

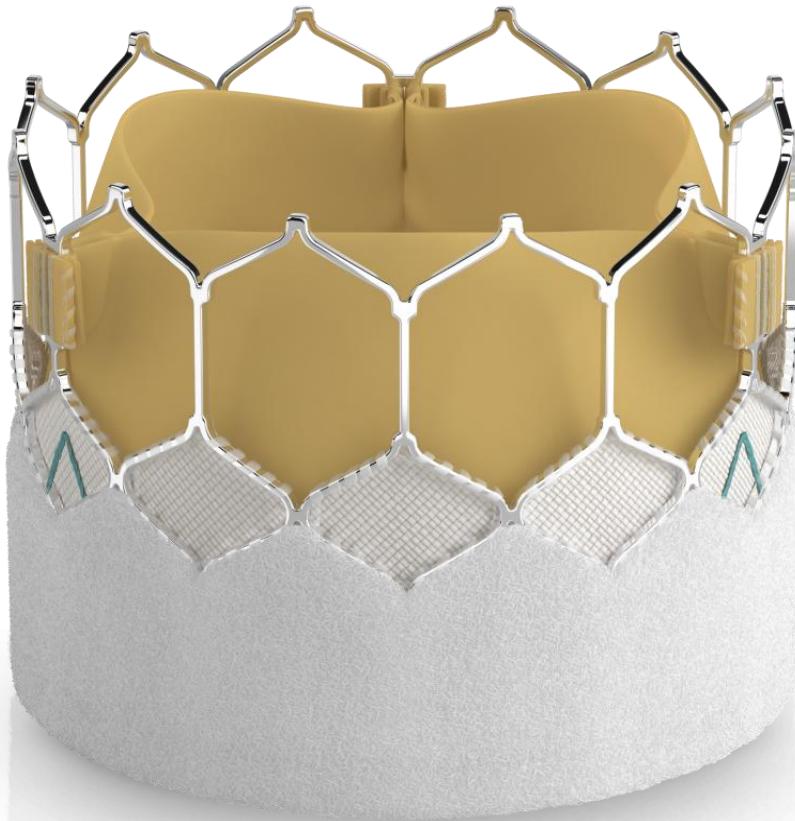
Introducing

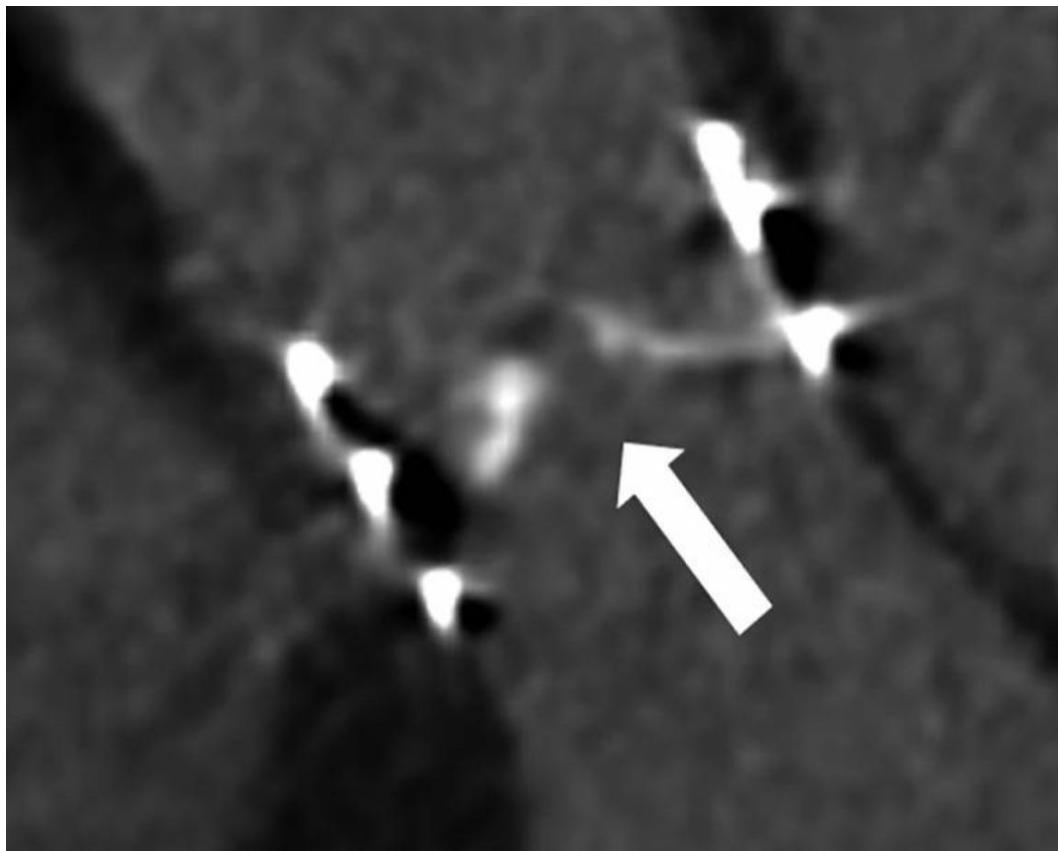
SAPIEN 3 Ultra RESILIA system

The Ultimate Lifetime Management Strategy

R E S I L I A

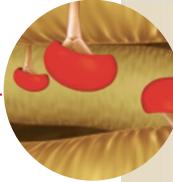
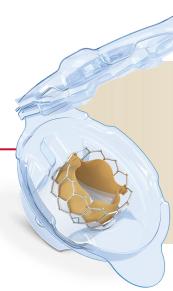
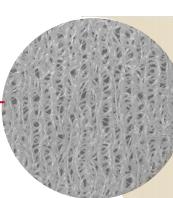


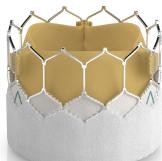




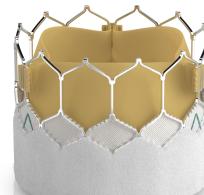
SAPIEN 3 Ultra RESILIA valve



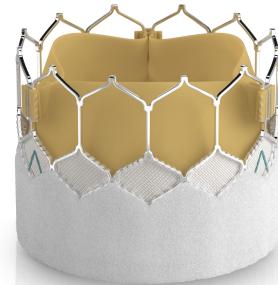
-  **Advanced calcium-blocking tissue technology**
-  **Dry tissue storage**
-  **Taller, textured outer skirt extended to 29mm valve**



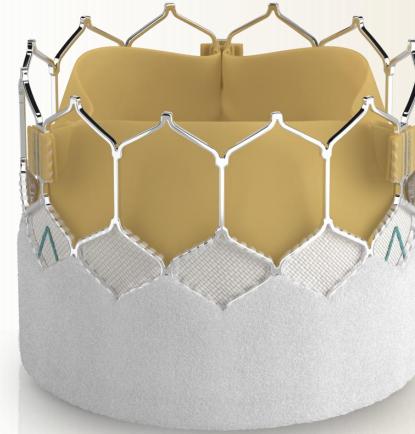
20 mm



23 mm



26 mm



