

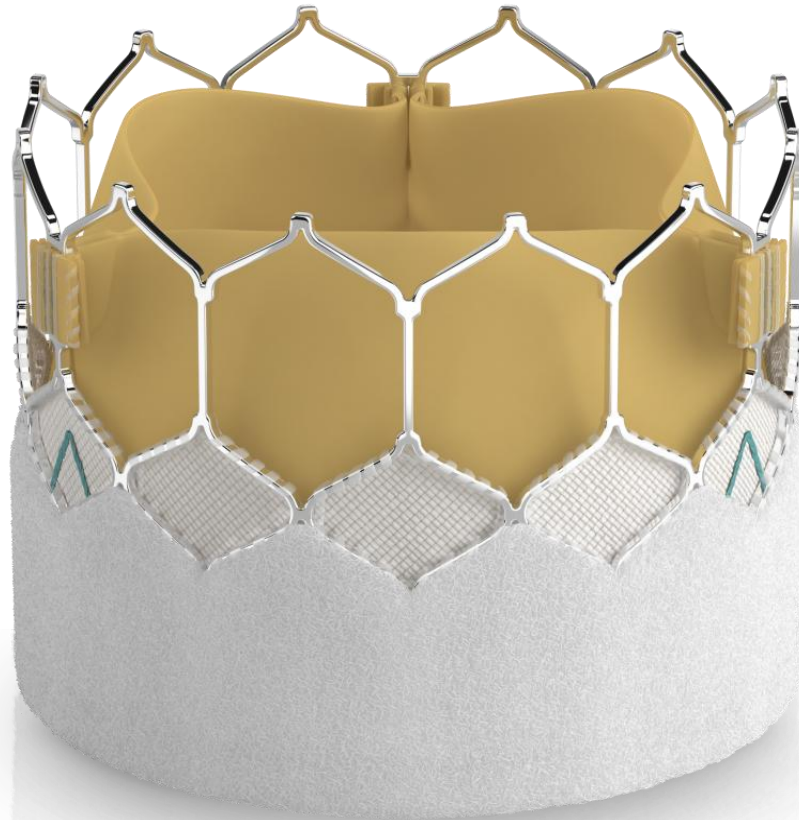
Introducing  
**SAPIEN 3 Ultra  
RESILIA system**

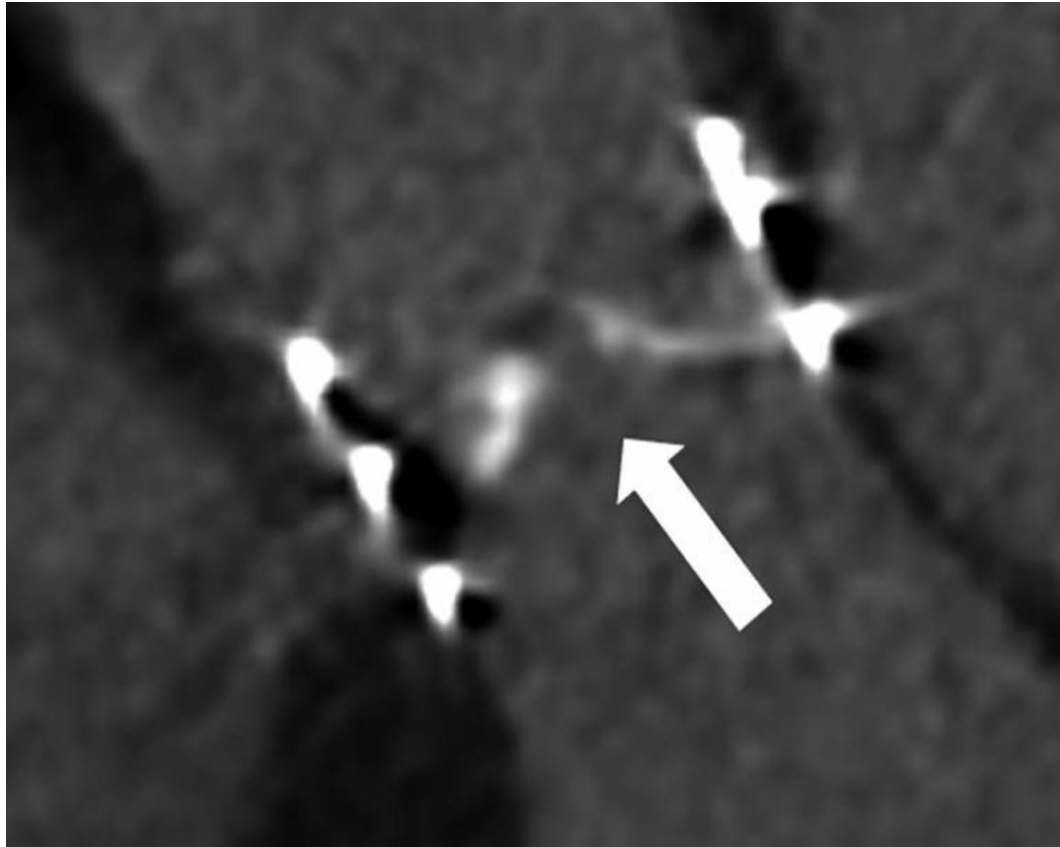
The Ultimate Lifetime Management Strategy

