

SAPIEN 3 Ultra RESILIA valve

Excellent 1-year clinical
outcomes



The SAPIEN 3 Ultra RESILIA valve delivers excellent 1-year outcomes in a real world study¹

Low rates of paravalvular leak (PVL)

Outstanding outcomes

Excellent hemodynamics

Outstanding outcomes observed across all SAPIEN 3 Ultra RESILIA valve sizes in Transcatheter Valve Therapy (TVT) registry data.

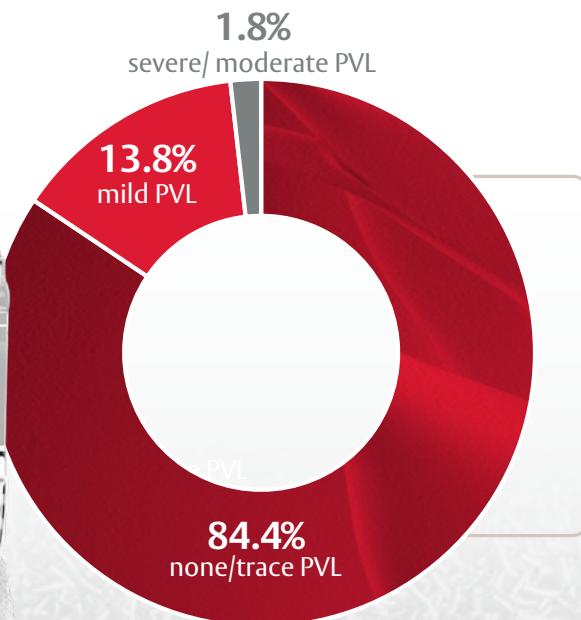
781 sites



4,500+
matched pairs
of patients

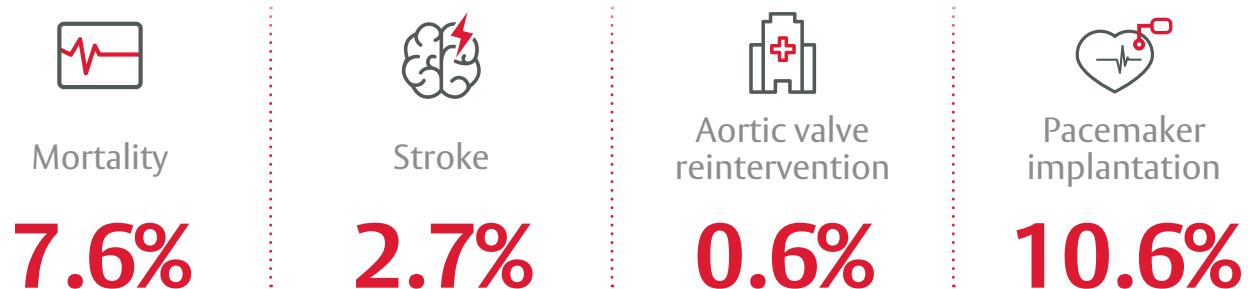
Enhanced sealing skirt provides low rates of PVL

SAPIEN 3 Ultra RESILIA valve at 1 year

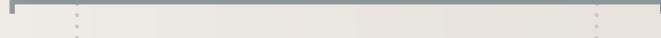


98.2%
none/trace or mild PVL

Extremely low rates at 1-year:



