

# WiSE<sup>®</sup> System

## Insertion of an Implantable Endocardial Pacing System

ICD-10 Coordination and Maintenance

Committee Update

Spring 2025

# US Heart failure & CRT

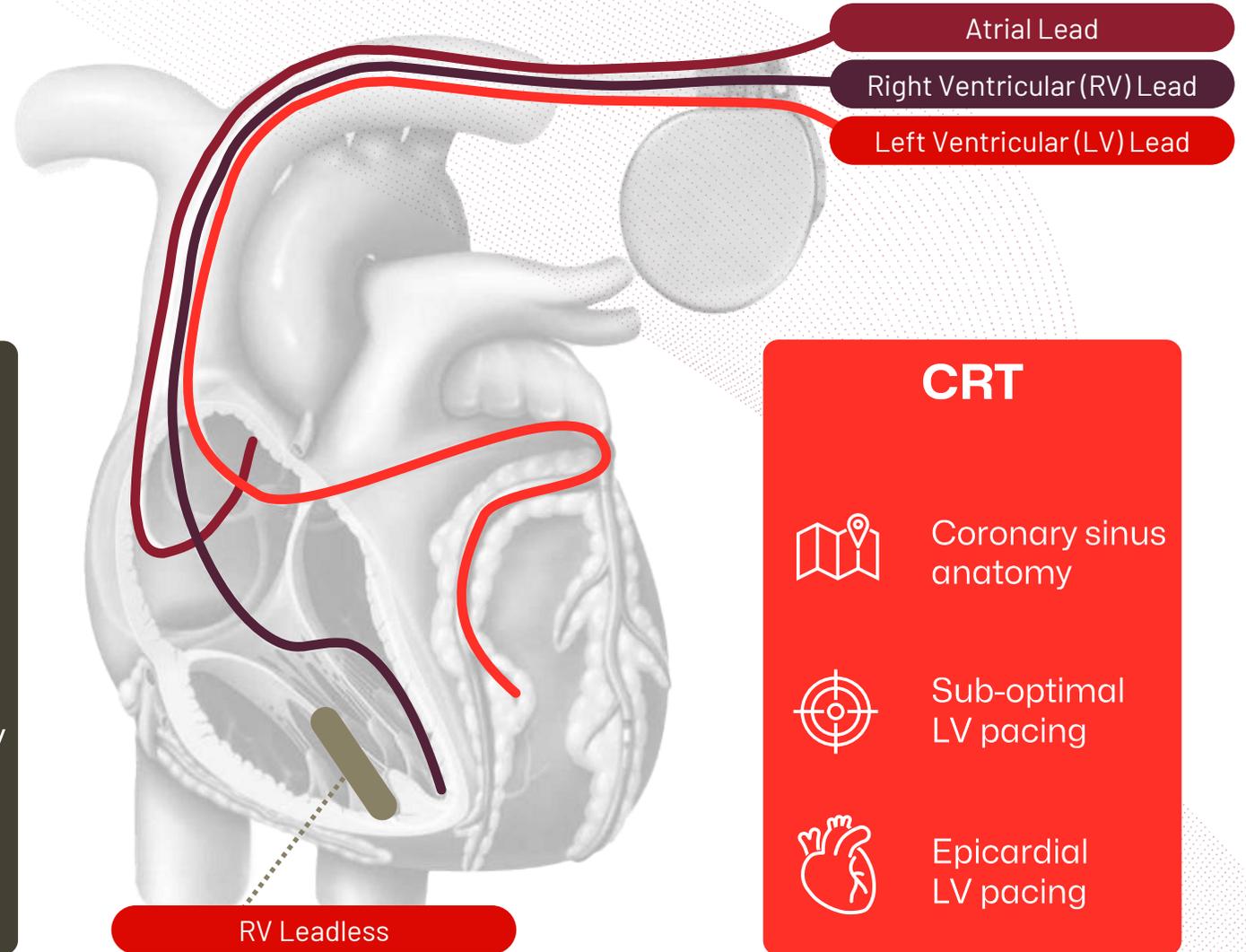
~6.2 million affected by Heart Failure. Additional ~1 million cases diagnosed each year.

