

ACURATE neo2™
Aortic Valve System

**Boston
Scientific**
Advancing science for life™



Precision today, access tomorrow.



From routine, to challenging.

A valve as versatile as your cases.

Uniquely designed with an **open-frame** and **supra-annular leaflets**, the ACURATE *neo2*TM Valve delivers the performance you expect today, without restricting the access you demand tomorrow.¹

The ACURATE *neo2* Aortic Valve System is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

1. Reobtain Coronary Ostia Cannulation Beyond Transcatheter Aortic Valve Stent (RE-ACCESS); NCT04026204. *J Am. Coll. Cardiol. Interv.* 2020.

Why TAVI practitioners are switching to the ACURATE *neo2* Valve:



Trusted outcomes.

- Best-in-class PPI
- Single-digit gradients
- Advanced PVL performance

Unrestricted design.

- Unrestricted coronary access
- Long-term hemodynamics
- Engineered to last

Precise procedures.

- Smooth deliverability
- Predictable alignment
- Accurate positioning

Hybrid benefits deliver the “best of both”.

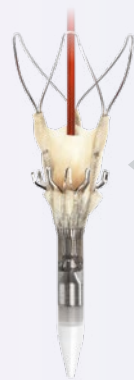
The first of its kind, ACURATE *neo2* is the only valve designed to offer the best benefits of both supra- and intra- valve platforms.

Open-frame design

Provides unrestricted access for future interventions

Supra-annular leaflets

Achieves large EOAs and single-digit gradients¹



Active PVseal™

60% larger* sealing skirt conforms to the native aortic annulus

Accurate positioning

Upper- and lower-crown anchoring provides first-time, precise procedures



*Next-generation ACURATE *neo2* Valve vs. ACURATE *neo*™ Valve

1. Möllmann H, Holzhey DM, Hilker M, et al. The ACURATE *neo2* Valve System for transcatheter aortic valve implantation: 30-day and 1-year outcomes. *Clin Res Cardiol.* 2021;110:1912-1920.



Best-in-class PPI.

Lower your patients' risk of needing a pacemaker. With top-down deployment and upper- and lower-crown anchoring, ACURATE *neo2* minimizes LVOT protrusion to:¹

- Reduce the risk of new conduction disturbances
- Reduce patient length of stay

6%
new permanent
pacemaker rate*¹
*in hospital

ACURATE *neo2* permanent pacemaker rate among pacemaker-naïve patients at 30 days in the PMCF study: 6.5%²

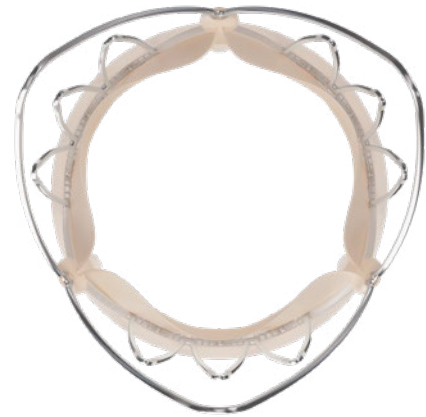
1. Early *neo2* Registry. Full Core-Lab Results of TAVI with the New ACURATE *neo2* Valve. TVT Congress. Presenter: Andreas Rück. July 20, 2021.
2. Kim W., et al; Clinical outcomes of the ACURATE *neo2* transcatheter heart valve: a prospective, multicenter, observational, post-market surveillance study, *EuroIntervention* 2022. DOI: 10.4244/EIJ-D-22-00914



 **Trusted outcomes**

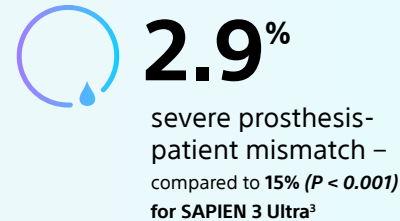
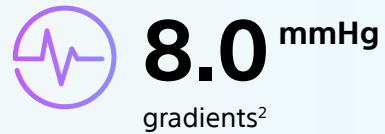
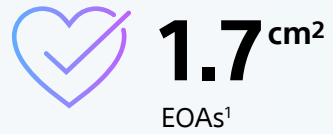
Single-digit gradients.

