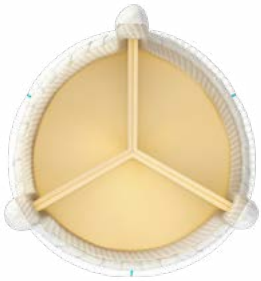
Medtronic



New Data
EACTS 2023

Avalus™
Bioprosthesis

Surgical Aortic Valve Replacement

Quality data. Better heart decisions.

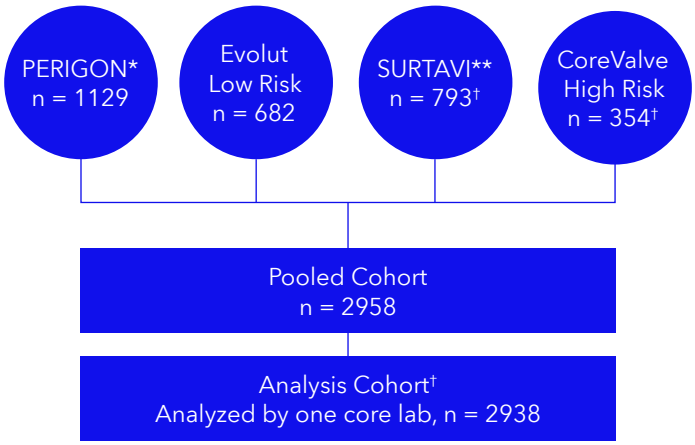
Discover the largest data set of contemporary surgical aortic valves, analyzed by a single core lab.[1] Using this data set, Medtronic created a tool for cardiac surgeons that is a novel, robust instrument for evaluating valve performance.

Discover the ultimate valve performance evaluation tool you've been waiting for.

Study design

Previous publications on hemodynamic performance of multiple surgical valves have been limited[2,3] by a small sample size, a lack of contemporary valves and a lack of the standardized echo technique of a single core lab.

Medtronic and Mayo Clinic partnered together to pool data from four large clinical trials of surgical aortic valve replacement (SAVR) and created **the largest surgical valve data set with echocardiograms evaluated by a single core lab to date.**[4-7]



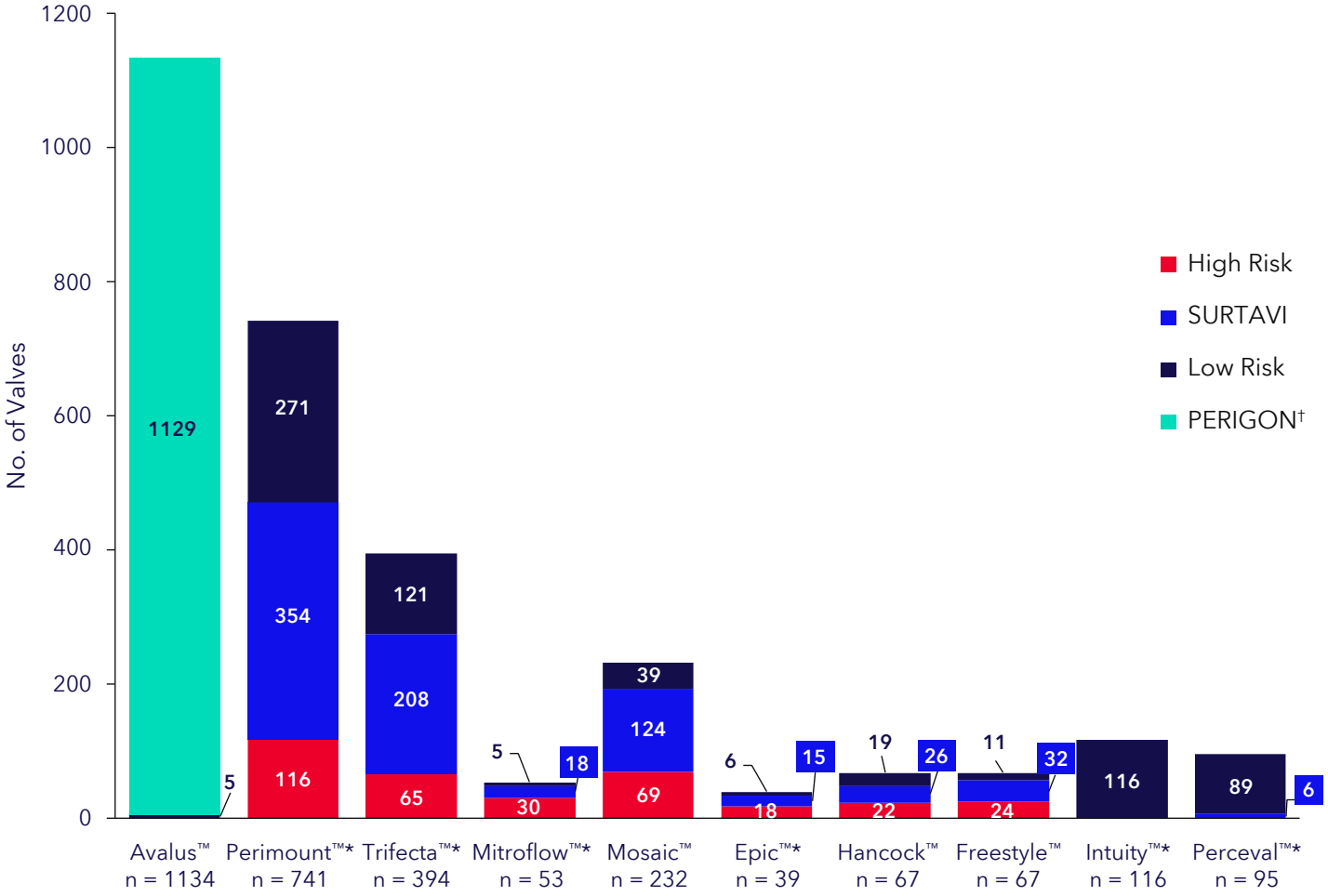
*PERIcardial SurGical AOrtic Valve ReplacemeNt (PERIGON) Pivotal Trial of the Avalus bioprosthesis.

**SUrgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) trial.

†20 exclusions due to small sample size: 3F™* (8), Enable™*(2), Solo Smart™* (3), Carbomedics™* (2), Flex Cuff™* (1), Oxane-21™* (1), Regent™* (3).

The standardized data acquisition and use of a single core lab **help ensure the consistency in echo assessment methods** needed for robust hemodynamic analysis.[8]

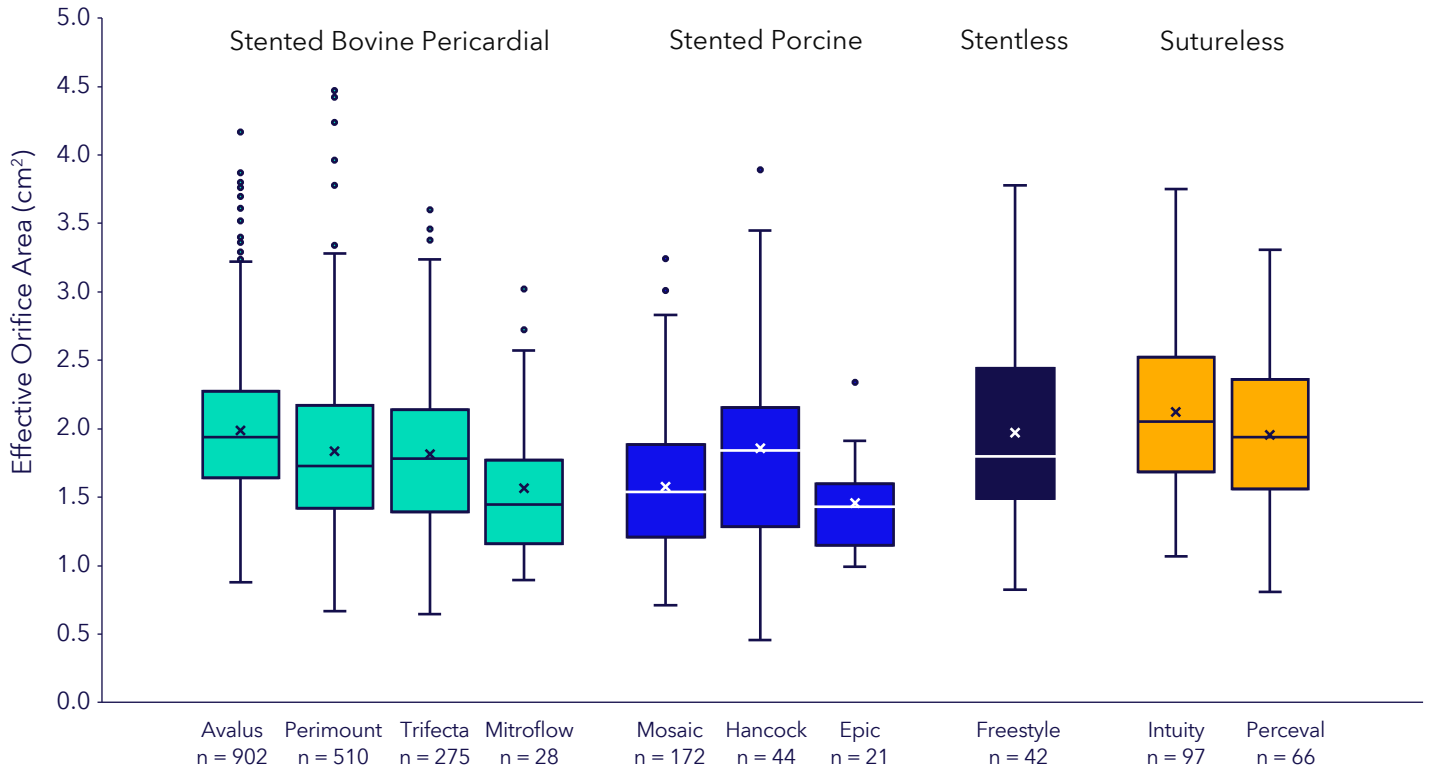
