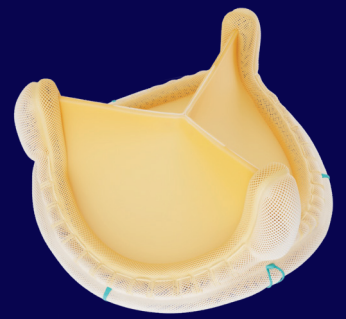


Medtronic



Avalus Ultra™  
bioprosthesis

Fit for the  
future  
right from  
the start.



With every beat,  
expect more.



# Avalus Ultra™ valve is our **most advanced** surgical aortic tissue valve.



## Benefits for you and your patients

## Fit for the future, right from the start.

Innovating on the strong foundation of the Avalus™ valve with 10 years of clinical experience. This next-generation technology was specifically designed to empower cardiac patients to regain their quality of life. Additionally, it provides a robust foundation for future TAV in SAV reinterventions to support the future health journey of cardiac patients.



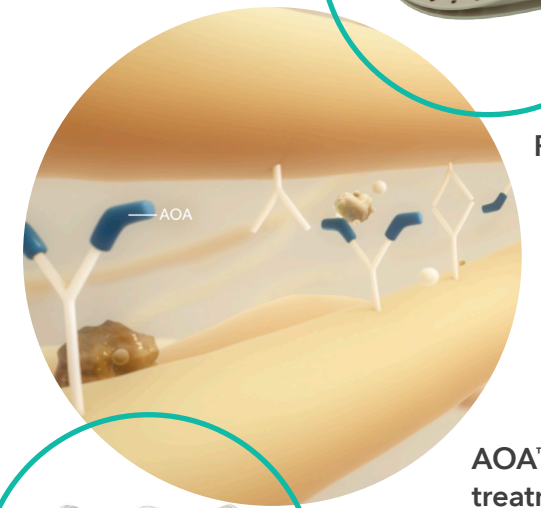
## Durable design for long-term performance†

- Avalus Ultra™, based on the proven Avalus™ design which has shown industry-leading Effective Orifice Areas (EOA) and great hemodynamic performance.<sup>6</sup>
- A decade of reliable clinical experience of the Avalus™ valve with its unique non-deformable, circular base made from PEEK for lasting stability during and after implant.<sup>1-3</sup>
- The amino oleic acid (AOA™) anti-calcification tissue treatment‡ used across a suite of Medtronic valves to help drive durable valve replacements in half a million patients over the last 30 years.
- Medtronic's 50+ years of innovation in heart valve technology, with trusted internally mounted valve leaflets which are proven for durable performance.<sup>4</sup>

Circular Base



PEEK

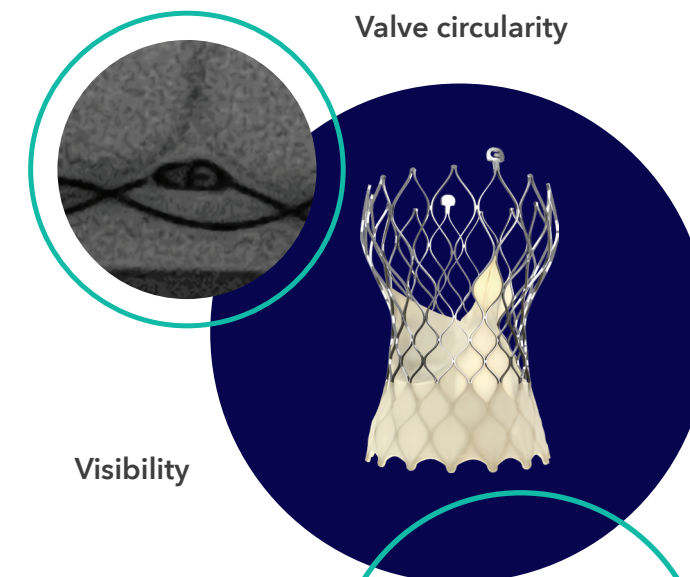


AOA™ tissue treatment



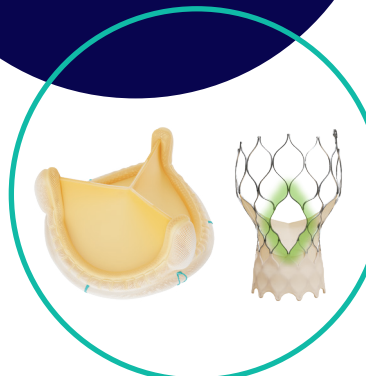
10 years of Avalus™

Valve circularity



Visibility

Large internal diameter



## Excellent fit for lifelong patient care

- Circular TAVI landing zone: a non-deformable base<sup>2,3</sup> with a generous internal diameter paired with the cylindrical opening of the stent posts may help facilitate accurate TAVI placement.
- Clear visibility: the strategic placement of a platinum-iridium coil at the valve's annulus enhances fluoroscopy imaging during TAV in SAV procedures and may facilitate accurate TAVI placement.
- Precision identification: a radiopaque tantalum badge offers an additional layer of certainty, allowing for easy identification of the implanted valve during follow-up examinations and during future reinterventions.

