

SAPIEN 3 TAVI

# Superior to surgery for low-risk patients with severe aortic stenosis\*



With more than a decade of evidence in randomised clinical trials, transcatheter aortic valve implantation (TAVI) with the SAPIEN 3 system is now approved for use in patients with severe aortic stenosis, **independent of surgical risk.**

**Give your low-risk patients the lowest risk procedure**

\*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.<sup>1</sup>

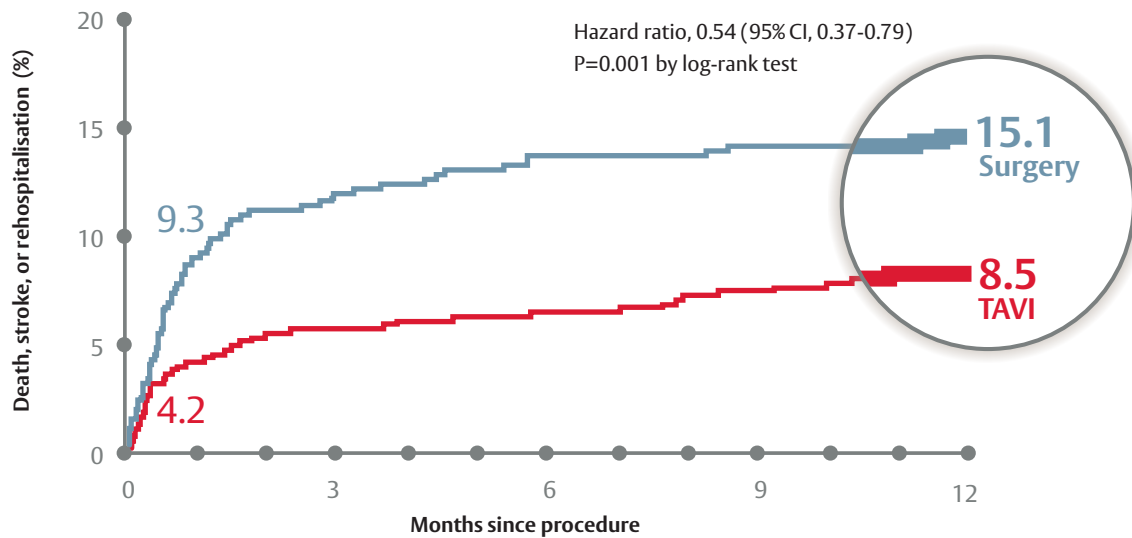


Edwards

# You can give your low-risk patients the lowest risk procedure with Edwards SAPIEN 3 TAVI

In low risk-patients, the PARTNER 3 Trial proves **SAPIEN 3 TAVI is superior to surgery on the composite primary endpoint** (all-cause death, all stroke, and rehospitalisation) and multiple pre-specified secondary endpoints at 1 year.<sup>1</sup>

Time-to-event curve for primary composite endpoint



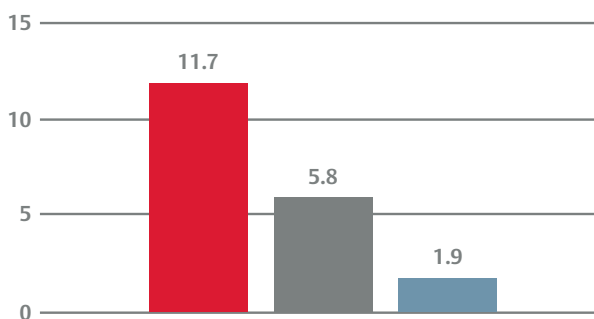
No. at risk

	0	3	6	9	12	
Surgery	454	408	390	381	377	374
TAVI	496	475	467	462	456	451

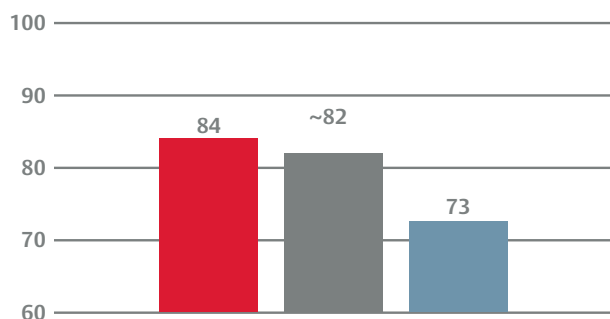
Figure adapted from Mack MJ, et al. 2019

