STUDY DESCRIPTION
This study was a retrospective, single-center observational analysis comparing the feasibility, safety, and valve hemodynamics between Avalus and Magna™ valves in patients who underwent surgical aortic valve replacement: 87 patients with an Avalus bioprosthesis and 381 patients with a Magna valve were enrolled. Valve hemodynamics, adverse events, and outcomes were recorded up to one year postoperatively.

CONCLUSION
Avalus bioprosthesis implantation resulted in good hemodynamic performance and good in-hospital outcomes similar to those of Magna in this patient group of overall smaller body size — including in those with smaller valve sizes (19 and 21 mm) — which are typically more difficult to implant.

HEMODYNAMIC PERFORMANCE
MPG and EOA measures were not significantly different between the two valves, up to one year postoperatively.

Small-size Avalus valves (19 or 21 mm) were successfully implanted with the same surgical procedure used for Magna.

In addition, these smaller valves produced an MPG and EOA similar to that of the Magna valves, achieving good hemodynamic functionality in patients with a small body size.

GOOD AVALUS FUNCTIONALITY, SIMILAR MPG AND EOA WITH MAGNA, EVEN IN THE SMALLEST SIZES.

SUCCESSFUL IMPLANTATION OF AVALUS VALVE SMALL SIZES

Mean Pressure Gradient (mm HG) at 1-year Follow-up

Effective Orifice Area (cm²) at 1-year Follow-up

CONCLUSION
Avalus bioprosthesis implantation resulted in good hemodynamic performance and good in-hospital outcomes similar to those of Magna in this patient group of overall smaller body size — including in those with smaller valve sizes (19 and 21 mm) — which are typically more difficult to implant.
As seen in this recent study, the Avalus patients had great hemodynamic results.

**AVALUS BIOPROSTHESIS IN SMALL SIZES**

**DESIGN BENEFITS**

**INTERNALLY MOUNTED LEAFLETS AND AOA™† TREATMENT FOR LONG-TERM DURABILITY**

**POLYMER STENT FOR STRENGTH AND FLEXIBILITY, AND RESISTANCE TO PERMANENT DEFORMATION FOR STABLE HEMODYNAMICS**

**LOW-PROFILE GEOMETRY AND RADIOPACITY FOR LIFETIME PATIENT MANAGEMENT**

**LOW-PROFILE SOFT SEWING CUFF FOR ENHANCED IMPLANT EXPERIENCE**

*No clinical data is available which evaluates the long-term impact of AOA treatment in patients.

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 bioprostheses 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. Note: Manuals can be viewed using a current version of any major internet browser.