



WiSE[®] System

Insertion of an Implantable Endocardial Pacing System

ICD-10 Coordination and Maintenance
Committee Update
Spring 2025

US Heart failure & CRT

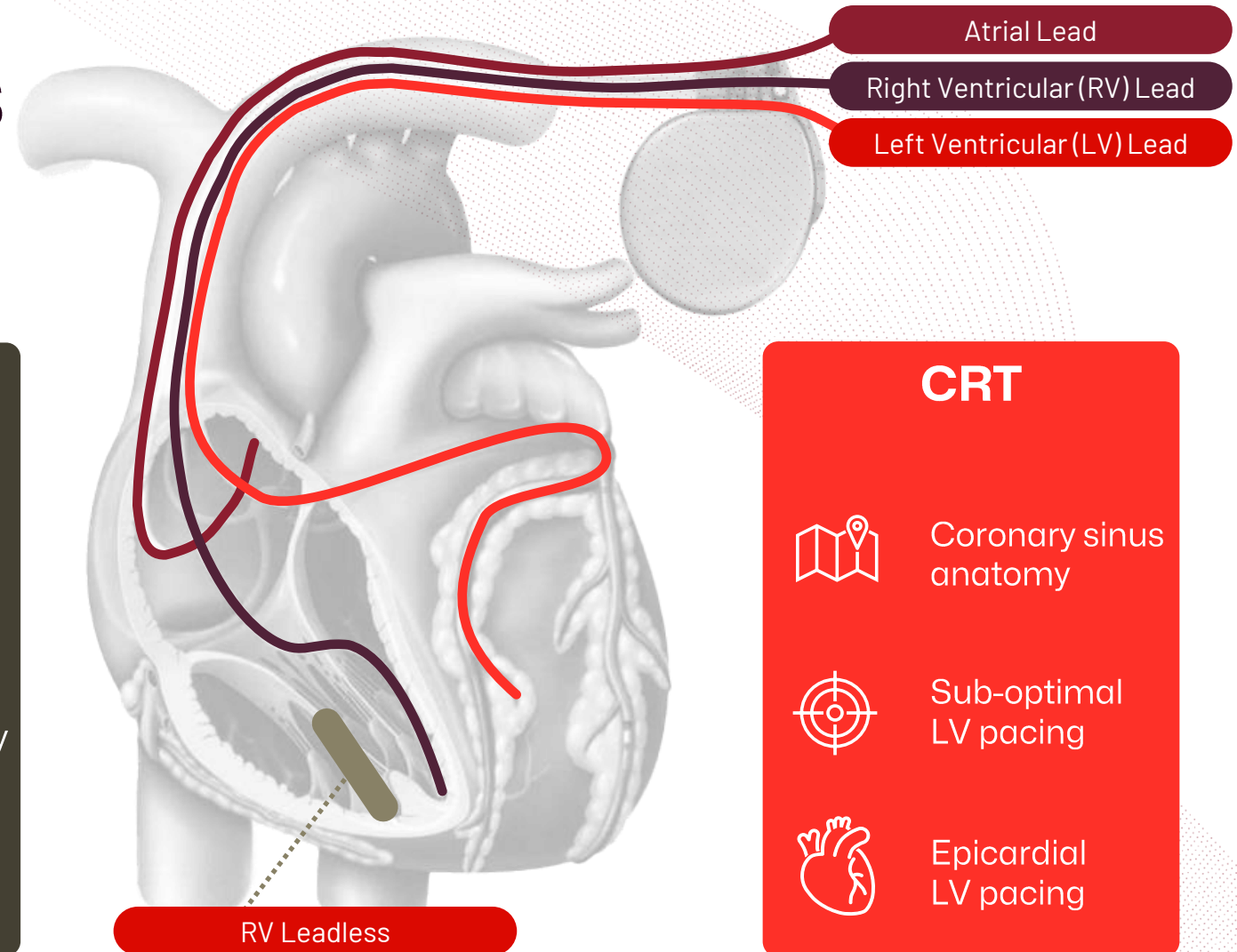
~6.2 million affected by Heart Failure. Additional ~1 million cases diagnosed each year.

