Medtronic

Avalus Ultra™ Bioprosthesis

Fit for the future, right from the start.

The Avalus Ultra valve experience

Engineered for ease of use

A next-level bovine aortic valve engineered for easy suture placement and valve insertion into the supra-annular position.[1,2]

Clear visibility

Enhanced radiographic visualization helps with future valve-in-valve procedures and patient lifetime management.[2,3]

Straightforward sizing

Sizing is simple with the Avalus Ultra sizer due to the barrel end mirroring the valve profile and size, and its atraumatic commisure post shape on the replica end, enhancing visibility during sizing.[2,4]

Built on established evidence

The Avalus Ultra valve's design is built on the 10 years of clinical experience with the Avalus™ valve. The Avalus Ultra bioprosthesis is supported by the robust and real-world evidence of the Avalus valve, which demonstrates durability, excellent EOAs, stable low gradients, and valve circularity.[5,6]

Engineered for ease of use

The Medtronic mission to extend life begins when you make the right valve choice for your patients. We believe in developing devices that can help you extend people's lives so they can get back to doing what they love. The Avalus Ultra valve design features keep the patient top of mind.

Low valve profile

- The reduced Avalus Ultra valve profile is designed to facilitate ease of implant.[2,3]
- The valve dimensions and geometry help to enable future valve-in-valve replacements.[7,8]
- Low commissure post widths and valve profile facilitate knot tying and ostia clearance.[1,2,9]

Circular base frame

Circularity is crucial, but not all aortic valves maintain circularity. Noncircular or deformed surgical valves can have decreased durability and poor blood flow.[10-13]

- Nondeformable polyetheretherketone (PEEK) base is designed to allow the valve to maintain circularity during and after implant.[7,8]
- Flexible support frame with firm base is designed to maintain circularity and consistent hemodynamic performance.[6,7,10-13]

Flexible sewing cuff

- A flexible and pliable sewing cuff is designed to facilitate needle penetration, secure valve seating and exceptionally low PVL (paravalvular leak) rates.[1-3,14]
- Easy suture placement with large, visible sewing markers.[2]
- The green, V-shaped suture on the Avalus Ultra valve sewing cuff identifies the location of the AU radiopaque badge.[3]

Laser cut leaflets

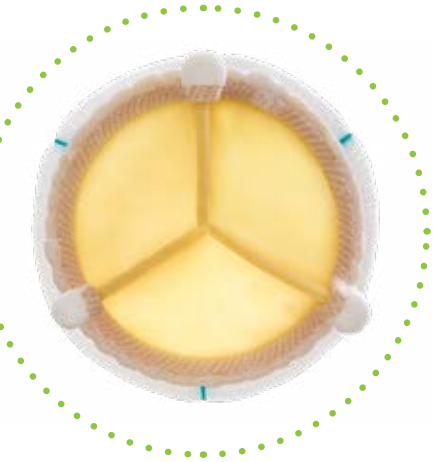
- The valve has excellent leaflet coaptation, designed to close smoothly and fully to effectively reduce central jet of blood flow.[14]
- The interior mounted leaflets are designed for long-term valve durability and to reduce the risk of coronary obstruction.[6,14-16]
- Laser cut holes along the commissures facilitate consistent valve assembly and stable hemodynamic performance.[6,14]

Clear visibility

Visibility like never before, the platinum-iridium coil and tantalum badge are designed to sit at the annulus of the valve to assist TAV (transcatheter aortic valve) placement for future valve-in-valve procedures.[2,3]

- The radiopaque coil helps enhance visibility of the Avalus Ultra valve on fluoroscopy imaging for valve-in-valve procedures.[2,3]
- The radiopaque coil has a unique tantalum badge that helps identify which valve a patient has implanted.

Straightforward sizing



With varying valve anatomies, every one is unique, therefore, ensuring the right valve fit is critical to your patient's health and future. The Avalus Ultra valve's design and sizer facilitate the right valve size for the right patient.

- The replica end of the sizer represents the valve sewing cuff to help determine valve fit.[2]
- The replica end atraumatic commisure post shape enhances visibility during sizing and helps to reduce the risk of obstructing patients anatomy.[2,3]
- The simulated cuff on the barrel end of the sizer reflects the implanted valve profile.

Built on established evidence

The Avalus Ultra valve is a premier choice for lifetime patient management. Built upon the original Avalus valve platform, the Avalus Ultra valve is supported by the robust, real-world clinical evidence of the Avalus valve due to its excellent EOAs and stable low gradients.[5] Over the span of 10 years, more than 2,000 Avalus patients have been studied and helped demonstrate consistent performance.

