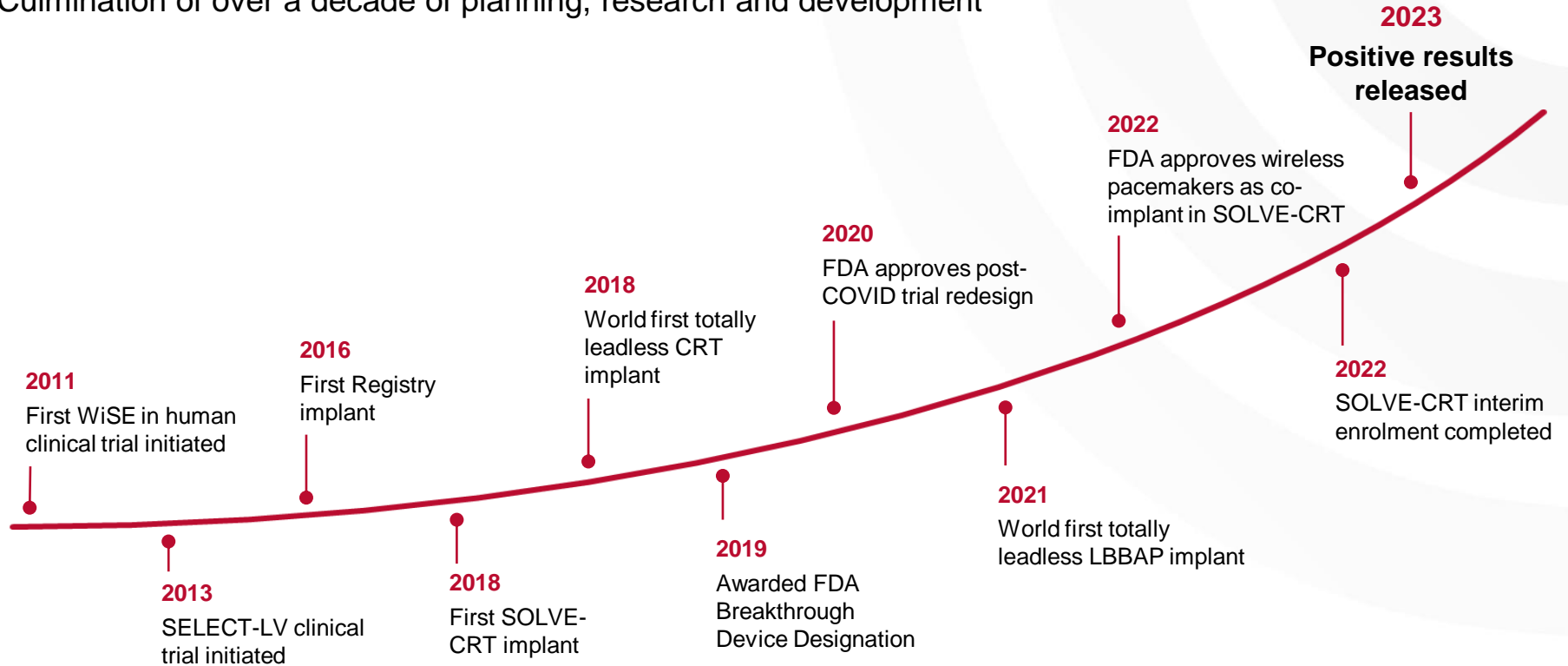


SOLVE-CRT Pivotal Trial Top-line Data

May 2023

Achievement of a significant milestone

Culmination of over a decade of planning, research and development



Pivotal SOLVE-CRT trial overview

Trial design to provide clinical data to support a PMA application to the FDA

Trial design and goals

Purpose: Assess the safety and effectiveness of the WiSE device

Design: International, multi-centre study following initial 31-patient US roll-in study (completed and published)

Population: Acute lead failures, chronic lead failures, high risk upgrades and leadless upgrades

Primary Efficacy Endpoint: More than a -9.3% reduction in left ventricular end systolic volume (lower volume = improved heart function)

Primary Safety Endpoint: > 70% patients without device or procedure-related complications

Trial results

-16.4%
p = 0.003

Improvement in
heart function vs
-9.3% target

80.9%
p < 0.001

Patients without
complication vs
>70% target

Multi-phase trial completed

COMPLETE

COMPLETE¹

COMPLETE

Randomised Phase
n = 108

Single-arm Phase
n = 75

Primary
data
analysis

Efficacy endpoint met

WiSE device confirmed to significantly improve heart function in patients compared to benchmark



Primary efficacy endpoint met

-16.4% decrease in left ventricular end systolic volume at 6 months compared to -9.3% performance goal, showing improved heart function