Cardiac Resynchronization Therapy (CRT) is recommended for a subset of HF patients.

~130,000 patients receive a CRT system annually.

Despite being standard of care, conventional CRT has many limitations.

Current Pacing Challenges



Leads



Complex
vascular
access



Lead
fractures



Lead
infections

Leadless



Asynchronous
pacing

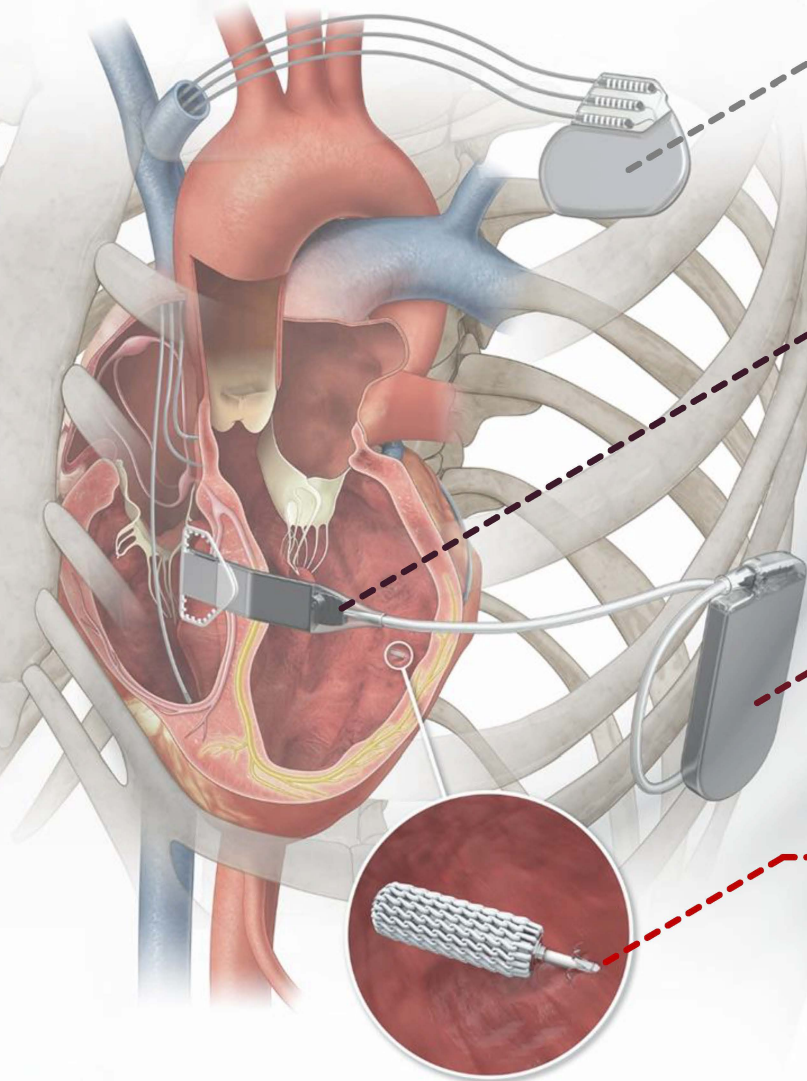


Pacing induced
cardiomyopathy



High risk
upgrade to CRT

WiSE[®] System Overview



CO-IMPLANT DEVICE

Pre-existing device to provide RV pacing

TRANSMITTER

Phased array ultrasound Transmitter synchronizes with RV pacing pulse to transmit ultrasound energy to the Electrode

