

Primary Results from the ASSURE WCD Clinical Evaluation Post Approval Study (ACE-PAS)

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#AHA25

On Behalf of the ACE-PAS Steering & Events Committee

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Background

Wearable Cardioverter Defibrillator (WCD) for Sudden Cardiac Death Protection

ICD explant or
bridge to transplant

Sustained VT/VF or
SCD Survivor

Post MI,
LVEF \leq 35%
– wait 40 days

Post PCI/CABG –
wait 90 days

Newly diagnosed HF
– wait 90 days

ICD indicated, but delayed
Level IIa¹

ICD not yet indicated to allow for reassessment
Level IIb¹

- WCD's provide non-invasive, short-term protection against SCD
- Next generation WCD technology provides opportunity for contemporary data regarding the SCD risk of these patient populations

Study Device: ASSURE WCD¹

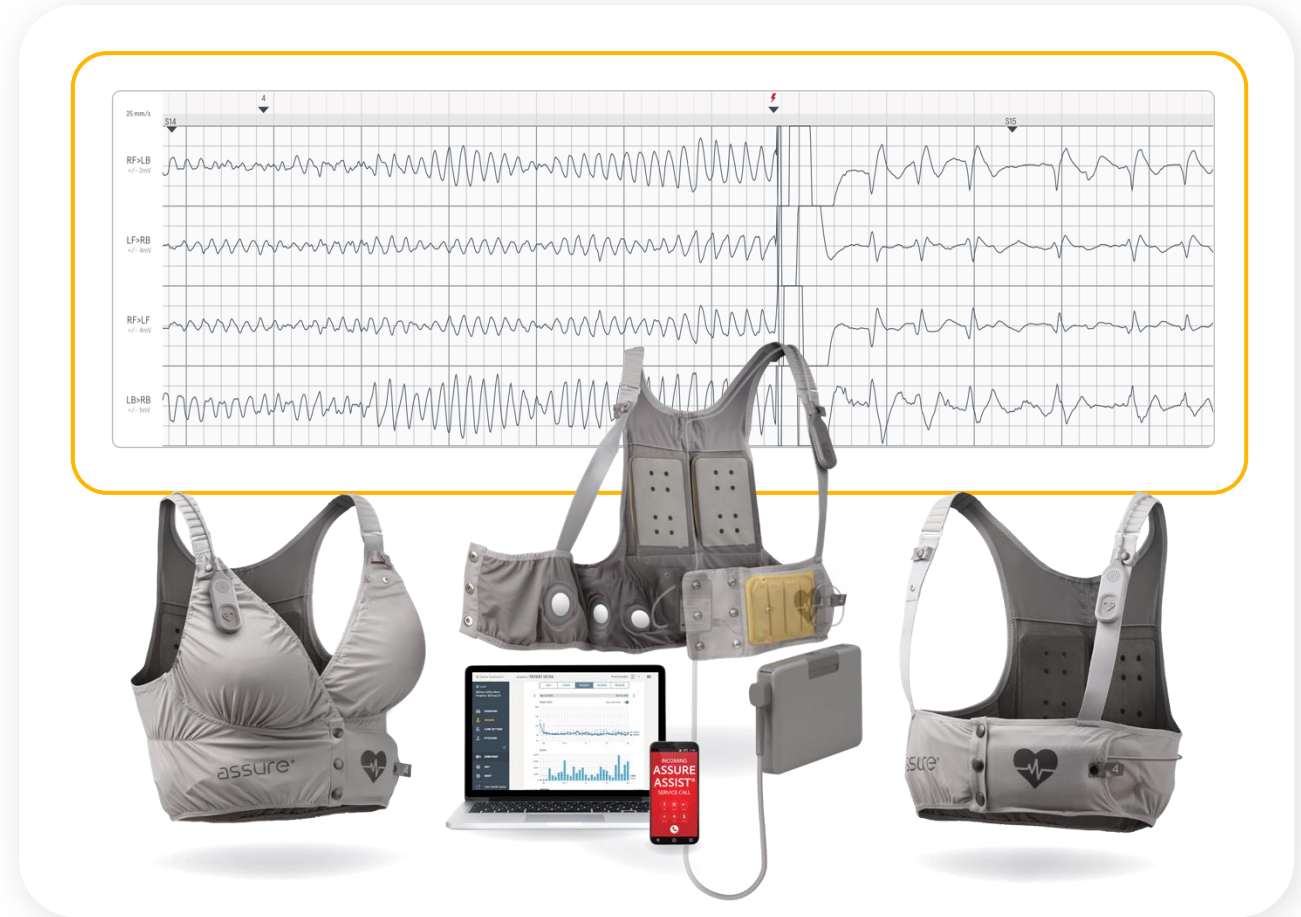
ASSURE WCD designed to:

- Improve comfort and compliance
- Provide High-Fidelity ECG recordings
- Reduce the false shock alarm rate
- Maintain high shock efficacy for VT/VF

FDA IDE trials demonstrated:

- Low false positive shock alarm rate²
- High VF conversion rate³

FDA approved in July 2021



Study Device: ASSURE WCD¹



Methods: Study Overview



STUDY DESIGN	<ul style="list-style-type: none">• Prospective, non-randomized, active surveillance registry• Designed for safety and effectiveness in routine clinical practice• Non-inferiority trial, prespecified boundaries^{1,2}
PRIMARY ENDPOINTS	<ul style="list-style-type: none">• Effectiveness: All-shock conversion rate $\geq 89.0\%$¹• Safety: Inappropriate shocks per patient-month $\leq 0.0075$²
STUDY POPULATION	<ul style="list-style-type: none">• Adult patients prescribed the ASSURE WCD in the US
SAMPLE SIZE	<ul style="list-style-type: none">• Required at least 271 appropriate VT/VF shock events for the primary effectiveness endpoint (5% non-inferiority margin)

¹ Based on reported performance (94%) in German national registry with a 5% noninferiority margin (Wäbñig NK et al. Circulation. 2016;134(9):635-43).
² Upper 95% confidence limit of combined incidence rates: a) Wäbñig NK et al. Circulation. 2016;134(9):635-43, b) Kutiyifa V et al. Circulation. 2015;132(17):1613-619, and c) FDA Premarket Approval (PMA) P010030/S056: Wearable Cardioverter Defibrillator (WCD), ZOLL Manufacturing Corporation

Results: Selected Baseline Characteristics

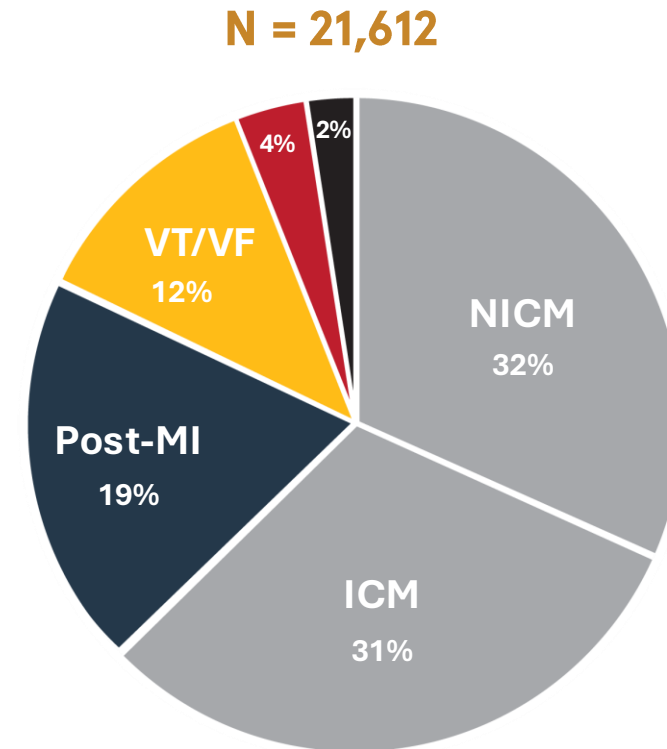


DEMOGRAPHICS	N = 21,612 (% or mean \pm SD)
Age (years)	64 \pm 14
Female sex (%)	34%
BMI (kg/m ²)	29.5 \pm 6.9
LVEF %	25.3 \pm 9.7

