

REFERENCES

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² Abdel-Wahab M, et al. Five-year outcomes after TAVI with balloon-expandable vs. self-expanding valves: Results from the CHOICE randomised clinical trial. Presented at EuroPCR 2019; Paris, France.

³ Deutsch MA, Erlebach M, Burri M, et al. Beyond the five-year horizon: long-term outcome of high-risk and inoperable patients undergoing TAVR with first-generation devices. *EuroIntervention*. May 20, 2018;14(1):41-49.

⁴ Søndergaard L. Long-term follow-up of transcatheter and surgical bioprosthetic aortic valves in patients with severe aortic stenosis and lower surgical risk. Presented at PCR Valves e-Course; November 24, 2020.

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⁶ Gerckens U, Tamburino C, Bleiziffer S, et al. Final 5-year clinical and echocardiographic results for treatment of severe aortic stenosis with a self-expanding bioprosthesis from the ADVANCE Study. *Eur Heart J*. September 21, 2017;38(36):2729-2738.

BRIEF STATEMENT: Refer to Instructions for Use for a complete list of warnings, precautions, indications, and contraindications or speak to your Medtronic representative.

ENGINEERED FOR TODAY AND TOMORROW

Medtronic TAVI Platform



Medtronic

Medtronic Australasia Pty Ltd
2 Alma Road
Macquarie Park, NSW 2113
Australia
Tel: +61 2 9857 9000
Fax: +61 2 9889 5167
Toll Free 1800 668 670

Medtronic New Zealand Ltd
Level 3 - Building 5, Central Park
Corporate Centre
666 Great South Road
Penrose, Auckland 1051
Fax: +64 9 918 3742
Toll Free: 0800 377 807

medtronic.com.au
medtronic.co.nz

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TAVI DURABILITY DATA

BUILT ON A FOUNDATION OF RESULTS⁶

With its supra-annular, self-expanding valve frame, Evolut™ TAVI is built on the original CoreValve platform which has consistently sustained⁶ large EOAs and low mean gradients over time — all of which lead to low rates of SVD.

Durability is of increasing concern as low risk patients are treated who may have decades of life left. These patients need a valve that will not only accommodate their activity levels, but will also remain hemodynamically stable for years to come.

HOW IS SVD DEFINED?

- As the treatment modalities for aortic stenosis have changed, so too have the definitions of failure.
- Whereas with surgical valves the structural failure was confirmed on explant during the redo surgery, TAVI relies on echographic interrogation of the valve to determine whether the haemodynamics remain stable, signaling the valve's durability.

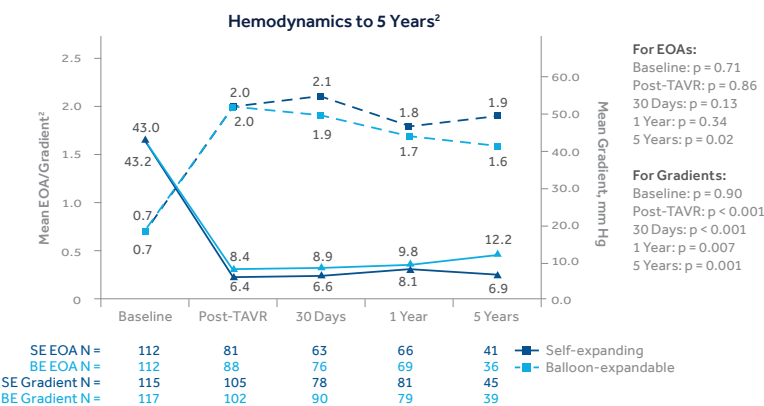
Structural valve deterioration (SVD)¹

- Moderate or greater haemodynamic SVD
- Mean gradient ≥ 20 mm Hg or
- Mean gradient ≥ 10 mm Hg change from baseline or
- Moderate/severe intra-prosthetic aortic regurgitation (AR) (new or worsening from baseline)

CLINICAL TRIALS

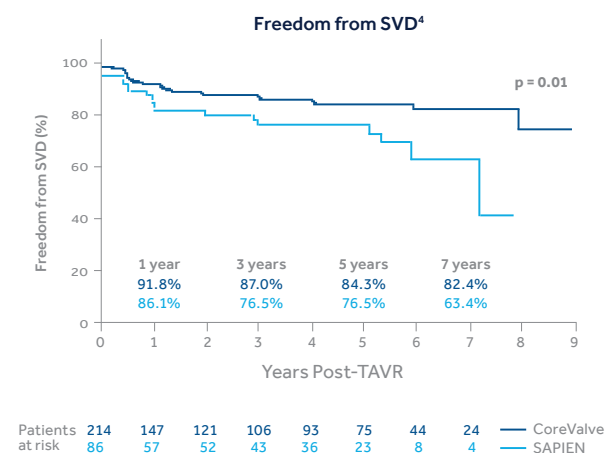
CHOICE² 5 YEARS

- In this prospective, randomised study, CoreValve™ TAV remained haemodynamically stable at **5 years** whereas the SAPIEN™* TAV had a 20% decline in EOA and a 30% increase in gradient.
- CoreValve also had a statistically significant advantage in terms of reduced SVD over SAPIEN (0.0% vs. 6.6%; $p = 0.018$).



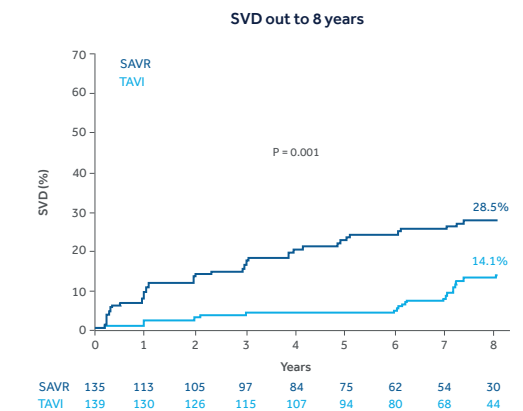
DEUTSCH³ 7 YEARS

- Retrospective analysis from a single-centre registry
- This chart demonstrates significantly less SVD for CoreValve than SAPIEN out to **7 years**. Relief from SVD: 82.4% for CoreValve; 63.4% for SAPIEN.
- When looking at SVD, at every timepoint (**1, 3, 5, and 7 years**), there was numerically less SVD with CoreValve than with SAPIEN.



NOTION⁴ 8 YEARS

- The NOTION trial is a multi-centre, randomised, head-to-head comparison of CoreValve TAVI versus SAVR followed out to **8 years** in lower surgical risk patients ≥ 70 years of age that are eligible for surgery. TAVI had significantly less haemodynamic SVD out to **8 years**.
- The NOTION 8-year data shows SVD rates in a lower surgical risk patient population. The data provides a signal of durability for the CoreValve platform versus SAVR.



ITALIAN REGISTRY⁵ 8 YEARS

- Multicentre registry
- Together with NOTION, this is the longest-term data on the self-expanding, supra-annular CoreValve platform. Data demonstrates very low rates of moderate and severe haemodynamic SVD. The cumulative incidence of moderate and severe SVD at **8 years** are 3.0% and 1.6%, respectively.
- Additionally, the bioprosthetic valve failure (BVF) was also very low at 7.3% (includes any valve intervention, severe SVD, and any valve-related deaths), signaling durability for the CoreValve platform. The mean gradients remained low through **8 years**.

