



## ACURATE *neo*<sup>™</sup>

Aortic Valve System

### MORENA Multicenter Comparison Study ACURATE *neo* vs. SAPIEN 3

Multicenter Comparison of Novel Self-expanding vs. Balloon-expandable Transcatheter Heart Valves

Husser O, et al. *JACC: Cardiovasc Interv.* 10.2078-2087. 10.1016/j.jcin.2017.06.026.

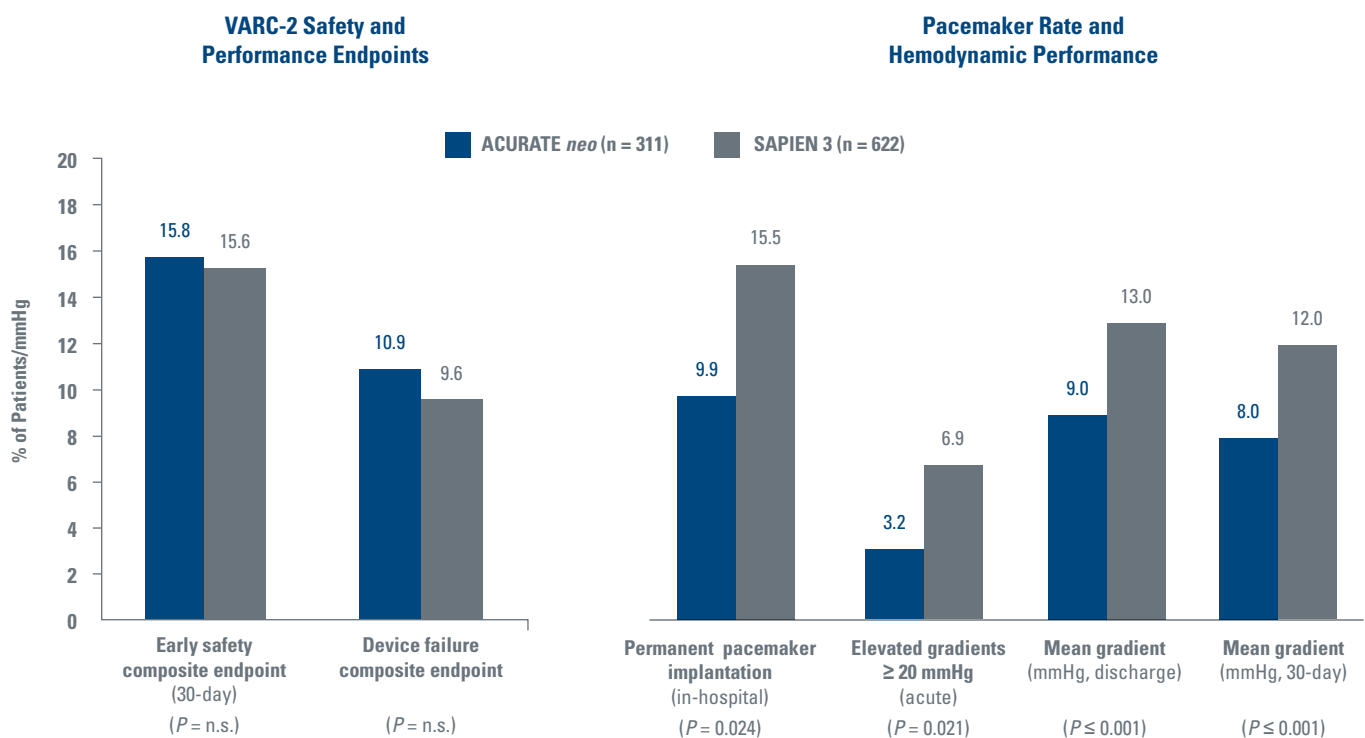
## Study Design

The MORENA Registry is the first head-to-head comparison of the ACURATE *neo* and SAPIEN 3 Aortic Valve Systems. This study evaluated device failure and early safety of both devices at 30 days. Observational 1:2 propensity-matched multicenter comparison of ACURATE *neo* (n = 311) and SAPIEN 3 (n = 622) from three high-volume centers in Germany.

## Clinical Highlights

**ACURATE *neo* comparable to SAPIEN 3 in key safety outcomes**  
 with no significant differences at 30 days in VARC-2 procedural, performance, and safety outcomes.

**ACURATE *neo* superior to SAPIEN 3 in hemodynamic performance and rate of permanent pacemaker implantation (PPI).**



## Key Results

### Device Failure (According to VARC-2)

	ACURATE <i>neo</i> n = 311	SAPIEN 3 n = 622	P Value
<b>Device Failure*</b>	10.9%	9.6%	0.539
Procedural mortality	1.0%	0.3%	0.340
Correct position	99.0%	99.0%	0.999
Intended performance†	90.0%	90.7%	0.753
PVL II +	4.8%	1.8%	0.008
Elevated gradient (≥ 20 mmHg)	3.2%	6.9%	0.021
Multiple valves	2.3%	1.1%	0.251
Conversion	1.6%	0.6%	0.170

\*Multiple events possible; counting only first event

†No prosthesis mismatch, mean aortic valve gradient < 20 mmHg, or peak velocity < 3 m/s, without moderate or severe prosthetic valve aortic regurgitation of the first implanted prosthesis

### Mortality and Safety at 30 days

	ACURATE <i>neo</i> n = 311	SAPIEN 3 n = 622	P Value
<b>Early Safety Composite Endpoint at 30 Days*</b>	15.8%	15.6%	0.941
All-cause mortality	2.3%	1.9%	0.742
Stroke (disabling, non-disabling, transient ischemic attack)	2.3%	3.1%	0.484
Coronary artery obstruction requiring intervention	0.6%	0.0%	0.046
Major vascular complication	10.3%	8.6%	0.710
Life-threatening bleeding	4.2%	4.4%	0.910
Acute kidney injury (AKIN 2/3, including renal replacement)	3.2%	2.8%	0.669
Valve-related dysfunction requiring repeat procedure (BAV, TAVR, SAVR)	0.3%	0.0%	0.159
New permanent pacemaker implantation†	10.2%	16.4%	0.018

\*Multiple events possible; counting only first event

†Excluding patients with pacemaker at baseline

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