CO-MORBIDITIES	N = 21,612 (%)
Hypertension	72%
Hyperlipidemia	61%
Coronary artery disease	58%
Atrial Fibrillation history	37%
Diabetes	33%
COPD	14%
Prior Stroke or TIA	9%
Cancer	9%

Results: WCD Prescription Indication

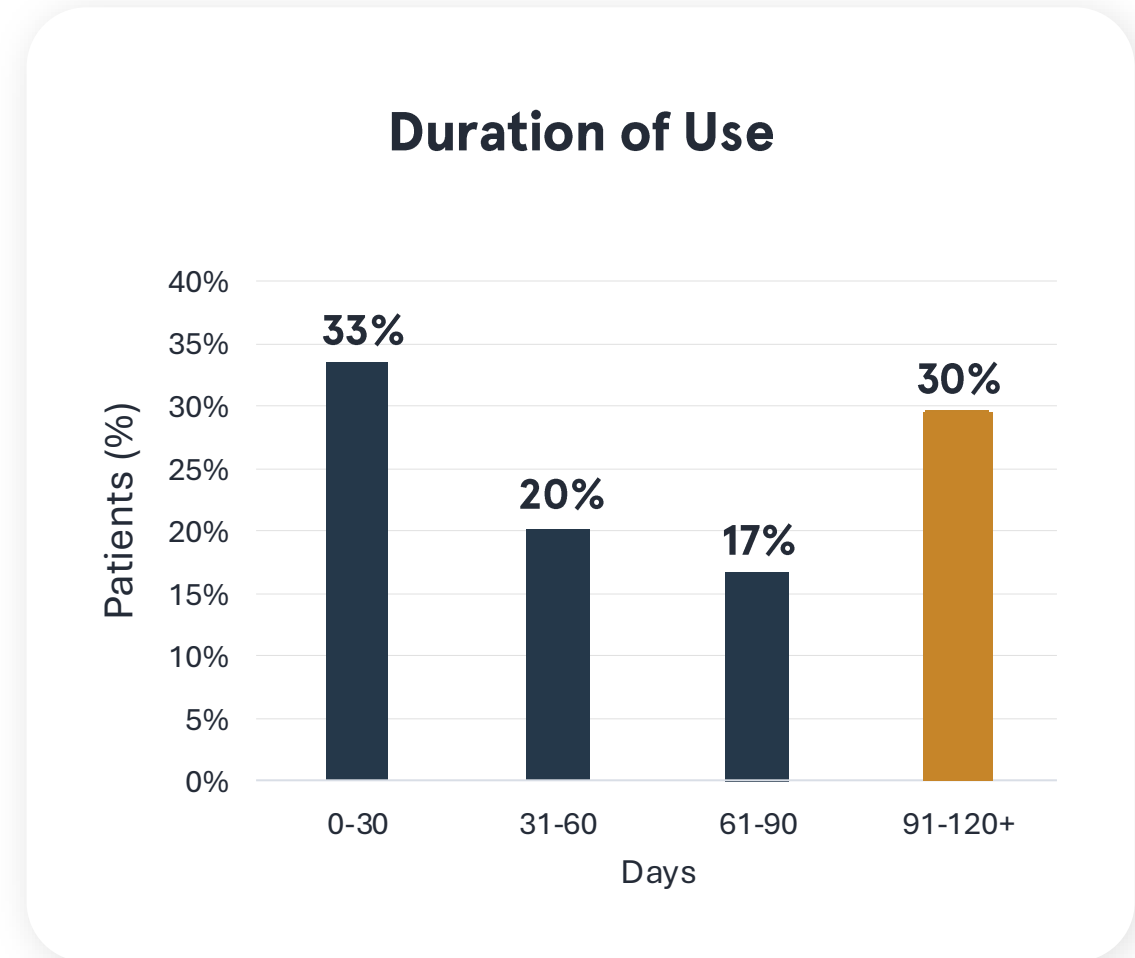
- Dilated Cardiomyopathy, LVEF \leq 35%
- Post-MI, LVEF \leq 35%
- Sustained VT/VF or SCD survivor
- ICD explant
- Other high-risk for SCD



Results: Wear Compliance & Duration of Use

	N = 16,441*
Daily usage, median (IQR) hours	23.1 (16.1 – 23.9)
Duration of use, median (IQR) days	54 (20 – 97)
Cumulative wear time	41,816 months