Taller, textured skirt technology to reduce PVL now available on 29 mm valve for large annuli patients.

Life



Time

Management

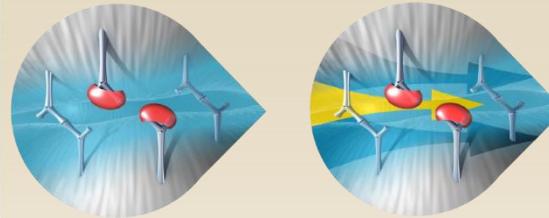
RESILIA tissue

Glutaraldehyde stabilization



Free Aldehydes

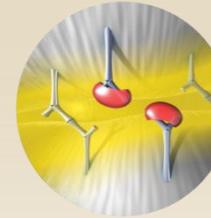
Advanced calcium-blocking technology



Stable-Capping
Permanently
blocks free
aldehydes

Glycerolization
Glycerol displaces
water in the tissue
and preserves
tissue integrity,
which enables dry
storage

RESILIA tissue



Glycerolized
Tissue



Stable Storage
Long-term viability

Life

Time

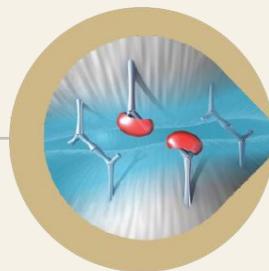
Management

Edwards RESILIA



SAPIEN 3 Ultra valve

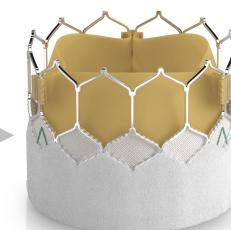
Advanced calcium-blocking tissue technology