R E S L I A

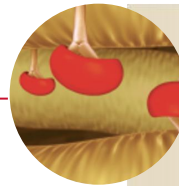
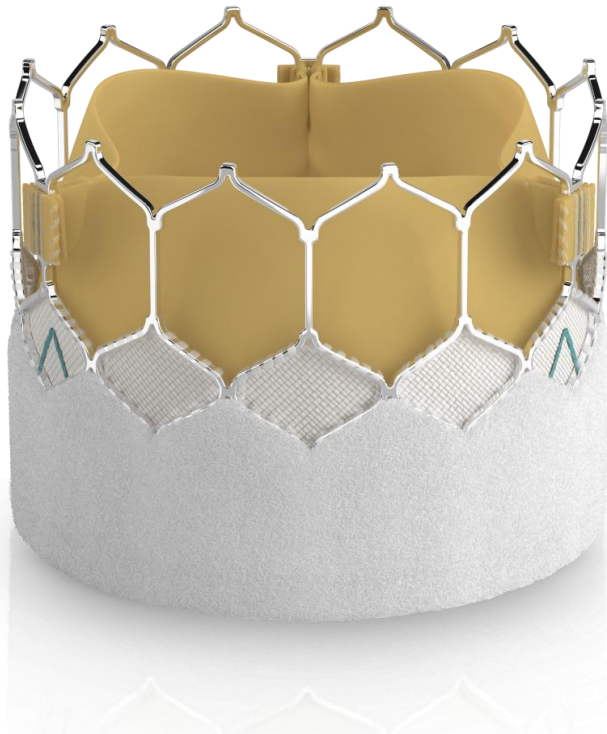


Edwards

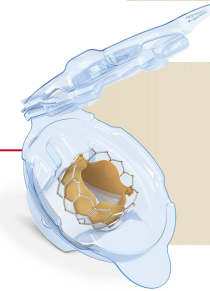




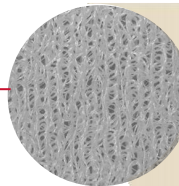
# SAPIEN 3 Ultra RESILIA valve



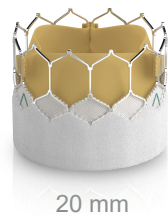
**Advanced calcium-blocking  
tissue technology**



