



SURGICAL AORTIC VALVE REPLACEMENT

Quality data. Better heart decisions.

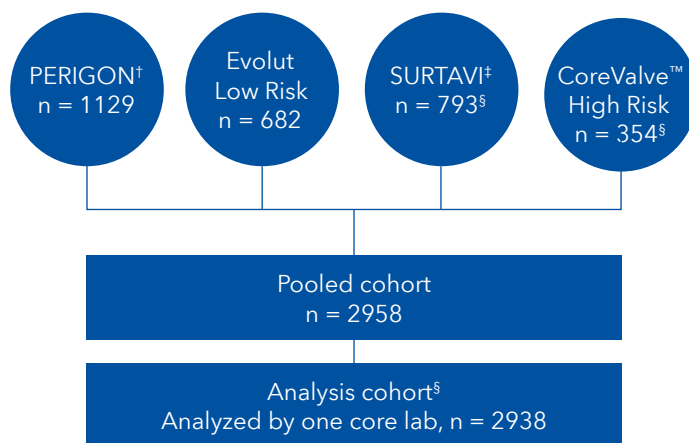
Discover the largest data set of contemporary surgical aortic valves, analyzed by a single core lab.¹ Using this data set, Medtronic created a tool for cardiac surgeons that is a novel, robust instrument for evaluating valve performance.

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.**⁴⁻⁸



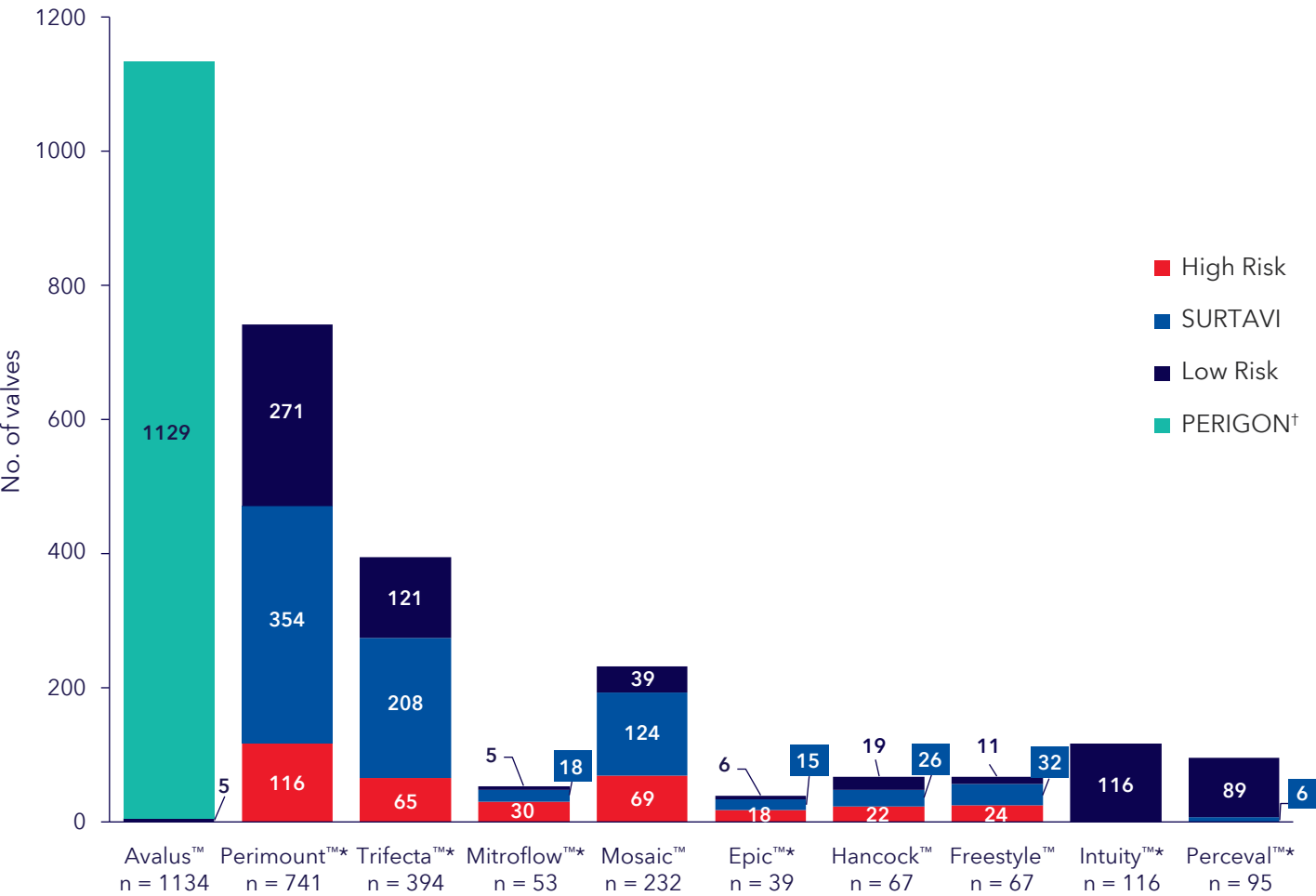
† PERIcardial SurGical AOtic Valve ReplacemeNt (PERIGON) Pivotal Trial of the Avalus bioprosthesis.

