INTRODUCING
THE AVALUS™
AORTIC VALVE
BY MEDTRONIC.

PROVEN
PLUS.

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.

Avalus™ Bioprosthesis

Indication:
An aortic valve prosthesis intended for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves.

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 bioprostheses 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.

Medtronic

medtronic.com/avalus

References:

Avalus™ Bioprosthesis

Ordering and Specifications

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<tr>
<th>Valve Order Number</th>
<th>Valve Size</th>
<th>Internal Orifice Diameter</th>
<th>External Sewing Ring Diameter</th>
<th>Valve Profile Height</th>
<th>Aortic Protrusion</th>
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Ordering:
- Valve Handle: T4020
- Avalus Sizers: T4005
- Valve: T4400

Accessories

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<th>Description</th>
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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.
Supra-annular design to enhance hemodynamics

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

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

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

Designed to achieve 100% coaptation and minimize central regurgitation.

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

PROVEN

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

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

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.