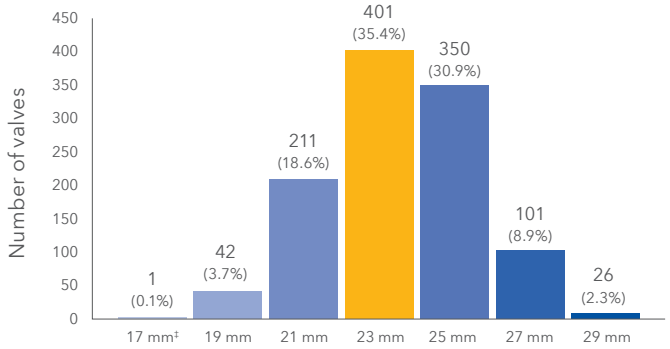
Medtronic

Avalus™ Bioprosthesis

PERIGON Pivotal Trial 7-year clinical update

The PERIGON Pivotal Trial[1] was designed to evaluate the safety and effectiveness of the Avalus stented bovine pericardial bioprosthesis in a patient population undergoing surgical aortic valve replacement. A total of 1,132 patients were implanted with the Avalus valve, with 268 from Canada, 475 from Europe, and 389 from the United States. The pivotal trial had a planned duration of 5 years, which was extended to 12 years to continue data collection. Nineteen sites agreed to participate in long-term follow-up, and 576 patients were re-consented. At 7 years, the survival rate was 83%, and the rate of freedom from structural valve deterioration (SVD) and severe hemodynamic dysfunction (SHD) requiring reintervention was 99%.†

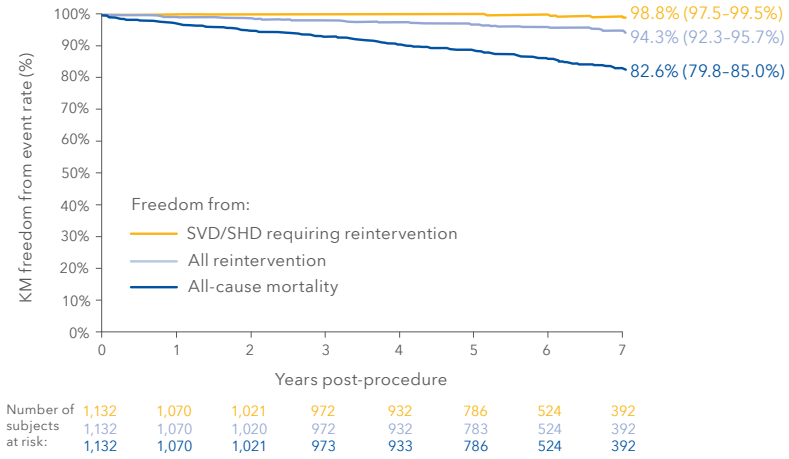
Valve size distribution



‡ The Avalus valve size 17 mm is approved for commercial use only in Japan.

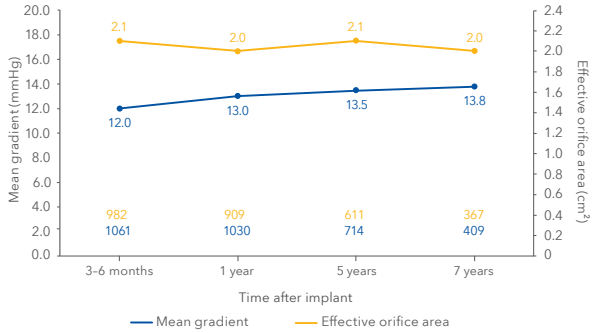
Kaplan-Meier survival analysis

Freedom-from-event rate for SVD/SHD requiring reintervention, all reintervention, and all-cause mortality



Echocardiographic findings

All valve sizes§



§ Data are not paired.

Baseline demographics

Patient characteristics	N = 1,132
Age, years	70.1 ± 8.9
Male sex	75.4%
BSA, m^2	2.0 ± 0.2
STS risk of mortality	2.0 ± 1.4%
NYHA class I/II	58.2%
NYHA class III/IV	41.8%
Atrial fibrillation	10.6%
Coronary artery disease	43.8%

Procedural data

Procedural characteristics	N = 1,132
Primary indication	
Aortic stenosis	84.3%
Aortic regurgitation	5.7%
Mixed AS/AR	9.5%
Failed prosthesis	0.5%
Surgical approach	
Median sternotomy	79.8%
Less invasive approach◊	20.2%
Concomitant CABG	32.2%

