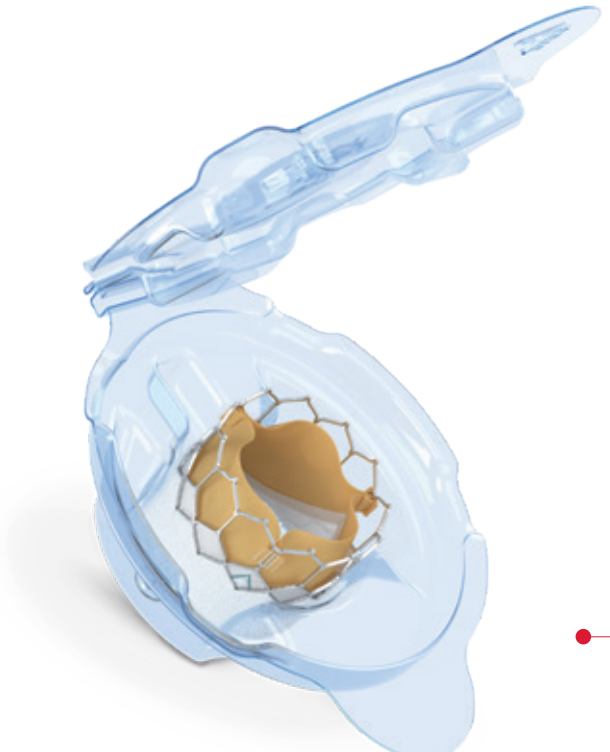
Introducing SAPIEN 3 Ultra RESILIA valve

Together, we're taking TAVR further

Edwards

Building on the benefits of the SAPIEN 3 platform

SAPIEN 3 Ultra valve, now powered by RESILIA tissue



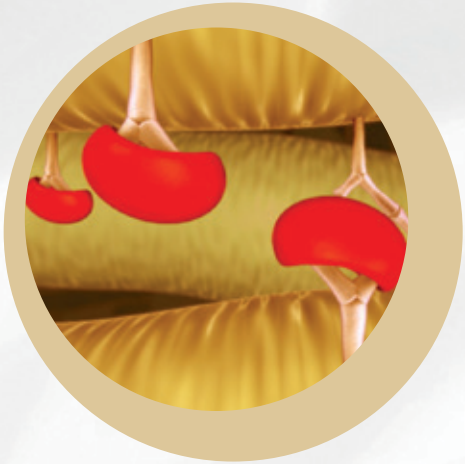
- Advanced calcium-blocking technology*[1]
- Same tissue technology used in the #1 implanted surgical valve in the US
- Potential to improve valve longevity and reduce reintervention†[1]
- The only transcatheter heart valve (THV) with dry tissue storage

*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.

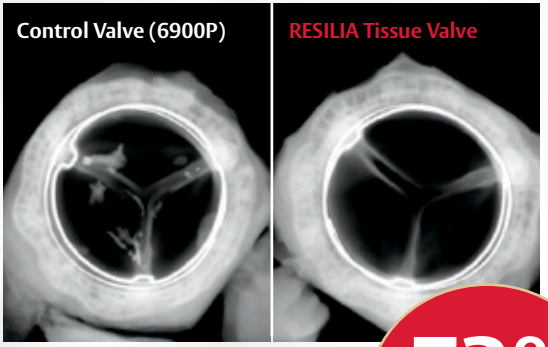
†RESILIA tissue tested against tissue from commercially available bovine pericardial valves from Edwards Lifesciences in a juvenile sheep model. Flameng, et al. *J Thorac Cardiovasc Surg.* 2015;149:340-345.

Now with proprietary RESILIA tissue technology

RESILIA tissue's stable-capping process blocks calcium from binding to tissue*[1]



See the difference



RESILIA tissue reduced calcification, when compared to traditional surgical valve tissue treatments†[1]

72% lower calcium content[1]

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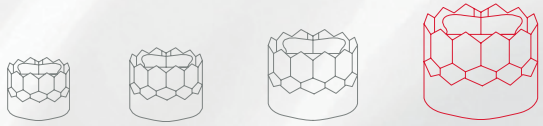
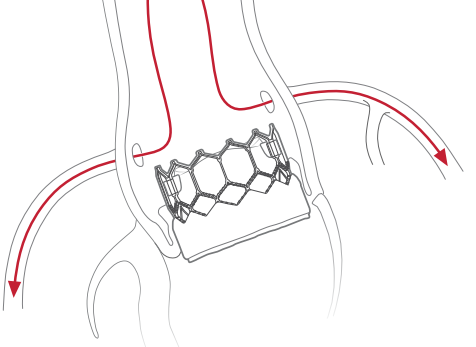


29 mm valve extends paravalvular leak (PVL) outer skirt technology to larger-annulus patients[2]

SAPIEN 3 TAVR fully addresses the vital considerations for lifetime management



Superior outcomes‡[3]

1% death and disabling stroke at one year[3]

90.9% none/trace PVL at discharge[4]

6.5% new pacemaker rate at 30 days[3]

Future treatment options

100% successful post-TAVR coronary access rate (68/68 patients[5])

The only valve with a **THV-in-THV** indication

‡ In the PARTNER 3 trial, SAPIEN 3 TAVR was proven superior to surgery on the primary endpoint of all-cause death, all stroke, and rehospitalization (valve-related or procedure-related, and including due to heart failure) at one year and multiple pre-specified secondary endpoints in low-risk patients.

For today and the future, your first valve choice matters

SAPIEN 3 Ultra RESILIA valve

- Builds on the benefits of the proven SAPIEN 3 platform
- Addresses calcification, the leading cause of tissue valve failure*[1]
- Fully addresses the vital considerations for optimal lifetime management
  - Superior outcomes†[4]
  - Facilitates future treatment options‡[5]
  - Durability that stands up to SAVR§[6]

Discover how to take your patients farther.

Learn more about SAPIEN 3 Ultra RESILIA valve at **SAPIEN3UltraRESILIA.com**

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† In the PARTNER 3 trial, SAPIEN 3 TAVR was proven superior to surgery on the primary endpoint of all-cause death, all stroke, and rehospitalization (valve-related or procedure-related, and including due to heart failure) at one year and multiple pre-specified secondary endpoints in low-risk patients.
‡ Indications for aortic THV-in-THV and demonstrated future coronary access (68/68 patients).
§ Propensity matched analysis of intermediate risk patients using VARC 3 definitions of structural valve deterioration (SVD) and SVD-related bioprosthetic valve failure at 5 years.

1. Flameng W, Hermans H, Verbeken E, et al: Randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. *J Thorac Cardiovasc Surg.* 2015;149:340-345.
2. Data on file. Edwards Lifesciences. 2022.
3. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med.* 2019; 380:1695-1705. doi:10.1056/NEJMoa1814052.
4. Nazif TM, Cahill TJ, Daniels D, et al. Real-world experience with the SAPIEN 3 ultra transcatheter heart valve: a propensity-matched analysis from the United States. *Circ Cardiovasc Interv.* 2021;14:e010543.
5. Tarantini G, Nai Fovino L, Le Prince P, 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;13:e008972.
6. Pibarot P, Ternacle J, Jaber W, et al. Structural deterioration of transcatheter versus surgical aortic valve bioprostheses in PARTNER-2 trial. *J Am Coll Cardiol.* 2020;71:1830-1843.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician.

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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