



**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*<sup>™</sup> Valve delivers the performance you expect today, without restricting the access you demand tomorrow.<sup>1</sup>

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
- Built 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- annular valve platforms.

### Open-frame design

Provides unrestricted access for future interventions

### Supra-annular leaflets

Achieves large EOAs and single-digit gradients<sup>1</sup>



### 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.



Trusted outcomes

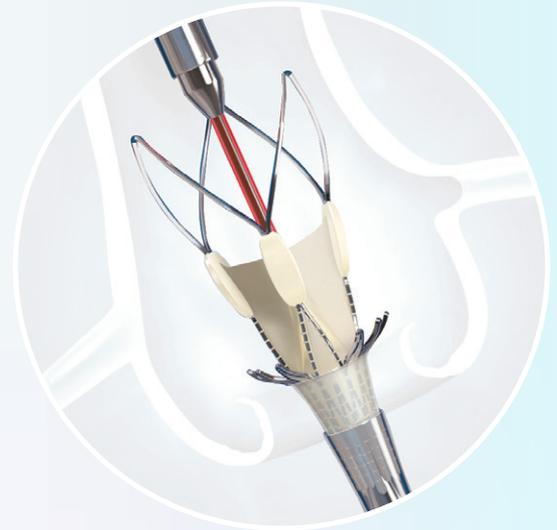
## Best-in-class PPI.

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

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

**6%**  
new permanent  
pacemaker rate\*<sup>1</sup>  
\*in hospital

1. Early *neo2* Registry. Full Core-Lab Results of TAVI with the New ACURATE *neo2* Valve. TVT Congress. Presenter: Andreas Rück. July 20, 2021.



**ACURATE *neo2***<sup>™</sup>  
Aortic Valve System



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.



**1.7** cm  
EOAs<sup>1</sup>



**8.0** mmHg  
gradients<sup>2</sup>



**1.4** %  
severe prosthesis-patient mismatch –  
compared to **16.2%** ( $P < 0.001$ )  
for SAPIEN 3 Ultra<sup>3</sup>

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.

2. Early neo2 Registry. Full Core-Lab Results of TAVI with the New ACURATE neo2 Valve. TVT Congress. Presenter: Andreas Rück. July 20, 2021.

3. Multicenter comparison of latest-generation self-expanding versus balloon-expandable transcatheter aortic valves. TCT Congress. Presenter: Won-Keun Kim. 2021.



Trusted outcomes

## Advanced PVL performance.

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

**2.7%**  
moderate or  
greater PVL<sup>1</sup>

**37.6%**

**59.6%**

 Moderate or severe

 Mild

 None or trace

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(12):1912-1920.



Active PVseal™ conforms to native valve annulus



**ACURATE *neo2***<sup>™</sup>  
Aortic Valve System



Unrestricted design

## Unrestricted coronary access.

Lower-risk TAVI requires preserved future access.<sup>1</sup>  
STEMI following TAVI resulted in:

- ▶ **4x higher PCI failure rate**
- ▶ **33% increased mortality rate<sup>2</sup>**