*Completed wear (n=16,441); Actively wearing at data cutoff (n=5,171)



Results: Primary Effectiveness Endpoint



VT/VF All-Shock Conversion

Endpoints	Performance Goal	VT or VF events (n/N)	% Success
All-shock conversion	≥ 89%	303 / 303	100% (95% LCB: 98.9%)
First shock conversion	Report Only	294 / 303	97% (95% LCB 95.7%)

- 1.21% (261) patients received at least one shock for VT/VF
- Incidence rate 0.6% per patient-month* (7.5 per 100 patients years)

*261 patients/41,816 cumulative months

Results: Primary Safety Endpoint

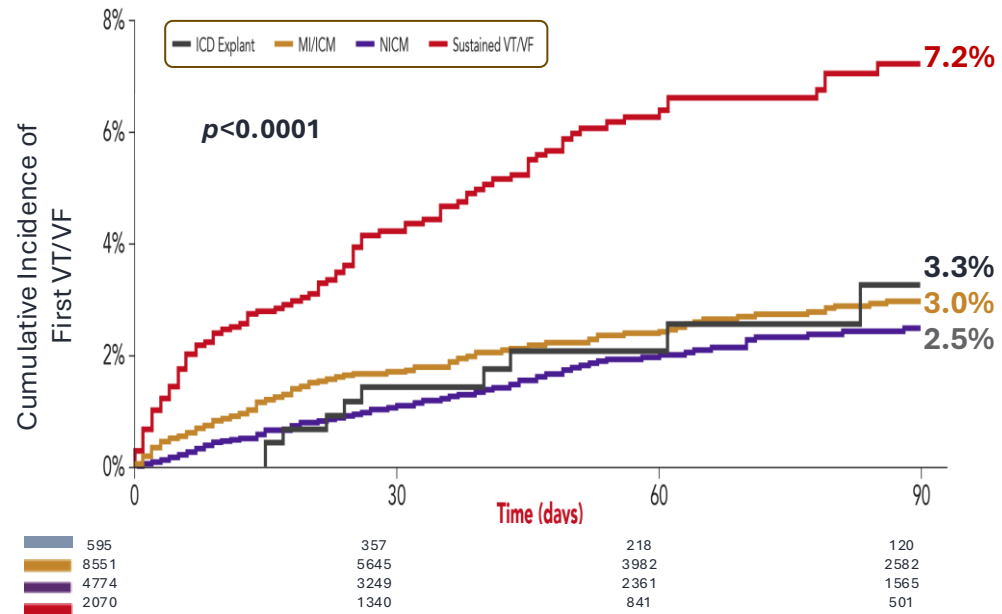
Inappropriate Shock Rate

Endpoints	Performance Goal	Patients with ≥ 1 Shock	Cumulative Wear Time	Incidence Rate (per patient-months)
Inappropriate shock rate	≤ 0.0075 per patient-months	273 (1.26%)	41,816 months	0.0065 (95% UCB: 0.0073)

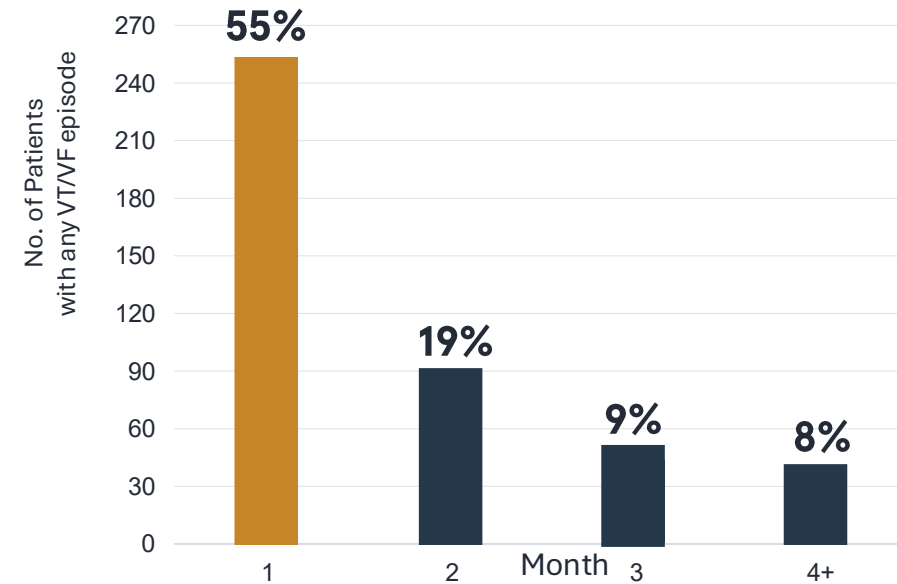
- **94%** of patients were free from any false positive shock alarm