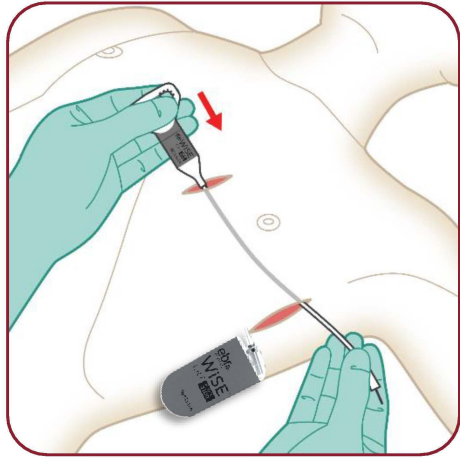
BATTERY

Implanted subcutaneously at the left mid-axillary line, powers the Transmitter

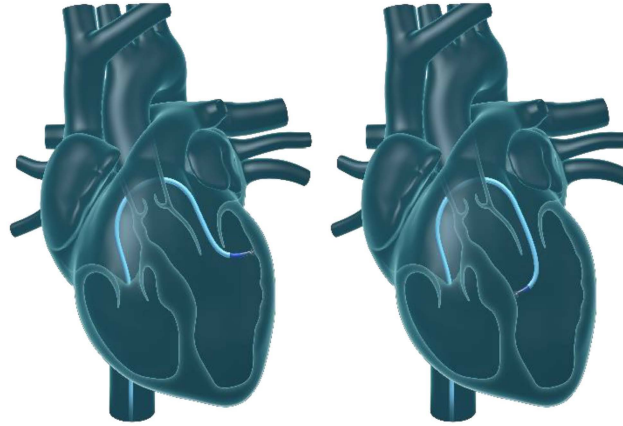
ELECTRODE

Implanted endocardially, this Electrode converts ultrasound into electrical energy to pace the LV