Implanted valves by study and model, N



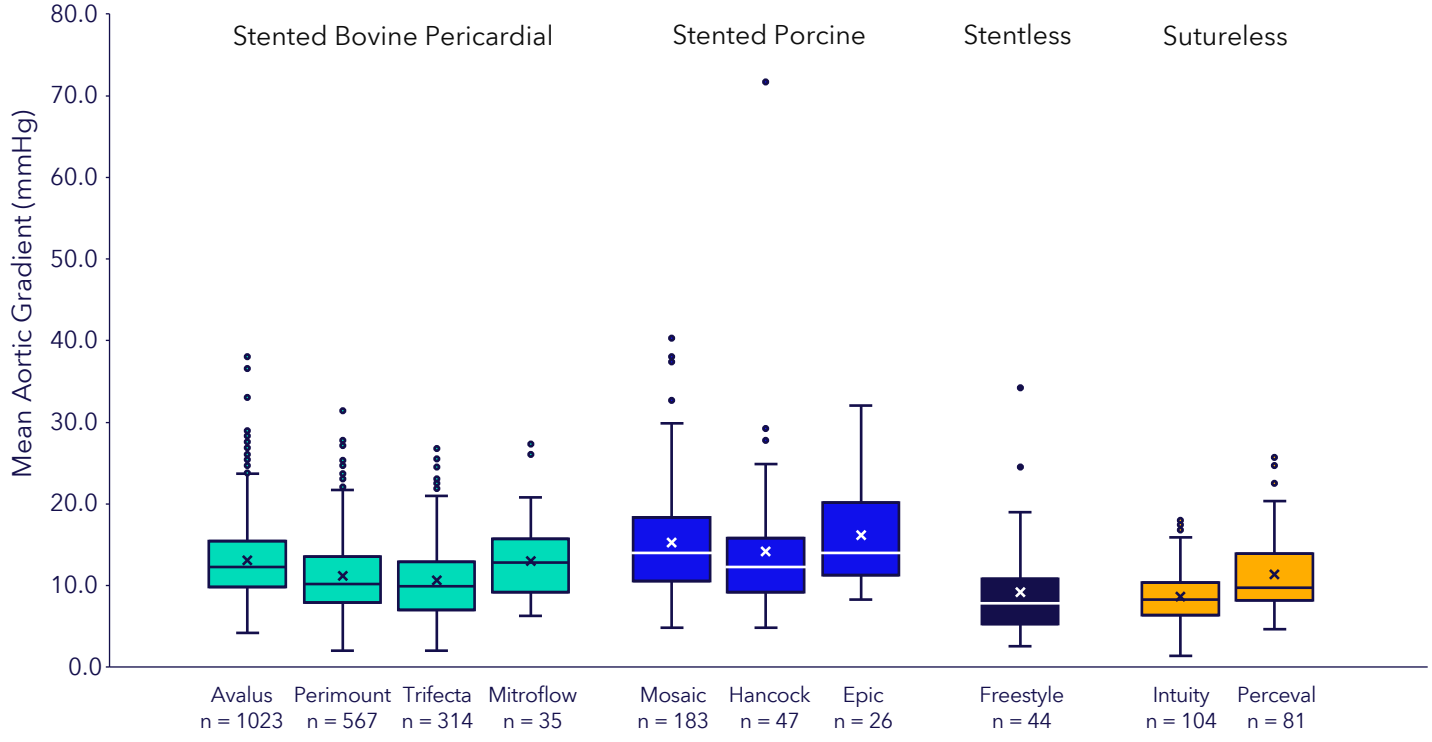
†The Avalus valve size 17 mm is only approved for commercial use in Japan. Given that the Avalus valve size 17 mm was included in the PERIGON Pivotal Trial, all data, including the 17 mm data, from the Analysis Cohort is disclosed here. The Avalus 17 mm data accounts for less than 0.05% of the total echo data represented in this analysis.