†Demonstrated by the Avalus™ valve. AWT and animal testing has been completed with Avalus Ultra™.

‡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.

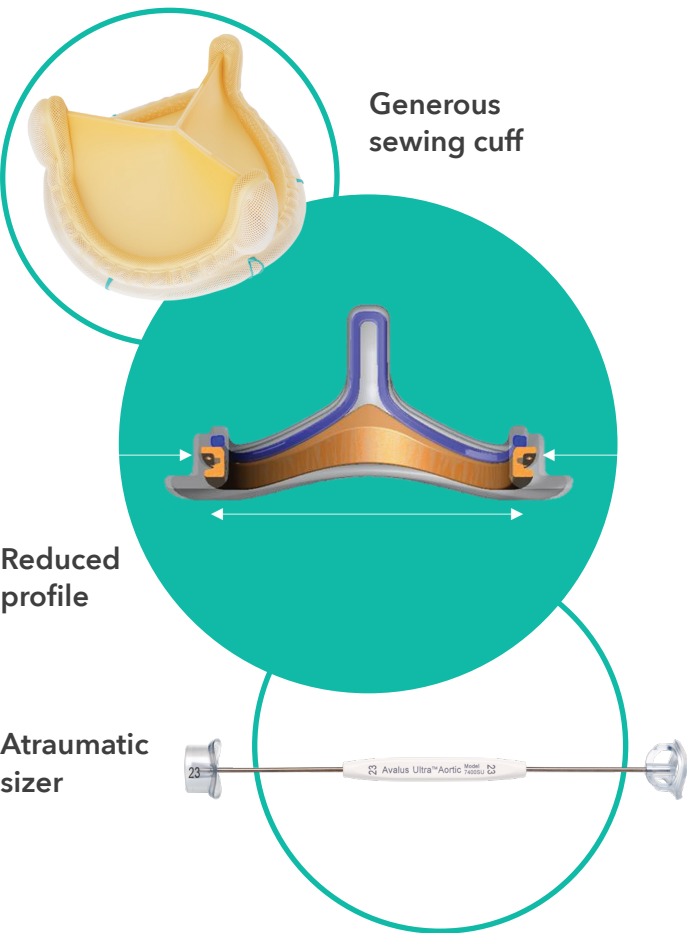


# Excellent and stable hemodynamics†

- The Stable Gradients for both younger ( $\leq 65$ ) and older ( $> 65$ ) patients,<sup>5</sup> supported by the solid clinical evidence of the Avalus™ valve on a large 1100+ patients' cohort.
- An industry-leading Effective Orifice Area (EOA)<sup>6</sup> supported by the clinical evidence of the Avalus™ valve. Large EOAs are beneficial, as they can help increase cardiac output which may support patients who embrace an active lifestyle.
- The 100% leaflet coaptation design, allowing the valve to close smoothly and fully to effectively reduce central jet of blood.<sup>6</sup>