‡ SURGical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) trial.

§ Twenty 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.⁹

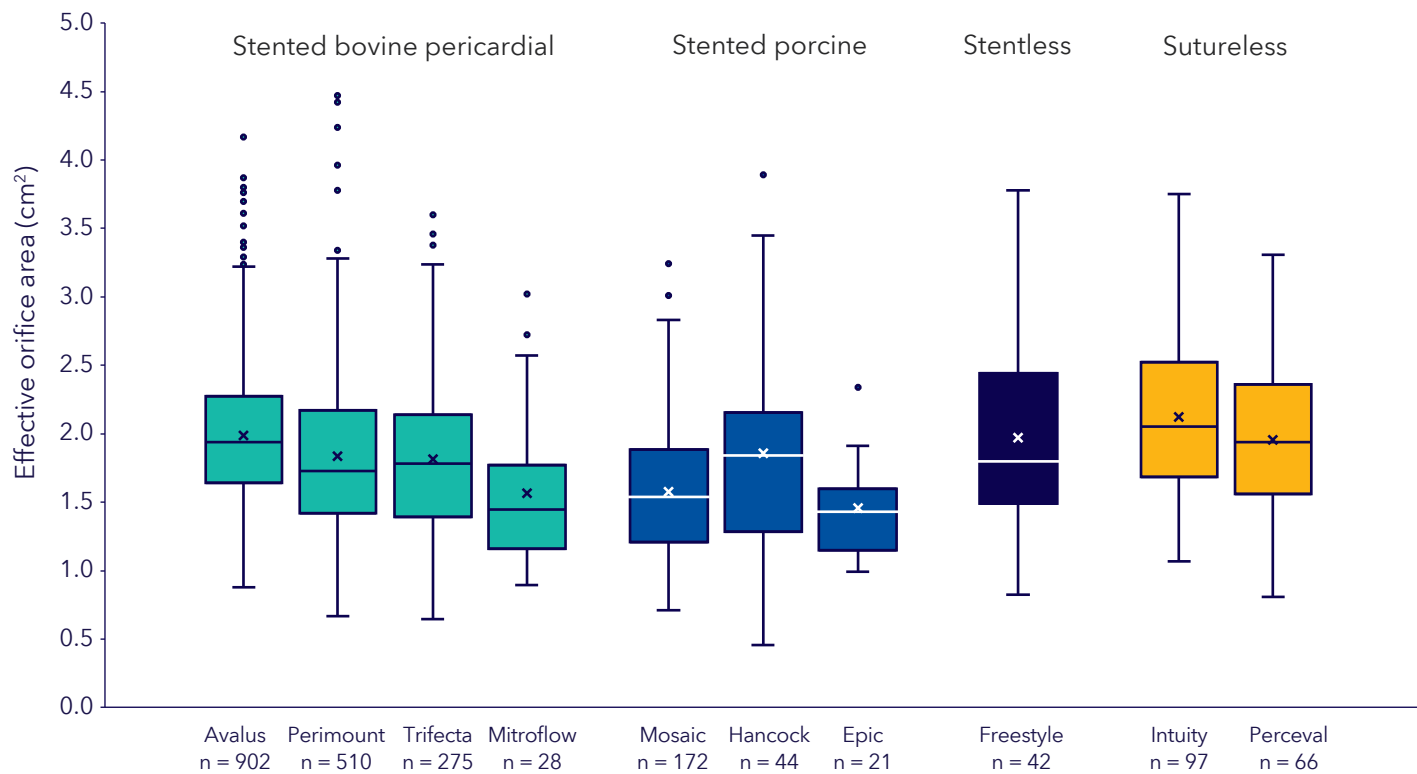
Implanted valves by study and model, N



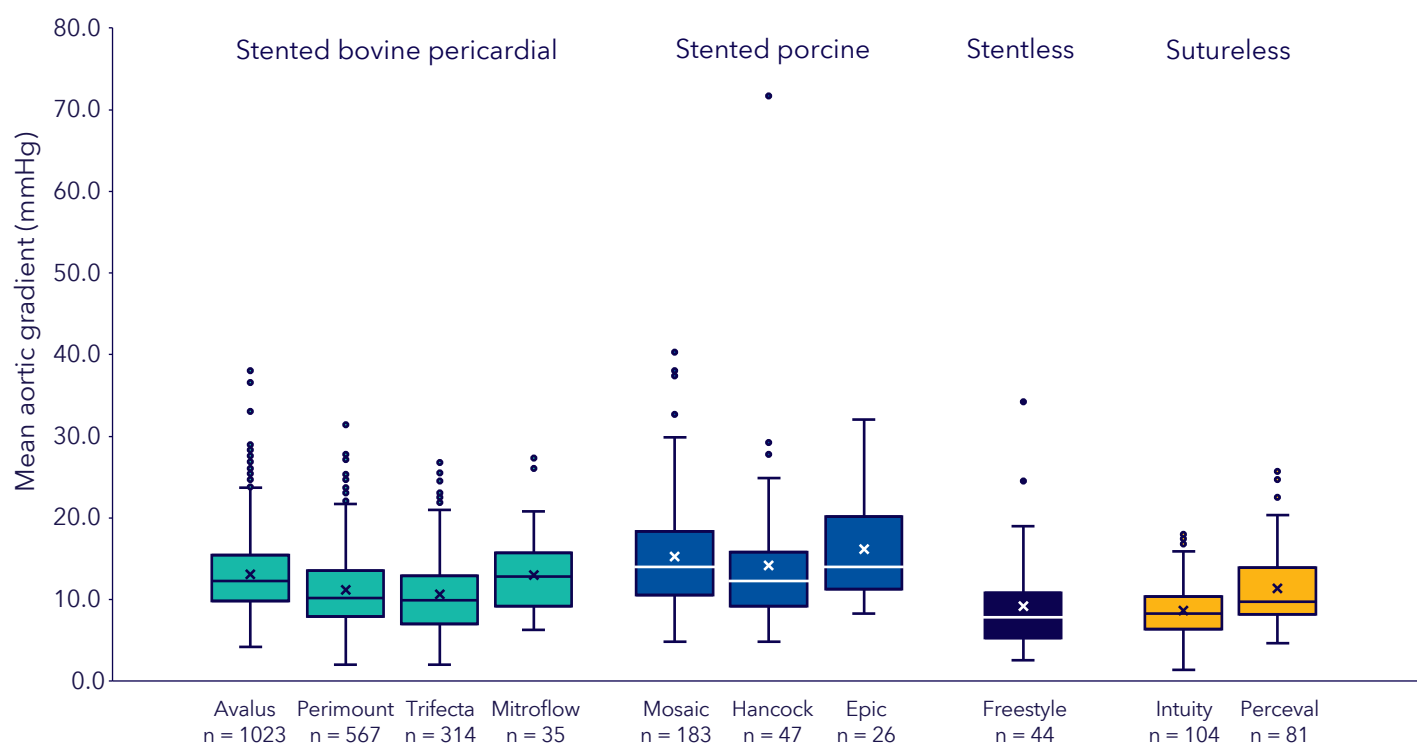
† The Avalus valve size 17 mm is only approved for commercial use in Japan. The Avalus valve size 29 mm is currently limited to investigational use and not approved for sale in the United States. Given that the Avalus valve sizes 17 mm and 29 mm were included in the PERIGON Pivotal Trial, all data, including the 17 mm and 29 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. The 29 mm data accounts for less than 1% of the total echo data represented in this analysis.

