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PROVE - ACURATE *neo2*™ Post Market Safety and Performance Surveillance in Aortic Stenosis - Registry

Designed to be the largest multi-center prospective study to evaluate safety, efficacy, and device performance of ACURATE *neo2* in an all-comer patient population with independent core lab analysis.

PROVE Registry Study Design

Multicenter, prospective, single-arm registry of N=1,044 patients with severe symptomatic aortic stenosis

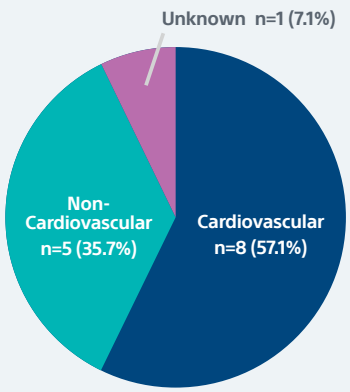
- 1,044 patients participated in the registry across 27 centers in Germany, France, Switzerland and Sweden
- **Inclusion Criteria:** Treatments of an all-comer population following the instructions for use (IFU) for the ACURATE *neo2* Aortic Valve System
- **The PROVE registry consisted of an all-comer patient population:**
  - 45.6% had a severe calcification pattern of the annulus
  - 2.5% bicuspid aortic anatomies
  - 0.8% with severe aortic regurgitation at baseline along with severe aortic stenosis
  - 0.3% TAV-in-SAV, and 0.1% TAV-in-TAV procedures performed

Primary Endpoint: All-cause mortality at 30 days

Additional Endpoints: All stroke, myocardial infarction, major vascular complications, severe bleeding, any acute kidney injury, new permanent pacemaker implantation, re-hospitalization

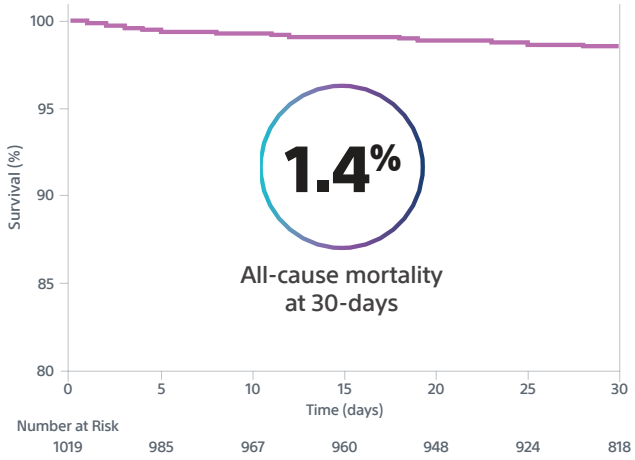
Primary Endpoint[1]

ACURATE *neo2* demonstrated a 1.4% all-cause mortality rate at 30 days in an all comer population.