Sustained quality of life improvements*



1 day

Median length of stay

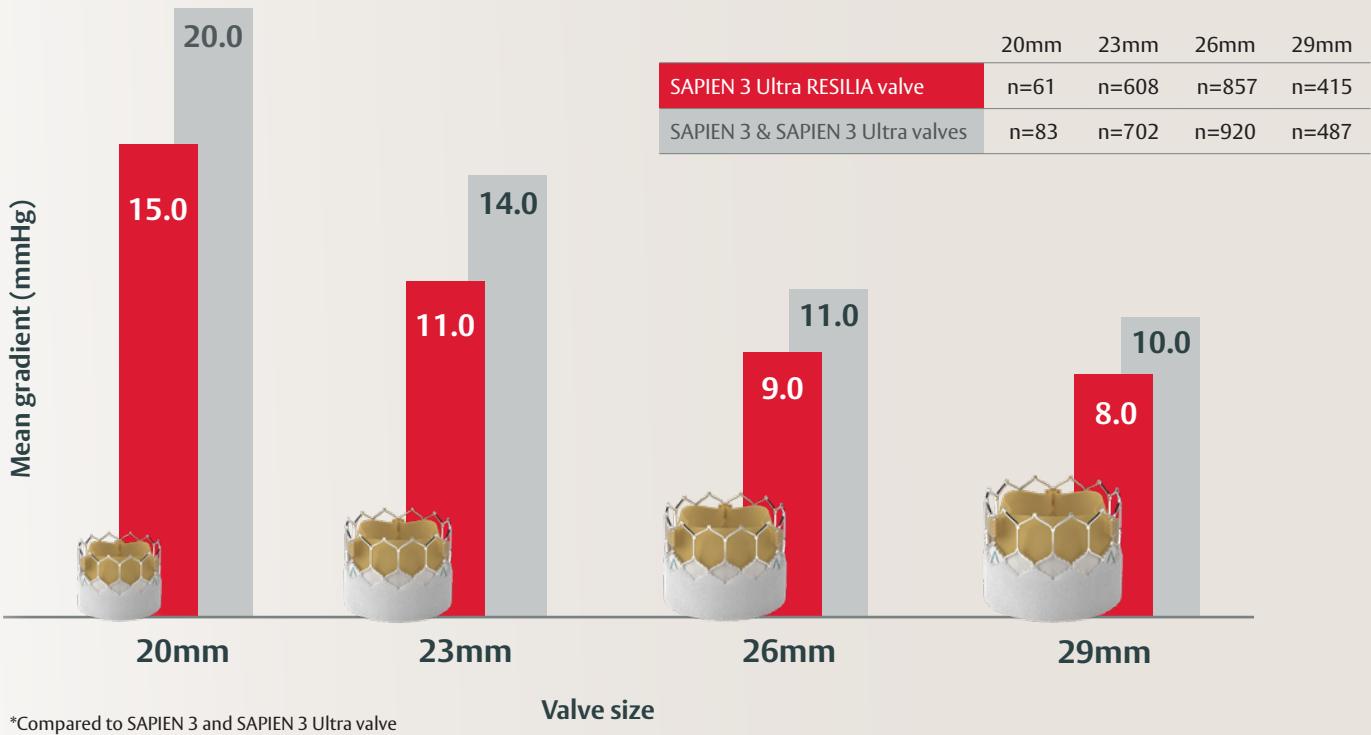


93.3%

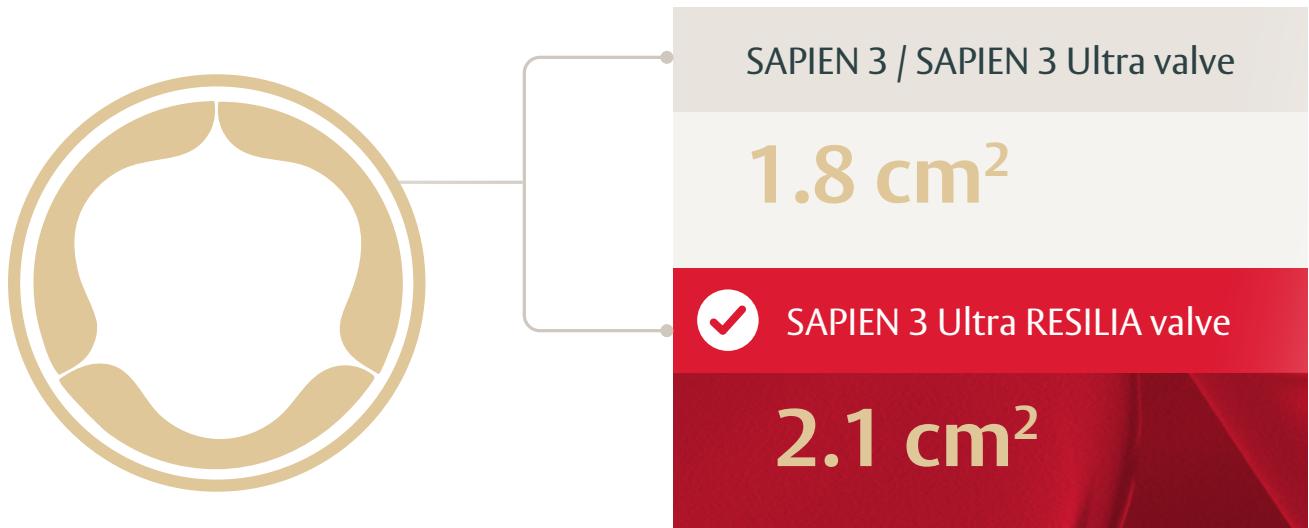
Discharged directly home

Excellent hemodynamics

Significantly lower echo-measured gradients sustained at 1 year*†



Larger EOA measurements across all valve sizes*



*Compared to SAPIEN 3 and SAPIEN 3 Ultra valves. Data collected at discharge. P Value <0.0001

The only transcatheter valve featuring RESILIA anti-calcification tissue technology²



Potential to improve valve longevity and reduce risk of reintervention²

A significant reduction in calcium accumulation compared to other tissue technologies*†

The only approved THV with dry tissue storage

Same tissue technology as the #1 implanted surgical valve in the world*

* RESILIA tissue tested against tissue from commercially available bovine pericardial valves from Edwards Lifesciences in a juvenile sheep model. Flameng, et al. J Thorac Cardiovasc Surg. 2015;149:340-345.

† No clinical data are available to evaluate the long-term impact of RESILIA tissue in patients. Additional clinical data for up to 10 years of follow-up are being collected to monitor the long-term safety and performance of RESILIA tissue.