Avalus evidence timeline

Mid 2000s
Research development

2014
PERIGON
First implant

2019
Comparative in-vitro fatigue test[16]

2020
AVALUS CLINICAL CONFIDENCE (ACE)
UZ LEUVEN REAL-WORLD REGISTRY

2021
PERIGON
5-year data
- Comparative hemodynamics studies
  TADOKORO, et al.
  PROVE-PERI

2022
PERIGON
- Young patient analysis
- MICS implantability analysis

2023
AVALUS CLINICAL CONFIDENCE (ACE)
UZ LEUVEN REAL-WORLD REGISTRY
- Avaris registry data
- Echo Valve Normals

2024
PERIGON
7-year data expected

2025 and beyond
PERIGON
12-year data expected

Check out the ACE Registry data

AOA™ tissue treatment

For over 30 years, the Medtronic amino oleic acid (AOA) treatment has proven to be an innovative tissue treatment for over a half of a million patients across a suite of Medtronic devices.

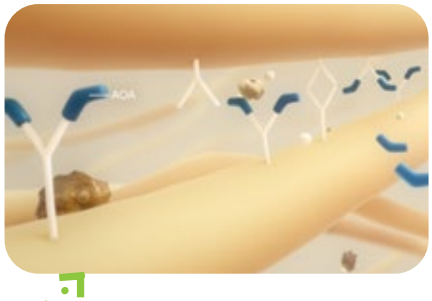
The Avalus Ultra valve benefits from AOA treatment, which reduces calcification in the tissue leaflets.[†,17-19]

After fixation

- Free aldehydes are present.

AOA treatment

- AOA covalently bonds with free aldehydes.
- Lipids are washed away.
- Subsequent storage in glutaraldehyde allows any remaining free aldehydes to crosslink.



After treatment

- Large AOA molecule slows diffusion of calcium into tissue matrix.

† The benefits of AOA tissue treatment have been demonstrated through animal testing. No direct clinical evaluation of the benefits of AOA treatment in humans has been conducted.

The Avalus Ultra valve's design is built on the core foundational benefits of the Avalus valve:

Durability

0
SVD† through 5 years[6]

Functionality

>95%
of patients reported NYHA Class I or II at 5 years[6]

Efficiency

5
years of stable low mean gradients[6]

Safety

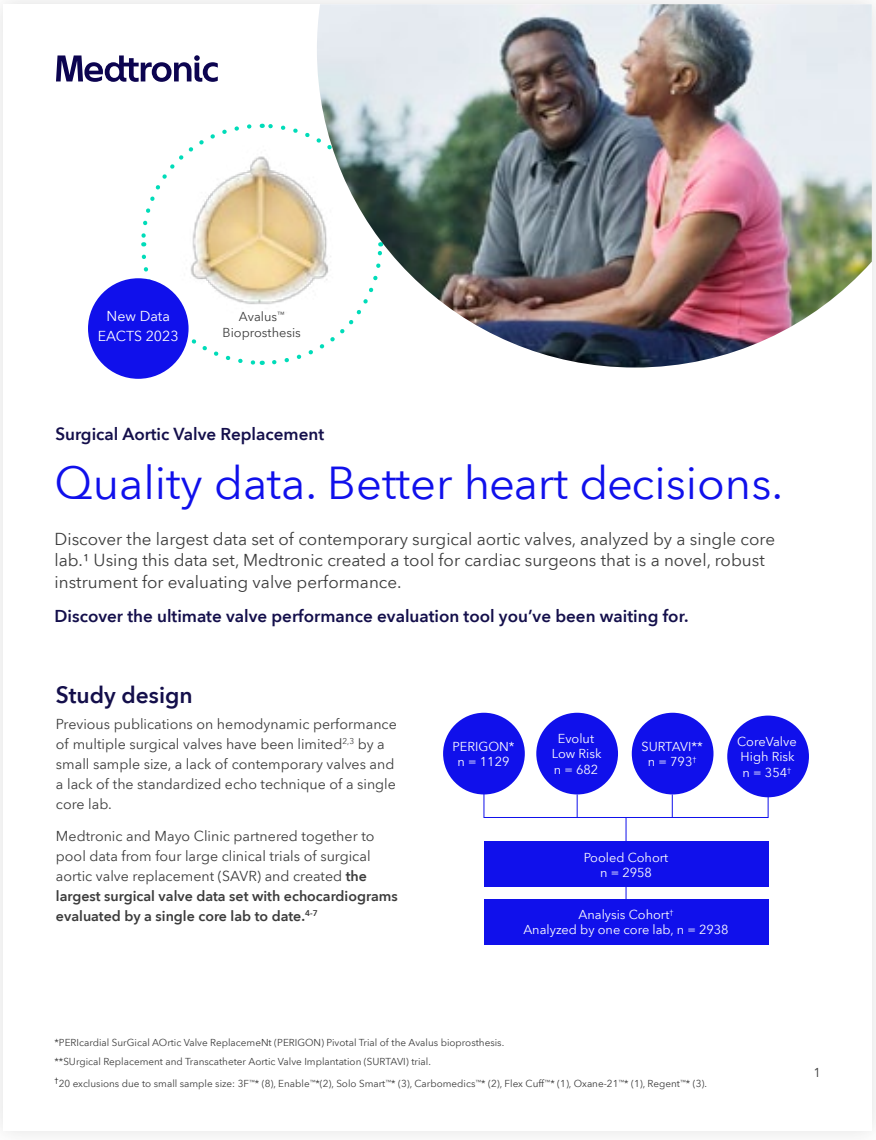
98.5%
freedom from valve-related mortality through 5 years[6]