Protect your patient's future. Minimize the risk of patient-prosthesis mismatch, even in patients with small annuli.



Supra-annular leaflets help you deliver **large EOAs** and **low mean gradients**.

See the evidence.



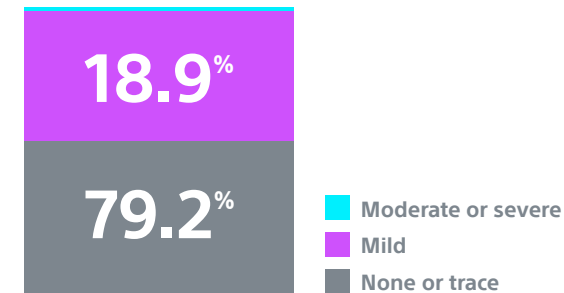
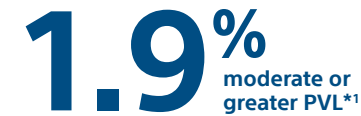
ACURATE neo2 mean aortic gradients at 30 days in the PMCF study: 8.6mmHg. ACURATE neo2 mean effective orifice area at 30 days in the PMCF study: 1.6 sq. cm³

- Möllmann H, Holzhey DM, Hilker M, et al. The ACURATE neo2 Valve System for transcatheter aortic valve implantation: 30-day and 1-year outcomes. *Clin Res Cardiol.* 2021;110:1912-1920.
- Early neo2 Registry. Full Core-Lab Results of TAVI with the New ACURATE neo2 Valve. TVT Congress. Presenter: Andreas Rück. July 20, 2021.
- Kim W., et al; Clinical outcomes of the ACURATE neo2 transcatheter heart valve: a prospective, multicenter, observational, post-market surveillance study, *EuroIntervention* 2022. DOI: 10.4244/EIJ-D-22-00914

 **Trusted outcomes**

Advanced PVL performance.

Protect against PVL with the ACURATE neo2 Valve's advanced sealing skirt:



- * At 30-days, Echocardiographic and CT imaging independently core lab adjudicated
- Kim W., et al; Clinical outcomes of the ACURATE neo2 transcatheter heart valve: a prospective, multicenter, observational, post-market surveillance study, *EuroIntervention* 2022. DOI: 10.4244/EIJ-D-22-00914



Active PVseal™ conforms to native valve annulus



 **Unrestricted design**

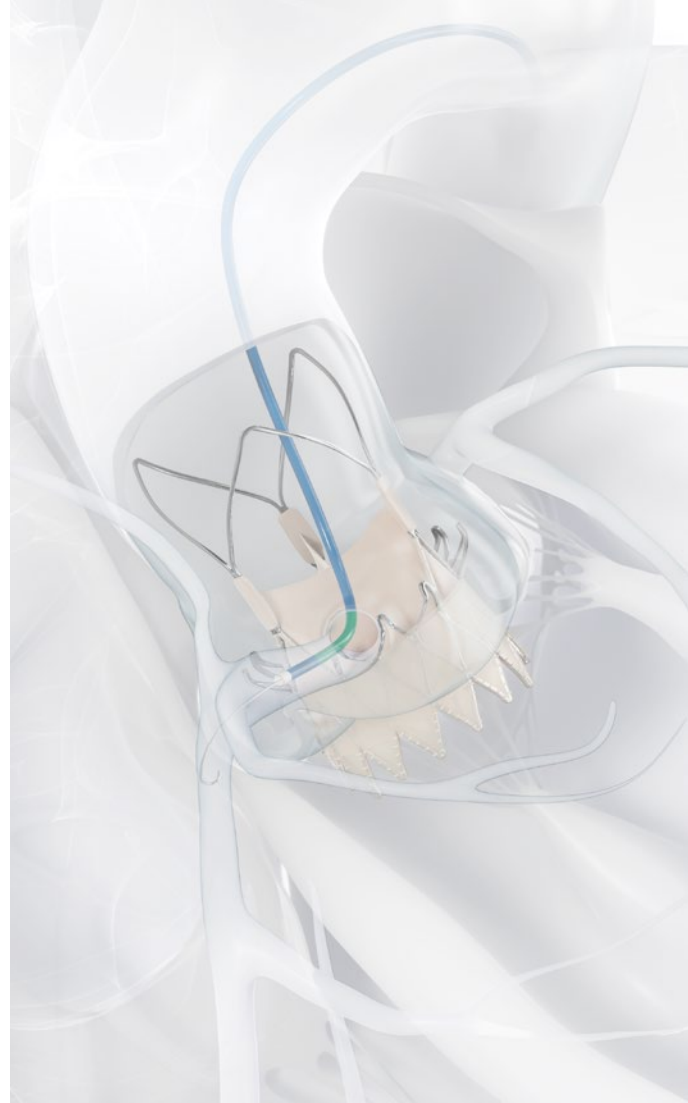
Unrestricted coronary access.

