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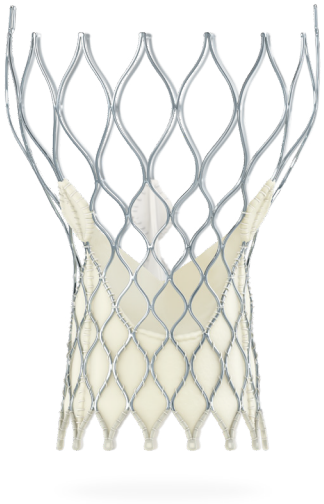
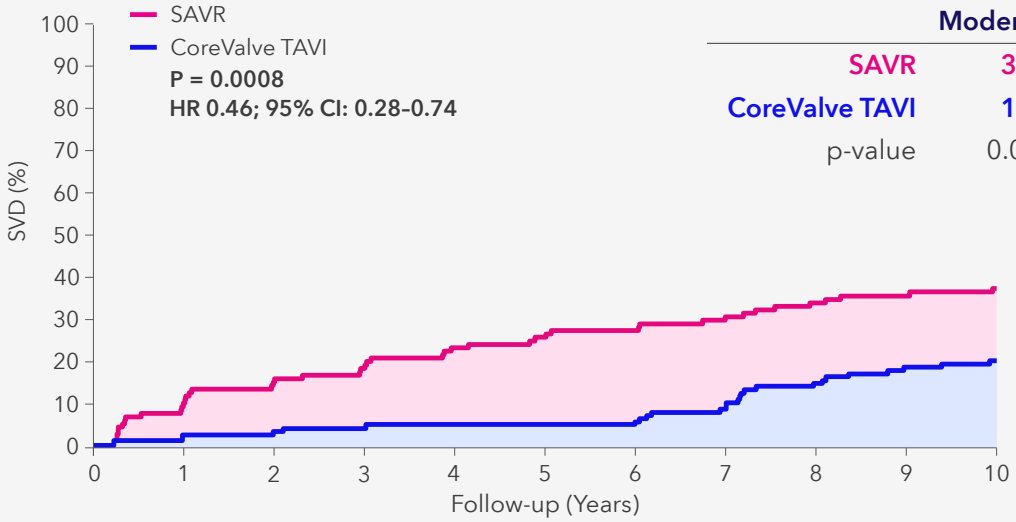
A decade of durability.

CoreValve™ TAVI platform demonstrates statistically better durability versus surgery at 10 years[†1] in lower surgical risk patients.

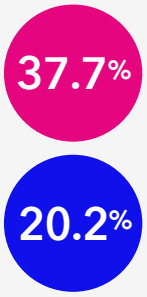


Statistically lower rates of moderate or greater structural valve deterioration (SVD) out to 10-years versus surgery.[‡]

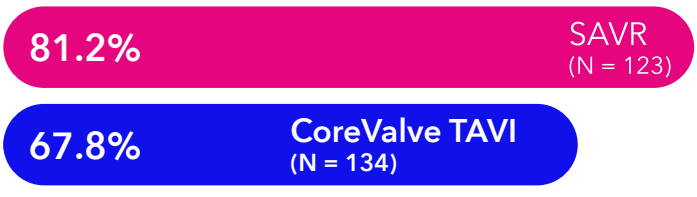
SVD out to 10 years



	Moderate SVD	Severe SVD
SAVR	36.0	11.0
CoreValve TAVI	19.4	3.1
p-value	0.0008	0.014



Statistically lower bioprosthetic valve dysfunction (BVD) vs. surgery at 10-years.[‡]



P = 0.007

TAVI risks may include, but are not limited to, death, stroke, damage to the arteries, bleeding, and need for permanent pacemaker.

[†]In patients at lower surgical risk over the age of 70. Devices used: CoreValve 100%.
[‡]Bioprosthetic Valve Dysfunction (BVD)[2] was defined as: moderate or severe hemodynamic SVD (Mean gradient ≥ 20 mm Hg or Mean gradient ≥ 10 mm Hg change from 3 months post-procedure or moderate/severe intra-prosthetic aortic regurgitation (AR) (new or worsening from discharge), NSVD (moderate to severe patient-prosthesis mismatch or more than mild paravalvular leak), clinical valve thrombosis, and endocarditis.

Patient demographics[3]

Characteristic % (n) or mean ± SD	CoreValve TAVI N = 145	SAVR N = 135	p-value
Age (yrs)	79.2 ± 4.9	79.0 ± 4.7	>0.05
Male	53.8% (78)	52.6% (71)	>0.05
Society of Thoracic Surgeons score (STS)	2.9 ± 1.6	3.1 ± 1.7	>0.05

References

[1] Jørgensen T. The NOTION trial Ten-year follow-up after transcatheter or surgical aortic valve implantation in severe aortic valve stenosis. Presented at ESC Congress, Amsterdam; August 2023.

[2] Capodanno D, Petronio AS, Prendergast B, et al. Standardized definitions of structural deterioration and valve failure in assessing long-term durability of transcatheter and surgical aortic bioprosthetic valves: a consensus statement from the European Association of Percutaneous Cardiovascular Interventions (EAPCI) endorsed by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J.* December 1, 2017;38(45):3382-3390.

[3] Jorgensen TH, Thyregod HGH, Ihlemann N, et al. Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement. *Eur Heart J.* August 7, 2021;42(30):2912-2919.

Brief Statement

See the CoreValve™ Evolut™ R, the CoreValve™ Evolut™ PRO and the Evolut™ PRO+ device manuals 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 medtronic.eu.

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.

The commercial name of the Evolut™ R device is Medtronic CoreValve™ Evolut™ R System, the commercial name of the Evolut™ PRO device is Medtronic CoreValve™ Evolut™ PRO System, and the commercial name of the Evolut™ PRO+ device is Medtronic Evolut™ PRO+ System.

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This material is for Healthcare Professionals in countries with applicable health authority product registrations.

Important: Always refer to the Instructions For Use (IFU) packaged with the product/e-IFU for complete instructions, indications, contraindications, warnings, and precautions.

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