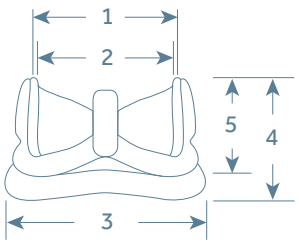
AVALUS™ BIOPROSTHESIS

Indications for Use

The Avalus bioprosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves.

Ordering Information

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

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Product Specifications

Sterilization	Liquid chemical sterilization
Shelf Life	1.5 years
Packaging (Sterile Barriers)	Valve jar: glass Valve jar lid: polypropylene Valve lid liner: silicone
Tissue Fixation	Uniaxial fixation
Storage Temperature	5° C to 25° C (41° F to 77° F)
Storage Solution	Buffered 0.2% glutaraldehyde solution
Rinsing Procedure	2 rinse basins each containing 500 mL of sterile, normal saline solution Single 30-second rinse. Store in a second basin until use.
MRI Compatibility	Non metallic — MR safe MR — poses no known hazards in all MR environments.

Materials List

Valve Holder	Blue acetal homopolymer
Valve to Valve Holder Sutures	Black nylon
Valve Leaflets	Bovine pericardium cross-linked in 0.5% glutaraldehyde
Wireform	Polyetheretherketone (PEEK)
Base Frame	Polyetheretherketone (PEEK) impregnated with barium sulfate
Fabric Covering Wireform and Base Frame	Polyester
Valve Sewing Cuff	Polyester, valve component sutures, polyester, force fiber suture, UHMWPE
Retainer Jar & Retainer Cap	Homopolymer
Serial Number Tag	Polypropylene

Accessories

Avalus Sizer	Polysulfone (handle and head), nitinol (wire)
Tray	Polyphenylsulfone
Handle	Stainless steel

Tissue Treatment

Anti-calcification Treatment	Alpha-amino oleic acid (AOA™) treatment

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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