WiSE Procedure Overview

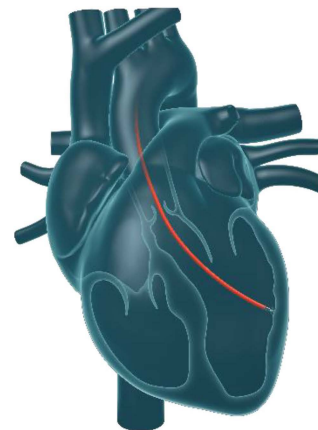


Transmitter and Battery Placement

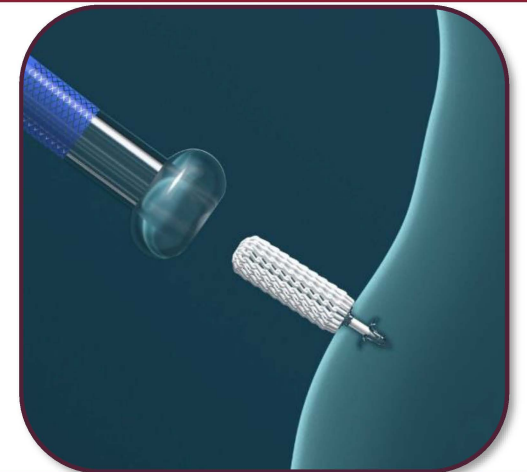


Transseptal Approach

OR



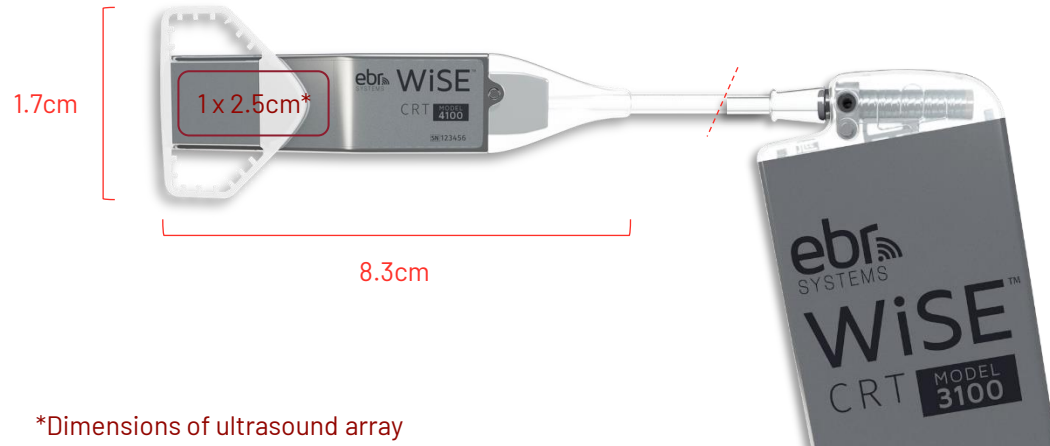
Retrograde Aortic Approach*



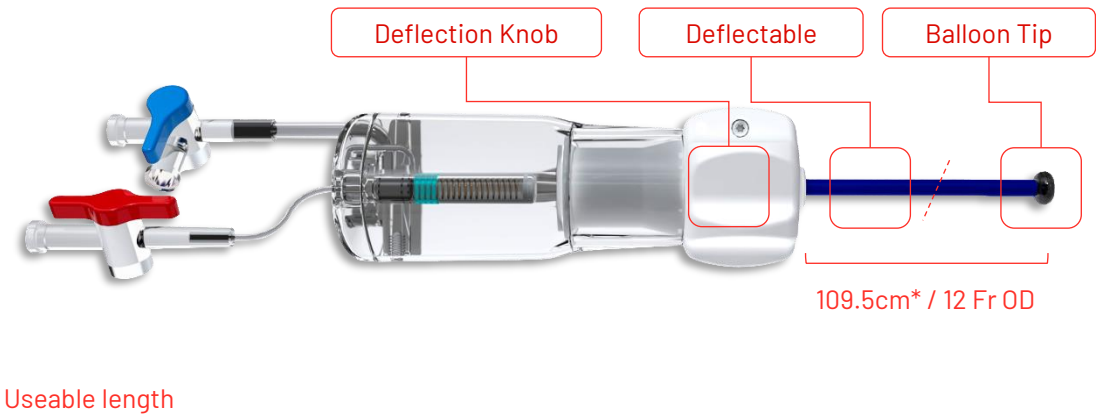
Electrode Placement

WiSE[®] Components

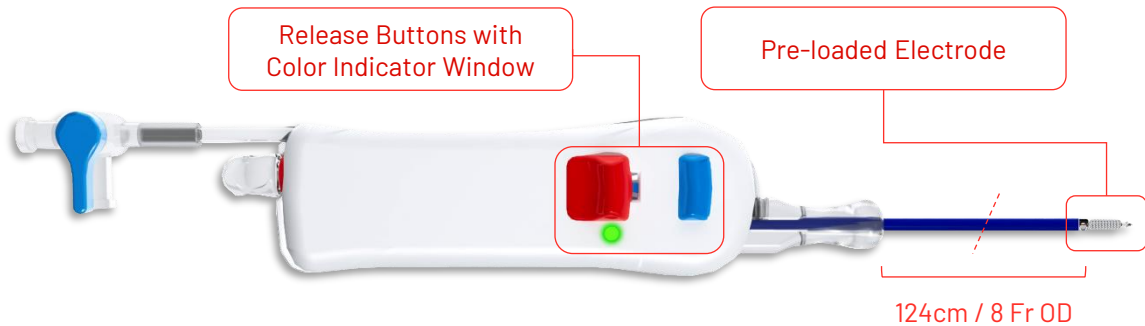
Transmitter (M4100) & Battery (M3100)



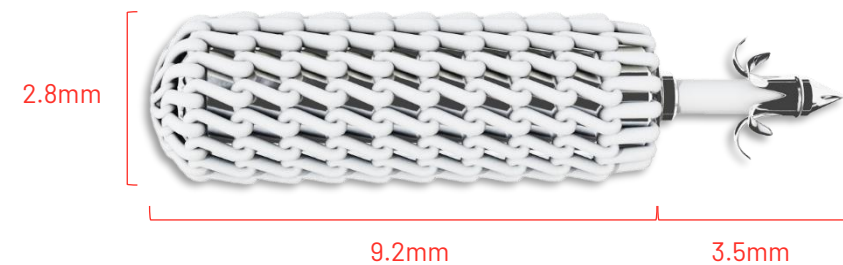
Delivery Sheath (M2000)



Electrode Catheter (M1000)