Stable capping
permanently blocks
calcium binding sites
within tissue



Dry tissue storage
Glycerolization replaces
calcium-attracting
glutaraldehydes



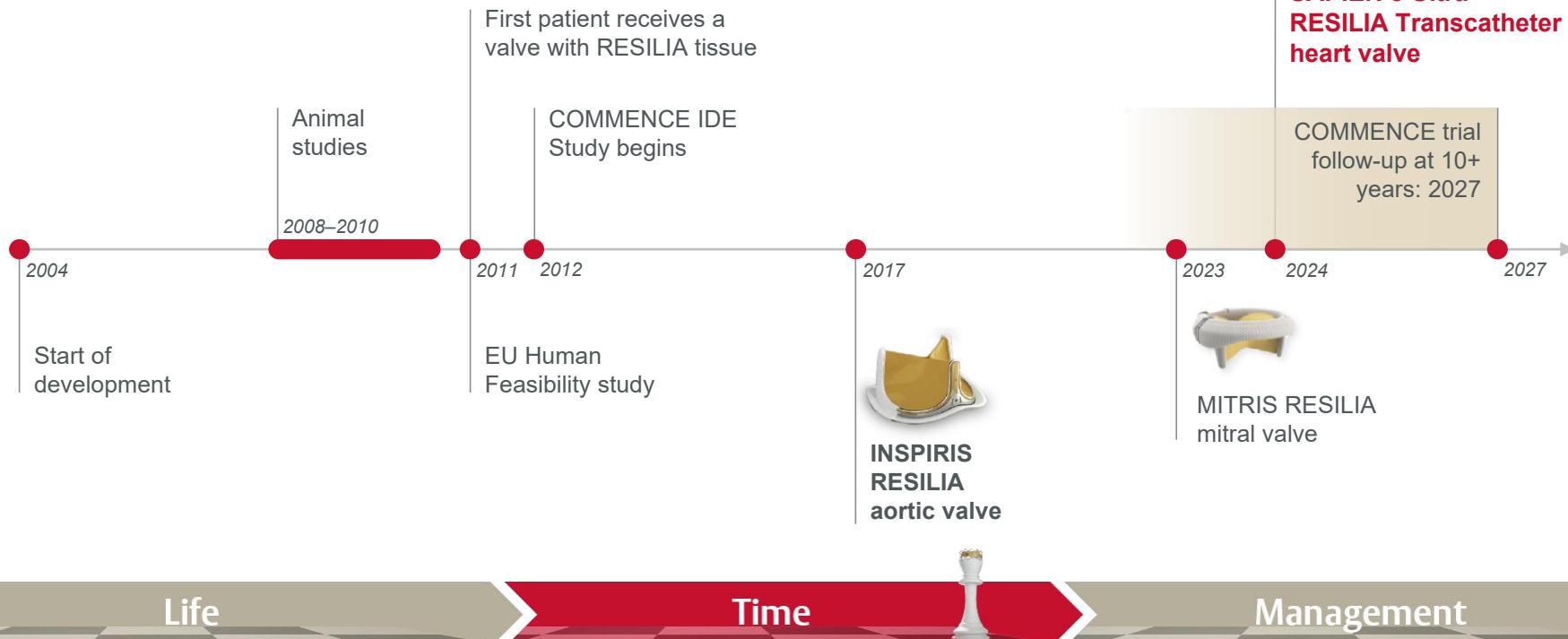
SAPIEN 3 Ultra RESILIA valve

Life

Time

Management

RESILIA tissue is the product of nearly 20 years of research and development



Improving valve technology



2017

INSPIRIS RESILIA
Surgical Aortic Valve



2023

MITRIS RESILIA
Surgical Mitral Valve



2024

SAPIEN 3 Ultra RESILIA
Transcatheter Heart Valve

Life

Time

Management



Demonstrated durability

5
years

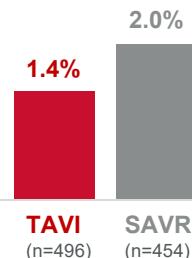
All-cause BVF

% of patients at 5 years



SVD-related BVF

% of patients at 5 years



2.2%
reintervention
at 5 years

Durability proven similar to SAVR at 5 years

BVF = Bioprosthetic valve failure; SVD = Structural valve deterioration.

