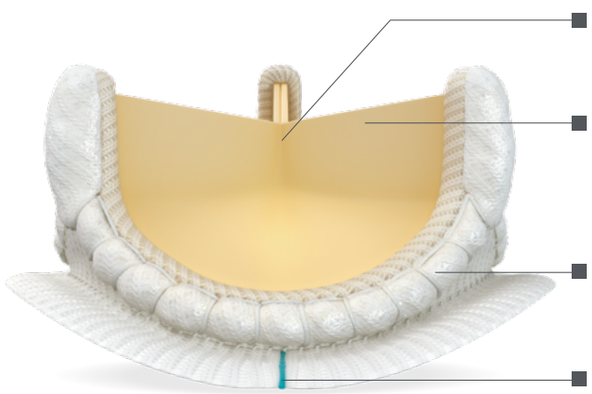
We designed the next generation bovine pericardial valve for better overall performance, improved implant experience, and a contemporary design to facilitate future valve-in-valve (ViV).

Interior-mounted leaflets minimize damaging contact with the frame — a design platform for long-term durability.

AOA™ tissue treatment* to mitigate calcification — over 20 years of clinical use on the Medtronic surgical tissue valve portfolio.[1,2]



PROVEN

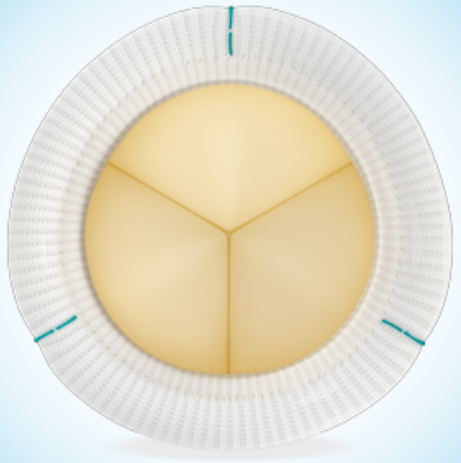


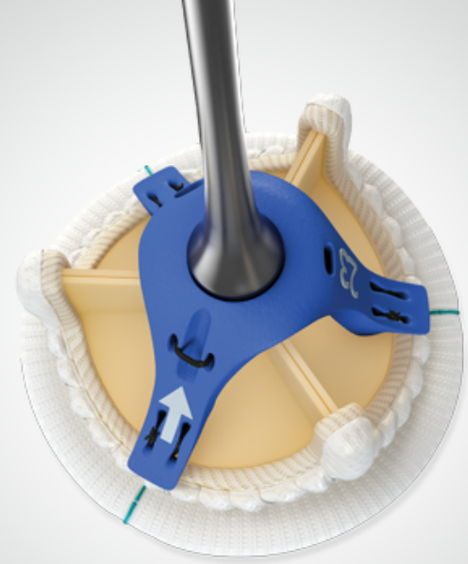
- Supra-annular design to enhance hemodynamics[3]
- Three laser cut bovine pericardial leaflets matched for thickness and deflection to provide consistent performance
- Two-part polymer frame minimizes stress zones on leaflets
- Sewing markers facilitate suture placement and valve orientation

*No clinical data is available which evaluates the long-term impact of AOA treatment in patients.

PLUS

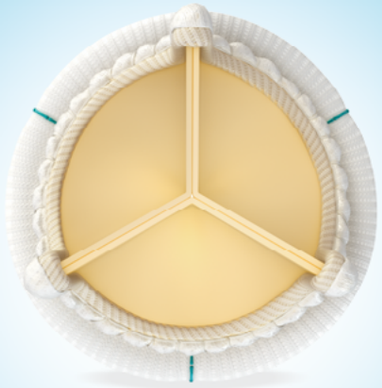
Polyetheretherketone (PEEK) polymer stent provides strength and flexibility, and offers resistance to permanent deformation.





Ease of Implant for You

- Soft and pliable sewing cuff facilitates needle penetration, suture placement, and valve seating for an improved implant experience
- Lower valve profile and narrow commissure posts expand ostia clearance and give you more space for knot tying
- Streamlined valve holder improves visibility in both standard and minimally invasive approaches
- Simple one-cut release



Designed to achieve 100% coaptation and minimize central regurgitation.