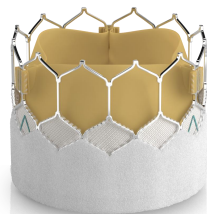
**Dry tissue storage**



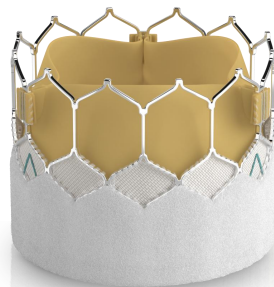
**Taller, textured outer skirt  
extended to 29mm valve**



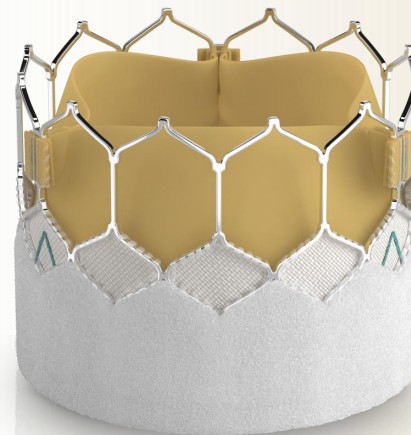
20 mm



23 mm



26 mm



29 mm

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

Life

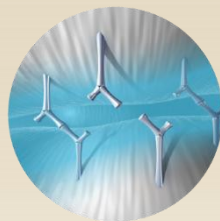


Time

Management

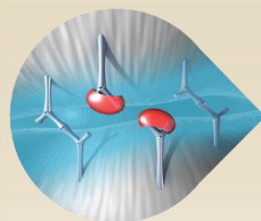
# RESILIA tissue

## Glutaraldehyde stabilization

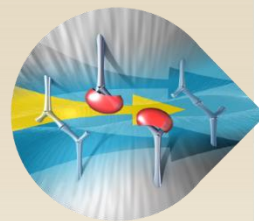


**Free Aldehydes**

## Advanced calcium-blocking technology

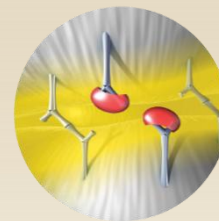


**Stable-Capping**  
Permanently  
blocks free  
aldehydes



**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

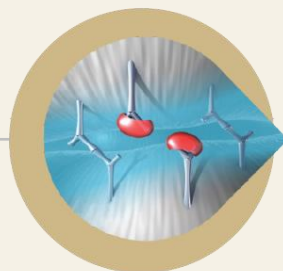
Time

Management

# Edwards RESILIA



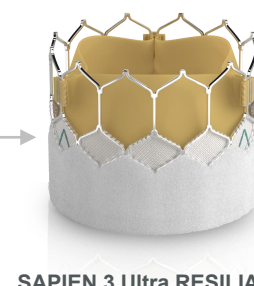
## Advanced calcium-blocking tissue technology