Results

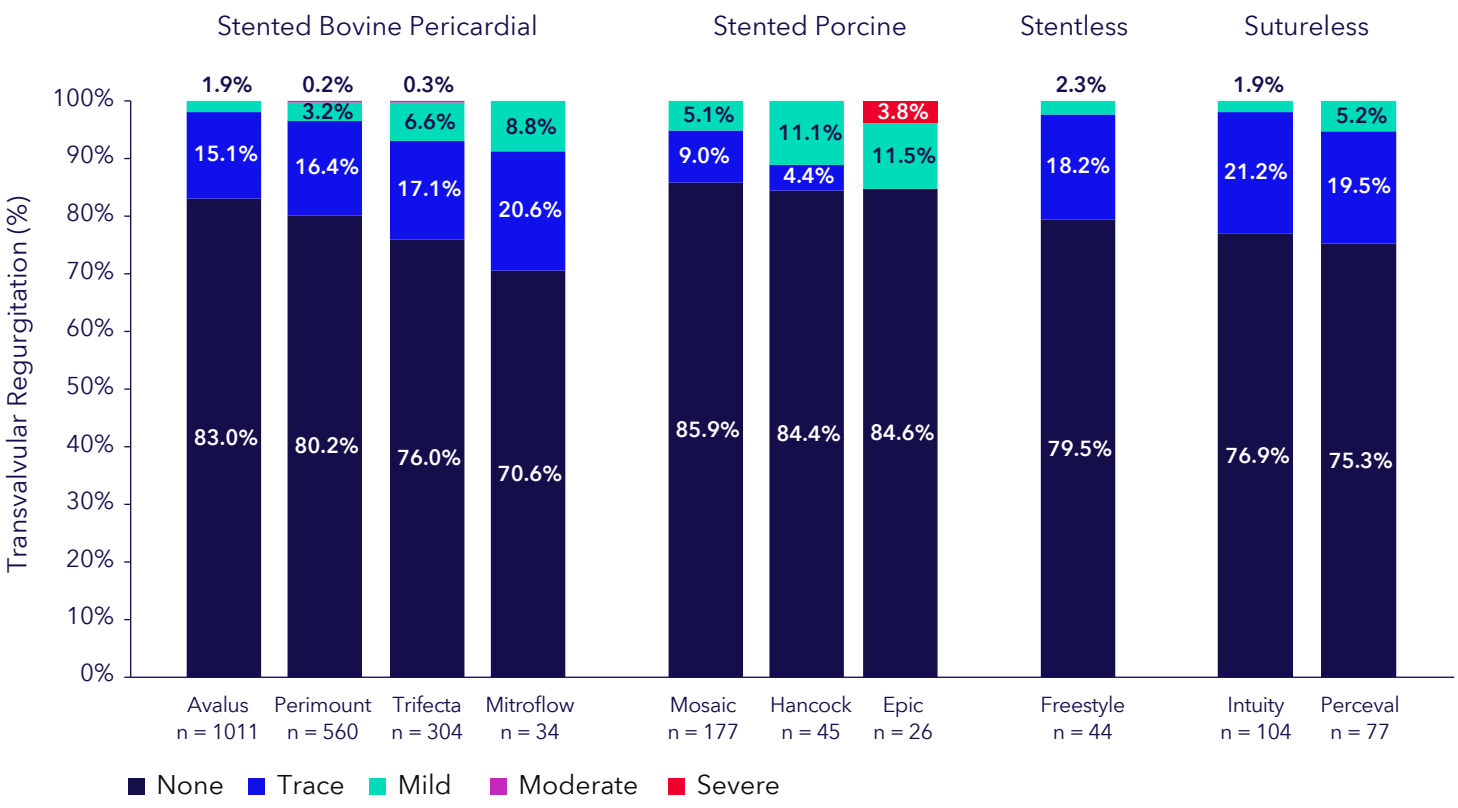
Effective orifice area (EOA) at one year



