The ACURATE *neo*™ and *neo2*™ Valve Systems

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Based on the strength of data from randomized trials and real-world clinical studies, transcatheter aortic valve replacement (TAVR) has become a popular and effective alternative to surgical valve replacement in patients with symptomatic aortic stenosis. The ACURATE *neo*™ (Boston Scientific, Marlborough, MA, USA) valve system has been commercially available for transfemoral TAVR in Europe since 2014. ACURATE *neo2*™ is an evolution of the *neo* design and was declared CE marked by the manufacturer in 2020. The *neo* and *neo2* valves have been studied in high-risk patients, and the currently active randomized trial for *neo2* will include over 1,500 patients of all risk categories in the USA. The goal of this review is to help inform the TAVR community about the ACURATE valve.

Keywords

ACURATE *neo* valve system, transcatheter aortic valve replacement (TAVR), symptomatic aortic stenosis

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Transcatheter aortic valve replacement (TAVR) has seen worldwide explosive growth. The current USA guidelines no longer use risk in choosing between TAVR and surgical aortic valve replacement, and the European guidelines have extended the recommendation for TAVR to lower risk groups.[1,2] This rapid expansion has been driven by data from randomized trials showing TAVR as either non-inferior or superior to surgery.[3–6] The ACURATE *neo2*™ system (Boston Scientific, Marlborough, MA, USA) was declared CE marked by the manufacturer for use in Europe in higher-risk patients. The current ACURATE IDE trial (NCT03735667) will test the ACURATE *neo2* valve against commercially available valves in all risk categories in the USA.[7] This manuscript will discuss the valve system, the current data and why this valve may be a good choice in all risk groups, but particularly in younger, lower-risk patients.

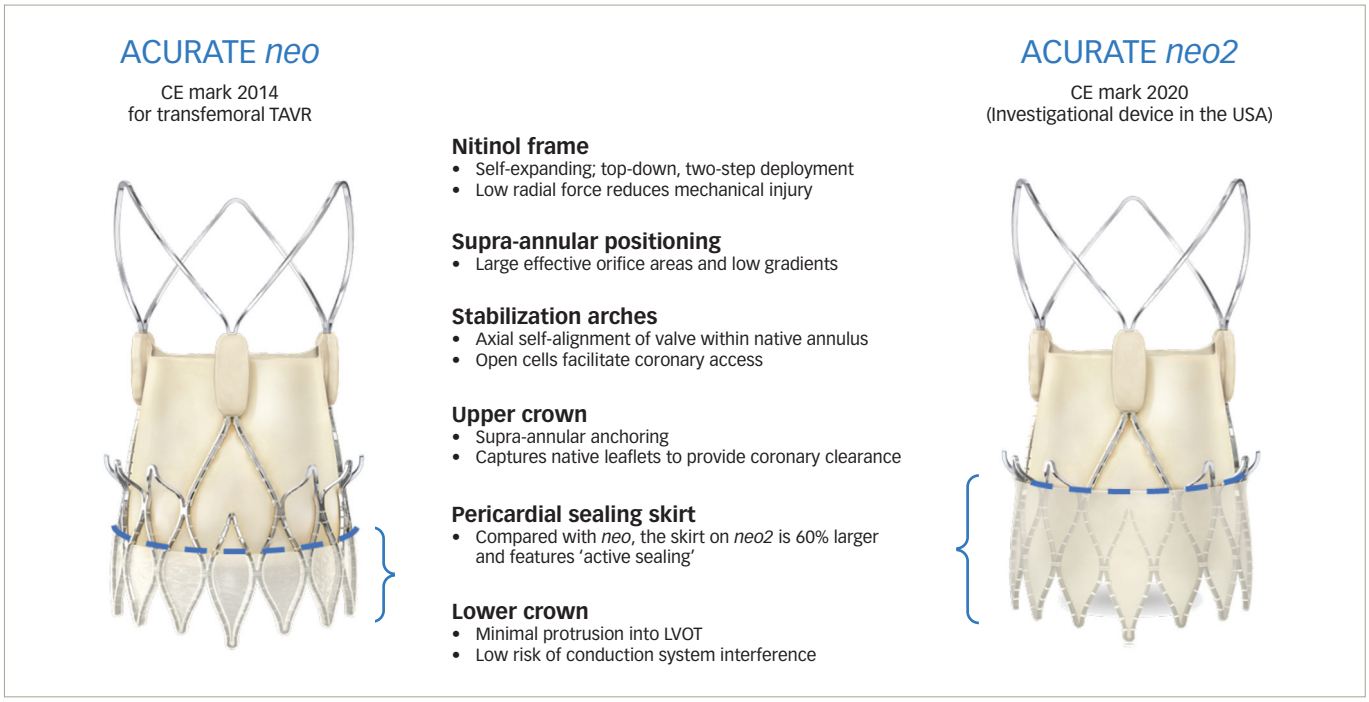
The ACURATE *neo2* valve maintains key features of the ACURATE *neo*™ while introducing new innovations designed to alleviate some of the most common complications of TAVR (*Figure 1*). The valve is comprised of a self-expanding nitinol frame with porcine pericardium leaflets in a supra-annular position, which favours large effective orifice areas (EOAs) and low transvalvular gradients.[8,9] The top-down, two-step deployment provides haemodynamic stability during the procedure, with annular co-axial alignment aided by the stabilization arches. The radial force exerted by the valve frame is relatively low, reducing the risk of annular rupture and mechanical injury during implantation.[8] The ACURATE *neo2* has an open-cell design, which facilitates coronary access, and the upper crown both anchors the valve to reduce the risk of embolization and captures the native valve leaflets to provide coronary clearance.[8,10] The lower crown of the valve protrudes minimally into the left ventricular outflow tract to reduce the risk of conduction system interference.[8,9]