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

## CRT



Coronary sinus anatomy

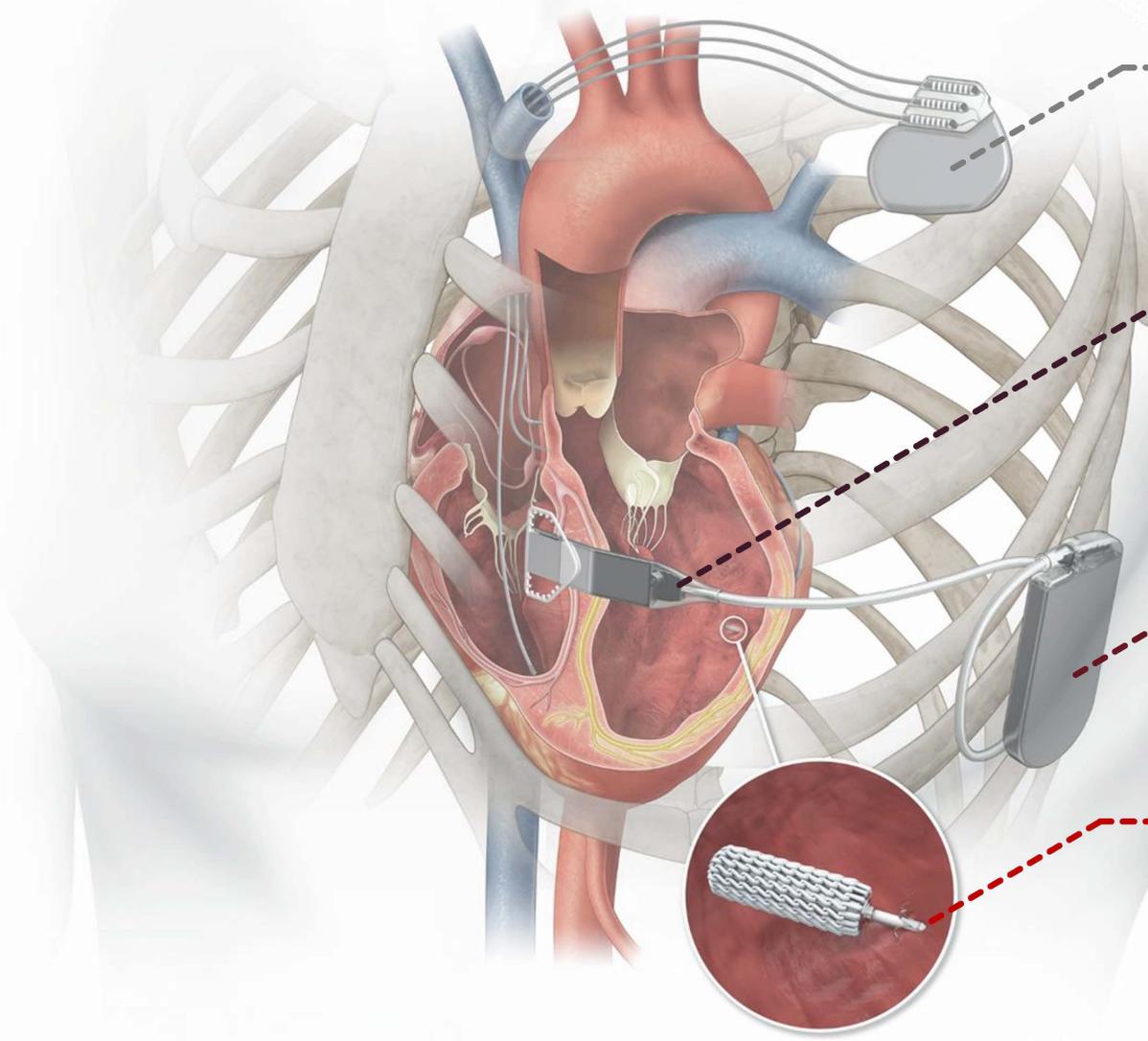


Sub-optimal LV pacing



Epicardial LV pacing

# WiSE<sup>®</sup> 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

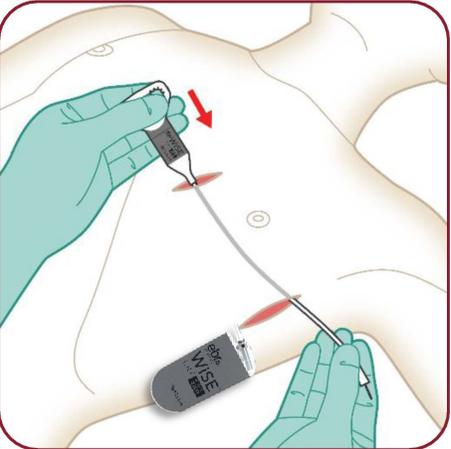
