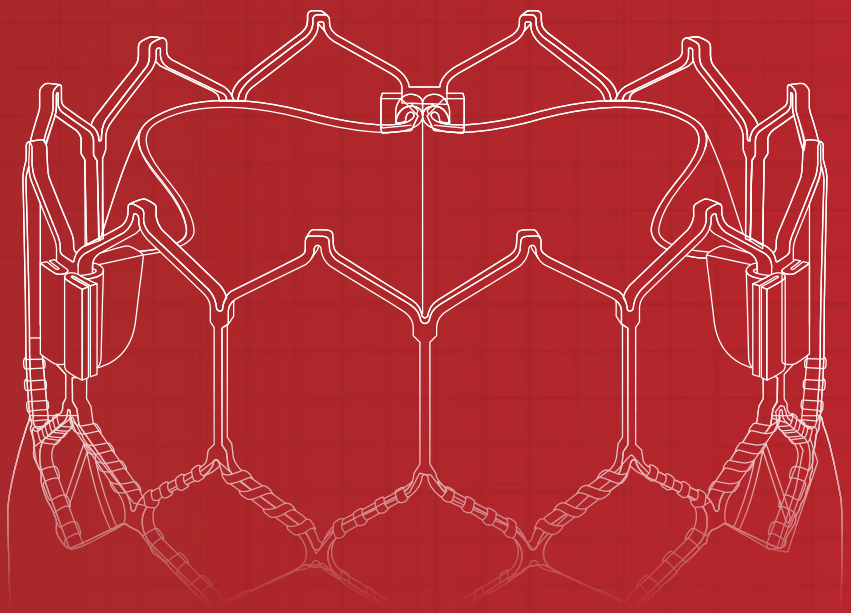
# Only **Edwards SAPIEN 3 TAVI** is proven superior to surgery[1]



**1%** death or disabling stroke **at 1 year**[2]

Low-risk patients deserve the lowest-risk procedure

[1]PARTNER 3 Trial proved SAPIEN 3 TAVI is superior to surgery on the primary endpoint (all-cause death, all stroke, and rehospitalisation) and multiple pre-specified secondary endpoints.

[2]Compared to 2.9% death or disabling stroke at 1 year for surgery (*P*=0.03).

Edwards

# Low-risk patients are unique

## 93% of aortic stenosis patients have improved quality of life after the procedure as their main goal[2]

They are often younger, healthier and more active than higher surgical risk patients. Because they have fewer comorbidities, their primary concern is their severe symptomatic aortic stenosis.

| Baseline Patient Characteristics As Treated (AT) Populations | | | |
|---|---|---|---|
| | PARTNER 3 Trial Low-risk[1] (n=950) | PARTNER IIA Trial Intermediate-risk[5,6] (n=1938) | PARTNER IA Trial High-risk[7] (n=657) |
| Mean Age | 73 | 82 | 84 |
| STS Score | 1.9 | 5.8 | 11.8 |
| NYHA Class III/IV | 27.7% | 76.7% | 94.5% |
| KCCQ Score | 70.2 | 54.1 | 41.8 |
| CAD | 27.8% | 67.8% | 75.9% |
| Previous CABG | 2.4% | 24.6% | 43.3% |
| COPD | 5.6% | 30.8% | 43.7% |
| PPI | 2.6% | 11.8% | 21.2% |

[2]Coylewright, M., et al. "Patient-defined goals for the treatment of severe aortic stenosis: a qualitative analysis."; Health Expect.; 2016; 19:1036–1043

# Superior to surgery for the outcomes that matter most[†1]

**PARTNER 3 trial clinical events at 30 days and 1 year[1,8]**

| | 30 Days | | 1 Year | | |
|---|---|---|---|---|---|
| | **SAPIEN 3 TAVI (n=496)** | Surgery (n=454) | **SAPIEN 3 TAVI (n=496)** | Surgery (n=454) | *P*-Value |
| **Primary Endpoint** | | | | | |
| **All-cause Death, All Stroke, and Rehospitalisation at 1 Year 8.5% TAVI vs 15.1% for Surgery $P_{superiority}$ = 0.001** | | | | | |
| All-cause Death | **0.4%** | 1.1% | **1.0%** | 2.5% | *P*=0.09 |
| All Stroke | **0.6%** | 2.4% | **1.2%** | 3.1% | *P*=0.04 |
| Rehospitalisation[‡] | **3.4%** | 6.5% | **7.3%** | 11.0% | *P*=0.046 |

## Low-risk patients expect to have a procedure that carries the lowest risk

| Additional Endpoints* | | | | | |
|---|---|---|---|---|---|
| Rehospitalisation Due to Heart Failure | **0.2%** | 0.9% | **1.4%** | 3.6% | *P*=0.029 |
| Life-threatening/Disabling or Major Bleeding | **3.6%** | 24.5% | **7.7%** | 25.9% | *P*<0.001 |
| Disabling Stroke | **0.0%** | 0.4% | **0.2%** | 0.9% | *P*=0.14 |
| New-onset AFib | **5.0%** | 39.5% | **7.0%** | 40.9% | *P*<0.001 |
| AKI | **0.4%** | 1.8% | **0.4%** | 1.8% | *P*=0.05 |
| Moderate or Severe PVL | **0.8%** | 0.0% | **0.6%** | 0.5% | *P*=1.0 |
| New PPI | **6.5%** | 4.0% | **7.3%** | 5.4% | *P*=0.21 |

**P-values listed for additional endpoints, except for new-onset atrial fibrillation, have not been adjusted for multiplicity.*

[†8]PARTNER 3 trial proved SAPIEN 3 TAVI is superior to surgery on the primary endpoint and multiple pre-specified secondary endpoints.