**100%**

ACURATE *neo*<sup>TM</sup>  
Valve platform

100% successful  
coronary  
cannulation  
n = 72

**82%**

Evolut<sup>TM</sup> R/PRO

82% successful  
coronary  
cannulation  
n = 123

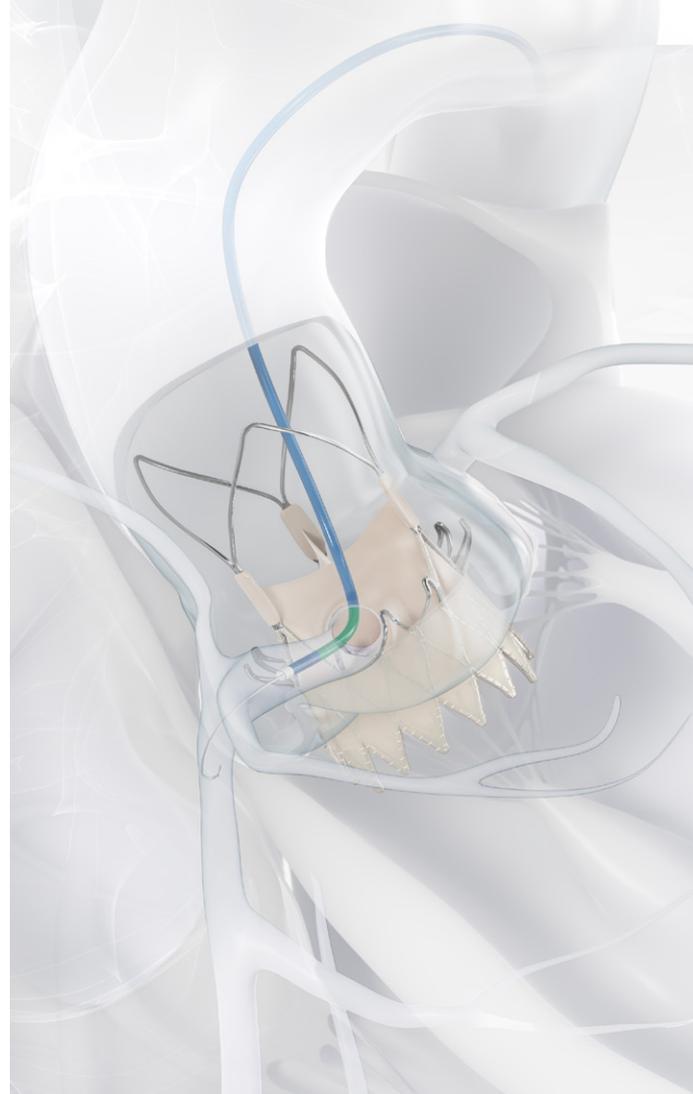
**99%**

SAPIEN

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.<sup>1</sup>

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

## Excellent durability.<sup>3</sup>

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

## Accelerated wear testing equivalent to 25 years demonstrated robust wear resistance and excellent hydrodynamic performance<sup>1</sup>



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:**

**91.2%** vs. **86.6%**

ACURATE neo2<sup>1</sup>

Evolut R/PRO<sup>1</sup>

( $P < 0.002$ )



\* The iSLEEVE Expandable Introducer Sheath is indicated for vessels  $\geq 5.5$ mm.  
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*<sup>TM</sup> was the only valve to **100%** avoid moderate or severe commissural misalignment.<sup>1</sup>

### Precise positioning.

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



**3.9 min.**

deployment time<sup>2</sup>

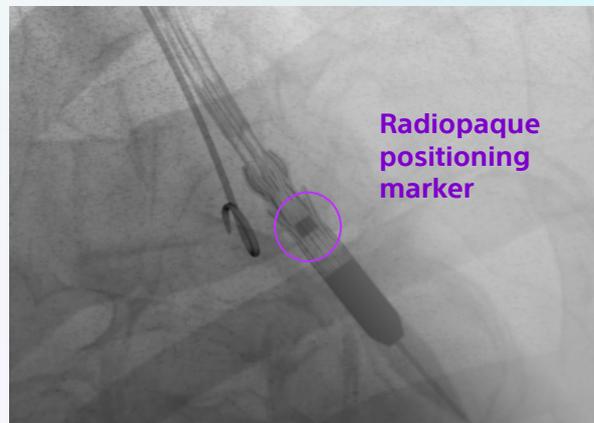
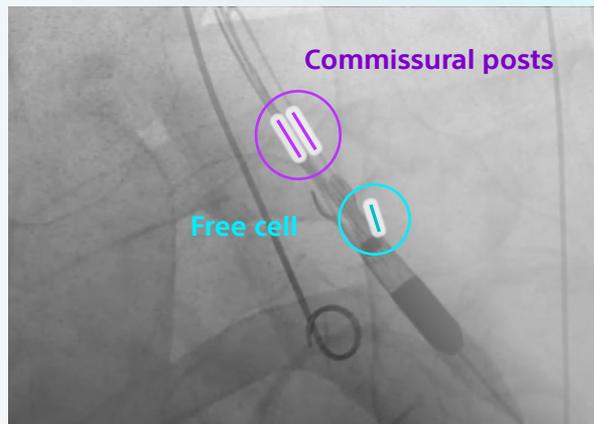


**97.5%**

procedural success<sup>2</sup>

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.



## Ordering Information

Ref/Catalog Number	Description	Units
<b>ACURATE neo2 Aortic Valves</b>		
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
<b>ACURATE neo2 Transfemoral Delivery System</b>		
SYM-DS-005	ACURATE neo2 Transfemoral Delivery System	1



Caution: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions of use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations. Illustrations for information purposes – not indicative of actual size or clinical outcome.

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