AVALUS™ BIOPROSTHESIS **PROVEN STRONG HEMODYNAMICS**

Innovations in the treatment of Aortic Stenosis have accelerated fast, advanced by cutting-edge technologies. With 40+ years of industry experience, constant innovation and investment in heart valve research and development, Medtronic is here to support you in choosing the right valve for the right patient. As proven by the high quality clinical data, the design advancements incorporated into Avalus™ Bioprosthesis lead to efficient and stable hemodynamics:

CLINICAL EVIDENCE

4-5 YEARS STABLE LOW MEAN GRADIENTS, COMPARABLE TO OR LOWER THAN OTHER VALVES[1]

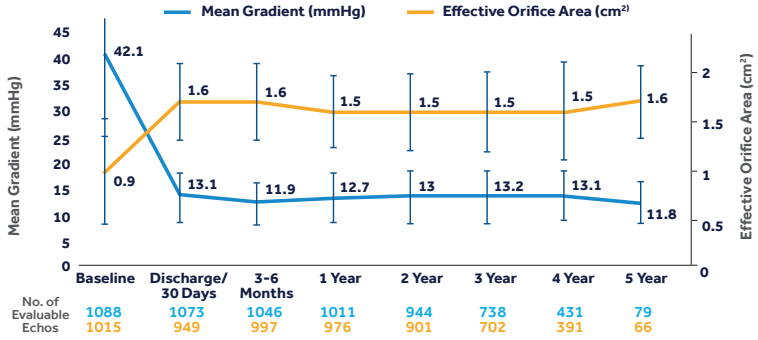
> 95% OF PATIENTS OVER 4-5 YEARS WITH LESS THAN MILD CENTRAL REGURGITATION[1]

2-3 TIMES LESS CASES OF TRANSVALVULAR REGURGITATION COMPARED TO OTHER VALVES[2]

>92% OF PATIENTS IN NYHA CLASS I AND II OVER 4-5 YEARS FOLLOW-UP[1]

MEAN PRESSURE GRADIENTS AND EFFECTIVE ORIFICE AREA

The PERIGON Pivotal trial **confirmed substantial improvements** of peak and mean aortic pressure gradients and mean EOA after implantation of the Avalus™, and these improvements were maintained over time[1].



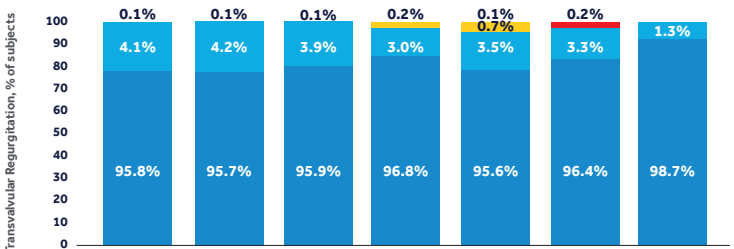
TRANSVALVULAR REGURGITATION

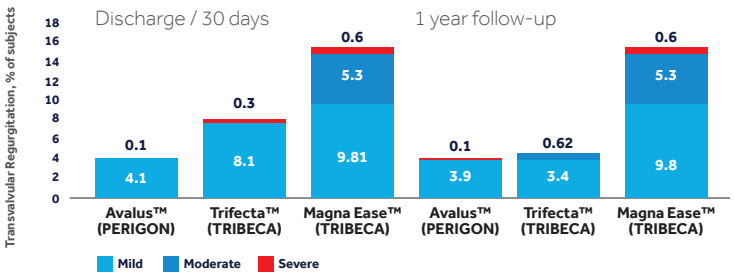
The PERIGON Pivotal trial demonstrated **no trace or extremely low cases of severe transvalvular regurgitation** after Avalus™ implantation[1].

At discharge/30 days, transvalvular regurgitation was classified as none/trace in 95.8% of patients, mild in 4.1% of patients, moderate in 0.1% of patients, and severe in 0.0% of patients[1].

At 1 year, transvalvular regurgitation was classified as none/trace in 95.9% of patients, mild in 3.9 % of patients, moderate in 0.1% of patients, and severe in 0.1% of patients[1].

When compared with other stented aortic valves, evaluated in the TRIBECA study[2], **Avalus™ compares favourably to other valves.**





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AVALUS™ BIOPROSTHESIS **PROVEN STRONG HEMODYNAMICS**

The Next Generation stented pericardial aortic valve, developed by Medtronic. With Avalus™ your patients will benefit from efficient and stable hemodynamics, proven by high-quality clinical evidence[1].