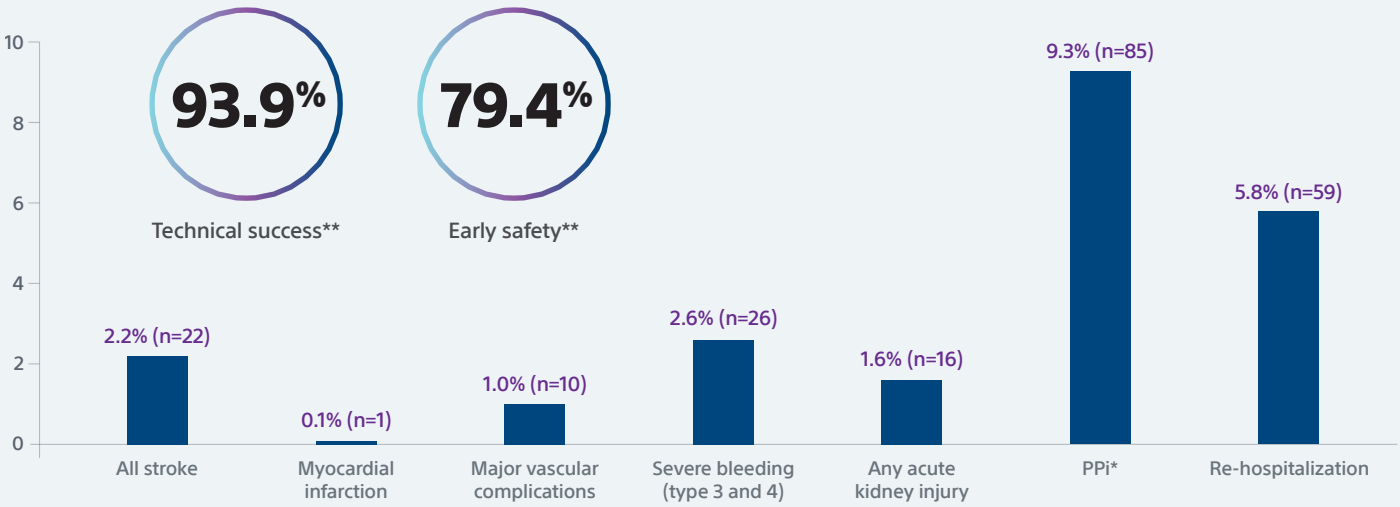
Cause of Death

30 Day Primary Endpoint: All-Cause Mortality

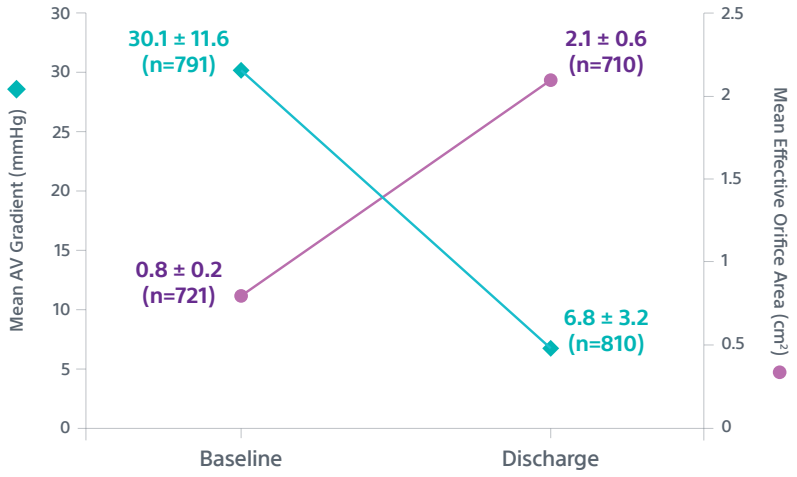


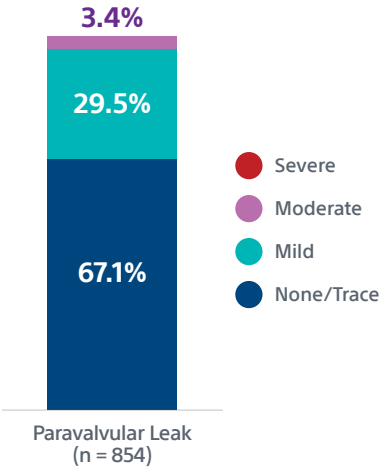
Additional Endpoints[1]

Key ACURATE *neo2*™ Clinical Endpoints at 30 Days



ACURATE *neo2* Haemodynamic Performance at Discharge***





1.4%
All-cause mortality at 30 days

88.0%
30 day device success**

6.8±3.2
Transvalvular gradient at discharge (mmHg)

9.3%
PPi at 30 days*

* Among pacemaker naive patients (n=911). ** Assessed per VARC-3 Criteria. *** Independent Core-Lab Image analysis.

These 20 patients were considered enrolled in the registry (Intent to Treat population) at the time they provided the consent, but did not receive ACURATE neo2 for various reasons – mostly logistical reasons.

1. The Prove - ACURATE *neo2* Post Market Safety and Performance Surveillance in Aortic Stenosis – Registry, Presented by Dr Holger-Thiele, EuroPCR 2024.

CAUTION: In Europe, ACURATE *neo2* Aortic Valve System is CE-marked. In the USA, ACURATE *neo2* is an investigational device and restricted under federal law to investigational use only. Not available for sale. The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

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