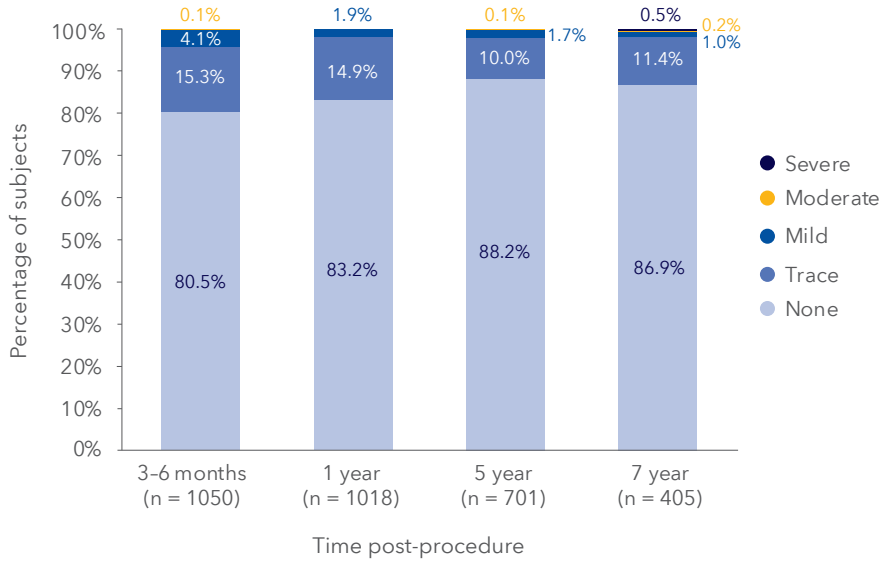
† SVD was defined as a confirmed intrinsic abnormality causing stenosis or regurgitation. SHD was defined as severe stenosis and/or severe transvalvular regurgitation and/or reintervention without adequate evidence to adjudicate SVD, nonstructural valve dysfunction, endocarditis, or valve thrombosis.
◊ Hemisternotomy or right thoracotomy. For 1.2% of patients, the surgical approach was classified as "other."

Echocardiographic findings, cont.

Transvalvular regurgitation

All valve sizes¶

Excellent and stable hemodynamics[1]



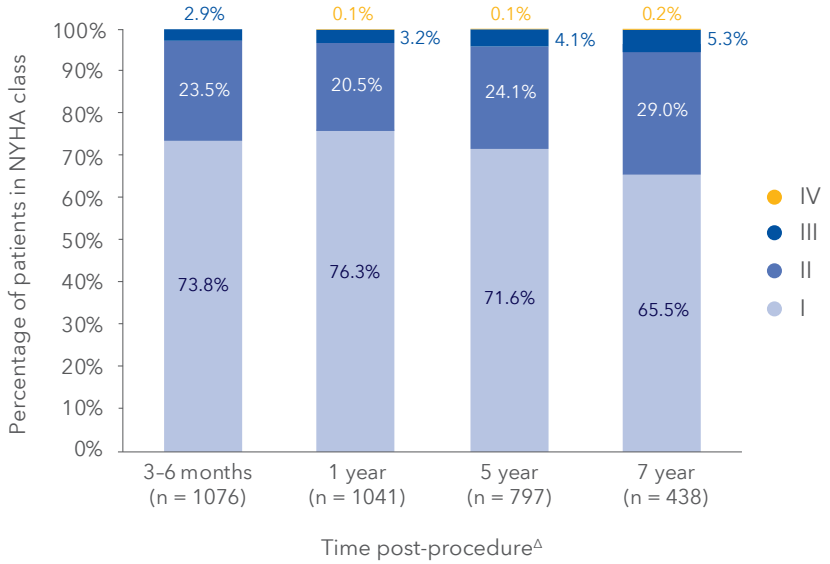
¶ Data are not paired.

NYHA classification by visit

NYHA classification

All valve sizes#

95% of subjects reported NYHA class I or II at 7 years[1]



Data are not paired.
Δ Baseline NYHA: class I, 11.1%; class II, 47.1%; class III, 39.8%; and class IV, 1.9%.

1. Sabik JF III, Rao V, Moront MG, et al. 7-Year follow-up of >1100 patients who received a contemporary pericardial aortic bioprosthesis. Presented at: 38th Annual Meeting of the European Association for Cardio-Thoracic Surgery; October 9-12, 2024; Lisbon, Portugal.

Avalus™ Bioprosthesis
Important Labeling Information for 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.

Important Labeling Information for 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 www.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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