S-ICD: A SAFE AND EFFECTIVE SOLUTION

S-ICD has major safety advantages over TV-ICD systems: the data shows that 99.7% of patients experienced freedom from complications in the first 30 days after implant, and 98% were complication-free after the first year.

Crucially, during the mean follow-up period, there were:

- Zero endovascular infections
- Zero systemic infections
- Zero electrode failures.

Summary

- After 3.1 years of follow-up, the S-ICD demonstrates safety & efficacy comparable to studies with TV-ICDs, and avoids the serious complications associated with TV-ICD leads in the heart.
- S-ICD demonstrated superior discrimination for AF and SVT compared to rates reported for TV-ICD.5,6
- In this population of patients the need for ATP was rare.
- Results were consistent across all subgroups: S-ICD therapy is appropriate for a wide range of patients.

**EFFORTLESS Midterm Outcomes**

This S-ICD registry analysing over 3 years of follow-up in ~1000 patients demonstrates safety & efficacy comparable to studies with TV-ICDs, and avoids the serious complications associated with TV-ICD leads in the heart. The EFFORTLESS registry is collecting outcomes in 985 patients during a 5 year follow-up (82 patients have completed the protocol-defined 5 year follow-up).

**THE EFFORTLESS COHORT INCLUDED A WIDE RANGE OF PATIENTS**

Patients were registered at multiple European centres and had diverse demographic and clinical characteristics.

**PREVENTION INDICATION**

- Primary Cardiac Disease
- Patient Characteristics

<table>
<thead>
<tr>
<th>Overall (N= 985)</th>
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<tbody>
<tr>
<td>Duration of follow up, yrs</td>
</tr>
<tr>
<td>Age at implantation, yrs</td>
</tr>
<tr>
<td>Male</td>
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<tr>
<td>BMI, kg/m²</td>
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<tr>
<td>Ejection fraction, %</td>
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<td>QRS duration, ms</td>
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**IMPLANT PROCEDURE**

**Procedural Characteristics (N= 985)**

| Implant time (skin-to-skin) | 67 minutes (+/- 20) |
| Early (11-16 implants) | 73 minutes (+/- 32) |
| Late (>16 implants) | 60 minutes (+/- 22) |

**Anaesthesia (GA, Concious sedation, local)**

- General anaesthesia 60.4 %
- Conscious sedation 33.6 %
- Local anaesthesia 19.0 %

**Other Primary**

- Ischaemic 11 %
- Non-ischaemic 19 %

**Ischaemic**

- Channel-opathy 19 %
- Other 19 %

**Other Primary**

- Other 19 %
- Other 19 %

**Low EF < 35 %**

- Other Primary 31 %
- Primary Low EF 31 %
- Secondary 35 %

**HCM**

- Hypertrophic Cardiomyopathy 32 %

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EFFORTLESS 3-YEAR RESULTS
Results were consistent across all age groups and subgroups in the study, including ischaemic and non-ischaemic cardiac disease, and primary and secondary prevention patients.

The 3.4% annual rate of appropriate shocks was similar to the rate in ATP-enabled TV-ICD devices, demonstrating that S-ICD only treats the most clinically important ventricular arrhythmias.2,4

5.3% of IAS rates (with S-ICD, at 1 year) was due to cardiac oversensing, particularly T-wave oversensing. Only 7.6% of the EFFORTLESS cohort had second generation S-ICD detection algorithms designed to reduce IAS due to cardiac oversensing.

Modelling of EFFORTLESS episodes with the SMART Pass algorithm, a high pass digital filter designed to reduce IAS due to T-wave oversensing, reduced IAS to 3.8% (at 1 year). Equivalent to rates seen in TV-ICD studies.5-8

Actual EFFORTLESS episodes were modelled using SMART Pass technology (generation 2.5 S-ICD).

Combining the cohorts with recurrent MVT and those exchanged for ATP would lead to 0.9% (annualised) of patients who might have benefitted from ATP.

INAPPROPRIATE THERAPY FOR AF/SVT WAS LOWER THAN RATES REPORTED FOR STUDIES WITH TV-ICD
EFFORTLESS data shows that S-ICD delivers appropriate shocks for spontaneous VT/VF with over 97% efficacy.1

Inappropriate shock rates (IAS) were similar to rates from TV-ICD registries in patients of a similar age, despite the fact that nearly one third of the patients in this registry had inherited cardiac diseases known to have inappropriate shock rates up to 22% in studies with TV-ICDs.5-8

S-ICD performs better than TV-ICD in:1,9
- Detecting SVT
- Detecting AF
- Appropriately withholding therapy

AF= atrial fibrillation; SVT= supraventricular tachycardia

Only 1.5% (at 1 year) of patients experienced IAS due to SVT or AF.

SMART PASS DECREASES THE RATE OF IAS
Modelling of EFFORTLESS episodes with the SMART Pass algorithm, a high pass digital filter designed to reduce IAS due to T-wave oversensing, reduced IAS to 3.8% (at 1 year). Equivalent to rates seen in TV-ICD studies.5-8

Results clearly showed that development of a new need for pacing or ATP was low.1

<table>
<thead>
<tr>
<th>Reason S-ICD extraction</th>
<th>Nr. of patients</th>
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<tbody>
<tr>
<td>New pacing requirement</td>
<td>1 (0.1%)</td>
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<tr>
<td>New ATP indication</td>
<td>5 (0.5%)</td>
</tr>
<tr>
<td>New CRT indication</td>
<td>4 (0.4%)</td>
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Smart Pass decreases the rate of IAS by 71% caused by oversensing and 57% overall IAS rate.

OUTCOMES AFTER S-ICD IMPLANTATION: 1-YEAR
Freedom from S-ICD Complication (1 Year) 98.0%
Freedom from inappropriate Shock for AF/SVT (1 Year) 98.5%
No Change to TV-ICD 98.9%
Shock Efficacy 97.4%