You refuse to compromise.
We couldn’t agree more.

Edwards SAPIEN 3 Ultra TAVR

Welcome to the Higher Standard.
Your standard.

Edwards

Edwards SAPIEN 3 TAVR

Designed to meet your Higher Standard

With so much at stake, there is no room for compromise.
SAPIEN 3 TAVR helps you:

- **Deliver the outcomes you demand**
- **Perfect the pathway** through efficient procedures so you can get your patients back home quickly
- **Control for the future** to continue to meet the emerging needs of new patient populations

Choose SAPIEN 3 TAVR. The valve designed to meet your Higher Standard.

SAPIEN 3 TAVR is built upon:

25,000+
patients studied in Edwards THV trials

450,000+
patients treated worldwide with Edwards TAVR valves

You asked.

Save lives, starting with the sickest patients	Extend lifesaving treatment to even more	Reset the bar to be even better than surgery	Continue to meet the emerging needs of new patient populations

TAVR in **2007**

TAVR **today**

We answered.

SAPIEN valve
Introducing TAVR as a lifesaving treatment option for patients who are inoperable or at high risk for surgery

SAPIEN XT valve
Non-inferior to surgery on mortality and stroke in intermediate-risk patients

SAPIEN 3 valve
The only THV proven superior* to surgery for low-risk patients

SAPIEN 3 Ultra valve
Further reducing paravalvular leak (PVL) and reaching new patients with expanded indications

*On the primary endpoint of death, stroke, and rehospitalization at 1 year

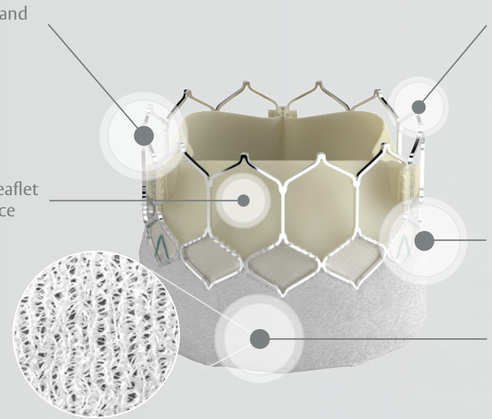
Delivering the outcomes you demand

You take outcomes to new heights.
We're right there with you.

Differentiated outcomes start with differentiated design

SAPIEN 3 Ultra valve

Building on the standard in TAVR to meet the needs of today

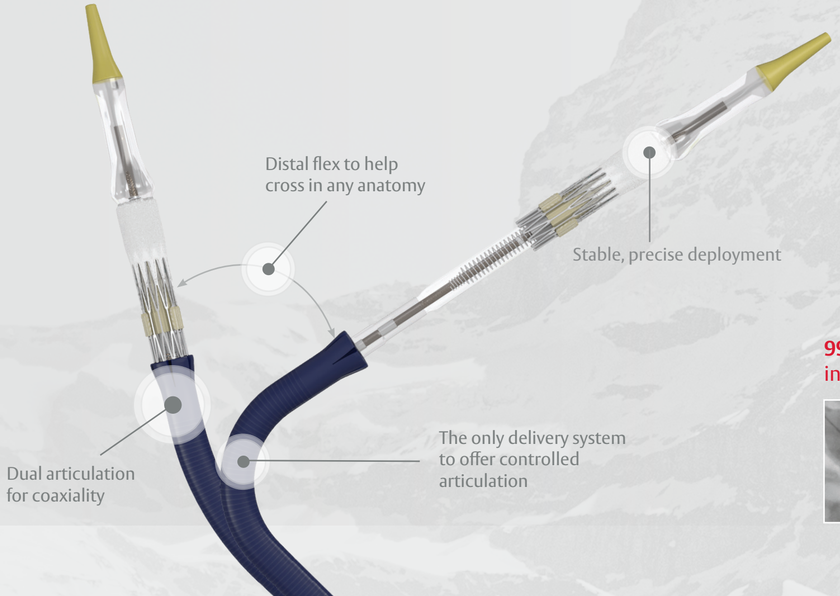


~40% taller, textured skirt†

*For 20, 23, and 26 mm sizes
†Compared to the Edwards SAPIEN 3 valve

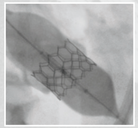
Edwards Commander Delivery System

Predictability and control to meet the increasing complexity of your procedures



0.6% all stroke at 30 days[1]