Industry-leading EOA

Designed for 100% coaptation

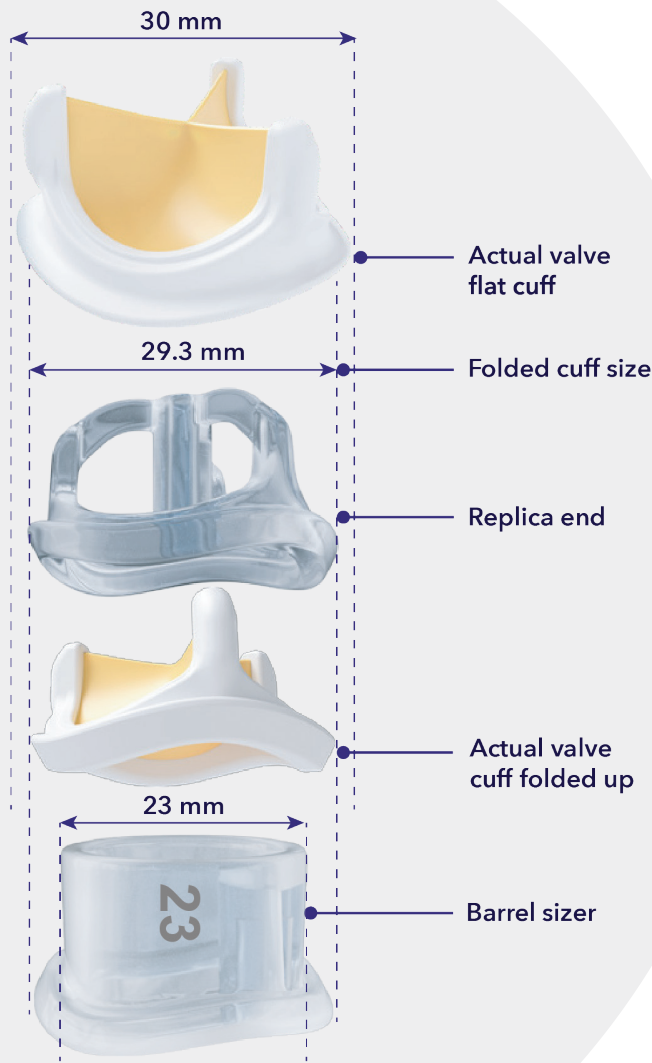


## Engineered for ease of implant

- The reduced valve dimensions and new sizers designed to facilitate improved valve size selection for each patient's anatomy.
- The flexible sewing cuff, which facilitates needle penetration and easy suture placement, securing valve seating and supporting low PVL (paravalvular leak) rates after implantation as demonstrated by the Avalus™ valve.<sup>6</sup>
- With straightforward sizing thanks to the atraumatic smooth shape of the replica end of the sizers, and simulated valve cuff, accurately mirroring the valve shape in implanted position for straightforward sizing.

# Sizing is simple with the Avalus Ultra™ sizer

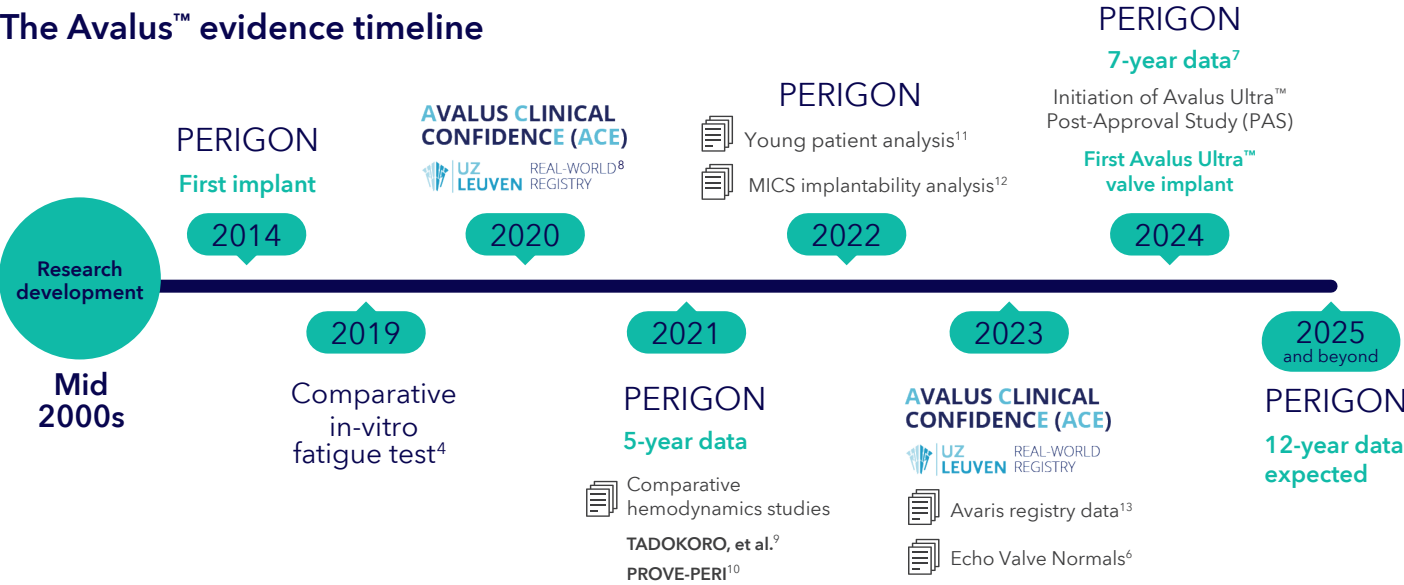
With varying valve anatomies, everyone is unique, therefore, ensuring the right valve fit is critical to your patient's health and future. The Avalus Ultra™ valve's design and sizer facilitate the right valve size for the right patient. Barrel end with a simulated cuff represents the actual labeled valve size.