Low surgical risk patients, compared with higher-risk patients, are often younger, healthier and more active, with fewer comorbidities. This is reflected in the population of the PARTNER 3 Trial compared with previous PARTNER trials:

Mean STS score



Mean age



PARTNER 3 Trial - Low-risk (n=1000)<sup>1</sup> ■  
 PARTNER IIA Trial - Intermediate-risk (n=2032)<sup>2</sup> ■  
 PARTNER IA Trial - High-risk (n=699)<sup>3</sup> ■

In the PARTNER 3 Trial, SAPIEN 3 TAVI demonstrated:

**99%** freedom from death at 1 year<sup>1</sup>

**99%** freedom from death or disabling stroke at 1 year<sup>1</sup>

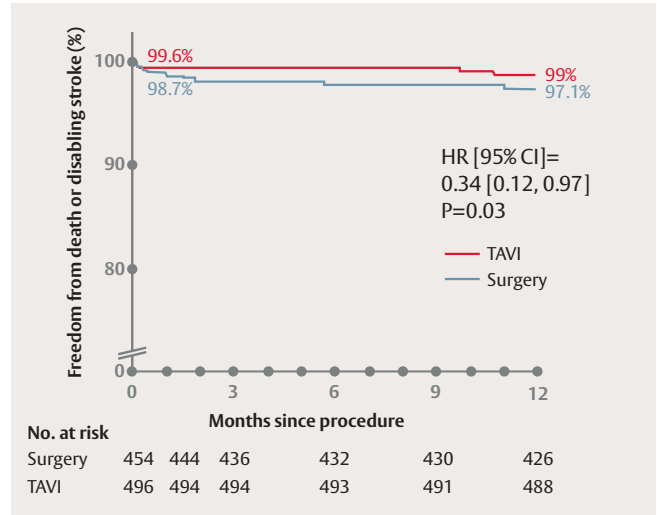
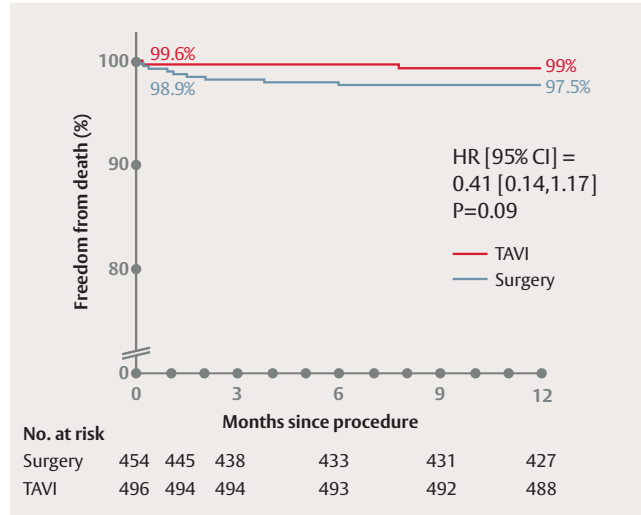





Figure adapted from Mack MJ, et al. 2019

With SAPIEN 3 TAVI, your low-risk patients can rapidly resume their everyday lives and avoid post-procedure complications<sup>1</sup>

**SAPIEN 3 TAVI**

 <p><b>Hospital stay with TAVI</b></p>	 <p><b>Discharged home after TAVI</b></p>	 <p><b>Rehospitalisation due to heart failure after TAVI</b></p>
<p><b>3 days</b> compared to 7 days with surgery (P&lt;0.001)<sup>1</sup></p>	<p><b>96%</b> compared to 73.1% with surgery (P&lt;0.001)<sup>1</sup></p>	<p><b>1.4%</b> at 1 year compared to 3.6% with surgery (P=0.029)<sup>4</sup></p>