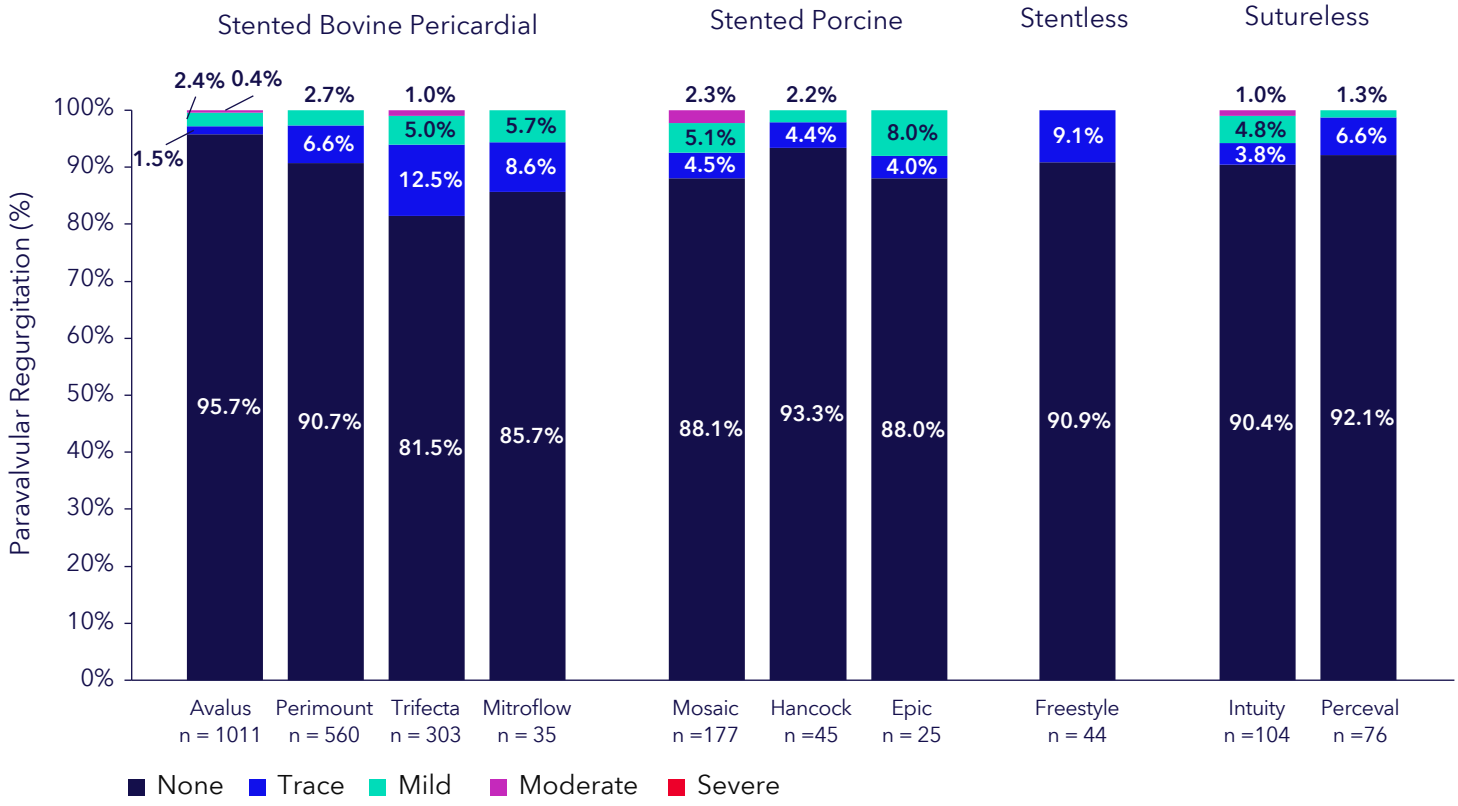
Mean pressure gradients (MPG) at one year



