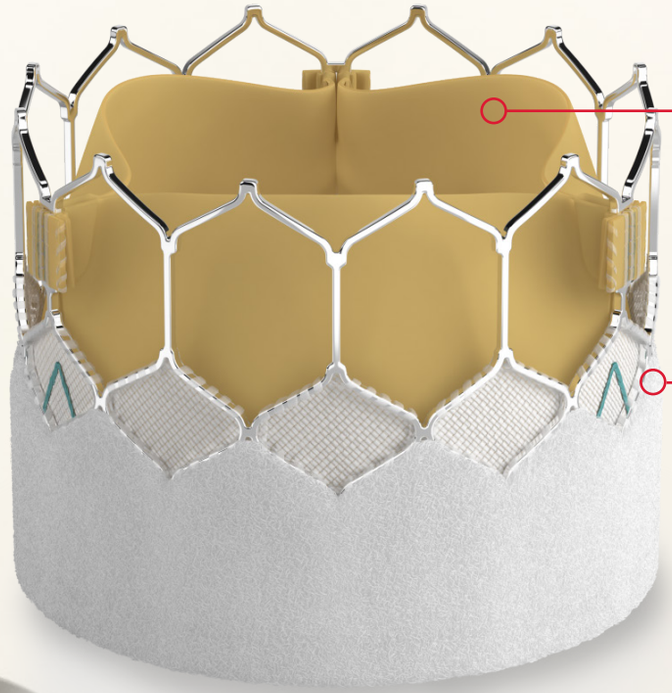
Edwards SAPIEN 3 Ultra RESILIA valve

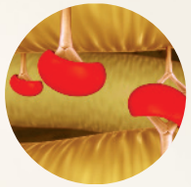
The ultimate solution for your lifetime management strategy

Edwards

The SAPIEN 3 Ultra RESILIA valve

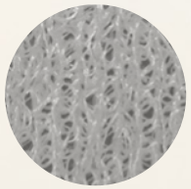
Effectively addressing calcification, a leading cause of tissue valve failure.





Advanced calcium-blocking tissue technology[1,2]

Potential to improve valve longevity and reduce risk of reintervention



Taller*, textured outer skirt extended to 29mm valve[1]

Delivering the PVL results you demand impacting immediate and long-term outcomes[3,4]

Only THV with dry tissue storage[1]

Mitigates calcium-attracting glutaraldehyde residuals

The **SAPIEN 3 Ultra RESILIA** valve represents the latest innovation on the **SAPIEN TAVI*** platform

* TAVI = Transcatheter Aortic Valve Implantation

SAPIEN 3 Ultra RESILIA valve

The right move now. Even better for what's next.

Life

Consistent outcomes that matter, starting with the index procedure

1% death and disabling stroke at 1 year[5]

Time

A comprehensive approach to a durable therapy that offers proven long-term patient outcomes

90% survival at 5 years[6]

Management

Making future options possible

Only valve with

THV-in-THV

indication[7] and design to facilitate future interventions[8]

Powered by RESILIA tissue technology

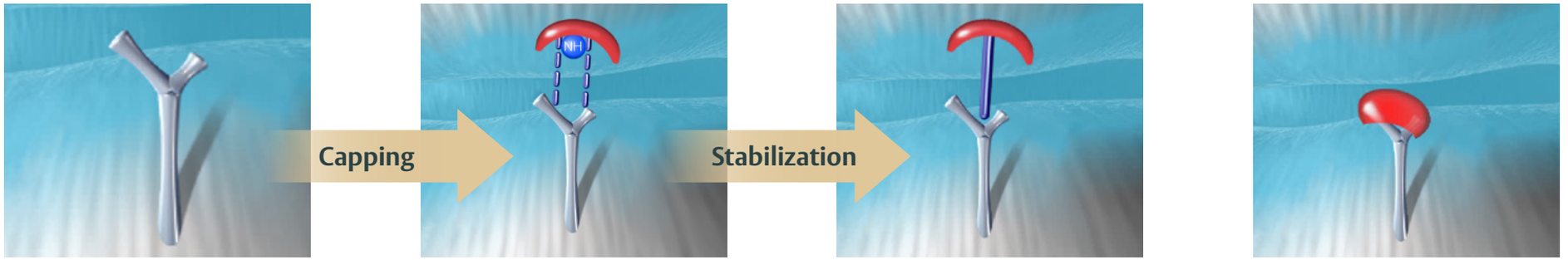
The **ultimate** lifetime management **solution** for all eligible patients

RESILIA tissue technology

A significant evolution with potential to improve valve longevity.