**Stable capping**  
permanently blocks  
calcium binding sites  
within tissue



**Dry tissue storage**  
Glycerolization replaces  
calcium-attracting  
glutaraldehydes

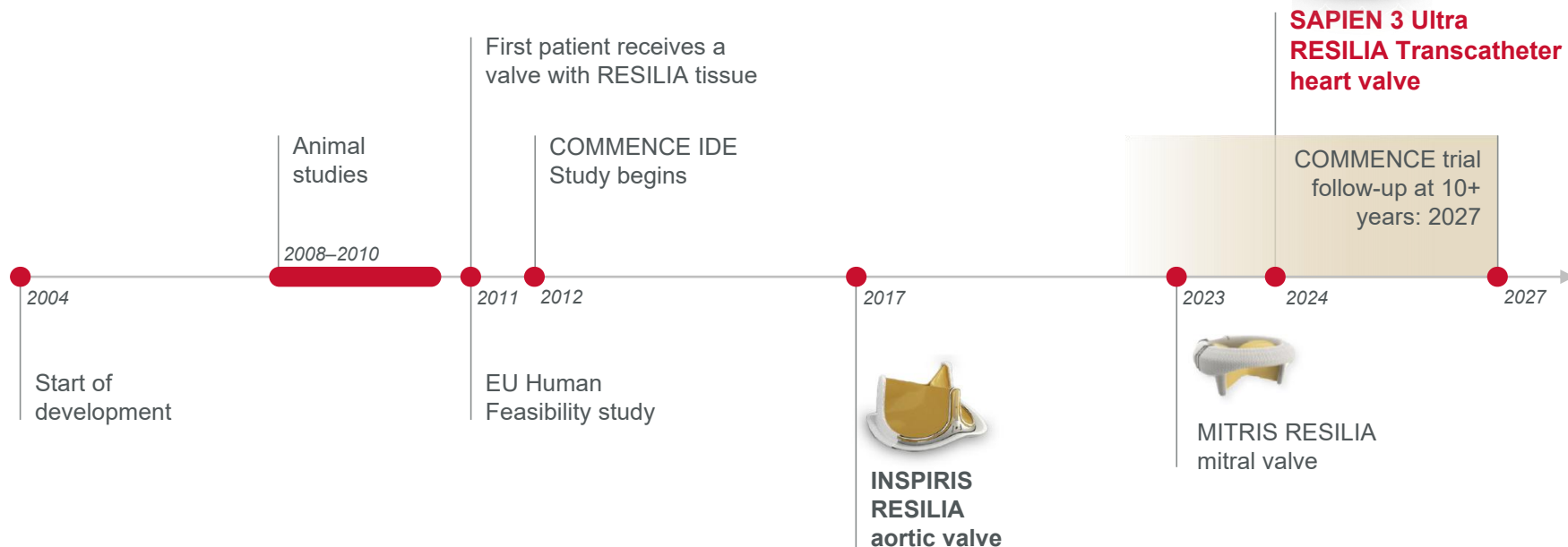


Life

Time

Management

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





# Improving valve technology



2017

## **INSPIRIS RESILIA**

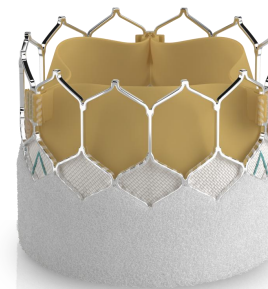
Surgical Aortic Valve



