Medtronic

Avalus Ultra™
bioprosthesis

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Proof that **shape matters**

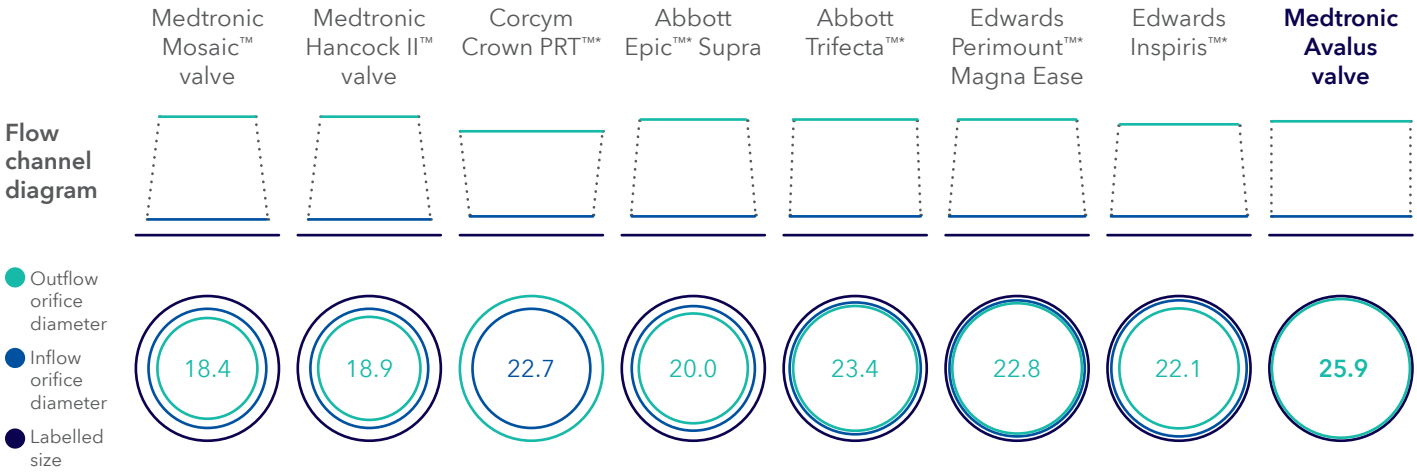
The Avalus™ platform advantage

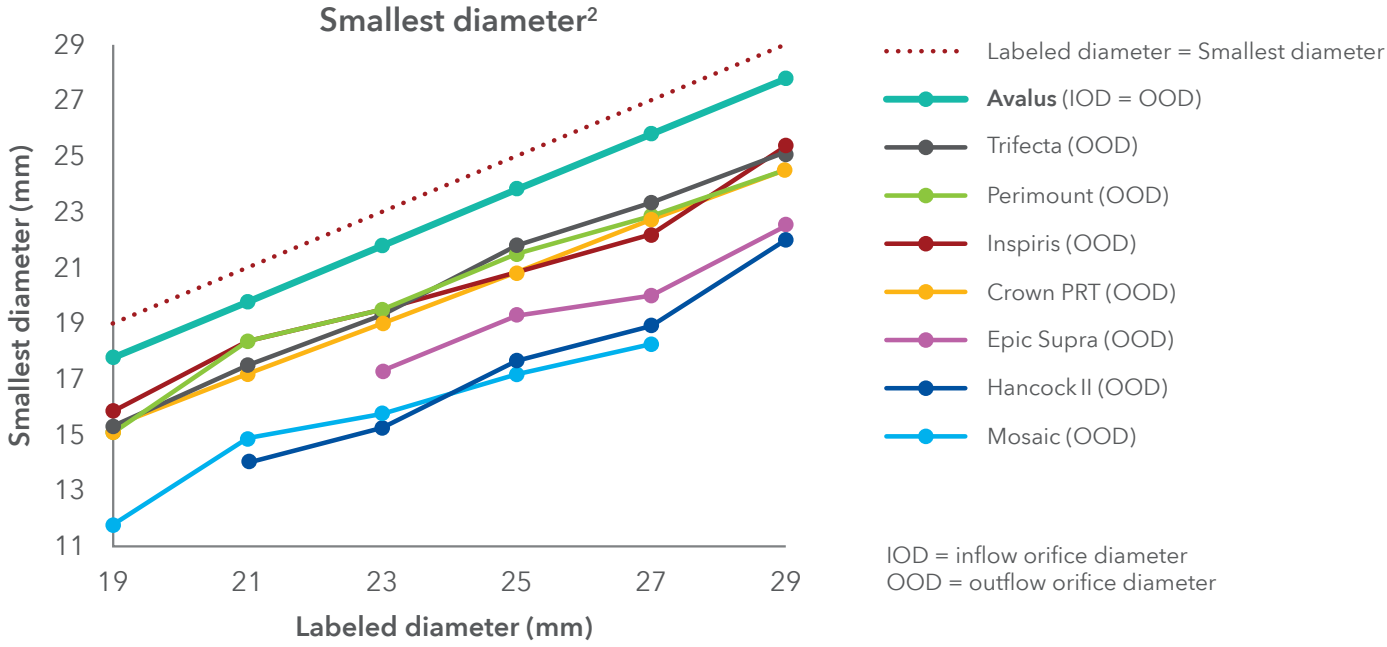
Why a valve designed for circularity can deliver excellent outcomes