Calcification is a primary driver of SVD for aortic tissue valves[9]

RESILIA tissue's advanced proprietary calcium-blocking technology targets free aldehydes, a key factor in calcification.[2]



Free Aldehyde

Step 1

A small amine binds a free aldehyde to form an unstable Schiff base

Step 2

Stabilization of the unstable Schiff base to form a covalent bond

Result

Free aldehyde is stable-capped

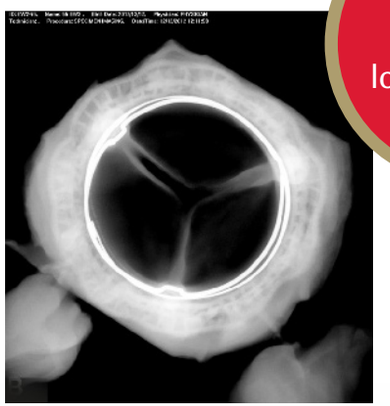
Unique glycerolization process **removes calcium-attracting gluteraldehyde residuals and allows for dry tissue storage,** preventing further exposure to free aldehydes[2]

SVD = structural valve deterioration
NSVD = non-structural valve dysfunction

RESILIA tissue is part of a comprehensive approach to durability

The SAPIEN 3 Ultra RESILIA valve addresses key drivers of SVD and NSVD

Control Valve (6900P)



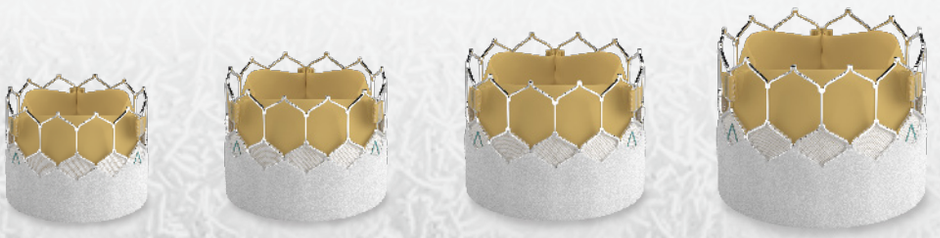
RESILIA Tissue Valve

72% lower calcium content[10]

RESILIA tissue showed **significant improvement** in calcium-blocking properties*

Paravalvular leak is a primary driver of NSVD for aortic tissue valves.[11]

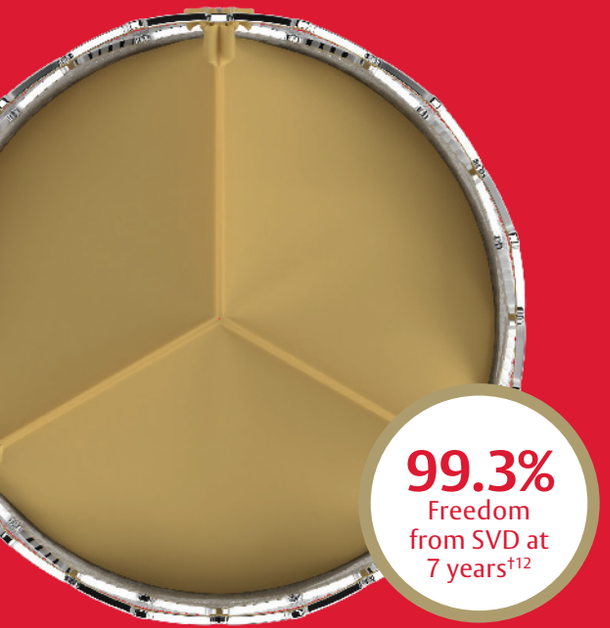
Taller, textured skirt technology to reduce PVL now available** on 29 mm valve for larger-annulus patients.



20 mm | 23 mm | 26 mm | 29 mm

*RESILIA tissue tested against tissue from commercially available bovine pericardial valves from Edwards Lifesciences in a juvenile sheep model.

**Compared to the SAPIEN 3 valve



SAPIEN 3 Ultra RESILIA valve

- Enhances potential durability with RESILIA tissue technology[1]
- Benefits of the proven predictability and superior outcomes of the SAPIEN 3 platform[5,6]
- Fully addresses the vital considerations for optimal lifetime management
  - Superior outcomes of the index procedure[5]
  - Durability that stands up to surgical aortic valve replacement[6]
  - Protects future treatment options[8]

† The COMMENCE trial evaluated performance of surgical aortic valves with RESILIA tissue

References

1. Data on file
2. De la Fuente et al. Advanced Integrity Preservation Technology Reduces Bioprosthesis Calcification While Preserving Performance and Safety. Journal of Heart Valve Disease. 2015.
3. Kodali S et al. Paravalvular regurgitation after transcatheter aortic valve replacement with the Edwards SAPIEN valve in the PARTNER trial: characterizing patients and impact on outcomes. Eur Heart J. 2015.
4. Makkar R et al. Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement. N Engl J Med. 2020.
5. Mack MJ et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med. 2019.
6. Mack MJ et al. Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years. N Engl J Med. 2023
7. Tarantini G, et al. Redo-Transcatheter aortic valve implantation using the SAPIEN 3/Ultra transcatheter heart valves - Expert Consensus on Procedural Planning Techniques, The American Journal of Cardiology, 2023
8. Tarantini G et al. Coronary access and percutaneous coronary intervention up to 3 years after transcatheter aortic valve implantation with a balloon-expandable valve. Circ Cardiovasc Interv. 2020.
9. Tod TJ et al. The association of bound aldehyde content with bioprosthetic tissue calcification. J Mater Sci Mater Med. 2016.
10. Flameng W, et al. A randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. J Thorac Cardiovasc Surg. 2015.
11. Pibarot et al. Structural Deterioration of Transcatheter Versus Surgical Aortic Valve Bioprostheses in the PARTNER-2 Trial. J Am Coll Cardiol. 2020 Oct 20;76(16):1830-1843.
12. Beaver T et al. Seven-Year Outcomes Following Aortic Valve Replacement with a Novel Tissue Bioprosthesis. Journal of Thoracic and Cardiovascular Surgery. 2023.

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