Transvalvular regurgitation (TVR) % at one year



Paravalvular regurgitation (PVR) % at one year



Data insights

- The data set provides valve normals, a useful tool for the evaluation of patients implanted with a specific valve model and size.
- The reference values reported in the data set can aid in evaluating whether an implanted valve is functioning normally after valve replacement.
- Data for 10 valve models of four surgical valve types are reported. Overall performance ranged from good to excellent for the individual tissue valve models and hemodynamic parameters.
- Hemodynamic performance at one year was good to excellent, with EOA ranging from 1.46±0.34 to 2.12±0.59 cm^2 and mean gradient ranging from 8.6±3.4 to 16.1±6.2 mmHg. Avalus and Freestyle valves demonstrated excellent performance with high EOAs and low MPGs at one year.
- For TVR, Avalus and Freestyle valves demonstrated outstanding performance at one year.
- For PVR, which is one of the key efficiency and safety end points, characterizing the quality of valve seating and sizing, Avalus valve showed superb performance: 97.2% with none/trace PVR.

Conclusion

This dataset overcomes shortcomings of previous surgical valve normals reports. The analysis demonstrates the hemodynamic performance that can generally be expected at one year with currently available valves. **This is the most robust SAVR valve normals analysis to date.*** Overall, performance ranged from good to excellent for the individual valve models, sizes, and hemodynamic parameters. The data from this analysis can serve as a benchmark for other studies and may be a useful resource to help guide patient management following SAVR.

Learn more about Avalus

*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.

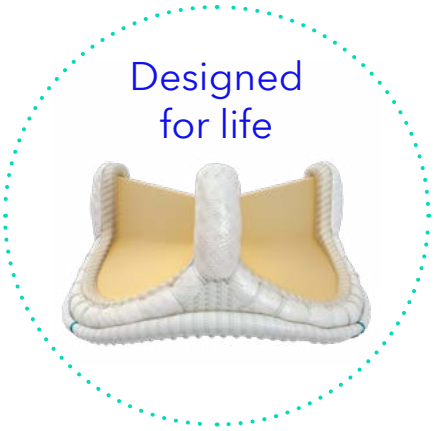
What does it mean for your valve choice?

The new data from this robust analysis provides **highly convincing clinical evidence of the safety and efficiency of the Avalus valve design.**

Durability

First implanted nearly 10 years ago, the Avalus valve is designed to last:

- Innovative AOA™ anti-calcification tissue treatment,* used on 500,000+ patients for over 30 years
- Internally mounted leaflet design, the gold standard for valve durability[9]



Circularity

Unique to the Avalus valve – and not available in other bovine tissue valves – its non-deformable polymer base combined with flexible stent post[10,11]:

- Enables efficient blood flow
- Allows regular leaflet motion
- Increases valve durability

Hemodynamics

Designed for 100% coaptation, the Avalus valve provides[1]:

- Large and stable EOAs, low and stable MPGs
- Low rates of TVR and PVR
- Low rates of PPM in both controlled and real-world studies

Lifetime management

Engineered in the modern era of transcatheter aortic valve implantation (TAVI), the Avalus valve provides:

- Cylindrical opening and circular base to accommodate TAVI landing
- Metal-free polymer frame, reducing risk of metal-on-metal corrosion

*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.

Learn more about the Avalus valve

References:

[1] Klautz RJM, Rao V, Reardon MJ, et al. Hemodynamic function of contemporary surgical aortic valves 1 year postimplant. Paper presented at: 37th Annual Meeting of the European Association for Cardio-Thoracic Surgery; October 4-7, 2023; Vienna, Austria.

[2] Rosenheck R, Binder T, Maurer G, Baumgartner H. Normal values for Doppler echocardiographic assessment of heart valve prostheses. *J Am Soc Echiocardiogr.* 2003;16:1116-27.