[‡] Valve-related, procedure-related, or heart-failure-related.

# Low-risk patients expect to resume their everyday lives rapidly post-procedure

**3 days of hospital stay with TAVI[8]**

compared to 7 days with surgery (*P*<0.001)

**96% discharged home from hospital with TAVI[8]**

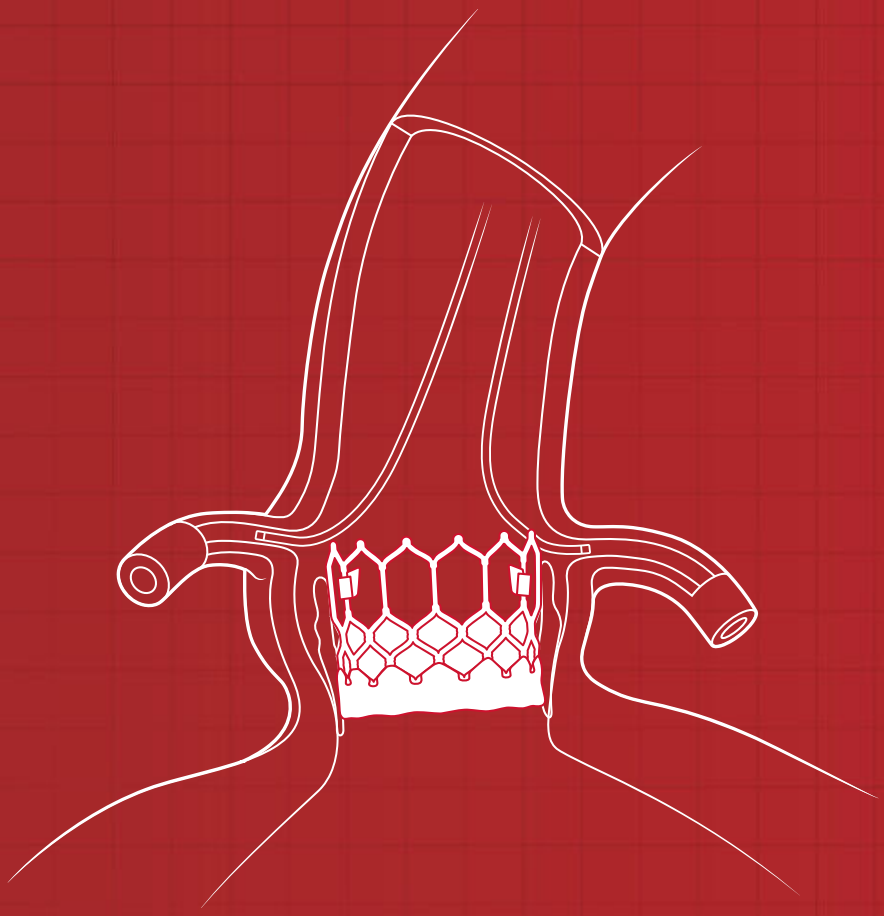
compared to 73.1% with surgery (*P*<0.001)

**1.4% rehospitalisation due to heart failure for TAVI patients at 1 year[8]**

compared to 3.6% with surgery (*P*<0.029)

# Engineered for the future

The SAPIEN 3 valve has a **short frame and large open cell design**, which supports easier future coronary access should your patient need to undergo a procedure post-TAVI.[9]



| SAPIEN 3 Valve | | | | |
|---|---|---|---|---|
| | 20 mm | 23 mm | 26 mm | 29 mm |
| Frame Height (mm) | 15.5 | 18.0 | 20.0 | 22.5 |
| Commissure Height (mm) | 13.1 | 15.3 | 16.9 | 19.1 |
| Inner Skirt Height (mm) | 7.9 | 9.3 | 10.2 | 11.6 |

# Give your patients the lowest-risk procedure with Edwards SAPIEN 3 TAVI[1]


**References:**

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(18):1695-1705.
2. Coylewright, M., et al. "Patient-defined goals for the treatment of severe aortic stenosis: a qualitative analysis." Health Expect.; 2016; 19:1036–1043
3. Baron SJ, Arnold SV, Wang, K, et al. Health status benefits of transcatheter vs surgical aortic valve replacement in patients with severe aortic stenosis at intermediate surgical risk: results from the PARTNER 2 randomized clinical trial. *JAMA Cardiol*. 2017;2(8):837-845.
4. Reynolds MR, Magnuson EA, Wang K et al. Health-related quality of life after transcatheter or surgical aortic valve replacement in high-risk patients with severe aortic stenosis. *J Am Coll Cardiol*. 2012;60(6):548-558.
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7. Smith CR, Leon MB, Mack MJ, et al. Transcatheter vs surgical aortic-valve replacement in high-risk patients. *N Engl J Med*. 2011;364(23):2187-2198.
8. The PARTNER 3 trial low-risk cohort 30-day and 1-year clinical event rates for TAVR with the SAPIEN 3 valve, AT population (n=950). 2015-08 PARTNER 3 Clinical Study Report. NCT02675114
9. Yudi MB, Sharma SK, Tang GHL, Kini A. Coronary angiography and percutaneous coronary intervention after transcatheter aortic valve replacement. *JACC*. 2018;71(12):1360-1378.


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