While both the *neo* and *neo2* valves have a pericardial sealing skirt to reduce paravalvular leak (PVL), the skirt on the ACURATE *neo2* is 60% larger, reaching to the waist of the stent. Additionally, the flexible ACURATE *neo* delivery catheter has been upgraded with a new atraumatic tip design, and when coupled with the low-profile expandable introducer, is able to accommodate a wide range of complex patient anatomies. The ACURATE *neo2* also features a new radiopaque positioning marker to enhance visualization and accuracy. Valve sizing remains the same, with the largest valve treating up to a 27 mm annulus, and the addition of a larger valve planned. Valve crimping and loading remains essentially unchanged in the new system.

ACURATE clinical evidence

Initial safety and effectiveness of transfemoral TAVR with the ACURATE *neo* valve were demonstrated in the TF89 'CE-approval cohort' (NCT03003650) and confirmed by the 1,000-patient SAVI-TF post-market registry (NCT02306226).[11–13] SAVI-TF had a procedural success rate of 98.7%, with no instances of annular rupture, ventricular septal perforation or coronary obstruction requiring intervention, and no cases of endocarditis or valve thrombosis through 30 days. Patients exhibited favourable clinical outcomes – the 1-year mortality rate (8.0%) was comparable to that observed in large registries of Sapien 3 (Edwards Lifesciences, Irvine, CA, USA) (11.8% in SOURCE 3; NCT02698956), CoreValve (Medtronic, Minneapolis, MN, USA) (16.0% in ADVANCE ; NCT01074658), and Lotus (Boston

Figure 1: ACURATE valve family design features



Images provided courtesy of Boston Scientific.
LVOT = left ventricular outflow tract; TAVR = transcatheter aortic valve replacement.

Scientific, Marlborough, MA, USA) (11.7% in RESPOND; NCT02031302) – and the rate of permanent pacemaker implantation was low (8.3% at 30 days and 9.9% at 1 year).[14–19] Patients in SAVI-TF exhibited low gradients and large EOAs (*Table 1*), as expected for a supra-annular valve, and a low rate of moderate or greater PVL at hospital discharge (4.1%) and at 1 year (3.6%).[8,9,11-13,20–30]