Results

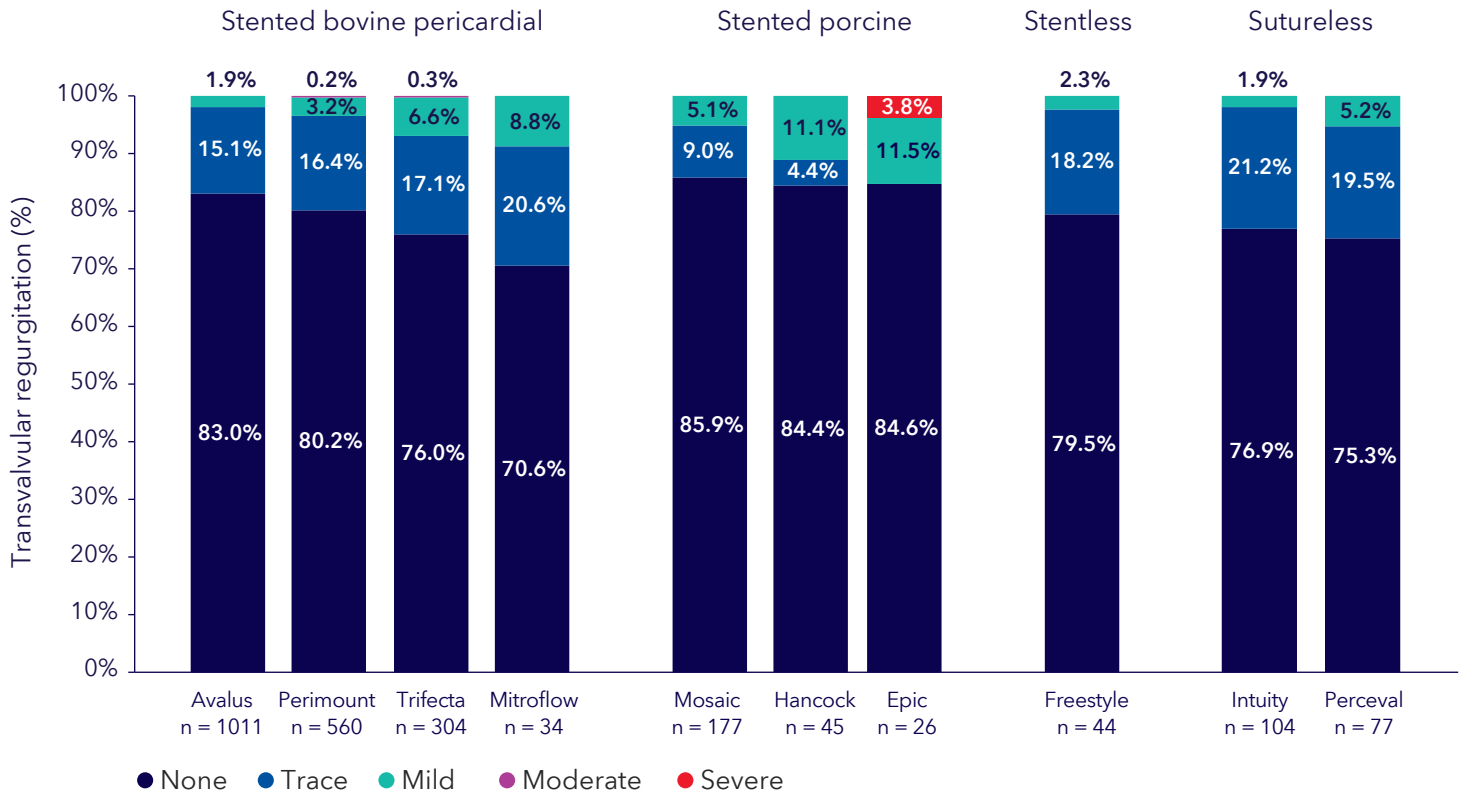
Effective orifice area (EOA) at one year