Lower-risk TAVI requires preserved future access.¹
STEMI following TAVI resulted in:

- **4x higher PCI failure rate**
- **33% increased mortality rate²**

100%	82%	99%
ACURATE neo™ Valve platform	Evolut™ R/PRO	SAPIEN
100% successful coronary cannulation n = 72	82% successful coronary cannulation n = 123	99% successful coronary cannulation n = 96

1. Reobtain Coronary Ostia Cannulation Beyond Transcatheter Aortic Valve Stent (RE ACCESS); NCT04026204. *J Am Coll Cardiol Interv.* 2020.
2. Faroux L, et al. ST-Segment Elevation Myocardial Infarction Following Transcatheter Aortic Valve Replacement. "https://www.jacc.org/journal/jacc" *J Am. Coll. Cardiol.* 2021 May, 77 (17) 2187 -2199.



 **Unrestricted design**

Long-term hemodynamic function.¹

Reduce the risk of valve deterioration and improve long-term cardiac function with a self-expanding, supra-annular design.²

Excellent durability.³

Supra-annular leaflets treated with BioFix™ anti-calcification process are designed with your patient's lifetime in mind.⁴

Accelerated wear testing equivalent to 25 years demonstrated robust wear resistance and excellent hydrodynamic performance³

1. Siqueira DA, Simonato M, Ramos AA, et al. Mid- to long-term clinical and echocardiographic outcomes after transcatheter aortic valve replacement with a new-generation, self-expandable system. *Catheter Cardiovasc Interv.* 2021.
2. Flameng, W, et al. Prosthesis-Patient Mismatch Predicts Structural Valve Degeneration in Bioprosthetic Heart Valves. *Circulation.* 2010; 121:2123-2129.
3. Sathanathan et al., Long-Term Durability of the Next-Generation Acurate neo 2, *Am. Coll. Cardiol. Interv.* 2020 JACC, Vol. 14, NO. 5, 2021 MARCH 8, 2021:583-92.
4. Anderson-Cunanan C et al, Calcification Assessment of the BSC-Symetis Valve Leaflet Material Treated with the Biofix™ Process *Am. Coll. Cardiol. Interv.* 2019, JACC CI, Vol. 12, NO. 4, 2019 FEB 2019, 535-936.

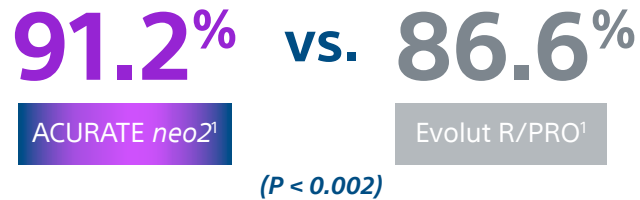


 Precise procedures

Smooth deliverability.

Expect uncompromised deliverability even in small and tortuous anatomies with low-profile iSLEEVE™* Expandable Introducer Sheath and intuitive, top-down deployment with the ACURATE neo2™ Valve.

 Superior device success among patients with horizontal aortas:



* The iSLEEVE Expandable Introducer Sheath is indicated for vessels \geq 5.5mm.
1. Gallo F, Gallone G, Kim W-K, et al. Horizontal aorta in transcatheter self-expanding valves: Insights from the HORSE International Multicentre Registry. *Circ Cardiovasc Interv.* 2021;14(9):e010641.