A number of independent head-to-head studies have compared the ACURATE *neo* to contemporary competitor devices (*Table 1*). While the *neo* was shown to perform well over a variety of procedural and clinical outcomes, these studies have produced conflicting data regarding PVL. In two separate propensity-matched comparisons between the ACURATE *neo* and the Sapien 3, the MoRENA registry and a study by Mauri et al., there was no difference between the devices in terms of procedural success or safety outcomes.[20,21] In both of these studies, the ACURATE *neo* was less likely to result in patient–prosthesis mismatch, with significantly better transvalvular mean gradient and EOA compared with Sapien 3, and patients treated with the *neo* had a significantly lower rate of permanent pacemaker implantation. While the incidence of PVL grade ≥2 at discharge was significantly greater with the *neo* versus Sapien 3 in the MoRENA study (4.8% versus 1.8%, respectively; p=0.008), the difference between devices was not significant in the Mauri et al. study (4.5% versus 3.6%; p=0.208). The NEOPRO registry, which included a propensity-matched comparison of the ACURATE *neo* and Evolut PRO, likewise found no significant differences in procedural success or 30-day clinical safety outcomes between the matched pairs.[22] In this study, patients treated with the ACURATE *neo* had significantly higher AV gradients, but the incidence of moderate or greater PVL was similar between the two groups (7.3% versus 5.7%; p=0.584).

More recently, the SCOPE I (NCT03011346) and SCOPE II (NCT03192813) studies evaluated outcomes in patients randomized to treatment with the ACURATE *neo* versus the Sapien 3 and the Evolut™ R/PRO (Medtronic, Minneapolis, MN, USA), respectively.[23–26] In the SCOPE I study, the ACURATE *neo* did not meet non-inferiority criteria compared with the Sapien 3 on the 30-day composite primary endpoints of all-cause mortality, stroke, life-threatening/disabling bleeding, major vascular complications, coronary obstruction, acute kidney injury, rehospitalization, repeat intervention and valve dysfunction (23.7% versus 16.5%; p=0.42).[24,31] Patients treated with the ACURATE *neo* were at greater risk for acute kidney injury (3% versus 1%; p=0.03) and moderate or greater PVL (9.4% versus 2.8%; p<0.001) at 30 days. A secondary analysis found that, for the individual components of death, stroke, rehospitalization, bleeding and vascular complications, outcomes were not significantly different between the two devices at either 30 days or 1 year.[23,31] Conduction disturbances were low for both valves, with new permanent pacemaker implantation rates ≤10%, and patients in SCOPE I treated with the ACURATE *neo* had more favourable gradients and valve areas compared with those treated with the Sapien 3, which led to statistically lower rates of prosthesis–patient mismatch for the *neo* (p<0.001).[31]

In the SCOPE II study, the primary endpoint was all-cause death or stroke at 1 year, evaluated in both the intent-to-treat (ITT) and per-protocol populations to establish non-inferiority.[26] While the ACURATE *neo* did not meet non-inferiority criteria versus Evolut R/PRO in the ITT analysis (15.8% versus 13.9%; p=0.05), thus missing the primary endpoint, it did meet non-inferiority criteria in the per-protocol analysis (15.3% versus 14.3%; p=0.03).[25] Patients treated with the ACURATE *neo* were shown to have a greater risk for cardiac death at 30 days (2.8% versus 0.8%; p=0.03) and 1 year (8.4% versus 3.9%; p=0.01), as well as more frequent incidence of moderate or severe PVL at 30 days (9.6% versus 2.9%; p<0.001).[25] However, the ACURATE *neo* did demonstrate a statistically significant advantage over the Evolut on the secondary endpoint of permanent pacemaker implantation at 30 days (10.5% versus 18.0%; p=0.003) and 1 year (11.0% versus 18.3%; p=0.004).

The primary contributing factor to the ACURATE *neo* not achieving non-inferiority in the SCOPE studies was a greater incidence of moderate

Table 1: Key clinical studies of the ACURATE *neo*/*neo2*[8,9,11-13,20-30]