[3] Winter MP, Zbiral M, Kietaibl A, Sulzgruber P, Kastner J, Rosenhek R et al. Normal values for Doppler echocardiographic assessment of prosthetic valve function after transcatheter aortic valve replacement: a systematic review and meta-analysis. *Eur Heart J Cardiovasc Imaging.* 2018;19:361-8.

[4] Klautz RJM, Kappetein AP, Lange R, Dagenais F, Labrousse L, Bapat V et al. Safety, effectiveness and hemodynamic performance of a new stented aortic valve bioprosthesis. *Eur J Cardiothorac Surg.* 2017;52:425-31.

[5] Adams DH, Popma JJ, Reardon MJ, Yakubov SJ, Coselli JS, Deeb GM et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med.* 2014;370:1790-8.

[6] Reardon MJ, Van Mieghem NM, Popma JJ, Kleiman NS, Sondergaard L, Mumtaz M et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. *N Engl J Med.* 2017;376:1321-31.

[7] Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med.* 2019;380:1706-15.

[8] Hahn RT, Pibarot P Weissman NJ et al. Assessment of paravalvular aortic regurgitation after transcatheter aortic valve replacement: intra-core laboratory variability. *J Am Soc Echocardiogr.* April 2015;28(4):415-22.

[9] David TE, Armstrong S, Maganti M et al. Hancock II bioprosthesis for aortic valve replacement: the gold standard of bioprosthetic valves durability? *Ann Thorac Surg.* September 2010;90(3):775-81.

[10] Faure ME, Sucha D, Schwartz FR, et al. Surgically implanted aortic valve bioprostheses deform after implantation: insights from computed tomography. *Eur Radiol.* May 2020;30(5):2651-2657.

[11] Gunning PS, Saikrishnan N, Yoganathan AP, McNamara LM. Total ellipse of the heart valve: the impact of eccentric stent distortion on the regional dynamic deformation of pericardial tissue leaflets of a transcatheter aortic valve replacement. *J R Soc Interface.* December 6, 2015;12(113):20150737.

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 **medtronic.com/manuals**.

Mosaic™ Bioprosthesis

Indications: For the replacement of malfunctioning native or prosthetic aortic and/or mitral heart valves. **Contraindications:** None known.

Warnings/Precautions/Adverse Events: Accelerated 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, hyperparathyroidism). Adverse events can include: angina, cardiac arrhythmia, cardiac dysrhythmias, death, endocarditis, heart failure, hemolysis, hemolyticanemia, hemorrhage, transvalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction, stroke, structural deterioration, thromboembolism, or valve thrombosis.

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 **medtronic.com/manuals**.

Hancock™ II Bioprosthesis

Indications: For patients who require replacement of their native or prosthetic aortic and/or mitral valves. **Contraindications:** None known.

Warnings/Precautions/Adverse Events: Accelerated 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, hyperparathyroidism). Adverse events can include: angina, cardiac arrhythmia, cardiac dysrhythmias, death, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, transvalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction, stroke, structural deterioration, thromboembolism, or valve thrombosis.

For additional information, please refer to the Instructions for Use provided with the product.

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 **medtronic.com/manuals**.

Freestyle™ Aortic Root Bioprosthesis

Indications: For the replacement of malfunctioning native or prosthetic aortic valves with the option of aortic root replacement. **Contraindications:** None known.

Warnings/Precautions/Adverse Events: Accelerated 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, hyperparathyroidism). Adverse events can include: cardiac dysrhythmias, death, endocarditis, hemolysis, hemorrhage, transvalvular or paravalvular leak, nonstructural dysfunction, structural deterioration, thromboembolism, valve thrombosis, or intracuspal hematoma.

For additional information, please refer to the Instructions For Use provided with the product.

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 **medtronic.com/manuals**.

Important labeling information for other geographies outside the United States

See the device manual for detailed information regarding the 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.

Medtronic

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Toll-free in USA: 800.633.8766
Worldwide: 1.763.514.4000
medtronic.com

LifeLine
Cardiovascular technical support
Tel: 1.877.526.7890
Tel: 763.526.7890
Fax: 763.526.7888
rs.cstechsupport@medtronic.com

UC202404501a IE
01/2024