2023

## **MITRIS RESILIA**

Surgical Mitral Valve



2024

## **SAPIEN 3 Ultra RESILIA**

Transcatheter Heart Valve

Life

Time

Management



## Demonstrated durability

5  
years

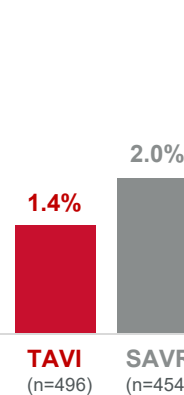
### All-cause BVF

% 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**

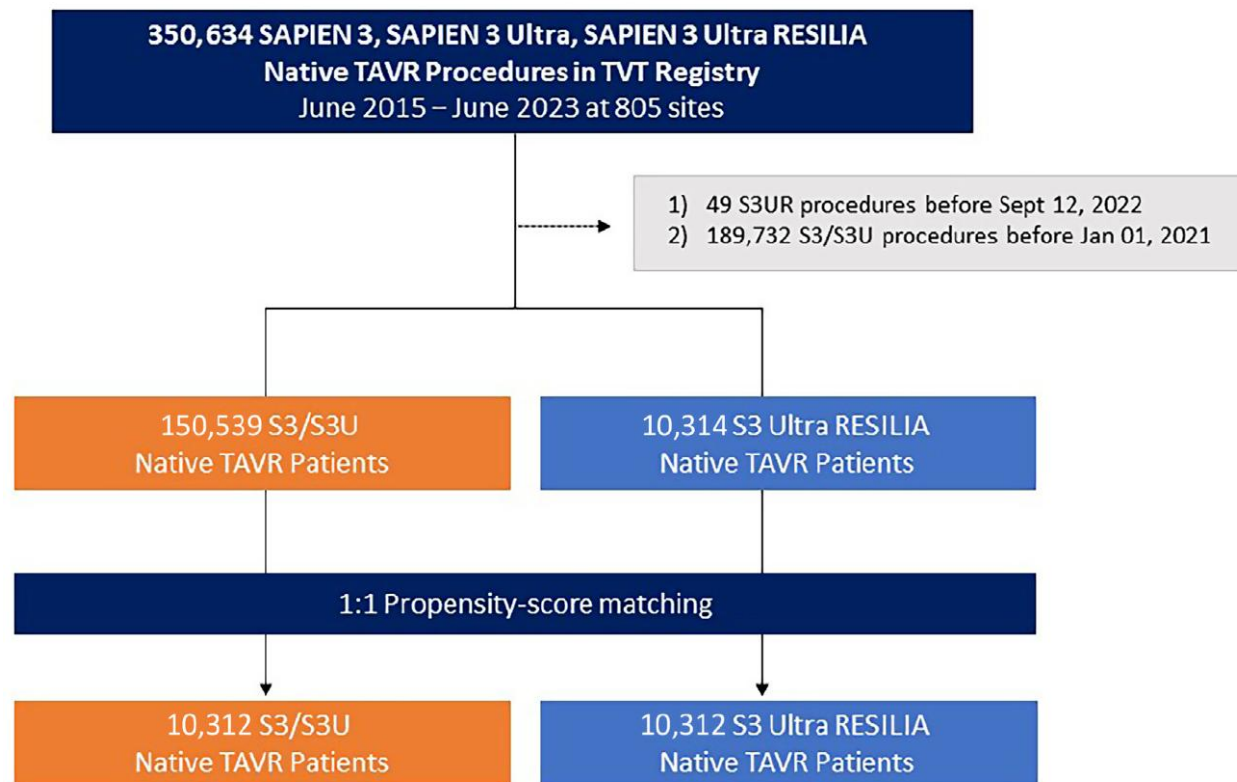
BVF = Bioprosthetic valve failure; SVD = Structural valve deterioration.