Electrode

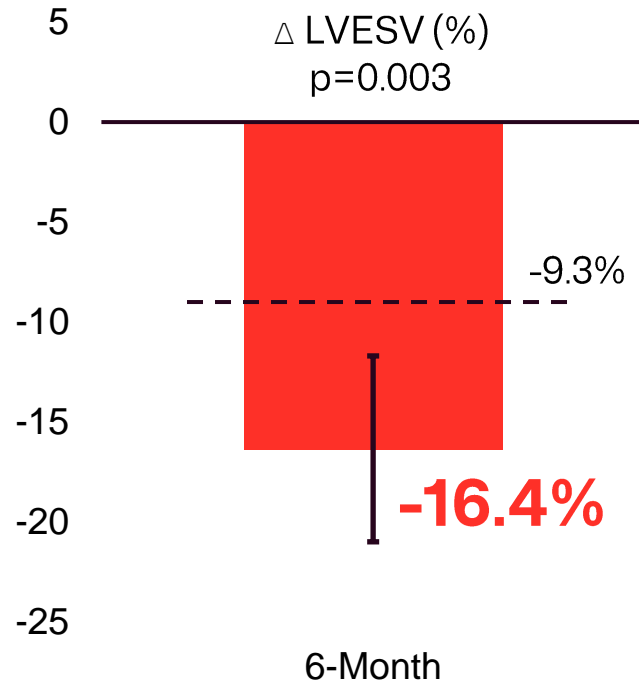


SOLVE-CRT Met Endpoints

Positive results at **interim analysis** confirm WiSE® as an effective treatment option for heart failure patients

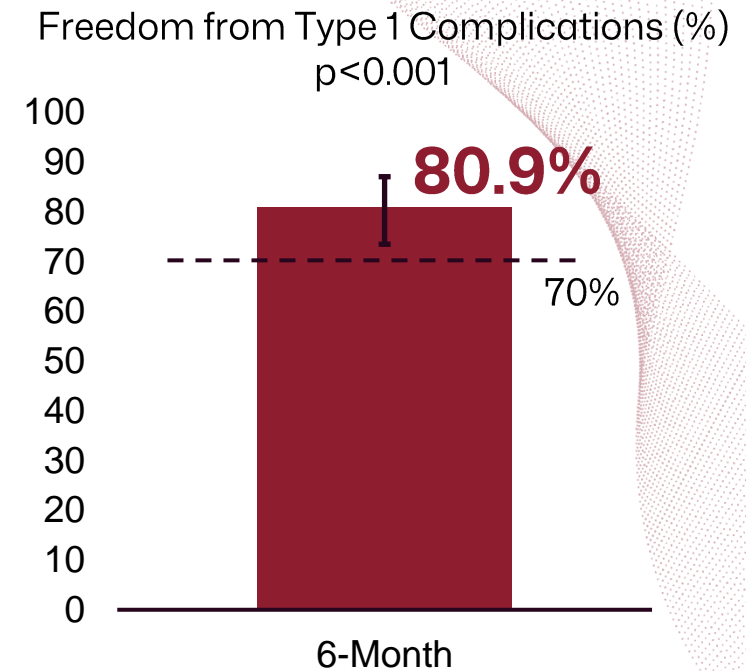
Efficacy

Success in high-risk patients
who have failed conventional CRT



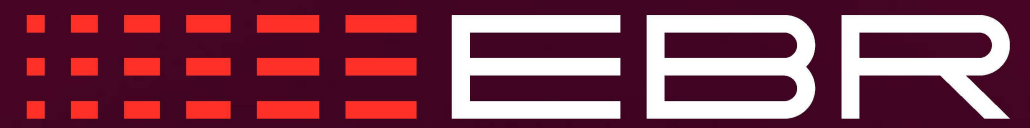
Safety

Comparable to Standard of Care
Rates similar to CRT upgrades



Documentation and Terminology

- Insertion, Left Ventricle, Percutaneous, Leadless Electrode
- Insertion, Subcutaneous Tissue and Fascia, Open, Battery and Ultrasound Transmitter for Intracardiac Pacing Electrode
- Terms associated with use of the WiSE® System include:
 - WiSE® CRT System
 - WiSE® System
 - Leadless CRT System
 - Leadless LV pacemaker
 - Leadless endocardial pacemaker
 - Leadless endocardial LV pacemaker



Thank you !