Study	Baseline characteristics			Clinical outcomes						Echocardiographic outcomes			
	Device (N)	Mean age (y)	STS score (%)	Early safety composite (%)	30 d major vascular complications (%)	30 d all-cause death (%)	1 y all-cause death (%)	30 d major/ disabling stroke (%)	30 d new PPI (%)	30 d mean AV gradient (mmHg)	30 d mean EOA (cm^2)	PVL grade ≥2 discharge /30 d (%)	PVL grade ≥2 1 y (%)
TF89 'CE-approval cohort' (NCT03003650)[11,12]	*neo* (89)	83.7	6.8 ± 4.1	15.7	3.4	3.4	22.5	2.2	10.3*	8.0 ± 2.9	1.8 ± 0.3	4.9	4.5
SAVI-TF (NCT02306226)[8,9,13]	*neo* (1,000)	81.1	6.0 ± 5.6	8.6	3.2	1.4	8.0	1.2	8.3	8.4 ± 4.0†	1.8 ± 0.5†	4.1†	3.6
MoRENA, matched population[20]	*neo* (311)	81	18 ± 10‡	15.8	10.3	2.3	--	2.3	10.2*†	12 ± 5	--	4.8†	--
	S3 (622)	81	18 ± 12‡	15.6	8.6	1.9	--	3.1	16.4*†	8 ± 4	--	1.8†	--
Mauri et al., matched population[21]	*neo* (92)	82.8	16.2 ± 8.8‡	6.5	2.2	1.1	8.3	3.3§	12.0	9.3 ± 3.9†	1.0 ± 0.3†	4.5†	3.9
	S3 (92)	81.9	16.6 ± 8.8‡	9.8	6.5	2.2	13.3	2.2§	15.2	14.5 ± 5.5†	0.8 ± 0.2†	3.6†	3.6
NEOPRO, matched population[22]	*neo* (251)	81.4	5.1 ± 3.1	10.6	4.9	3.2	--	2.0	11.0	8.3 ± 4.0†	--	7.3†	--
	Ev PRO (251)	81.6	5.3 ± 3.7	10.4	3.2	1.2	--	1.6	12.8	7.3 ± 3.6†	--	5.7†	--
SCOPE I (NCT03011346)[23,24,31]	*neo* (372)	82.6	3.7	--	8.0	2.0	11.1	2.0§	10.0	7.5 ± 3.7	1.8 ± 0.5	9.4	8.9
	S3 (367)	83.0	3.4	--	5.0	1.0	8.5	3.0§	9.0	11.2 ± 4.2	1.6 ± 0.4	2.8	3.6
SCOPE II (NCT03192813)[25,26]	*neo* (398)	83.4	4.6	--	--	3.0	13.0	2.0	10.5	--	--	9.6	4.0
	Ev R/PRO (398)	82.9	4.5	--	--	2.0	9.0	3.0	18.0	--	--	2.9	3.3
PROGRESS PVL (NCT02987894)[27,28]	*neo* (500)	81.8	6.0	9.2	3.6	2.2	11.3	2.4	10.2	6.7 ± 3.2	1.9 ± 0.6	4.6†	2.6
neo AS (NCT02909556)[29,30]	*neo*2	82.1	4.8	13.3	3.3	3.3	12.2	1.7	15.0	7.9 ± 3.2	1.7 ± 0.4	3.0	2.5

**Among PM-naïve patients; †Data reported at discharge/7 days post-TAVR; ‡Logistic EuroSCORE; §All stroke.*
AV = aortic valve; d = day; EOA = effective orifice area; Ev = Evolut; PPI = permanent pacemaker implantation; PVL = paravalvular leak; S3 = Sapien 3; STS = Society of Thoracic Surgeons; TAVR = transcatheter aortic valve replacement; y = year.

or greater PVL. Studies performed in a large single-centre cohort have shown that it is possible to reduce PVL rates for the ACURATE *neo* through careful attention to patient selection, including thoughtful sizing and consideration of aortic valve calcification.[32,33] In this cohort, the rate of PVL grade ≥2 at discharge was 3.7%.[33] Additionally, there appears to be a learning curve in the implantation technique. The PROGRESS PVL study (NCT02987894), which evaluated core laboratory-adjudicated echocardiographic data over time, included a large proportion of investigators with prior clinical experience with the ACURATE *neo*.[28] The rate of procedural complications was low and the valve was correctly positioned in 98.6% of patients.[27] As in prior *neo* studies, patients exhibited low transvalvular gradients and large EOAs overall. A paired analysis in a subset of patients (n=209) demonstrated improved PVL over the course of the study, with a rate of moderate or greater PVL of 4.3% at discharge and 2.9% at 1 year.[27]

In addition to patient selection and procedural considerations, the features incorporated into the next iteration of the ACURATE valve, *neo2*, are intended to reduce PVL in comparison to the prior generation ACURATE *neo* system. The addition of radiopaque markers to *neo2* helps to facilitate highly accurate valve positioning, and the enhanced and extended pericardial sealing skirt features a supra-annular flap that actively seals during each cardiac cycle. Clinical and echocardiographic outcomes in patients treated with the ACURATE *neo2* valve were investigated in the ACURATE *neo* AS study (NCT02909556).[29,30]