Research on a larger level

Previous publications on hemodynamic performance of multiple surgical valves have been limited by a small sample size, a lack of contemporary valves and a lack of the standardized echo technique of a single core lab.[20,21]

Medtronic and Mayo Clinic partnered together to pool data from four large clinical trials of SAVR and created **the largest surgical valve data set with echocardiograms evaluated by a single core lab to date.‡, 6,22-25**

Learn how you can use the data set

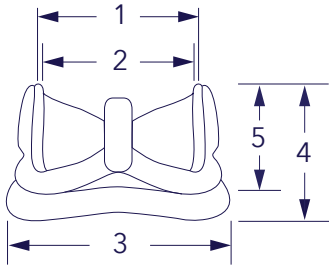


† SVD was defined as a confirmed intrinsic abnormality causing stenosis or regurgitation.

‡ Although all echos in the dataset were read by a single core lab and these are the most robust SAVR valve normals to-date, limitations exist. There were differences in the patient population among individual studies, including PERIGON enrolled patients with bicuspid anatomy and regurgitant lesions. The PERIGON and Evolut Low Risk patients were generally healthier than patients in the CoreValve High Risk and SURTAVI studies. Number of each valve model varied. PERIMOUNT™* bovine pericardial specific models were not consistently collected. There were differences in how annulus size was measured in the Randomized Controlled Trials (RCTs) and the observational study. Lastly, when using the valve normals as reference values, a measured hemodynamic valve worse than the reference value does not necessarily mean a valve is failing.

Ordering information

Item number	Valve size	Stent diameter (TAD)	Internal orfice diameter†		External sewing ring diameter	Valve profile height	Aortic protrusion
		(1)	(2)	(2a)	(3)	(4)	(5)
400U19	19 mm	19 mm	17.5 mm	18 mm	26.0 mm	13.0 mm	11.0 mm
400U21	21 mm	21 mm	19.5 mm	20 mm	28.0 mm	14.0 mm	12.0 mm
400U23	23 mm	23 mm	21.5 mm	22 mm	30.0 mm	15.0 mm	13.0 mm
400U25	25 mm	25 mm	23.5 mm	24 mm	32.0 mm	16.0 mm	14.0 mm
400U27	27 mm	27 mm	25.5 mm	26 mm	35.0 mm	17.0 mm	15.0 mm
400U29	29 mm	29 mm	27.5 mm	28 mm	37.0 mm	18.0 mm	16.0 mm