 Precise procedures

Predictable alignment.

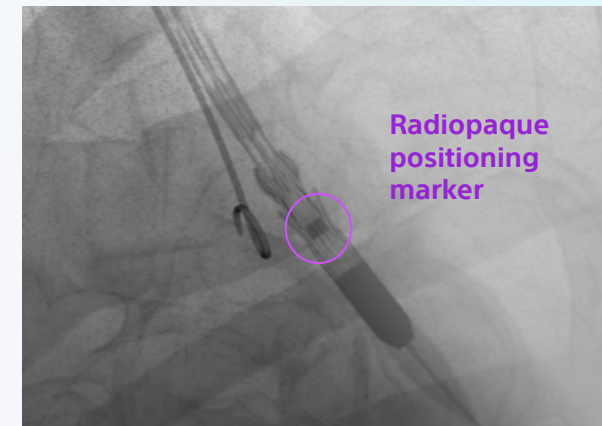
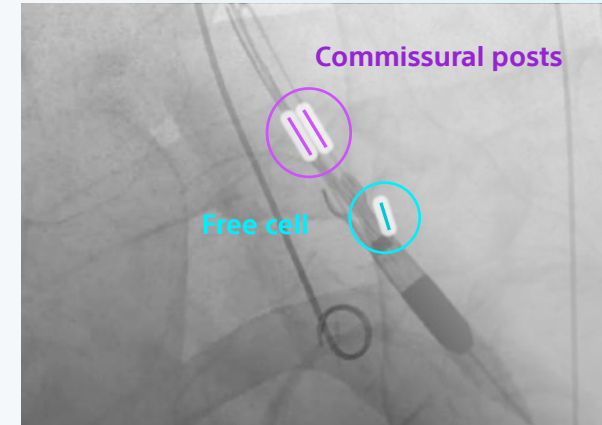
ACURATE neo2™ was the only valve to **100%** avoid moderate or severe commissural misalignment.¹

Precise positioning.

Easy-to-spot radiopaque positioning marker ensures enhanced visualization for delivering short procedures and high success rates.²



1. Bieliauskas G, Wong I, Bajoras V, et al. Patient-specific implantation technique to obtain neo-commissural alignment with self-expanding transcatheter aortic valves. *JACC Cardiovasc Interv.* 2021;14(19):2097-2108.
2. Möllmann H, Holzhey DM, Hilker M, et al. The ACURATE neo2 valve system for transcatheter aortic valve implantation: 30-day and 1-year outcomes. *Clin Res Cardiol.* 2021;110(12):1912-1920.
3. Kim W., et al; Clinical outcomes of the ACURATE neo2 transcatheter heart valve: a prospective, multicenter, observational, post-market surveillance study, *EuroIntervention* 2022. DOI: 10.4244/EIJ-D-22-00914



Ordering Information

Ref/Catalog Number	Description	Units
ACURATE neo2 Aortic Valves		
SYM-SV23-004	ACURATE neo2 Aortic Valve S	1
SYM-SV25-004	ACURATE neo2 Aortic Valve M	1
SYM-SV27-004	ACURATE neo2 Aortic Valve L	1
ACURATE neo2 Transfemoral Delivery System and Loading Kit		
SYM-DS-010	ACURATE neo2 Transfemoral Delivery System	1
SYM-AC-010	ACURATE neo2 Loading Kit	1
ACURATE neo2 Aortic Valve Generic Bundle Codes		
BUN67NEO2DSTF	Generic Bundle ACURATE neo2 Aortic Valve + Transfemoral Delivery System + Loading Kit	
BUN67NEO2DSTFIS14	Generic Bundle ACURATE neo2 Aortic Valve + Transfemoral Delivery System + Loading Kit + 14F iSLLEEVE	
BUN67NEO2IS14SAF	Generic Bundle ACURATE neo2 Aortic Valve + Transfemoral Delivery System + Loading Kit + 14F iSLLEEVE + SAFARI ²	
BUN67NEO2ISSAFSEN	Generic Bundle ACURATE neo2 Aortic Valve + Transfemoral Delivery System + Loading Kit + 14F iSLLEEVE + SAFARI ² + SENTINEL™	



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