Every indicated patient benefits from comprehensive lifetime management

SAPIEN 3 Ultra RESILIA valve: the leading solution for lifetime management

Life

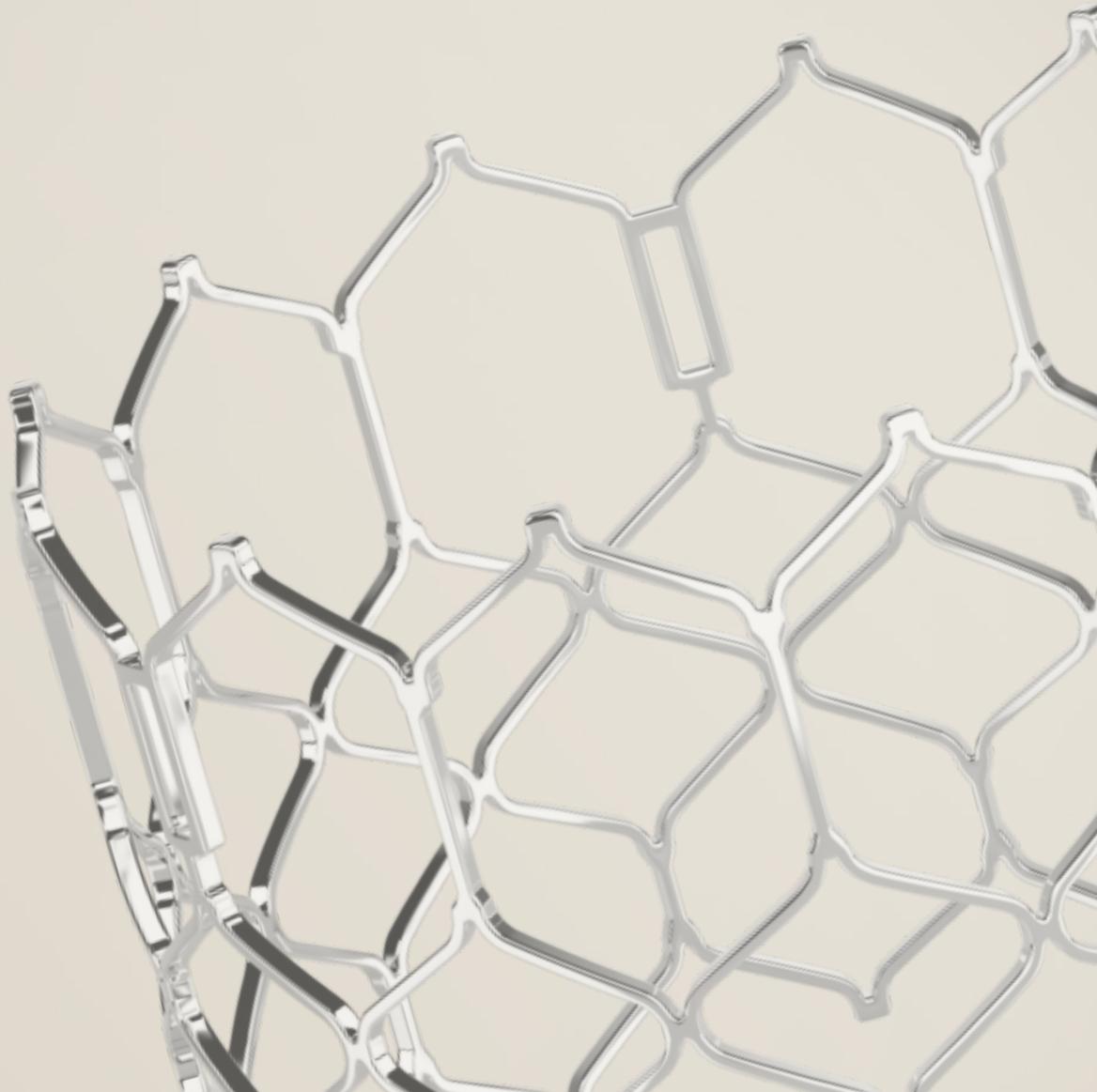
The lowest rate of death and disabling stroke in any pivotal TAVR trial³

Time

The highest rate of TAVR survival in any pivotal trial⁴

Management

Optimally designed to keep future options possible

**References:**

1. Kini A, et al. 1-year real-world outcomes of TAVR with fifth-generation balloon-expandable valve in the United States. *JACC Cardiovasc Interv.* 2024; S1936-8798(24)01711-4
2. Flameng W, et al. A randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. *J Thorac Cardiovasc Surg.* 2015;149:340-5.
3. Mack M.J., et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *New Eng Journal of Med.* 2019;380:1695-705.
4. Mack M.J., et al. Transcatheter aortic-valve replacement in low-risk patients at five years. *New Eng Journal of Med.* 2023;389:1949-60.

No clinical data is available to evaluate the long-term clinical impact or RESILIA technology in patients. Additional data for up to 10 years of follow-up is being collected to monitor the long-term safety and performance of the RESILIA tissue technology.

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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