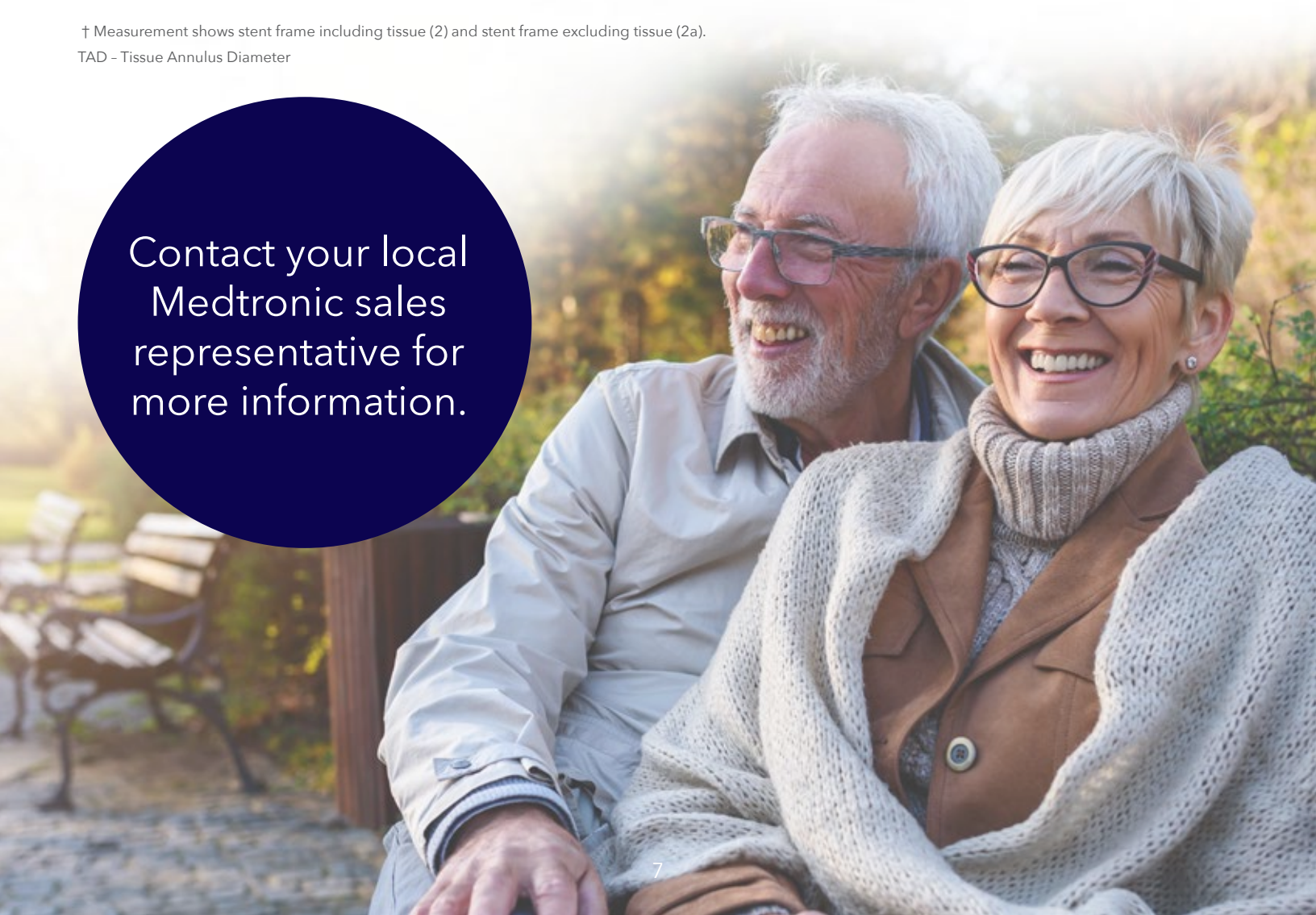


Item number	Description
7420	Valve handle
7400SU	Avalus Ultra sizer
T7400U	Avalus Ultra tray
7779	Jar wrench

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

TAD – Tissue Annulus Diameter

Contact your local Medtronic sales representative for more information.



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Indications, safety, and warnings

If you are located in the United States, please refer to the brief statement(s) below to review applicable indications, safety, and warning information. See the device manual for a full list of information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1.763.514.4000 and/or consult the Medtronic website at medtronic.com.

If you are located outside the United States, see the device manual for a full list of information regarding instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.com and select your appropriate country/region.

For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

Avalus Ultra™ Bioprosthesis

Indications: The Avalus Ultra 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. As with any implanted medical device, there is potential for patient immunological response, including an allergic response. Care should be exercised in patients with hypersensitivities to the device materials. Calcific degeneration could cause accelerated deterioration of the valve in patients with altered calcium metabolism (for example, chronic renal failure, hyperparathyroidism). Calcification may occur earlier in children, adolescents, or young adults. Premature calcification may also occur in older adults who accept a biologic prosthesis. Patients with a bioprosthesis that require chronic anticoagulation are at additional risk of bleeding. Stenosis and regurgitation of the bioprosthesis may occur in patients with coagulation disorders such as AT3 deficiency. Paravalvular leak is more likely to occur in patients with aneurysmal aortic or degenerative conditions, cystic medial necrosis, or Marfan syndrome. Adverse events can include: angina, aortic tissue damage, cardiac dysrhythmias, embolism, endocarditis, heart failure, hemolysis, hemolytic anemia, anticoagulant/antiplatelet-related hemorrhage, immunological response (including allergic response), inflammatory reaction, infection other than endocarditis, transvalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction (leaflet entrapment/impingement, obstructive pannus ingrowth, suture dehiscence, inappropriate sizing), pericardial effusion, pleural effusion, prosthesis regurgitation, prosthesis stenosis, stroke, structural deterioration (calcification, leaflet tear), tamponade, or valve thrombosis. These complications could lead to reoperation, explant of the bioprosthesis, permanent disability or organ damage, 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.

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