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



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



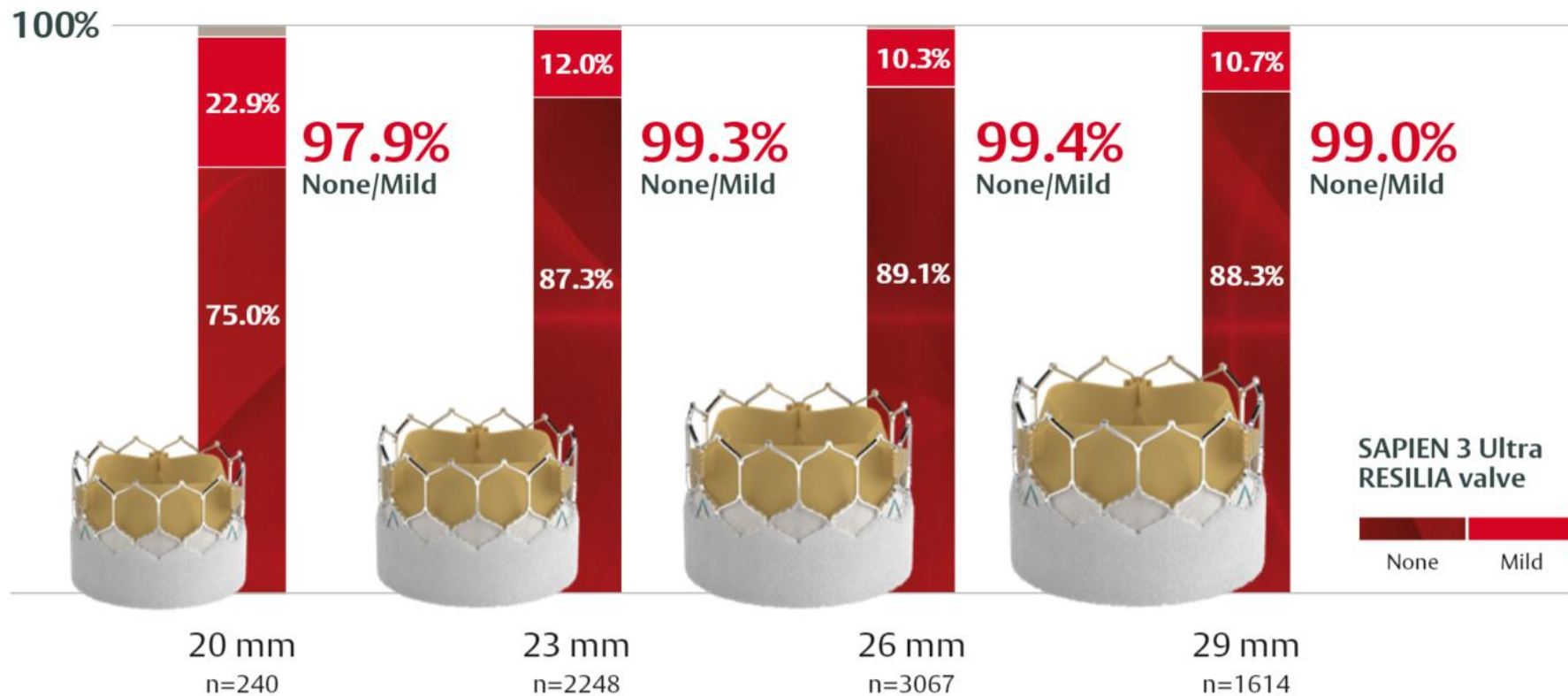
**94%**

of patients discharged  
directly to home

**99%**

Implant  
success

## Rates of PVL at 30 days



## Consistent Hemodynamics



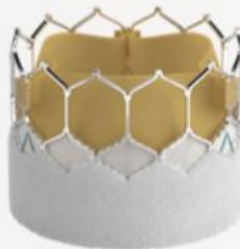
20 mm

