Medtronic

ACE: **A**valus **C**linical confidenc**E**

Choose clarity.

See the difference.

The Avalus™ platform – validated by real-world data from the ACE registry.

Investigator initiated study, supported by Medtronic.

Prof. Meuris

Prof. Verbelen

In today's evolving healthcare landscape, real-world evidence is key to understanding how devices perform in everyday practice and supporting confident, patient-centered decisions.

The ACE registry – led by UZ Leuven under Prof. Bart Meuris and Prof. Tom Verbelen – collects prospective, multicenter data from over 25 leading western European centers, providing robust insights into the Avalus valve's performance and safety across diverse patient populations.

This real-world evidence confirms the excellent results seen in the PERIGON clinical trial[1] and helps ensure every decision is guided by what truly matters: patient outcomes.

Study objective[2]

The multicenter, prospective **A**valus **C**linical confidenc**E** (ACE) registry evaluating the Avalus aortic pericardial tissue valve has successfully reached its target enrollment of 1,250 patients.

The dynamic evolution of cardiac surgery

- Increase in complex surgical procedures including concomitant cases[3]
- Debate between when TAVI or SAVR is the better approach
- Need for an evaluation of the clinical and hemodynamic performance of surgical aortic valves

Methods[2]

Prospective, single-arm registry. All-comers population providing real-world data: only exclusions are less than 18 years of age and salvage surgery. Enrollment 2021–2024.

27 sites across Europe in 10 countries: Belgium, Denmark, Finland, France, Germany, Italy, Israel, Portugal, Spain, and the Netherlands

Endpoints: mortality, stroke, bleeding complications, pacemaker need, ICU/hospital stay, prosthetic valve function, reintervention

- Data at discharge (complete) and one-year follow-up (ongoing)
- Extended follow-up is planned

Patient-prosthesis mismatch (PPM) was classified according to VARC-3 criteria, including adjustments for obesity (BMI ≥ 30 kg/m²).[4]

PPM	None	Moderate	Severe
BMI < 30	> 0.85 cm^2/m^2	0.85–0.66 cm^2/m^2	≤ 0.65 cm^2/m^2
BMI ≥ 30	> 0.70 cm^2/m^2	0.70–0.56 cm^2/m^2	≤ 0.55 cm^2/m^2

Patient cohort[2]

Baseline characteristics (N = 1,250)

	Mean ± SD or n(%)
Age	71.6 ± 6.5
Age range	42–92 years
< 65 years	149 (11.9%)
Female	278 (22.2%)
Male	972 (77.8%)
EuroSCORE II (ES II)	3.5 ± 5.7
ES II range	0.5–77.4
Single AVR	1.9 ± 2.3
Combined	4.4 ± 6.7
Renal impairment	
Moderate	542 (43.4%)
Severe	116 (9.3%)
Insulin-dependent diabetes	79 (6.3%)
Previous cardiac surgery	70 (5.6%)
Chronic pulmonary disease	87 (7%)

Procedural characteristics (N = 1,250)

	Mean ± SD or n(%)
Pulmonary hypertension	
Moderate	242 (19.4%)
Severe	31 (2.5%)
NYHA class	
I or II	889 (71.1%)
III or IV	361 (28.9%)
Urgency	
Urgent	155 (12.4%)
Emergent	12 (1%)
Bicuspid valve	324 (25.9%)
Single AVR	497 (39.8%)
Concomitant procedures	
CABG	325 (26%)
Mitral valve	112 (9%)
Tricuspid repair	48 (3.8%)
Ascending aorta	208 (16.6%)
Ablation treatment	80 (6.4%)
Root enlargement	7 (< 1%)

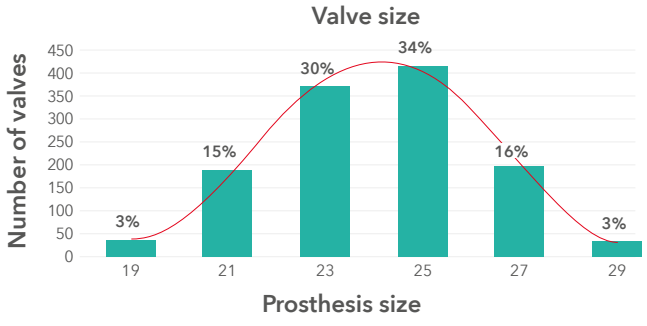
Results – Clinical outcomes[2]