Mack MJ, Leon MB, Thourani VH, et al. Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years. N Engl J Med. 2023

Life

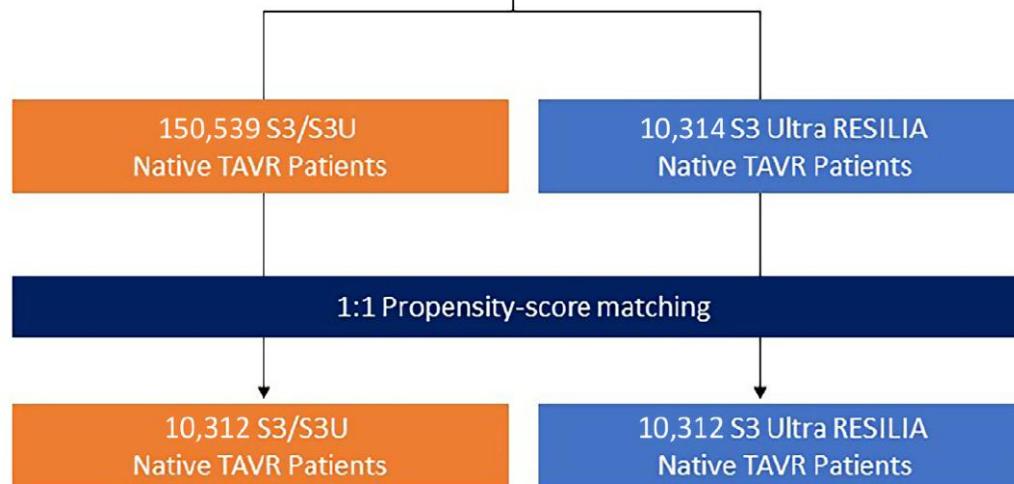
Time

Management

350,634 SAPIEN 3, SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA**Native TAVR Procedures in TVT Registry**

June 2015 – June 2023 at 805 sites

1) 49 S3UR procedures before Sept 12, 2022
2) 189,732 S3/S3U procedures before Jan 01, 2021



Stinis CT, et al. Real-World Outcomes for the Fifth-Generation Balloon Expandable Transcatheter Heart Valve in the United States.

