ASSURE® WCD Clinical Evaluation Post-Approval Study (ACE-PAS)

ace Post Approval Study

Findings from the largest real-world evaluation of wearable defibrillators demonstrate strong safety and effectiveness in clinical practice

PROVEN EFFECTIVENESS & VALIDATED SAFETY

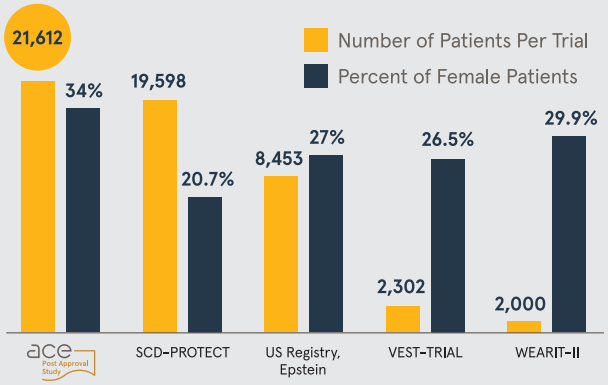
PRIMARY ENDPOINTS ACHIEVED

100%
All-shock Conversion

0.0065
Inappropriate Shocks Per Patient Months

97% First-shock Conversion

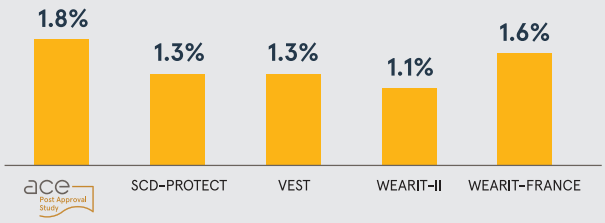
LARGEST TRIAL & BROADEST REPRESENTATION



40% of indicated patients are female[1]

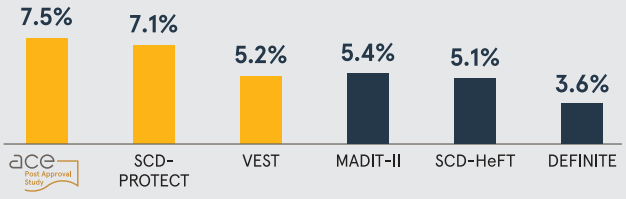
EARLY SUDDEN CARDIAC DEATH (SCD) RISK REMAINS HIGH IN NEWLY DIAGNOSED PATIENTS

90 DAY INCIDENCE RATE



Newly diagnosed patients are at significant risk of SCD during the first 90 days

ANNUALIZED INCIDENCE COMPARED TO ICD TRIALS



Landmark ICD trials show a comparable, or lower, risk of SCD

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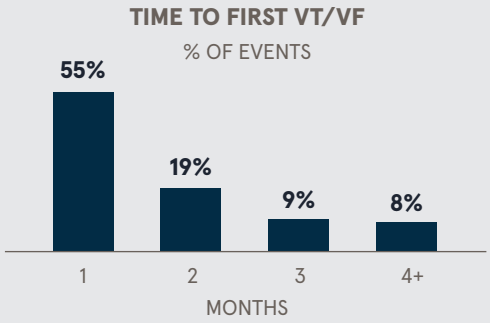
WCDS DELIVER CLINICALLY ACTIONABLE INSIGHTS

Detection of high rates of ventricular and atrial arrhythmias provides actionable data to guide timely intervention.

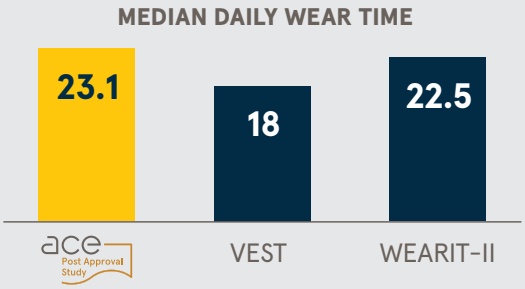
2.6% of patients had ≥ 1 VT or VF

4.2% of patients had high-rate, wide-complex AF (>170 bpm & ≥ 80ms R-wave)

The ACE-PAS investigators did not adjudicate all SVT/AF episodes. Only SVT episodes that triggered a tachyarrhythmia detection were adjudicated for AF. More patients are likely to have experienced AF/SVT that wasn't detected.



DEMONSTRATED STRONG PATIENT COMPLIANCE & AN IMPROVED PATIENT EXPERIENCE



94% of ASSURE patients are free from false alarms

87% fewer patients experience false alarms[2,3]

Disclaimer: A controlled, head-to-head study evaluating the comparative performance of these devices has not been done.

30% Patients wore the device for longer than 90 days, demonstrating effective protection for extended therapy optimization

Download the ACE-PAS Abstract Presented at AHA25

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1 Holle, Sarah L.D., et al. JACC: Advances, vol. 4, no. 10, Oct. 2025, p. 102056.
2 Poole JE, et al. Primary results from the post approval study of a next generation wearable cardioverter defibrillator system: the ACE-PAS trial. Circulation. 2025;152(suppl 3):[page numbers].
3 Arkles, J. et al. *J Interv Card Electrophyiol*. 2023;66(7):1723-1728.

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