# Patients experience sustained quality of life improvements with SAPIEN 3 TAVI<sup>5</sup>

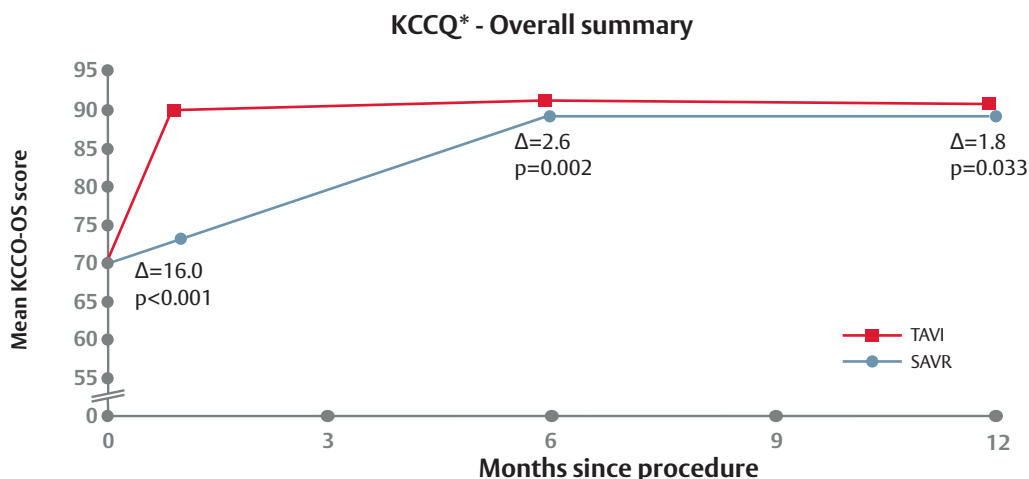


Figure adapted from Baron et al. 2019

SAPIEN 3 TAVI provides your patients with significantly greater health status benefits one month after the procedure, compared to surgery. **SAPIEN 3 TAVI is also associated with significantly improved late health status benefits at 12 months**, compared to surgery in this low-risk population.<sup>5</sup>

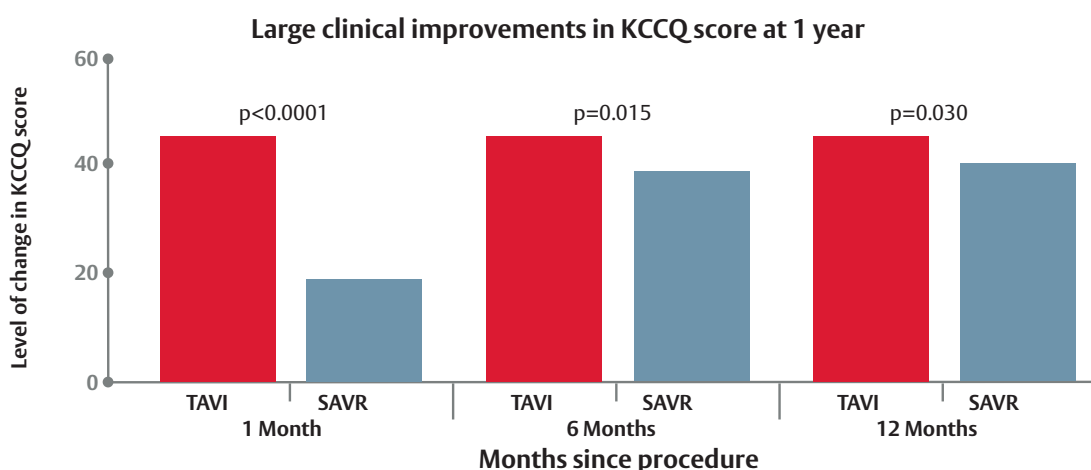


Figure adapted from Baron et al. 2019

**SAPIEN 3 TAVI can now help more patients than ever**

\*Defined as patients with Kansas City Cardiomyopathy Questionnaire Overall Summary (KCCQ-OS) Score > 20 points improvement from baseline

Abbreviations: TAVI: transcatheter aortic valve implantation; STS: Society of Thoracic Surgeons

**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. Leon M.B, Smith C.R, Mack MJ. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. 2016;374(17):1609-162
3. Mack MJ, Leon MB, Smith CR, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. Lancet. 2015; 385 (9986), 2477-84
4. Data on file at Edwards Lifesciences
5. Baron SJ, et al. Health Status after Transcatheter vs. Surgical Aortic Valve Replacement in Low-Risk Patients with Aortic Stenosis [published online ahead of print, 2019 Sep 18]. J Am Coll Cardiol.2019;50735-1097(19)37633-8. doi:10.1016/j.jacc.2019.09.007

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).

Edwards devices placed on the European market meet the requirements for bearing the CE marking of conformity.

Edwards, Edwards Lifesciences, the stylized E logo, Edwards SAPIEN, Edwards SAPIEN 3, PARTNER, PARTNER II, PARTNER 3, SAPIEN, and SAPIEN 3 are trademarks or service marks of Edwards Lifesciences Corporation. All other trademarks are the property of their respective owners.

© 2019 Edwards Lifesciences Corporation. All rights reserved. E10318/10-19/THV

Edwards Lifesciences • Route de l'Etraz 70, 1260 Nyon, Switzerland • edwards.com



Edwards