Any VT/VF Shocked & Unshocked

Time to First VT/VF by WCD Indication*



Time to First VT/VF*



2.6% of patients had 1 VT or VF episode

*Completed wear (n=16,441)

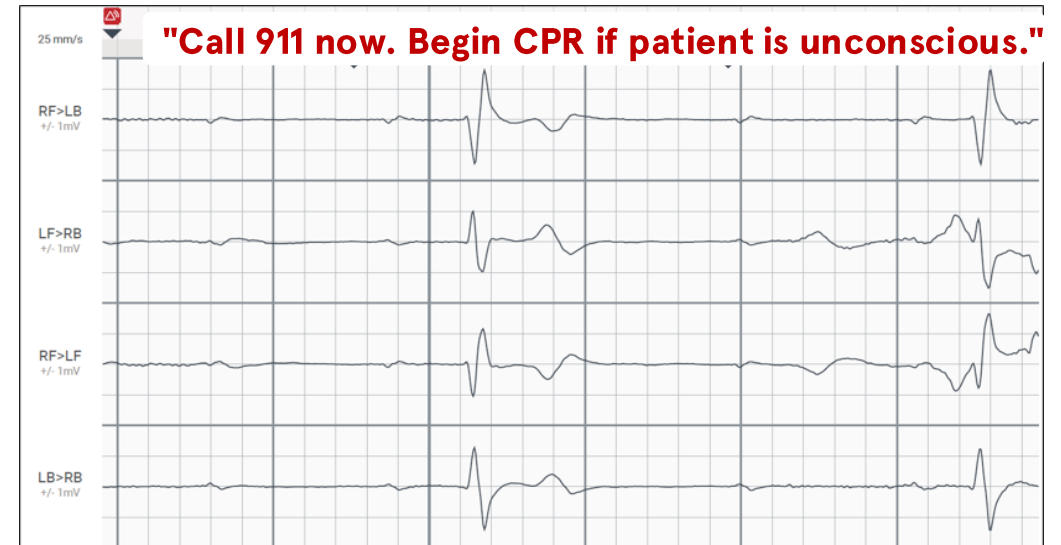
Results: Other Arrhythmias

High-rate Atrial Fibrillation



- 4.2% of patients had AF (>170 bpm)
- 35% had no previous documented history

Severe Brady/Asystole



- At least 0.3% of patients experienced severe bradycardia (<20 bpm) or asystole

Conclusions



- ACE-PAS represents the largest prospective WCD study with >20,000 patients
- ACE-PAS met both of its endpoints
 - Effectiveness: 100% all-shock VT/VF conversion
 - Safety: Inappropriate shock rate 0.0065 per patient-month
- ACE-PAS provides contemporary data describing the risk of life-threatening VT/VF in diverse populations with reduced LV function
- 2.6% of patients experienced life-threatening VT/VF over merely a few months

WCD's protect patients at elevated SCD risk while awaiting cardiac function improvement and/or ICD eligibility

Thank You

ACE Steering Committee

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Incidence Rate of Appropriate Shock By Indication

WCD Indication	Number of Patients with at least one VT/VF shock	Cumulative Months (Censored after 1st shock)	Appropriate Shock (per 100 patient-years) (95% CI)
All	261	41,754	7.5 (6.6 - 8.5)
MI/ICM	150	21,109	8.5 (7.2 - 10)
NICM	41	13,464	3.7 (2.6 - 5.0)
Survived VT/VF	60	4,851	14.9 (11.3 - 19.1)
ICD Explant	5	1,396	4.3 (1.4 - 10.0)
Other	5	934	6.4 (2.1 - 15.0)