†Demonstrated by the Avalus™ valve. AWT and animal testing has been completed with Avalus Ultra™.

# Avalus Ultra™ bioprosthesis design

## The next generation aortic tissue valve, built on a strong foundation and a decade of experience of Avalus™ valve



### AOA™ tissue treatment

Existing 30 years, and being used in over half a million patients across a suite of Medtronic devices, the Medtronic amino oleic acid (AOA™) treatment has proven to be an innovative tissue treatment.

The Avalus Ultra™ valve benefits from AOA™ treatment, which reduces calcification in the tissue leaflets.<sup>15-16,†</sup>



#### 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.

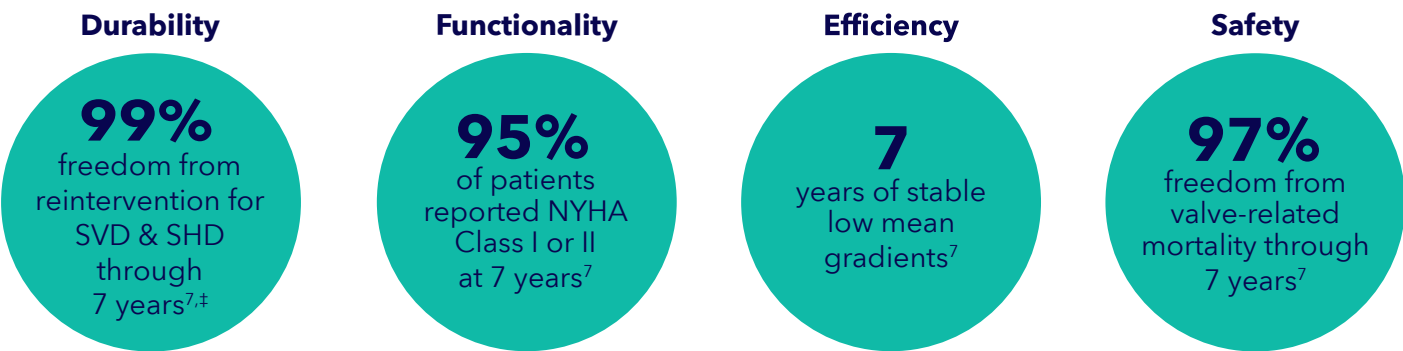
#### After treatment

- 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 is supported by over 7 years of robust, clinical evidence of the Avalus™ valve, having demonstrated excellent EOAs and stable low gradients.

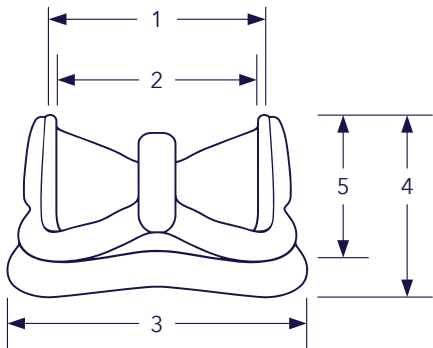
The Avalus Ultra™ valve’s design is built on the core foundational benefits of the Avalus™ valve:



## The Avalus Ultra™ valve dimensions and geometry facilitate valve-in-valve replacements.<sup>2,3,§</sup>

Avalus Ultra™ valve item number	Valve size	Stent diameter (TAD)	Internal orifice 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
T7400U	Avalus Ultra™ tray
7420	Valve handle
7400SU	Avalus Ultra™ sizers
7779	Jar wrench



‡Structural valve deterioration (SVD) was defined as a confirmed intrinsic abnormality causing stenosis or regurgitation. Severe hemodynamic dysfunction (SHD) was defined as severe stenosis and/or severe transvalvular regurgitation and/or reintervention without adequate evidence to adjudicate SVD, nonstructural valve dysfunction, endocarditis, or valve thrombosis.

§Measurement shows stent frame including tissue (2) and stent frame excluding tissue (2a). TAD - Tissue annulus diameter.