**EOA (cm<sup>2</sup>)**

**1.5**

**Mean gradient  
(mmHg)**

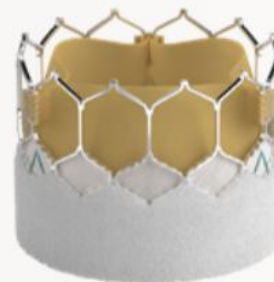
**12.0**



23 mm

**1.8**

**10.0**



26 mm

**2.0**

**8.0**

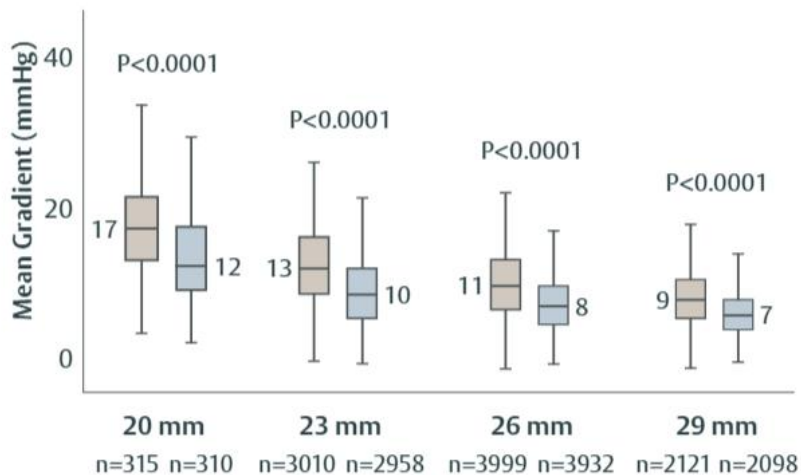


29 mm

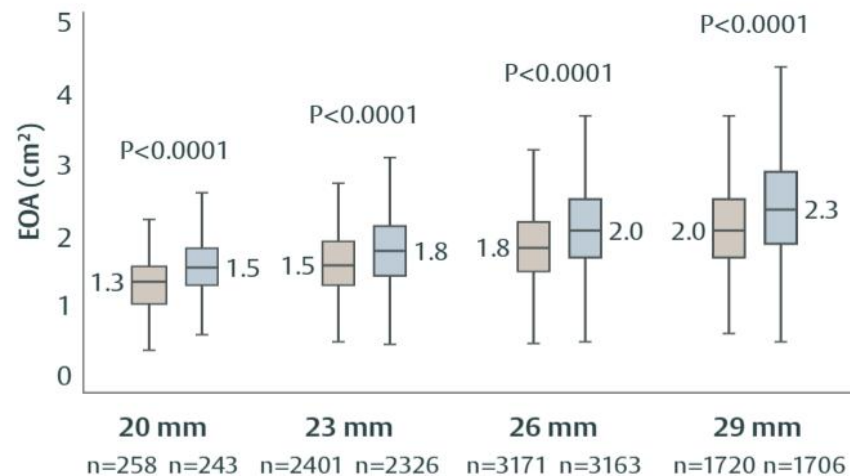
**2.3**

**7.0**

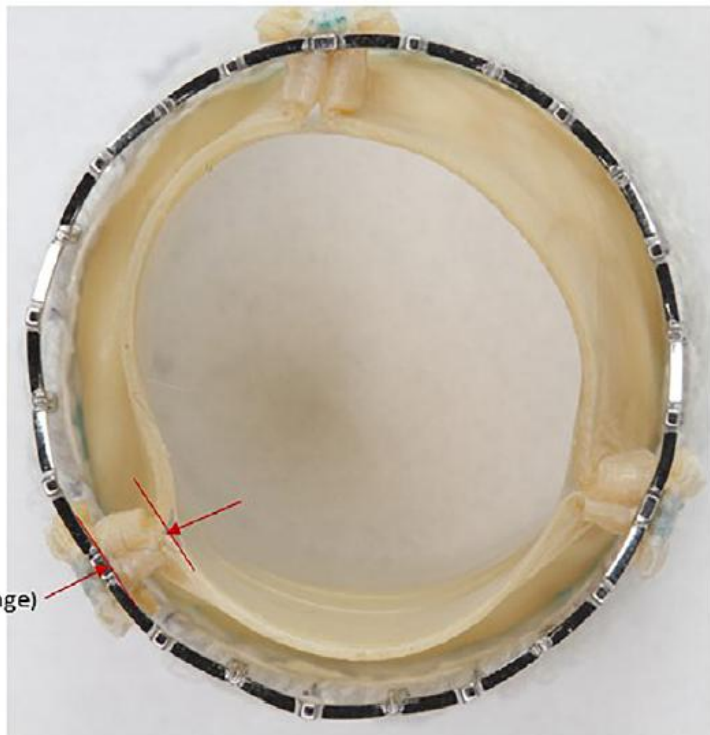
 SAPIEN 3 THV / SAPIEN 3 Ultra THV 
  SAPIEN 3 Ultra RESILIA THV