JACC Cardiovasc Interv. 2024 Apr 22

Low clinical events rate at 30 days



1.4%

30-day mortality



1.8%

30-day all stroke



8.3%

30-day pacemaker rate



1 day

Median length of stay

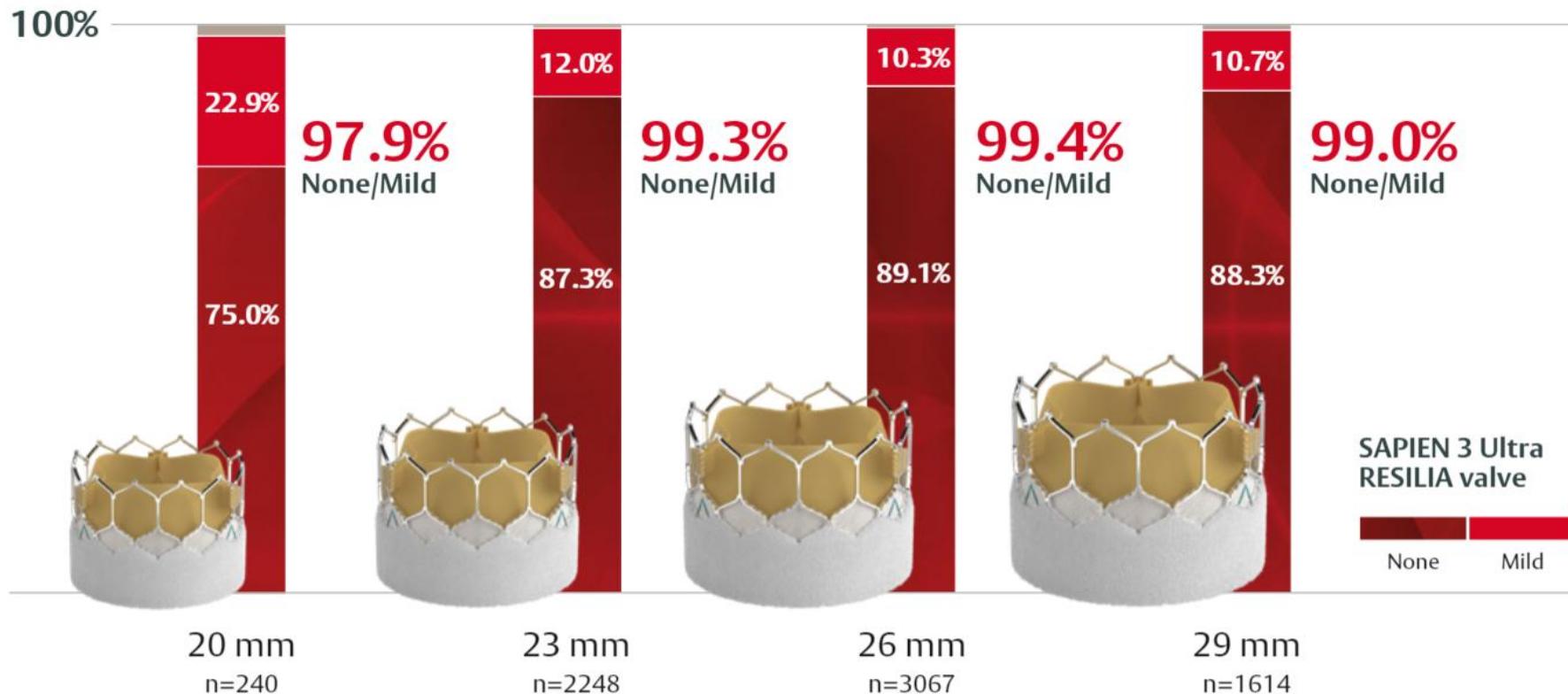


94%

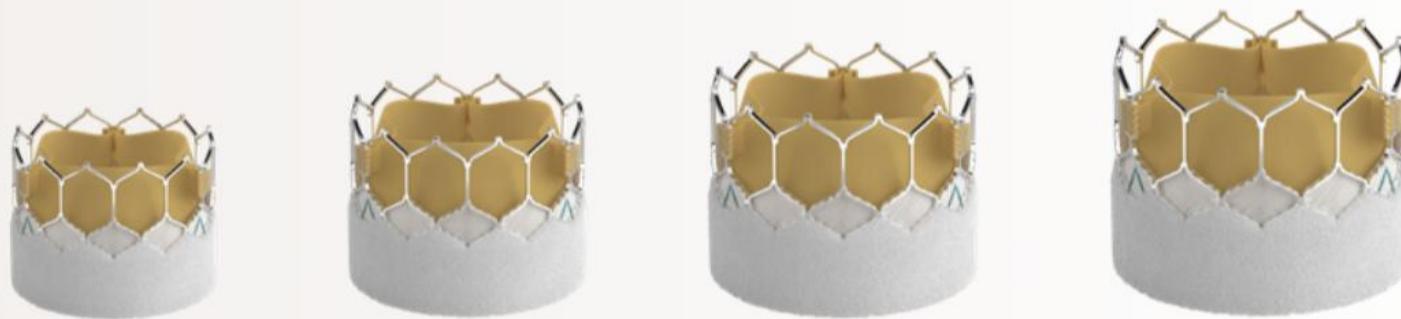
of patients discharged
directly to home

99%
Implant
success

