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:

1.3% MODERATE OR SEVERE PVL*

9 mmHg MEAN GRADIENT*

6.0% NEW PERMANENT PACEMAKER†

2.1% STROKE RATE† (major and minor)

1.3% MORTALITY‡

* Post-operative Echo, Site-Reported; † In-Hospital; ‡ 30-Days

BASELINE CHARACTERISTICS
n = 554

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<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Age</td>
<td>82</td>
</tr>
<tr>
<td>Female</td>
<td>66%</td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td>38%</td>
</tr>
<tr>
<td>Prior pacemaker</td>
<td>10%</td>
</tr>
<tr>
<td>EuroScore II</td>
<td>4.5%</td>
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<tr>
<td>STS score</td>
<td>3.7%</td>
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<tr>
<td>LVEF</td>
<td>56%</td>
</tr>
<tr>
<td>Aortic mean gradient</td>
<td>43 mmHg</td>
</tr>
<tr>
<td>Bicuspid</td>
<td>3%</td>
</tr>
<tr>
<td>Valve-in-valve</td>
<td>2%</td>
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**DEMONSTRATED PVL IMPROVEMENT**

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

Separate assessment of ACURATE neo2 demonstrated significant aortic regurgitation reduction.

![Post-procedure PVL](image)

**KEY PROCEDURAL HIGHLIGHTS**

**PROCEDURAL COMPLICATIONS, n = 554**

- Second valve implanted: 0.9%
- Annular rupture: 0.0%
- Coronary occlusion: 0.0%
- Intra-procedural 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%

**CONCLUSION**

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

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

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

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