99% deployment accuracy in the intended location[2]



Balloon-expandable platform delivers stable, precise deployment

Only SAPIEN 3 TAVR is proven superior to surgery in low-risk patients

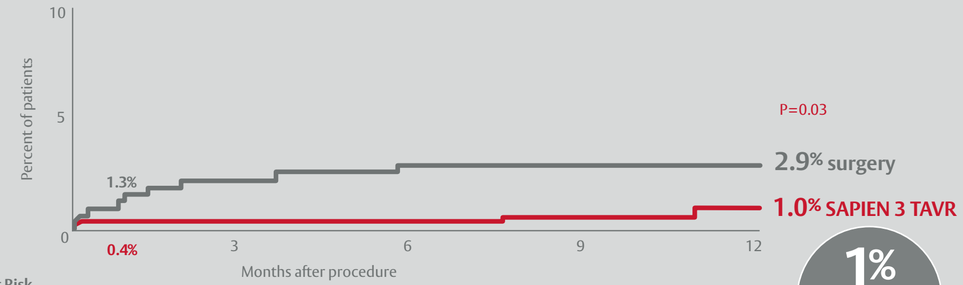
PARTNER 3 Low-Risk Trial

Primary endpoint:
Death, stroke, rehospitalization at 1 year[1]

TAVR	Surgery
8.5%	15.1%

Benefit of TAVR sustained at 2 years*[3]

Death or disabling stroke[1]



Number at Risk

Surgery	454	444	436	432	430	426
SAPIEN 3 TAVR	496	494	494	493	491	488

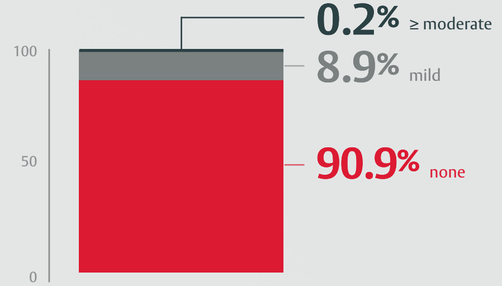
1% death or disabling stroke at 1 year[1]

* More death and stroke events in TAVR patients from 1 to 2 years; no significant differences at 2 years

Designed to deliver outcomes you demand, with no compromise

Excellent PVL performance

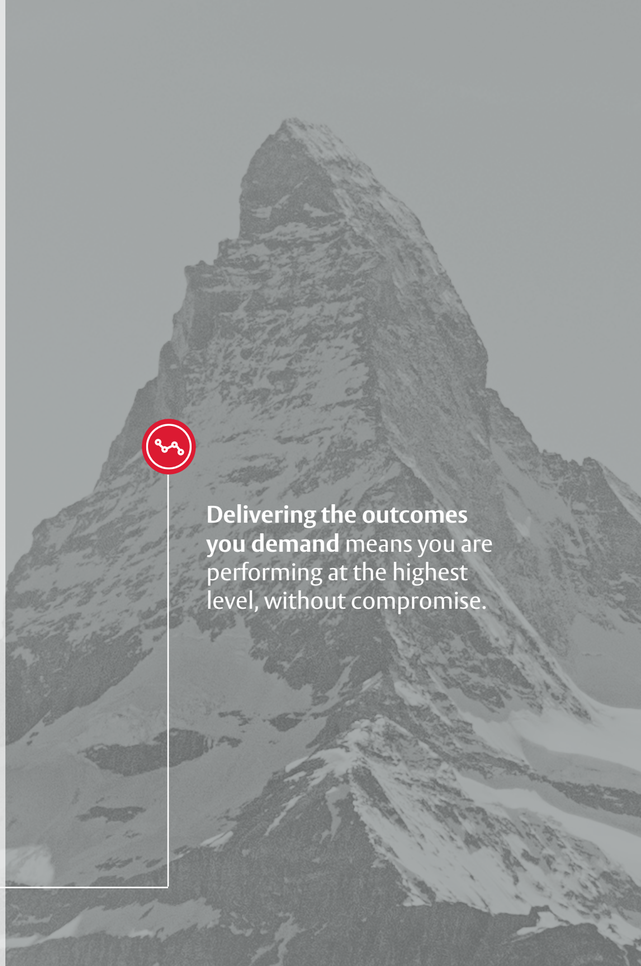
In a study of real-world patients, the SAPIEN 3 Ultra valve demonstrated[4]:



(n = 1115)
Discharge paravalvular leak

Single-digit new permanent pacemaker rates[1]

6.5% at 30 days **7.3%** at 1 year



Delivering the outcomes you demand means you are performing at the highest level, without compromise.

Perfecting the pathway

Your valve choice matters to your patients

Your procedural success helps patients get home faster

Procedural complications of TAVR lead to longer length of stay[5]

Achieve low complication rates with SAPIEN 3 TAVR*[1]

Permanent pacemaker implantation

+2 days — 6.5%

All stroke

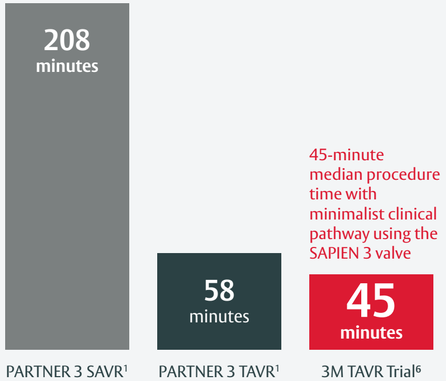
+5 days — 0.6%

Acute kidney injury

+7 days — 0.4%

Procedure times are shorter with SAPIEN 3 TAVR

Aortic valve replacement procedure times



PARTNER 3 SAVR[1] | PARTNER 3 TAVR[1] | 3M TAVR Trial[6]

45-minute median procedure time with minimalist clinical pathway using the SAPIEN 3 valve

*Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients at 30 days

Choosing SAPIEN 3 TAVR can help your patients stay out of the hospital

80% of patients discharged the next day[6]

With SAPIEN 3 TAVR:

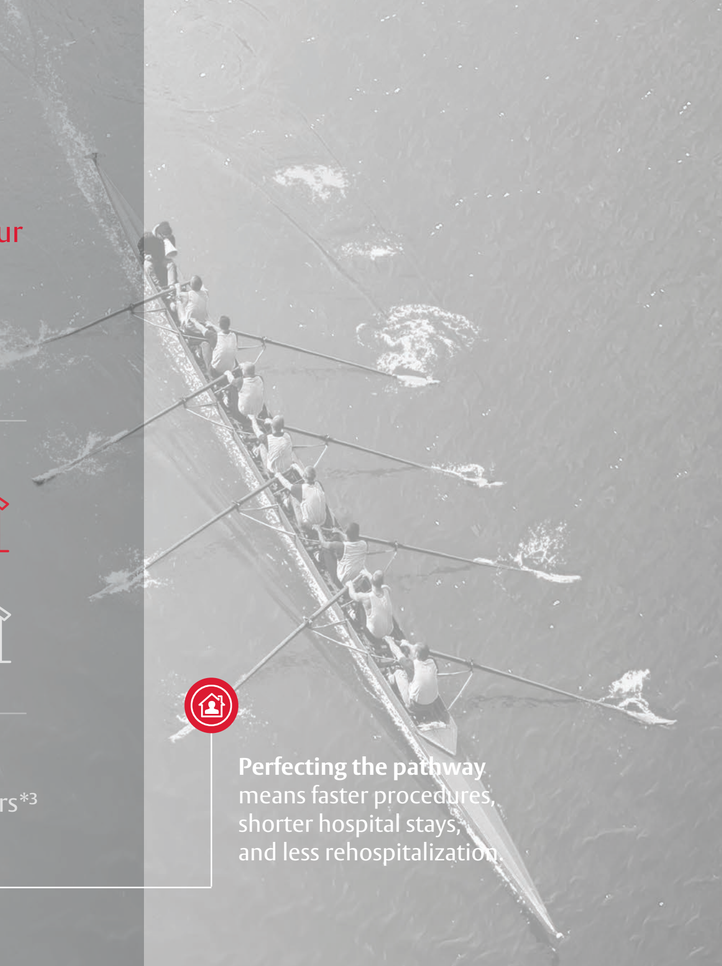
96% Discharged to home[1]