Early safety outcomes (≤ 30 days) N = 1,250

	Mean ± SD or n(%)	Baseline EuroSCORE II
30-day mortality	24 (1.9%)	3.5
Single AVR	3 (0.4%)	1.9
Combined cases	21 (2.8%)	4.4
Neurological deficit		
Stroke	19 (1.5%)	
TIA	10 (0.8%)	
Stay (days)		
ICU stay	3.1 ± 5.9	
Hospital stay	10.8 ± 9.4	
Bleeding	111 (8.9%)	
Surgical revision	71 (5.7%)	
Acute kidney injury		
Stage 1	97 (7.8%)	
Stage 2 or 3	60 (4.8%)	
AKIN		
Dialysis need	26 (2.1%)	
Pacemaker implant	52 (4.2%)	

Status at one-year follow-up (ongoing) N = 671

	n(%)
Mortality	21 (3.1%)
Need for reoperation	
Endocarditis	8 (1.2%)
Valve degeneration	0
Thrombosis	0



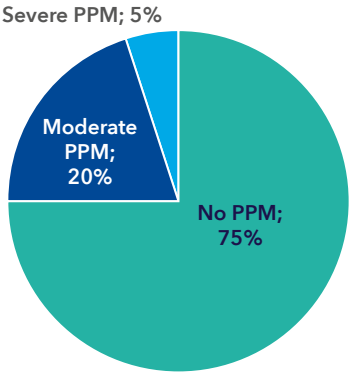
Results – Hemodynamic performance[2]

- Low stable mean gradients at discharge and follow-up
- Very low rates of severe and moderate mismatch
- Industry-leading effective orifice area (EOA)

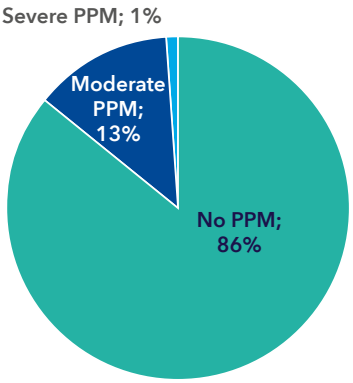
Hemodynamic outcome	Mean ± SD or n(%)		
	Baseline (N = 1,250)	Discharge (N = 1,226)	One year (N = 671)
MPG [mmHg]	41.3 ± 20	11.6 ± 5.2	12.2 ± 5.0
PPG [mmHg]	62.7 ± 30.1	20.7 ± 8.7	20.6 ± 8.6
EOA [cm²]	0.96 ± 0.6	2.0 ± 0.6	1.8 ± 0.5
EOAi [cm²/m²]	0.50 ± 0.3	1.0 ± 0.3	0.9 ± 0.3
PVL moderate-severe [n, %]	–	3 (0.2)	0

MPG: mean pressure gradient PPG: peak pressure gradient EOA: effective orifice area
EOAi: indexed effective orifice area PVL: paravalvular leak

BMI < 30



BMI ≥ 30



	No PPM	Moderate PPM	Severe PPM
BMI < 30 (n = 928)	75%	20%	5%
BMI ≥ 30 (n = 298)	86%	13%	1%

Conclusion[2]

- **Design:** Multicenter, prospective registry capturing real-world data. Target enrollment of 1,250 patients has been achieved.
- **Clinical outcomes:** Demonstrated low rates of mortality and stroke across a diverse patient population, including those undergoing combined, complex, and urgent procedures. Observed mortality was nearly 50% lower than predicted by EuroSCORE II.
- **Hemodynamic performance:** The Avalus valve exhibited excellent hemodynamic outcomes, with a notably low incidence of patient-prosthesis mismatch, attributed to its large internal orifice diameter.
- **Ongoing evaluation:** The ACE group will continue to monitor long-term outcomes and valve performance. Real-world data from this registry complements findings from the PERIGON Clinical trial.[1]

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 multicenter analysis. *Eur J Cardiothorac Surg*. December 26, 2024;67(1):ezae414.

2. Meuris B, Verbelen T, et al. The growing value of multicenter, prospective, real-world data: Early outcomes of 1250 patients with the Avalus valve. Presented at: EACTS 2025; October 8–11, 2025; Copenhagen, Denmark.

3. Pettersson GB, Martino D, Blackstone EH, et al. Advising complex patients who require complex heart operations. *J Thorac Cardiovasc Surg*. May 2013;145(5):1159–1169.e3.

4. Dismorr M, Glaser N, Franco-Cereceda A, Sartipy U. Effect of Prosthesis-Patient Mismatch on Long-Term Clinical Outcomes After Bioprosthetic Aortic Valve Replacement. *J Am Coll Cardiol*. March 14, 2023;81(10):964–975.

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.

Avalus Ultra™ Bioprosthesis

Important Labeling Information for the United States

Indications: The Avalus Ultra 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. 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.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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