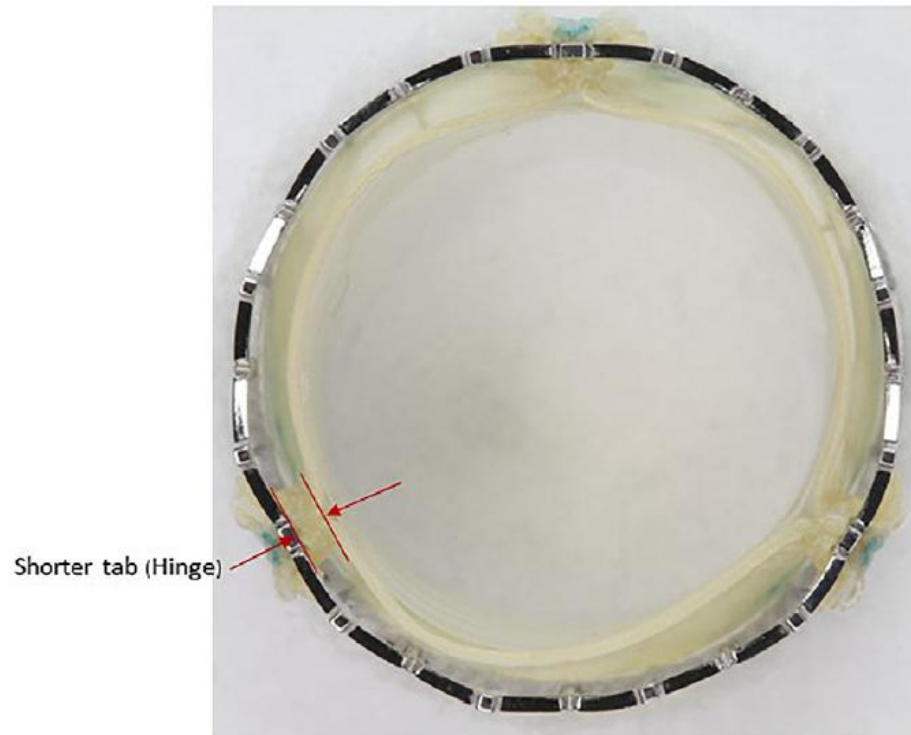
 SAPIEN 3 THV / SAPIEN 3 Ultra THV 
  SAPIEN 3 Ultra RESILIA THV



## SAPIEN 3 ULTRA 20MM



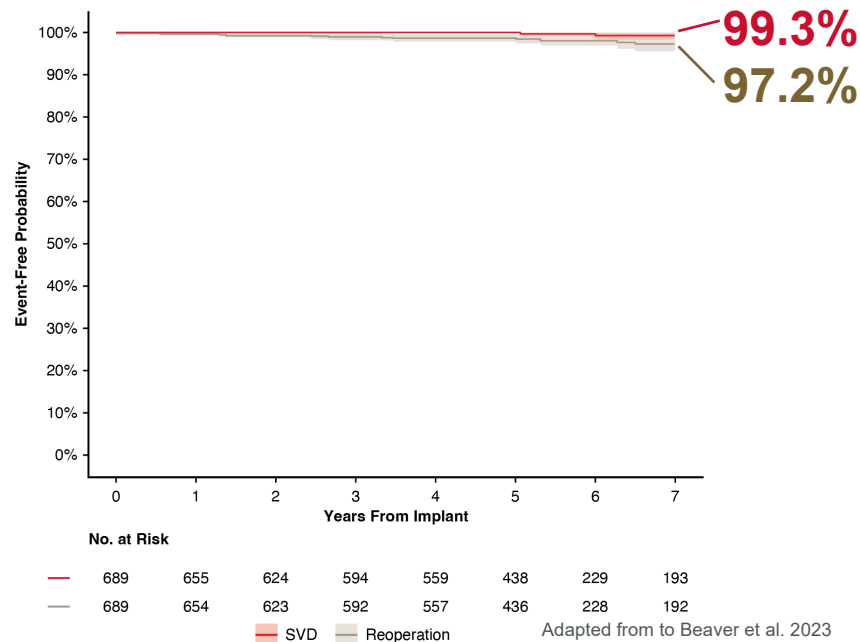
## SAPIEN 3 ULTRA RESILIA 20MM





# RESILIA tissue showed excellent and consistent outcomes over 7 years

RESILIA data from the COMMENCE aortic trial\* show:



**85.4%**

Freedom from  
all-cause  
mortality

**Stable  
hemodynamics  
at 7 years  
(echo-derived  
gradients)†**

\*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 as 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