Rates of PVL at 30 days

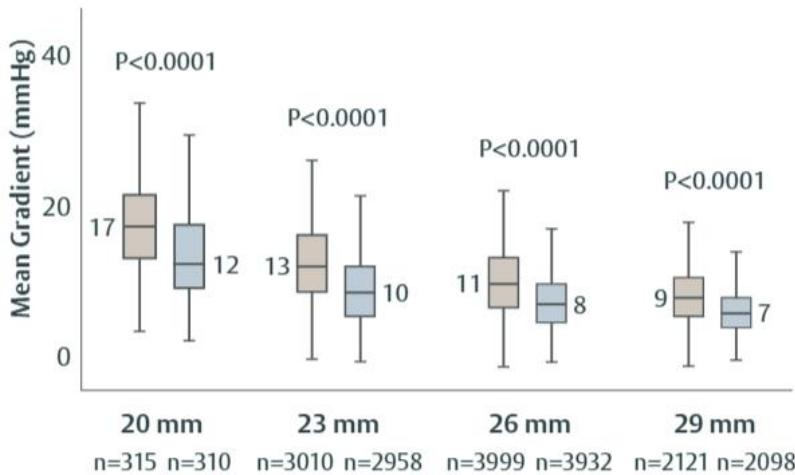


Consistent Hemodinamycs

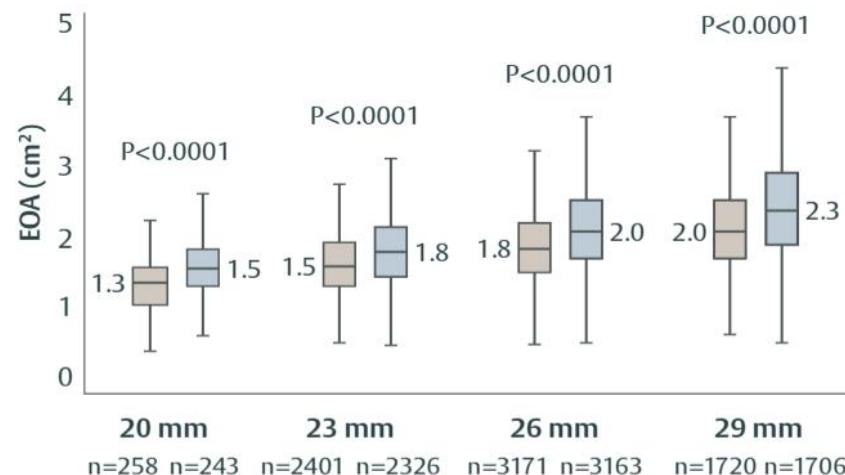


	20 mm	23 mm	26 mm	29 mm
EOA (cm ²)	1.5	1.8	2.0	2.3
Mean gradient (mmHg)	12.0	10.0	8.0	7.0

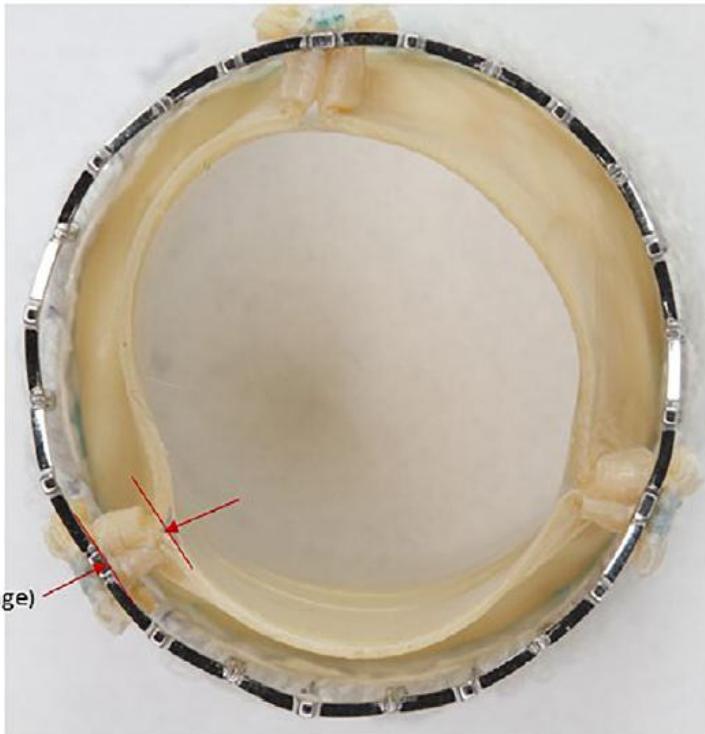
SAPIEN 3 THV / SAPIEN 3 Ultra THV SAPIEN 3 Ultra RESILIA THV