The Avalus valve has consistently delivered precision-engineered performance that can drive positive patient outcomes.[1]

Groundbreaking academic research proves shape matters. In their latest publication, Dr. Astrid van Boxtel and Dr. Tjark Ebels reveal a critical insight: most surgical bioprosthetic valves exhibit a conical flow channel. **But not the Avalus platform.** The Avalus platform is engineered with a nearly identical inlet orifice diameter (IOD) and outlet orifice diameter (OOD), creating a cylindrical shape designed for laminar flow, durability, and to avoid turbulent flow, high pressure gradients, and valve deterioration.[2]

Overview of 27 mm supra-annular bioprosthetic aortic stented valves[2]





IOD = inflow orifice diameter
OOD = outflow orifice diameter

All valves measured included the mounted tissue to show the true labeled diameter.

What sets the Avalus valve apart?

Cylindrical flow channel:
The Avalus valve's IOD and OOD are nearly identical, creating a cylindrical shape that can potentially reduce turbulence and pressure gradients. Other valves? Conical shapes may lead to compromised flow dynamics.[†,2]

More accurate labeling:
Unlike other aortic tissue valves, the Avalus valve's labeled size more accurately matches its true inlet diameter, giving surgeons confidence in predictable and reliable performance.[2]

What does this mean?

The finding that valves have a smaller OOD than IOD suggests a narrowing as blood passes through the surgical valve.

The narrowing flow shape may potentially lead to turbulent flow and flow resistance, which could impact pressure gradients and valve durability.

The Avalus platform, with a cylindrical design for laminar flow, has demonstrated industry-leading effective orifice areas (EOAs), low stable gradients, and excellent durability.[1]

Engineered to **perform.** Proven by **data.**

Discover the Avalus platform advantage. Contact your local sales representative for more information.

The Avalus platform has a larger flow channel, up to 3.8 mm larger, than other contemporary valves. Larger IOD/OODs may lead to better flow and a larger landing zone for future TAV-in-SAV if needed.[2]

Labeled diameter (mm)	Edwards Inspiris	Edwards Perimount and Magna Ease	Medtronic Avalus valve
Inlet orifice diameter (mm)			
19	17.7	17.6	17.8
21	19.6	19.6	19.8
23	21.6	21.6	21.8
25	23.4	23.4	23.8
27	25.4	25.3	25.8
29	27.3	27.1	27.8
Outlet orifice diameter (mm)			
19	15.9	15.3	18.1
21	18.4	18.4	19.7
23	19.5	19.5	21.9
25	20.9	21.5	24.4
27	22.1	22.8	25.9
29	25.4	24.5	28.2

† This statement is based on calculations of flow channel geometry from IOD and OOD dimensions.

1. Sabik JF III, Rao V, Dagenais F, et al. Seven-year outcomes after surgical aortic valve replacement with a stented bovine pericardial bioprosthesis in over 1100 patients: a prospective multicentre analysis. *Eur J Cardiothorac Surg*. December 26, 2024;67(1):ezae414.

2. van Boxtel AGM, Ebels T. The Outlet Orifice Diameter of Surgical Bioprosthetic Aortic Stented Valves Is Predominantly Much Smaller Than the Inlet Orifice Diameter. *Interdiscip Cardiovasc Thorac Surg*. August 5, 2025;40(8):ivaf163.

Avalus™ Bioprosthesis

Important Labeling Information for the United States

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 these devices 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 (IFU). If applicable, consult electronic IFUs (eIFUs) at www.medtronic.com/manuals. Note: eIFUs can be viewed using a current version of any major internet browser.

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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, and valve thrombosis. These complications could lead to reoperation, explant of the bioprosthesis, permanent disability or organ damage, or death.

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US-CV-2500216 v1.0
10/2025