# Controlling for the future Edwards SAPIEN 3 Ultra valve facilitates future coronary access

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

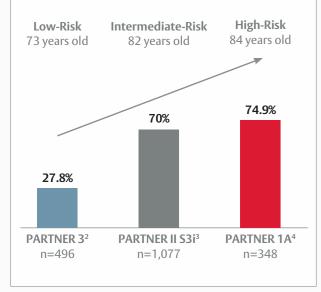


Edwards

# Your first-time valve choice today affects your patients' treatment options tomorrow.

Up to 75% of severe aortic stenosis patients undergoing TAVI suffers of CAD\* and may require future coronary intervention.<sup>1</sup>

#### Prevalence of CAD in TAVI patients.



Future intervention may be performed under limited TAVI experience.<sup>5</sup>

**78%** of PCI centers do not have a TAVI program<sup>5</sup>

>54% of the population live closer to a PCI-only center<sup>5</sup>



As post-TAVI PCI procedures increase in number, valve design becomes of primary importance.



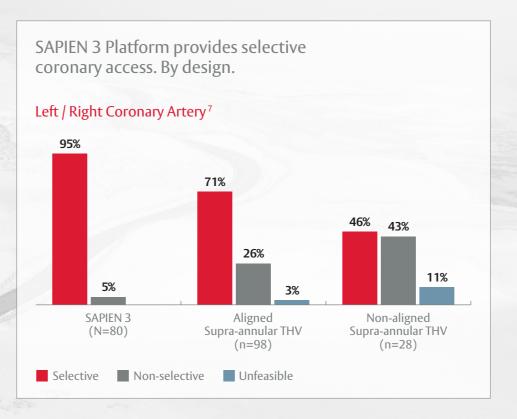
マ

VS.

~33% longer PCI procedure time in patients with prior TAVI<sup>6</sup>

**16.5%** PCI procedures failure in sAS patients with prior TAVI<sup>6</sup>

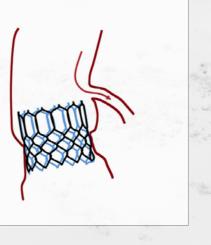
**3.9%** PCI failures in patients with no TAVI<sup>6</sup> (p < 0.001)



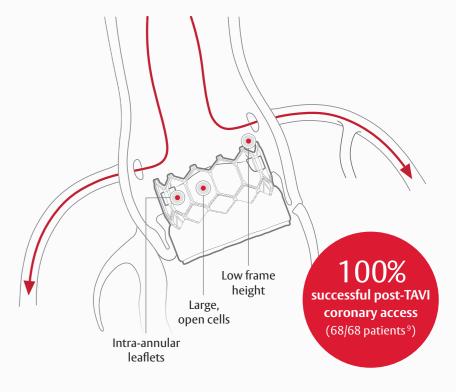
Choosing SAPIEN 3 valve as the first THV reduces the risk of impaired coronary access.

### 78.8%

free access to coronaries<sup>8</sup> after 2<sup>nd</sup> implant in low surgical risk population (N=137)



The SAPIEN 3 Ultra valve facilitates future coronary access with low frame height, intra-annular leaflets, and large open cells.<sup>(+)</sup>





## Edwards SAPIEN 3 Ultra valve CE Mark for Valve in Valve <sup>10</sup>

- THV in THV aortic
- THV in surgical aortic
- THV in surgical mitral

# Protect your patients by preserving their future treatment options with SAPIEN 3 Ultra valve. Your Higher Standard.

1. Yudi MB, Sharma SK, Tang GHL, Kini A. Coronary angiography and percutaneous coronary intervention after transcatheter aortic valve replacement. J Am Coll Cardiol. 2018;71(12):1360-1378

- 2. 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
- 3. Thourani VH, et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. Lancet. 2016 May 28;387(10034):2218-25
- 4. Smith CR, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. 2011 Jun 9;364(23):2187-98;
- 5. Frost & Sullivan. Changing Demographics and Reimbursement Policies to Generate Opportunities for Private Sector Growth. European Cardiac Catheterization Labs Market. 2016. Data on file.
- 6. Faroux L, Lhermusier T, Vincent F, et al. ST-Segment Elevation Myocardial Infarction Following Transcatheter Aortic Valve Replacement. JACC. 2021. VOL 77 (17).
- 7. Tarantini G, et al. Coronary Access After Transcatheter Aortic Valve Replacement With Commissural Alignment: The ALIGN-ACCESS Study, Circ Cardiovasc Interv. 2022 Feb;15(2):e011045
- 8. Rogers T, Greenspun B, Weissman G, et al. Feasibility of Coronary Access and Aortic Valve Reintervention in Low-Risk TAVR Patients. JACC. 2020. VOL 13 (16);
- 9. 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. DOI: 10.1161/CIRCINTERVENTIONS.120.008972
- 10. IFU Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System (2022-09)

(+) De Backer O, Landes, U, Fuchs A, et al. Coronary access after TAVR-in-TAVR as evaluated by computed tomography. JACC. 2020; 13 (21).

Ochiai T, Chakravarty T, Yoon S, et al. Coronary access after TAVR. JACC. 2020;13(6).

Tarantini G, Fovino LN. Coronary access after TAVR-in-TAVR Don't Put off Until Tomorrow What You Can Do Today. JACC. 2020;13 (21

Fovino LN, Scotti A, Massussi M, et al. Coronary Angiography After Transcatheter Aortic Valve Replacement (TAVR) to Evaluate the Risk of Coronary Access Impairment After TAVR-in-TAVR. J Am Heart Assoc. 2020.

Yudi, MB, Sharma SK, et al. Coronary Angiography and Percutaneous Coronary Intervenetion after TAVR. JACC. 2018:1360-78. (\$6079

Tarantini G, Fovino LN. Coronary Access and Percutaneous Coronary Intervention Up to 3 Years After Transcatheter Aortic Valve Implantation With a Balloon-Expandable Valve. Circulation, 2020, VOL 13 (7).

#### Medical device 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, Edwards Lifesciences, the stylized E logo, Edwards SAPIEN, Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, PARTNER, PARTNER II, PARTNER 3, SAPIEN, SAPIEN 3, and SAPIEN 3 Ultra are trademarks or service marks of Edwards Lifesciences Corporation or its affiliates.

© 2022 Edwards Lifesciences Corporation. All rights reserved. PP--EU-5186 v1.0

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

