Boston Scientific
Advancing science for life™

ACURATE *neo*™
Aortic Valve System

SAVI-TF POST-MARKET REGISTRY

Real-world Experience Using the ACURATE *neo* Prosthesis: 30-day Outcomes of 1,000 Patients Enrolled in the SAVI-TF Registry

Möllmann H, et al. *EuroIntervention.* 2018;13:e1764-e1770.

One-year Outcomes of the European Post-market Registry Using the ACURATE *neo* Transcatheter Heart Valve Under Real-world Conditions in 1,000 Patients

Kim WK, et al. *JACC: Cardiovasc Interv.* 2018;11(14):1368-74.

Study Design

European, single-arm, multicenter, all-comers registry, conducted at 25 centers, evaluating 1,000 patients following CE-marking of ACURATE *neo* between October 2014 and April 2016.

The SAVI-TF Post-market Registry was initiated to evaluate the safety and performance of the ACURATE *neo* Aortic Valve System in a large patient population treated according to the European clinical practice.

Clinical Highlights

High Procedural Efficiency

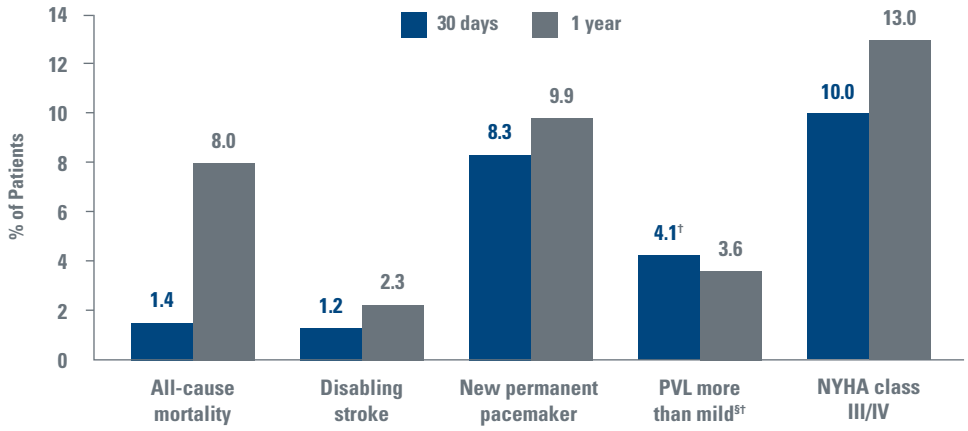
ACURATE *neo* showed high procedural success, low rates of complications, and short procedure times:

SAVI-TF POST-MARKET REGISTRY
N = 1,000 / 30-day outcomes

98.7%	6:34 mins	0.0%	1.2%	1.4%	8.3%
Procedural success	Average device usage time	Coronary obstruction*	Disabling stroke	All-cause mortality	New permanent pacemaker rate

*Requiring reintervention

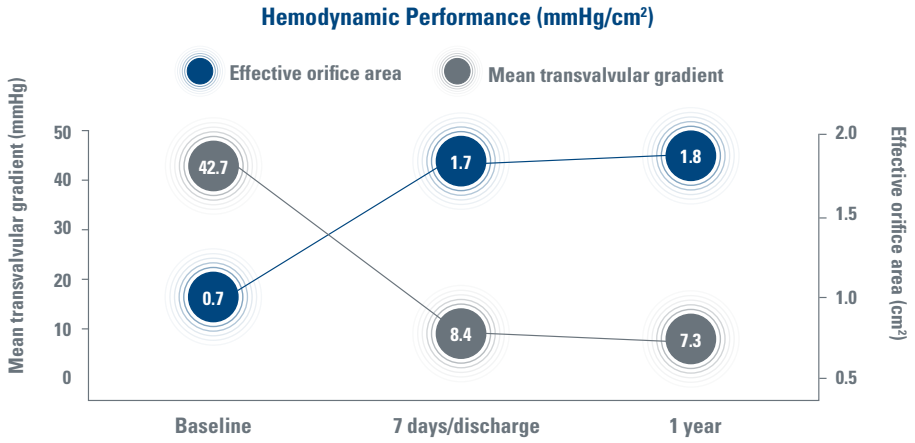
Clinical Summary



§ PVL more than mild was observed only in moderately and severely calcified annuli
† At discharge/7 days

Excellent Hemodynamic Performance

Large effective orifice areas and low transvalvular gradients at discharge and sustained at 1 year



Key Results

Echocardiographic Parameters	7 days/discharge	1 year
Effective orifice area (cm^2)	1.77 ± 0.46 (n = 416)	1.84 ± 0.43 (n = 257)
Mean aortic gradient (mmHg)	8.4 ± 4.0 (n = 807)	7.3 ± 3.7 (n = 484)
Aortic regurgitation	n = 844	n = 587
≤ Grade 1 (none to mild)	95.9%	96.4%
Grade 2 (moderate)	4.1%	3.4%
Grade 3 (moderate to severe)	0.0%	0.2%
Grade 4 (severe)	0.0%	0.0%

Clinical Outcomes	30 days/n = 998[a]	1 year/n = 983
Early safety[b]	**8.6%**	
Mortality cardiovascular	1.4% 1.0%	8.0% 3.5%
Stroke disabling	1.9% 1.2%	3.5% 2.3%
Life-threatening bleeding	1.3%	2.0%
Major bleeding	4.4%	
Acute kidney injury stage 2 or 3	1.3%	
Major vascular complication	3.2%	
Coronary obstruction requiring reintervention	0.0%	0.0%
Repeat procedure	0.0%	0.5%
Myocardial infarction	**0.3%**	**1.3%**
Endocarditis	**0.0%**	**0.8%**
Valve thrombosis	**0.0%**	**0.0%**
Cardiac tamponade	**0.4%**	
New pacemaker implantation	**8.3%**	**9.9%**

a) One patient withdrew consent after treatment; one did not return for 30-day visit.

b) A composite of all-cause mortality, all stroke, life-threatening bleeding, coronary obstruction requiring intervention, major vascular complication, acute kidney injury stage 2 or 3, and repeat procedure for valve-related dysfunction.

Boston Scientific
Advancing science for life™

www.bostonscientific.eu/ACURATE*neo*

SH-647903-AA Printed in Germany by medicalvision

DINSH0235EA