

ACURATE *neo2*™

Aortic Valve System

The Early neo2 Registry

1st Large Real-World Clinical Data

STUDY DESIGN

The Early neo2 Registry is an **investigator-initiated and conducted, single arm, 554 patient multi-center registry** that retrospectively assessed the ACURATE *neo2* valve's performance.

CLINICAL HIGHLIGHTS

LOW COMPLICATION RATES: The ACURATE *neo2* valve performed consistently in key patient outcomes:

BASELINE CHARACTERISTICS

n = 554

Age	82
Female	66%
Atrial Fibrillation	38%
Prior pacemaker	10%
EuroScore II	4.5%
STS score	3.7%
LVEF	56%
Aortic mean gradient	43 mmHg
Bicuspid	3%
Valve-in-valve	2%

1.3% MODERATE OR SEVERE PVL*

&

9mmHg
MEAN GRADIENT*

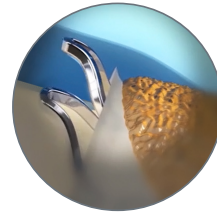
6.0%
NEW PERMANENT
PACEMAKER†

2.1%
STROKE RATE†
(major and minor)

1.3%
MORTALITY‡

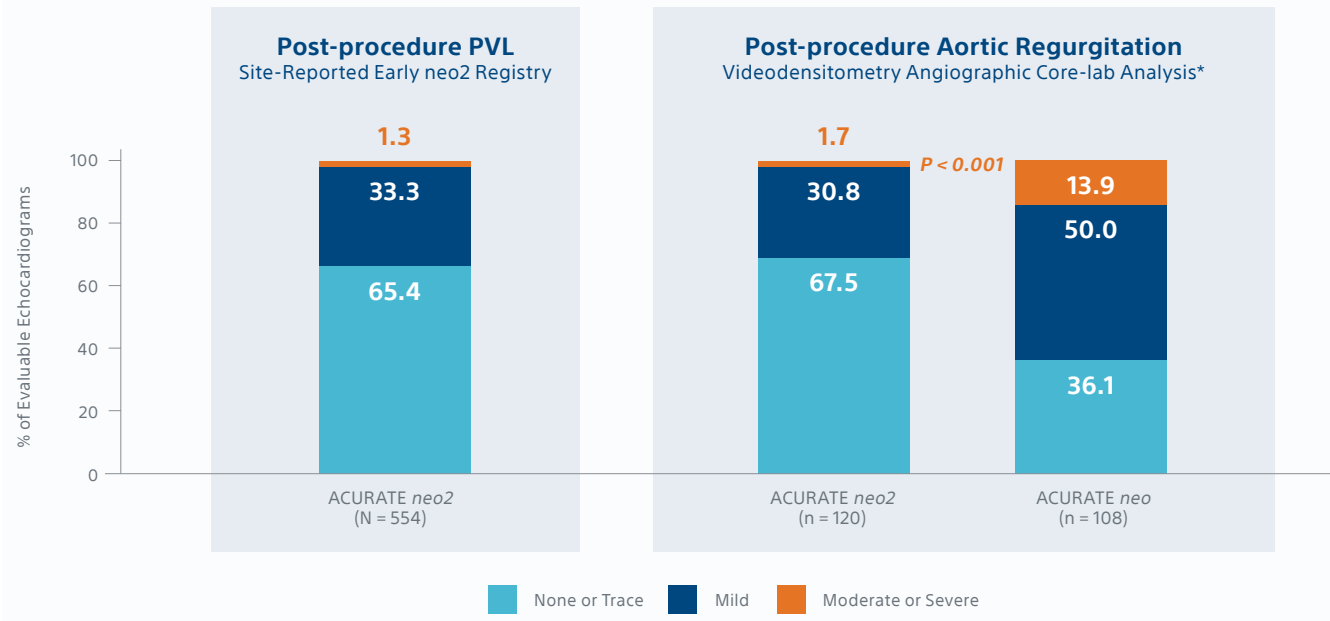
DEMONSTRATED PVL IMPROVEMENT^{1,2}

A separate core-lab adjudicated videodensitometry and angiography assessment of aortic regurgitation compared patients implanted with the ACURATE neo2 and ACURATE neo™ valves.



Active PVseal™: The ACURATE neo2 valve's extended sealing skirt conforms to the native valve annulus.

Separate assessment of ACURATE neo2 demonstrated significant aortic regurgitation reduction.



* n = 120 Early neo2 Registry patients implanted with ACURATE neo2 (Karolinska University Hospital and Kerckhoff Klinik), n = 108 patients implanted with ACURATE neo (Karolinska University Hospital)

KEY PROCEDURAL HIGHLIGHTS

PROCEDURAL COMPLICATIONS, n = 554

Second valve implanted	0.9%
Annular rupture	0.0%
Coronary obstruction	0.0%
Intraprocedural death	0.2%
Major vascular complication (in-hospital)	3.4%
Major or life-threatening bleeding (in-hospital)	4.8%
Acute kidney injury (AKIN grade 3)	0.2%

PROCEDURAL DATA, n = 554

General anesthesia	0.2%
Femoral access	99.6%
Pre-dilatation	87.0%
Post-dilatation	36.0%
Annulus size mm (average)	23.7**

** Small = 21%, Medium = 41%, Large = 38%

CONCLUSION

The results of the Early neo2 Registry reinforce the enhanced ability of the ACURATE neo2 valve with Active PVseal to minimize PVL.



Visit and learn more:
[bostonscientific.com/Earlyneo2Registry](https://www.bostonscientific.com/Earlyneo2Registry)

Continue optimizing TAVI, from access to outcomes.

0% Coronary Obstruction^{1,3,4} | Low PVL¹ | Low PPI¹ | Excellent Haemodynamics¹ | Low Complication Rates¹

Images for illustration purposes only, not indicative of actual size or performance

1. Rück A. Results from the Early neo2 registry Acurate neo2 TAVI valve. Euro PCR 2021 conference. 2021.
 2. Rück A. Quantitative Angiographic Assessment of Aortic Regurgitation Following the ACURATE neo2 Versus ACURATE neo – Valve Implantation. Euro PCR 2021 conference. 2021.
 3. Reobtain Coronary Ostia Cannulation Beyond Transcatheter Aortic Valve Stent (RE-ACCESS); NCT04026204 J Am Coll Cardiol Intv 2020.
 4. Möllmann H, Hengstenberg C, et al. Real-world experience using the ACURATE neo prosthesis: 30-day outcomes of 1,000 patients enrolled in the SAVI-TF registry. EuroIntervention. 2018;13:e1764-e1770.
 SH-1022714-AA