## **BATTERY**

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

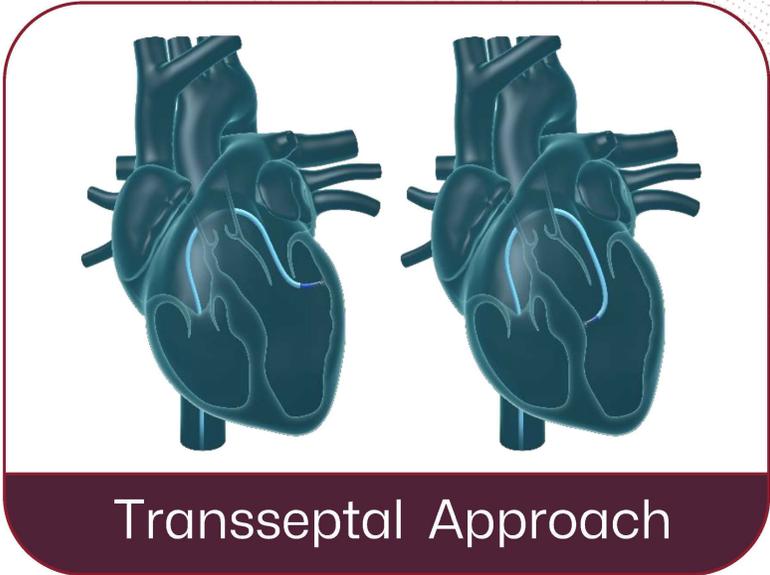
## **ELECTRODE**

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

# WiSE Procedure Overview

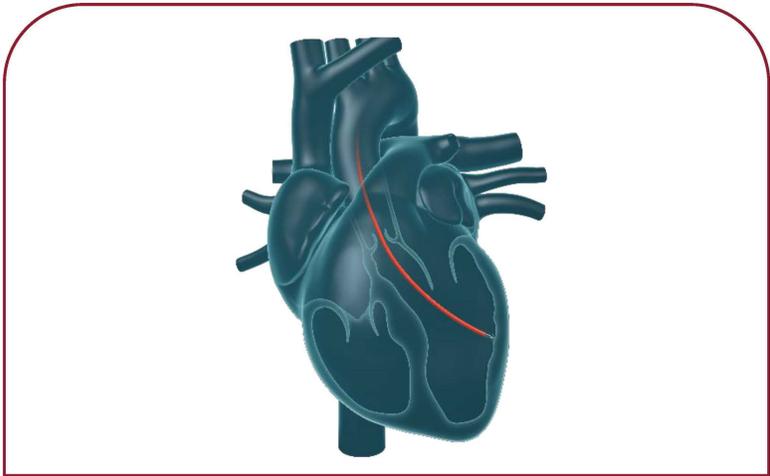


Transmitter and Battery Placement



