

## 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:<sup>1</sup>

**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.<sup>5-9</sup>
- 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.

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CRM-490401-AB AUG2017 Printed in Germany by medicalvision.

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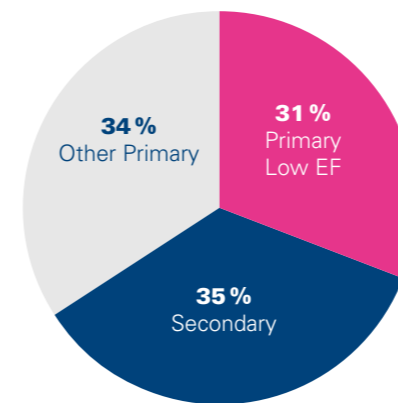
## EFFORTLESS Midterm Outcomes<sup>1</sup>

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

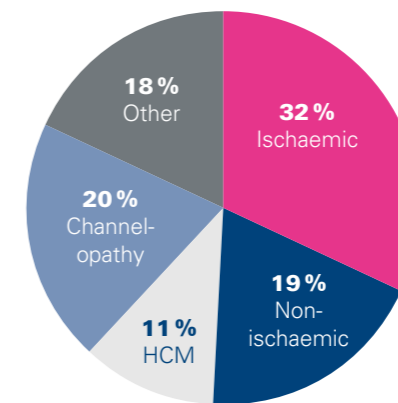
Patients were registered at multiple European centres and had diverse demographic and clinical characteristics.

#### PREVENTION INDICATION



Low EF ≤ 35%

#### PRIMARY CARDIAC DISEASE



HCM= Hypertrophic Cardiomyopathy

#### PATIENT CHARACTERISTICS

	Overall (N= 985)
Duration of follow up, yrs	3.1 ± 1.5
Age at implantation, yrs	48 ± 17
Male	709 (72.0)
BMI, kg/m <sup>2</sup>	27 ± 6
Ejection fraction, %	43 ± 18
QRS duration, ms	106 ± 25

### IMPLANT PROCEDURE

	Procedural Characteristics (N= 985)
Implant time (skin-to-skin)	67 minutes (+/- 20)
Early (1 - 16 implants)	73 minutes (+/- 32)
Late (>16 implants)	60 minutes (+/- 22)
Anaesthesia (GA, Conscious sedation, local)	
General anaesthesia	60.4 %
Conscious sedation	33.6 %
Local anaesthesia	6 %
Dual zone programming (at implant)	86 %

## 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.<sup>2-4</sup>

Only **2.2%** of patients experienced more than one episode of MVT over 3 years, and this did not correlate with ischaemic heart disease.

Reason S-ICD extraction	Nr. of patients
New pacing requirement	1 (0.1 %)
New ATP indication	5 (0.5 %)
New CRT indication	4 (0.4 %)



**Results clearly showed that development of a new need for pacing or ATP was low.<sup>1</sup>**

ATP= anti-tachycardia pacing  
 CRT= cardiac resynchronisation therapy  
 MVT= monomorphic VT

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.<sup>1</sup>

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.<sup>5-8</sup>

**S-ICD performs better than TV-ICD in:<sup>1,9</sup>**

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.

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.

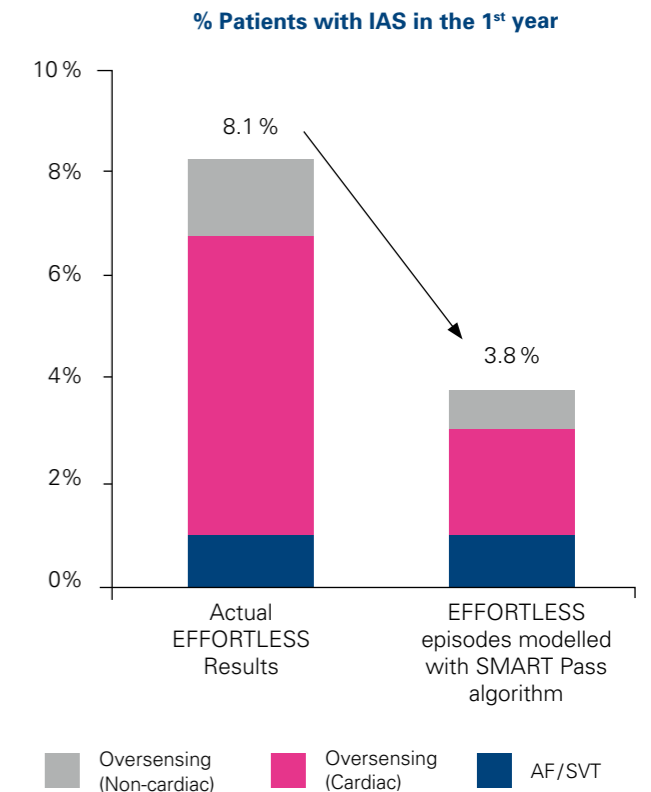
## SMART PASS DECREASES THE RATE OF IAS

Modelling of EFFORTLESS episodes with the SMART Pass algorithm, a high pass digital filter designed to reduce IAS due to TWOs, reduced IAS to **3.8%**<sup>10</sup> (at 1 year). Equivalent to rates seen in TV-ICD studies.<sup>5-8</sup>

**SMART Pass would have resulted in:<sup>6</sup>**

Reduction in IAS caused by oversensing	71 %
Reduction in any IAS	57 %
Overall IAS rate	<b>3.8%</b>

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



## OUTCOMES AFTER S-ICD IMPLANTATION: 1-YEAR

