Indications for Use

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

Ordering Information

<table>
<thead>
<tr>
<th>Avalus Valve Order Number</th>
<th>Valve Size</th>
<th>Stent Diameter (TAD)</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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</thead>
<tbody>
<tr>
<td>40019</td>
<td>19 mm</td>
<td>19 mm</td>
<td>17.5 mm</td>
<td>27.0 mm</td>
<td>13.0 mm</td>
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<td>25.5 mm</td>
<td>36.0 mm</td>
<td>17.0 mm</td>
<td>15.0 mm</td>
</tr>
</tbody>
</table>

TAD – Tissue Annulus Diameter

*Measurement shows stent frame including tissue (2) and stent frame excluding tissue (2a).

Accessories

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>7420</td>
<td>Valve Handle</td>
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<tr>
<td>7400S</td>
<td>Avalus Sizers</td>
</tr>
<tr>
<td>T7400</td>
<td>Tray, Accessory, Avalus</td>
</tr>
</tbody>
</table>
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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