Transseptal Approach

OR



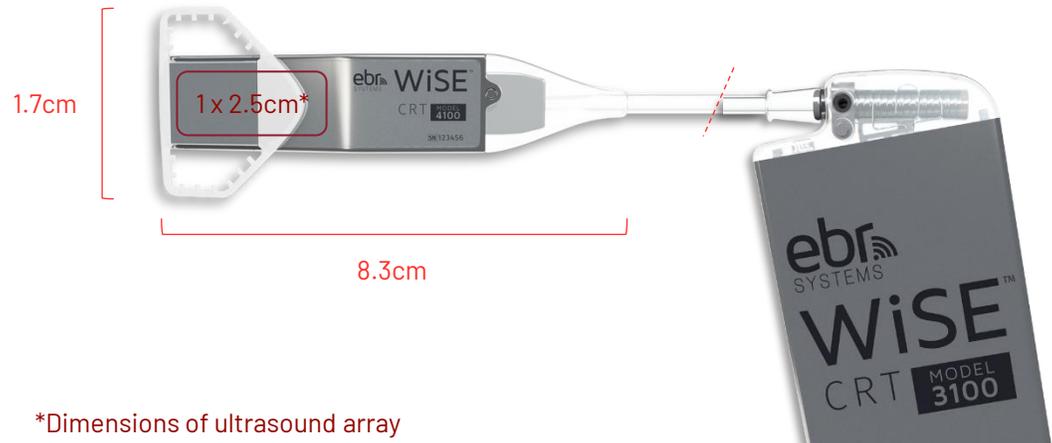
Retrograde Aortic Approach\*



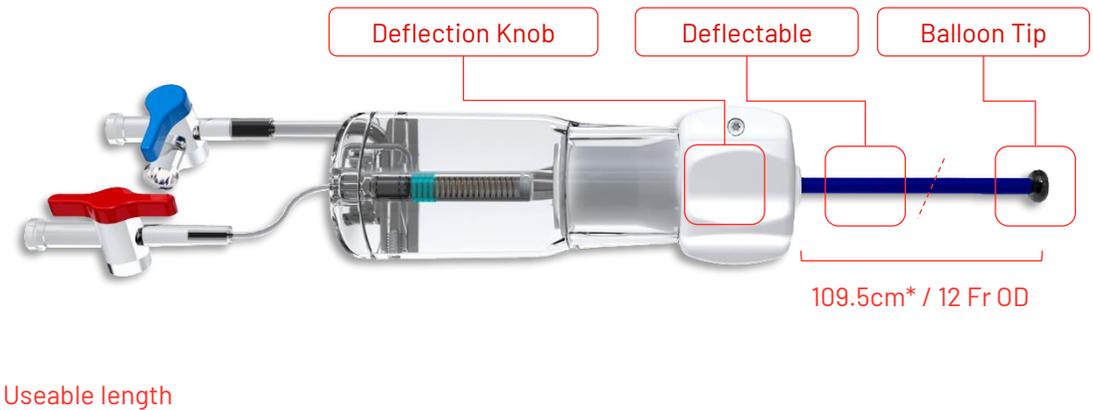
Electrode Placement

# WiSE<sup>®</sup> Components

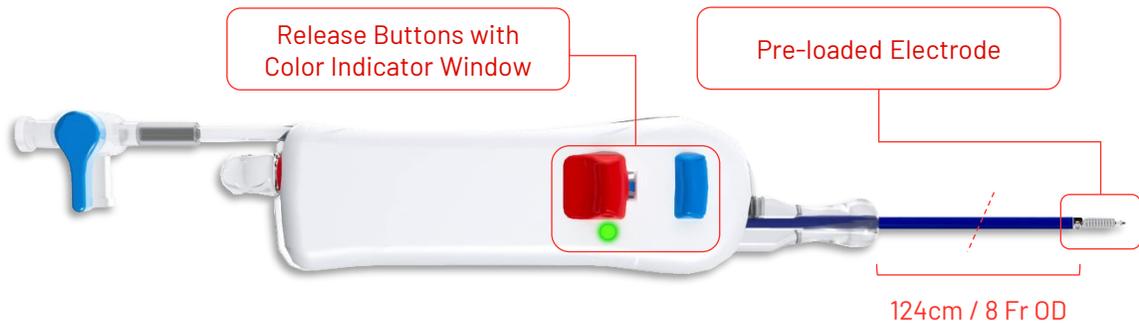
## Transmitter (M4100) & Battery (M3100)