# Fit for the future, right from the start.

Join us on the mission to  
advance Cardiac Surgery care



## References

1. Klautz RJM, Dagenais F, Reardon MJ, et al. Surgical aortic valve replacement with a stented pericardial bioprosthesis: 5-year outcomes. *Eur J Cardiothorac Surg*. August 2022;62(3):ezac374.
2. Based on internal test report D00997823, Avalus Ultra™ Full Valve Stiffness Design Verification Report.
3. Based on internal test report D00998399, Design Characterization Report: External Sewing Ring Diameter, Valve Housing External Diameter, and Inflow Orifice.
4. Vriesendorp MD, de Lind van Wijngaarden RAF, Rao V, et al. An in vitro comparison of internally versus externally mounted leaflets in surgical aortic bioprostheses. *Interact Cardiovasc Thorac Surg*. 2020 Mar 1;30(3):417-423. doi: 10.1093/icvts/ivz277.
5. Kiaii BB, Moront MG, Patel HJ, Ruel M, Bensari FN, Kress DC, Liu F, Klautz RJM, Sabik JF 3rd. Outcomes of Surgical Bioprosthetic Aortic Valve Replacement in Patients Aged ≤65 and >65 Years. *Ann Thorac Surg*. 2023 Sep;116(3):483-490. doi: 10.1016/j.athoracsur.2021.12.057. Epub 2022 Jan 20.
6. Klautz RJM, Rao V, Reardon MJ et al., Examining the typical hemodynamic performance of nearly 3000 modern surgical aortic bioprostheses. *Eur J Cardiothorac Surg*. 2024;65(5):ezae122.
7. Sabik JF 3rd, Rao V, Dagenais F, et al. 7-Year outcomes after surgical aortic valve replacement with a stented bovine pericardial bioprosthesis in over 1100 patients: a prospective multicenter analysis. *Eur J Cardiothorac Surg*. 2024 Nov 20:ezae414. doi: 10.1093/ejcts/ezae414.
8. Verbelen T, Roussel JC, Cathenis K, et al. Real-world data on the Avalus pericardial aortic valve: initial results from a prospective, multi-center registry. Presented at Heart Valve Society 2024, Boston, MA. February 18-21, 2024.
9. Tadokoro N, Fukushima S, Shimahara Y, et al. Comparison of safety and haemodynamic performance between the Avalus™ stented aortic valve bioprosthesis and Magna™ valve in Japanese patients. *Gen Thorac Cardiovasc Surg*. July 2021;69(7):1060-1069.
10. Sohn SH, Kim JS, Choi JW, et al. Preliminary Report from a Randomized Controlled Trial Comparing Two Bovine Pericardial Valves. *Thorac Cardiovasc Surg*. 2023;71(8):648-655.
11. Kiaii BB, Moront MG, Patel HJ, et al. Outcomes of surgical bioprosthetic aortic valve replacement in patients aged ≤65 and >65 years. *Ann Thorac Surg*. September 2023;116(3):483-490.
12. Velders BJJ, Vriesendorp MD, Reardon MJ, et al. Minimally invasive aortic valve replacement in contemporary practice: clinical and hemodynamic performance from a prospective multicenter trial. *Thorac Cardiovasc Surg*. August 2023;71(5):387-397.
13. Chiariello GA, Villa E, Bruno P, et al. Two innovative aortic bioprostheses evaluated in the real-world setting. First results from a two-center study. *J Cardiovasc Surg (Torino)*. June 2023;64(3):338-347.
14. Gott JP, Pan-Chih, Dorsey JM, et al. Calcification of porcine valves: a successful new method of antimicrobialization. *Ann Thorac Surg*. February 1992;53(2):207-215.
15. Girardot MN, Torrianni M, Girardot JM. Effect of AOA on glutaraldehyde-fixed bioprosthetic heart valve cusps and walls: Binding and calcification studies. *Int J Artif Organs*. February 1994;17(2):76-82.

† 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.

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at [www.medtronic.eu](http://www.medtronic.eu). For applicable products, consult instructions for use on [www.medtronic.com/manuals](http://www.medtronic.com/manuals). Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser. This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within the respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorization for use.

# Medtronic

Medtronic International Trading Sàrl.  
Route du Molliau 31  
Case postale  
CH-1131 Tolochenaz  
Tel: +41 (0)21 802 70 00  
Fax: +41 (0)21 802 79 00

[medtronic.eu](http://medtronic.eu)

©2025 Medtronic. Medtronic, Medtronic logo, and Engineering the extraordinary are trademarks of Medtronic. TM\* Third-party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic company.

2024-avalus-ultra-product--brochure-en-gb-emea-12718119