HEMODYNAMIC DESIGN BENEFITS

Flexible support frame made from Polyetheretherketone

For strength, flexibility and resistance to permanent deformation and contribute to maximum coaptation.

Firm base of the stent post made from Polyetheretherketone

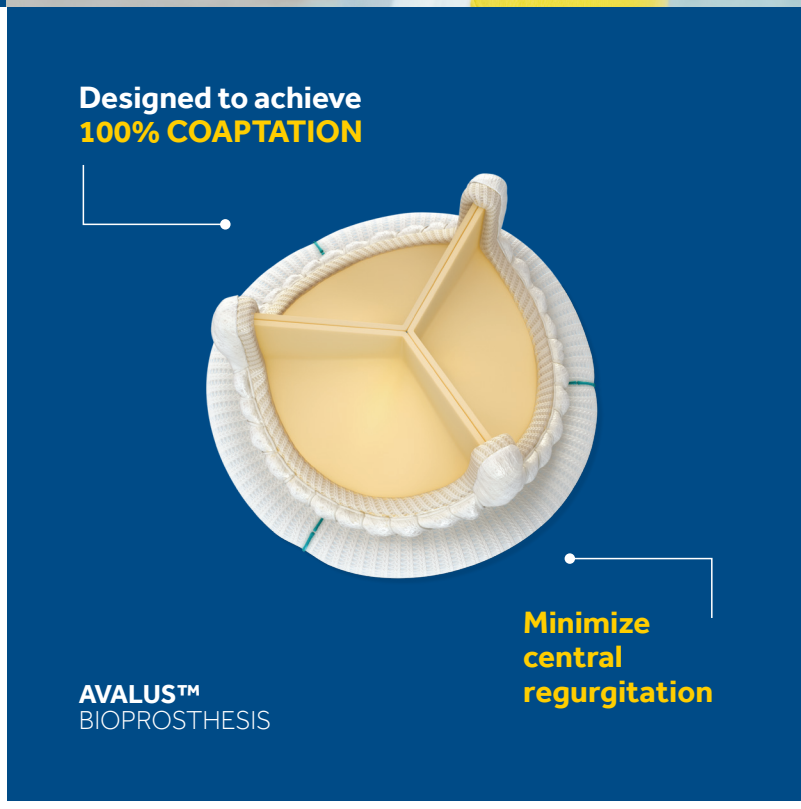
To maintain circularity for consistent hemodynamic performance during and after implantation.

Stent post deflection optimized for each valve size

To assure efficient central closing and maximize central coaptation.

Three laser cut leaflets matched for tissue thickness and deflection

To optimize uniformity of final assembled valves.



REFERENCES

1 The latest results of the Perigon Study, presented by Prof. RJ. Klautz at EACTS 2020. The PERIGON Pivotal Trial regarding the Avalus valve is a prospective, interventional, non-randomized, worldwide, multi-site trial, with each center following a common protocol. The study was designed in accordance with the recommendations of the EN ISO 5840:2009 standard for cardiac valve prostheses and the U.S. Food and Drug Administration (FDA) Heart Valve Guidance (2010; DRAFT) and conducted in accordance with the Declaration of Helsinki and good clinical practice guidelines. Valve-related events and deaths were adjudicated by an independent clinical events committee (CEC). All study echocardiograms were analyzed by an independent core laboratory (MedStar Health Research Institute, Washington, D.C.). Safety oversight was provided by an independent data and safety monitoring board (DSMB). This trial is registered at www.clinicaltrials.gov, NCT02088554

2 The Avalus™ TVR data from the PERIGON study, compared to the TVR results of Magna Ease™ and Trifecta™ valves as presented in Colli A, Marchetto G,Salizzoni S, Rinaldi M, Di MarcoL, Pacini Det al. The TRIBECAstudy: (TRI)fecta (B)ioprosthesis (E)valuation versus (C)arpentier Magna-Easein (A)ortic position. Eur JCardiothorac Surg 2016;49:478–85

Medtronic

Europe
Medtronic International Trading Sarl.
Route du Molliau 31
Case postale
CH-1131 Tolochenaz

Tel: +41 (0)21 802 70 00
Fax: +41 (0)21 802 79 00

medtronic.eu