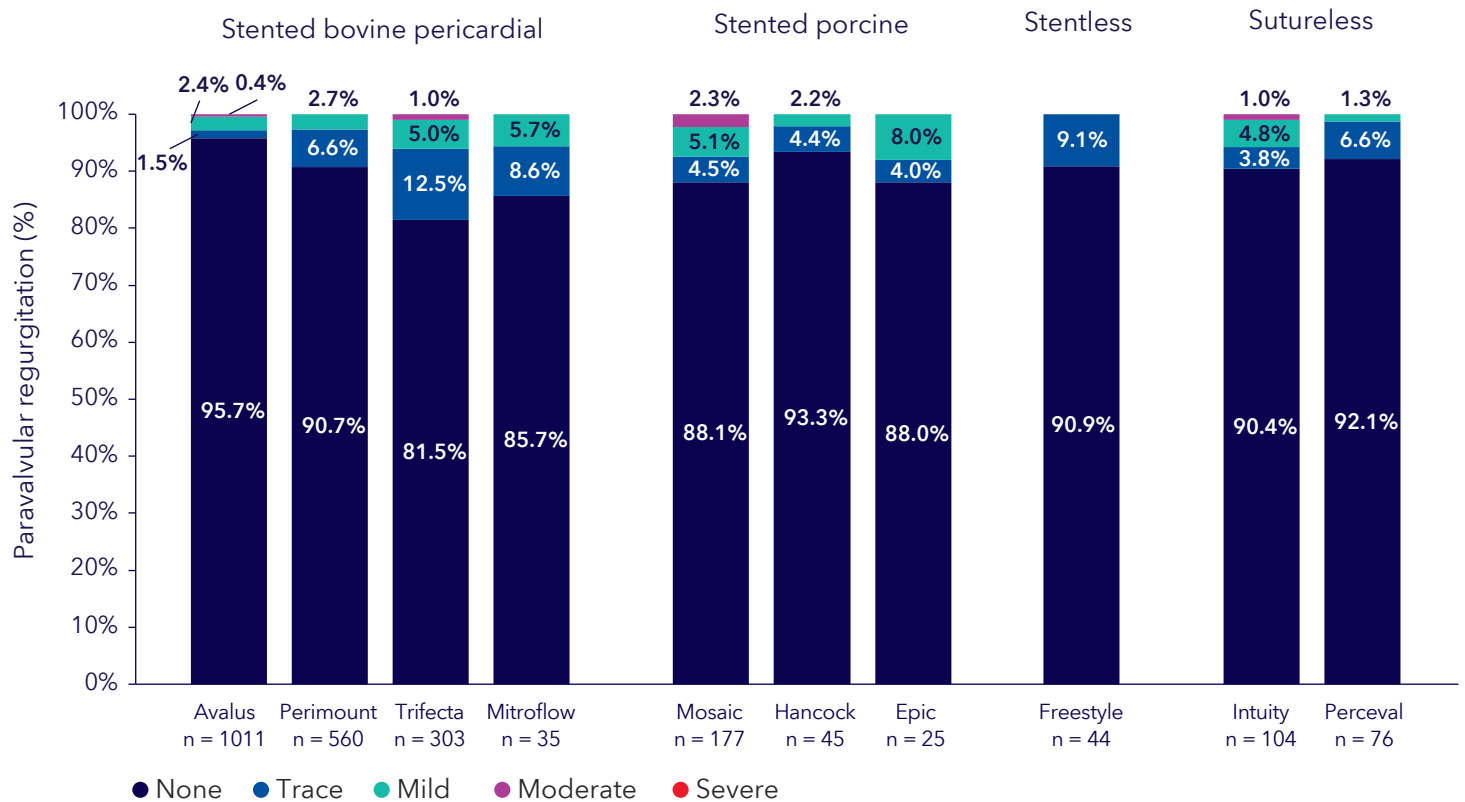
Mean pressure gradients (MPG) at one year



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 cm² 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 data set 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.



[†] Although all echos in the data set 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 Avalor valve design.**

Durability

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

- Highly efficient AOA™ anti-calcification tissue treatment,[†] used on 500,000+ valves for over 30 years
- Internally mounted leaflet design, the gold standard for valve durability¹⁰

Circularity

Unique to the Avalor valve – and not available in other valves – its non-deformable polymer base combined with flexible stent post:^{11,12}

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



Hemodynamics

Designed for 100% coaptation, the Avalor valve provides:

- Large and stable EOAs, low and stable MPGs¹
- Low rates of TVR and PVR¹
- Low rates of PPM in both controlled and real-world studies¹

Lifetime management

Engineered in the modern era of TAVI, the Avalor 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.



Scan the QR code to learn more about Avalor
at medtronic.com/avalusforlife

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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, hemolytic anemia, 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.

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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.

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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.

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