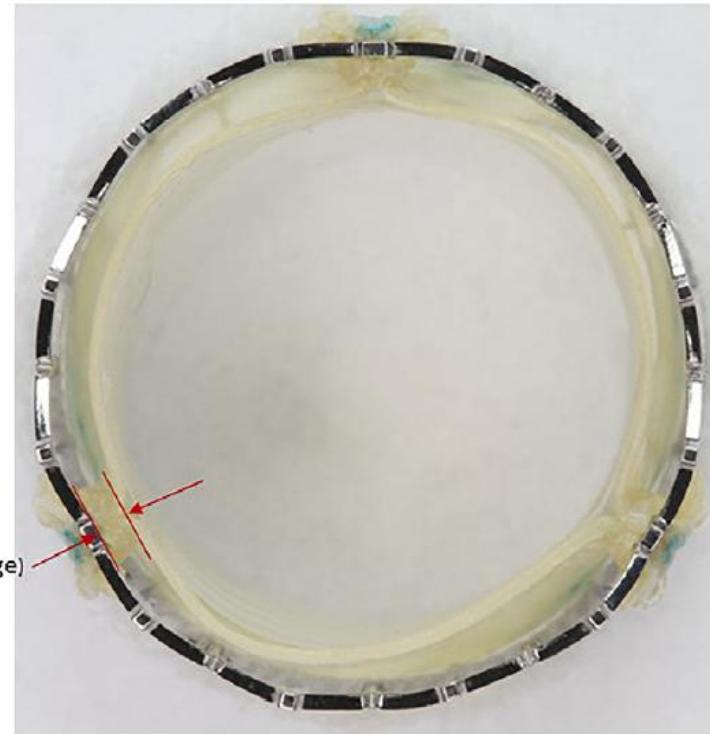
SAPIEN 3 THV / SAPIEN 3 Ultra THV SAPIEN 3 Ultra RESILIA THV



SAPIEN 3 ULTRA 20MM



SAPIEN 3 ULTRA RESILIA 20MM

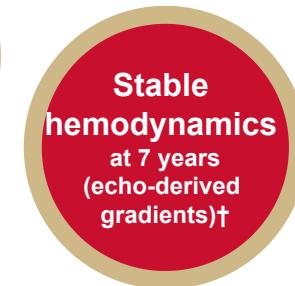
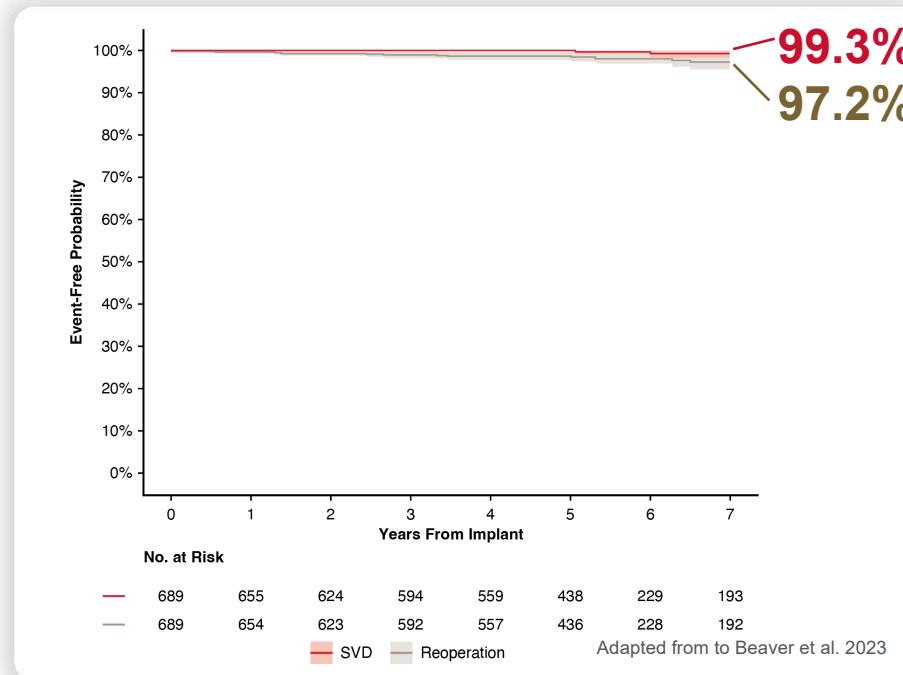


Longer tab (Hinge)

Shorter tab (Hinge)

RESILIA tissue showed excellent and consistent outcomes over 7 years

RESILIA data from the COMMENCE aortic trial* show:



*Includes the following valve sizes: 19 mm, 21 mm, 23 mm, 25 mm, 27 mm, 29 mm.
†SVD: Structural Valve Deterioration defined as dysfunction or deterioration involving the operated valve (exclusive of infection or thrombosis), as determined by reoperation, autopsy or clinical investigation (substantial increase in regurgitation, stenosis, incl. valve intrinsic changes such tear, fracture, etc.). SVD was adjudicated per Akin et al. 2008.

Beaver T, Bavaria J, Griffith B, et al. Seven-Year Outcomes Following Aortic Valve Replacement with a Novel Tissue Bioprosthesis. Journal of Thoracic and Cardiovascular Surgery. 2023

Life

Time

Management



Edwards