## Delivery Sheath (M2000)



## Electrode Catheter (M1000)



## Electrode

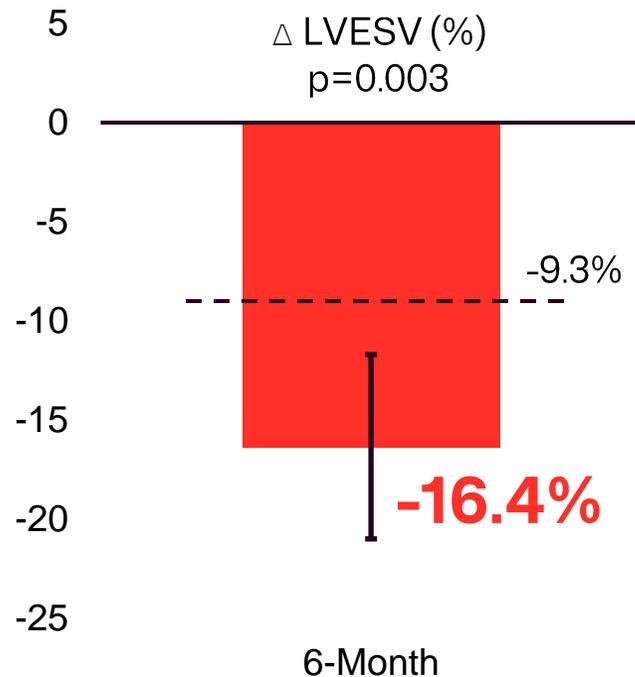


# SOLVE-CRT Met Endpoints

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

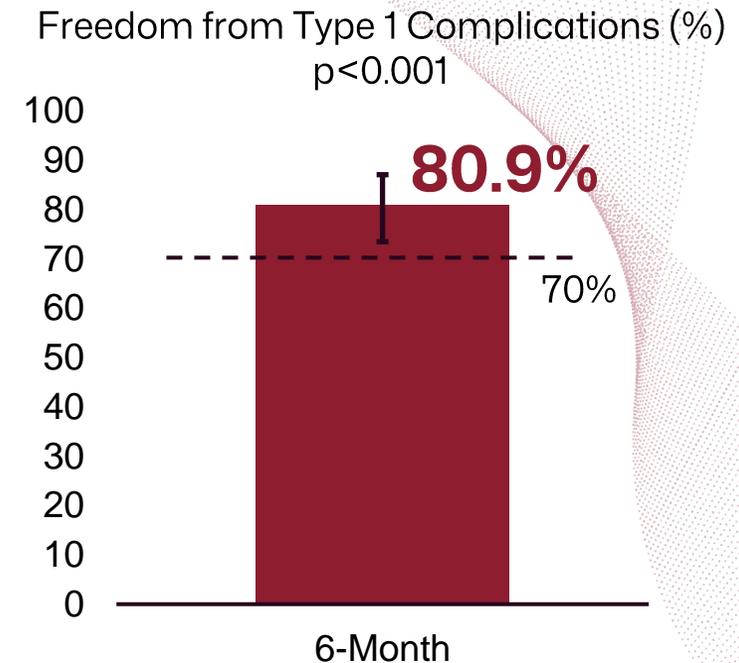
## Efficacy

Success in high-risk patients  
who have failed conventional CRT



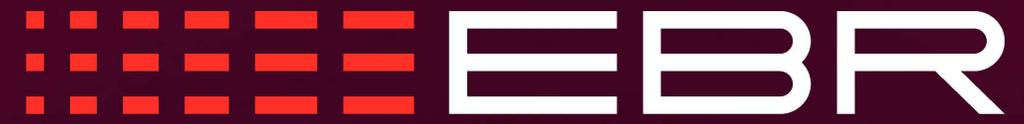
## Safety

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 !