Flexible support frame with firm base designed to maintain circularity and consistent hemodynamic performance.

Performance and Lifetime Management for Your Patients

- Valve dimensions and geometry enable future ViV replacements
- PEEK base frame impregnated with barium sulfate provides for radiopacity and visibility
- Polymer frame mitigates the risk of potential metal on metal corrosion with transcatheter stent materials
- MRI Safe in all MR environments without conditions

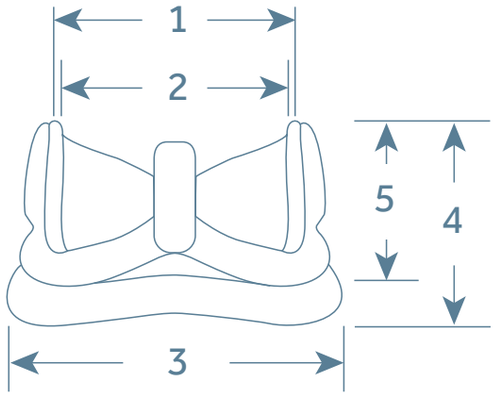
Ordering and Specifications

Avalus Valve Order Number	Valve Size	Stent Diameter (TAD)	Internal Orifice Diameter*		External Sewing Ring Diameter	Valve Profile Height	Aortic Protrusion
		(1)	(2)	(2a)	(3)	(4)	(5)
40019	19 mm	19 mm	17.5 mm	18 mm	27.0 mm	13.0 mm	11.0 mm
40021	21 mm	21 mm	19.5 mm	20 mm	29.0 mm	14.0 mm	12.0 mm
40023	23 mm	23 mm	21.5 mm	22 mm	31.0 mm	15.0 mm	13.0 mm
40025	25 mm	25 mm	23.5 mm	24 mm	33.0 mm	16.0 mm	14.0 mm
40027	27 mm	27 mm	25.5 mm	26 mm	36.0 mm	17.0 mm	15.0 mm

TAD – Tissue Annulus Diameter
*Measurement shows stent frame including tissue (2) and stent frame excluding tissue (2a).

Accessories

Order Number	Description
7420	Valve Handle
7400S	Avalus Sizers
T7400	Tray, Accessory, Avalus



References
1. Medtronic Freestyle® Aortic Root Bioprosthesis was first implanted clinically in August 1992. Freestyle Aortic Root Bioprosthesis 15-Year Clinical Compendium. ©2016 Medtronic.
2. Jamieson WR, Riess FC, Raudkivi PJ, et al. Medtronic Mosaic porcine bioprosthesis: assessment of 12-year performance. *J Thorac Cardiovasc Surg.* August 2011;142(2):302-7.
3. Ruzicka DJ, Hettich I, Hutter A, et al. The complete supraannular concept. *Circulation* 2009;120[suppl 1]:S139-S145.

Avalus™ Bioprosthesis

Indications: The Avalus bioprosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves. **Contraindications:** None known. **Warnings/Precautions/Adverse Events:** Only physicians who have received proper training in valve replacement should use this device. Accelerated structural deterioration due to calcific degeneration of bioprosthesis may occur in: children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, or hyperparathyroidism). Adverse events can include: angina, cardiac dysrhythmias, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, infection other than endocarditis, transvalvular or paravalvular leak, myocardial infarction, nonstructural valve dysfunction (leaflet entrapment/impingement, obstructive pannus ingrowth, suture dehiscence, inappropriate sizing or positioning, or other), pericardial effusion or tamponade, prosthesis regurgitation, prosthesis stenosis, prosthesis thrombosis, stroke, structural valve deterioration (calcification, leaflet tear or perforation, or other), thromboembolism, tissue dehiscence, and transient ischemic attack. These complications could lead to reoperation, explant of the bioprosthesis, permanent disability, or death. **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use. For countries that use eIFUs, consult instructions for use at www.medtronic.com/manuals. Note: Manuals can be viewed using a current version of any major internet browser.

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