With SAVR:

73% Discharged to home[1]

>90% did not need to be rehospitalized within 2 years*[3]

* As defined in the PARTNER 3 trial: valve related, procedure related, cardiac related rehospitalization



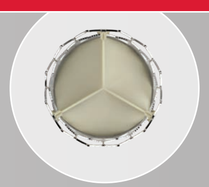
Perfecting the pathway means faster procedures, shorter hospital stays, and less rehospitalization.

Controlling for the future

You're always thinking ahead.
We can get behind that.

Continuing to meet the emerging needs of new patient populations with SAPIEN 3 Ultra TAVR

Designed for durability



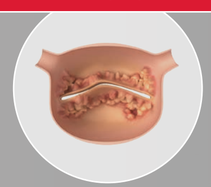
PARTNER II S3i: Excellent outcomes out to 5 years with durability similar to SAVR[7]

Designed to facilitate future coronary access

The SAPIEN 3 Ultra valve allows for future coronary intervention with a low frame height and large cell design

100%
successful coronary access post-TAVR[8]
68/68 patients

Excellent outcomes in low-risk bicuspid patients



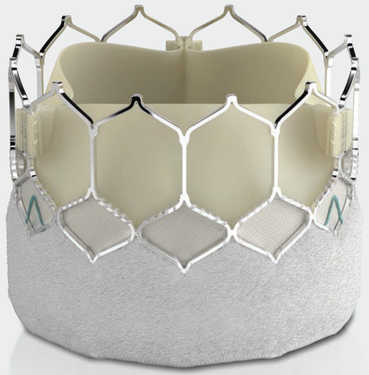
0% death or disabling stroke and very low rates of mild or greater PVL at 30 days[9]

A versatile option for future valve-in-valve procedures

Indicated to treat surgical aortic and mitral valves as well as transcatheter aortic valves, the SAPIEN 3 Ultra valve can be the preferred option for patients today and in the future

Controlling for the future means planning for the lifetime well-being of your patients.

You refuse to compromise.
We couldn’t agree more.



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1. 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.
2. PARTNER II Trial intermediate-risk cohort 30-day unadjusted clinical event rates for TAVR with the SAPIEN 3 valve, AT population (n=1077).
3. Mack MJ. Two-year clinical and echocardiographic outcomes from the PARTNER 3 low-risk randomized trial. Presented at ACC 2020; March 2020; Virtual meeting.
4. Nazif T, Daniels D, McCabe J, et al. Real-world experience with the SAPIEN 3 Ultra TAVR: A propensity matched analysis from the United States. Presented at: TVT Connect 2020; June 2020; Virtual meeting.
5. Data on file, analysis of 2018 Medicare SAF files.
6. Wood, DA, Lauck SB, Cairns JA, et al. The Vancouver 3M (multidisciplinary, multimodality, but minimalist) clinical pathway facilitates safe next-day discharge home at low-, medium-, and high-volume transfemoral transcatheter aortic valve replacement centers: the 3M TAVI study. *JACC Cardiovasc Interv.* 2019;12(5):459-469.
7. Kodali S, et al. SAPIEN 3 transcatheter aortic valve replacement compared with surgery in intermediate-risk patients: a propensity matched analysis of 5 year outcomes. Presented at: TVT Connect 2020; June 21, 2020; Virtual meeting.
8. Tarantini G, Fovino LN, 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(7):e008972.
9. The PARTNER 3 Trial, low-risk bicuspid registry, N=71. Edwards Lifesciences data on file.

See enclosed Important Safety Information.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician. SAPIEN 3 and SAPIEN 3 Ultra involve serious risks, including death, stroke, major bleeding, and major vascular complications.

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