Patients in the ACURATE *neo* AS study achieved a high rate of procedural success (97.5%).[29,30] There were no reinterventions for valve-related dysfunction and a low rate of major vascular complications (3.3%). Safety outcomes were consistent with results from prior studies of the ACURATE *neo* and comparable to those observed in other TAVI studies in similar patient populations. The VARC-2 composite safety endpoint rate at 30 days was 13.3%, which was lower than prior studies of the ACURATE *neo* (15.8% in the MORENA study; 16.4% overall in the NEOPRO study). Core laboratory-adjudicated data demonstrated significant early haemodynamic improvement, maintained through 12-month follow-up.[29,30] The overall rate of moderate PVL at 30 days was 3.0%, comparable to the rate observed with the Sapien 3 (3.6% by Mauri et al.; 2.8% in SCOPE I) and the Evolut R/PRO (3.0% in SCOPE II), and an improvement over ACURATE *neo*.[21,25,31] Overall, the ACURATE *neo* AS study demonstrated the safety and performance of the ACURATE *neo2* valve in patients with severe aortic valve stenosis.

Recently, promising data on real-world outcomes with the ACURATE *neo2* was presented from two investigator-led European registries. The ITAL-neo Registry, which evaluated 95 patients treated with the ACURATE *neo2*, reported a low rate of in-hospital stroke (1.1%) and excellent valve haemodynamics (8.2 mmHg pre-discharge mean gradient).[34] In this study, 3.1% of patients exhibited moderate or greater PVL at discharge, 56.9% had mild PVL and 40% had no detectable PVL. The observed PVL rates for patients with data available at 30 days (34/95) were further reduced: 0% moderate or greater PVL, 53% mild PVL and 47% no PVL. In the Early neo2 Registry (NCT04810195), which collected data from 554 patients treated with the ACURATE *neo2*, patients had a low in-hospital stroke rate (2.1%), an in-hospital new PPI rate of 6%, excellent valve haemodynamics (post-procedural mean gradient of 9 mmHg) and a low 30-day mortality rate (1.3%).[35,36] According to site-reported, post-procedure echocardiographic data, 1.3% of patients exhibited moderate/severe PVL, 33.3% had mild PVL and 65.4% had no/trace PVL.[34] This study also included a retrospective analysis of core-lab adjudicated echocardiographic data from patients treated with the *neo* (n=108) versus the *neo2* (n=120).[36] The ACURATE *neo2* was associated with a 5.5% absolute risk reduction of aortic regurgitation fraction (p<0.001) and the rate of moderate or severe aortic regurgitation was significantly lower with the *neo2* compared with the *neo* (1.7% versus 13.9%; p<0.001).[36]

Summary

The ACURATE *neo2* valve builds on the strengths of the well-tested ACURATE *neo* platform. The flexible delivery catheter allows for trackability through tortuous anatomy; radiopaque markers help to refine positioning; and a simple two-step, top-down deployment method allows for stable and predictable release, making it a reliable and relatively easy-to-use device. This ease of use, evidenced in the high rate of procedural success and low peri-procedural complication rates observed in clinical studies, will be an advantage as TAVR procedures become more commonplace and are performed in a wider patient population.

Extension of TAVR to younger, more active patients will require consideration for features related to long-term valve performance. As a supra-annular valve, the ACURATE *neo* offers a high degree of haemodynamic performance, with larger EOA and lower gradients compared with valves with an intra-annular leaflet position. The stent's open-frame design allows for preservation of coronary access, which is particularly important for patients who may have follow-up procedures. As with all TAVR systems, the potential for re-intervention and valve-in-valve procedures should be considered; while TAVR-in-TAVR has been successfully performed with ACURATE, there is certainly a need for additional experience. The enhancements to the anti-leak skirt for ACURATE *neo2* may further decrease PVL, which will be investigated in prospective clinical studies, including the currently enrolling ACURATE IDE Study comparing the ACURATE *neo2* to either the Sapien 3 or the Evolut R/PRO.[7] Continued commitment to head-to-head studies of TAVR devices will be critical in evaluating longer-term outcomes in a widening, diversified patient population. ❑

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