Success in high risk patients

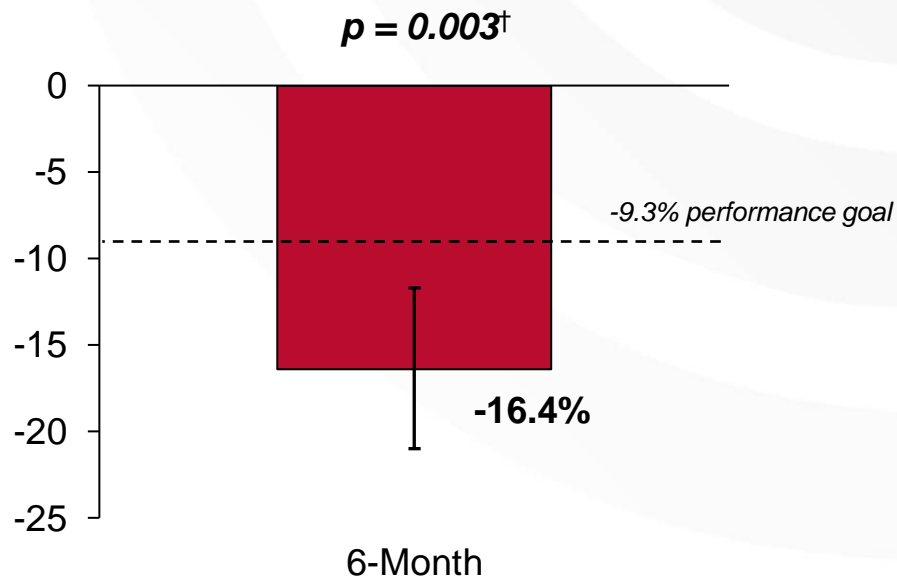
SOLVE-CRT patient pool consists of patients who have failed conventional CRT



Other key data

All data analysed to date shows consistent, positive results in reversing heart failure symptoms and physiology

Primary efficacy endpoint (% Δ LVESV¹)



Safety endpoint met

WiSE device considerably exceeds the primary safety endpoint with minimal patients experiencing device or procedure-related complications



Primary safety endpoint met

80.9% freedom from type I complications at 6 months compared to 70% performance goal



Safety profile comparable to SoC

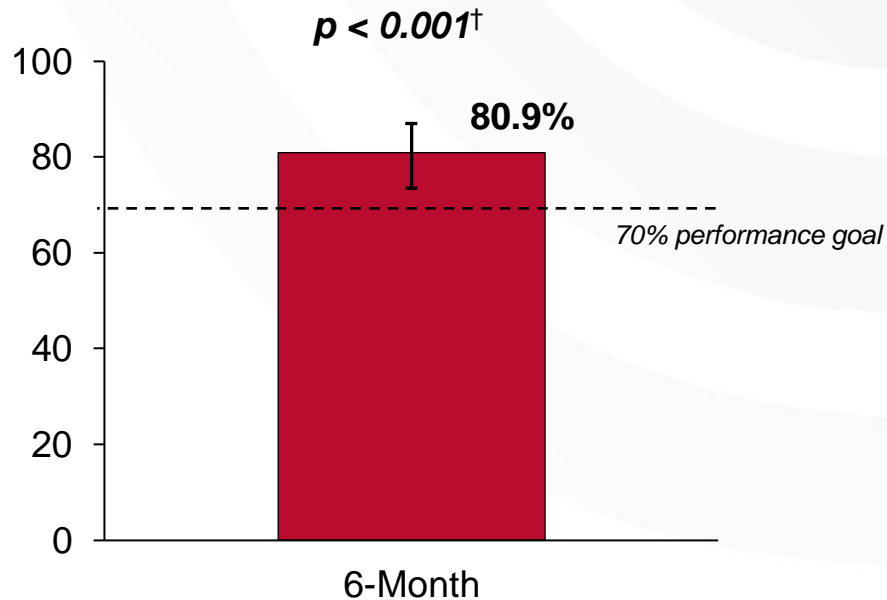
Other studies using standard of care (SoC) treatment for CRT upgrades have shown 81.3% freedom from device & procedure related complications¹



Other key data

Observed complication rates were higher in early phases and decreased with experience

Freedom from type I complications (%)



Supported by clinicians and patients

Trusted by leading healthcare professionals and demonstrated success in patients



Professor Prash Sanders

Director of Cardiac Electrophysiology and Pacing at the Royal Adelaide Hospital

“ *The WiSE CRT System represents a major advancement in cardiac pacing technology, I am impressed by the results of the SOLVE-CRT trial and look forward to seeing this product become available to patients who need it most. It is exciting to have a technology that may change the way we eventually undertake pacing. For heart failure patients who do not respond to traditional cardiac resynchronisation therapy, this technology is life changing. The difference between living a normal life as opposed to being constantly short of breath, often housebound, and unable to perform simple daily tasks is stark.* ”



Brian Oakley

Scout leader and avid Melbourne FC fan, unable to walk up MCG stairs due to pacing induced heart failure

“ *Nine months post WiSE implant, I am able to wash the cars readily and can now mow the lawns. It's going really well. I can do things now that I never thought I would be able to do again. I can do all the things that I could do prior to developing Heart Failure. I even went to the AFL game on Saturday and could walk up multiple flights of stairs. I haven't been able to do that for years! I would definitely recommend other patients consider the WiSE system if they were in a similar situation.* ”

Journey from here

EBR continues to achieve significant value catalysts and pave the way to future value creation

2022

- ✓ Complete SOLVE-CRT pivotal trial enrolment
- ✓ Support clinical sites and patient implants
- ✓ Presentations at cardiology conferences; publications in medical journals

2023

- ✓ SOLVE-CRT 6 Month follow up completed for final patient in February 2023
- ✓ **Headline data released at Heart Rhythm Society conference**
- ✓ **Positive trial data unlocks second tranche of growth capital facility**
- ✓ **Finalise PMA submission to the FDA (currently underway)**
- ❑ Submit manuscript to medical journal for peer-review publication

2024+

- ❑ Submit Clinical Module for PMA application to the FDA
- ❑ Submit Final Module including transmitter upgrades
- ❑ FDA approval in the US
- ❑ Commercial launch in the US
- ❑ Launch in select markets OUS¹ as reimbursement and regulatory coverage is secured
- ❑ Expand use of WiSE® into new patient groups and geographies

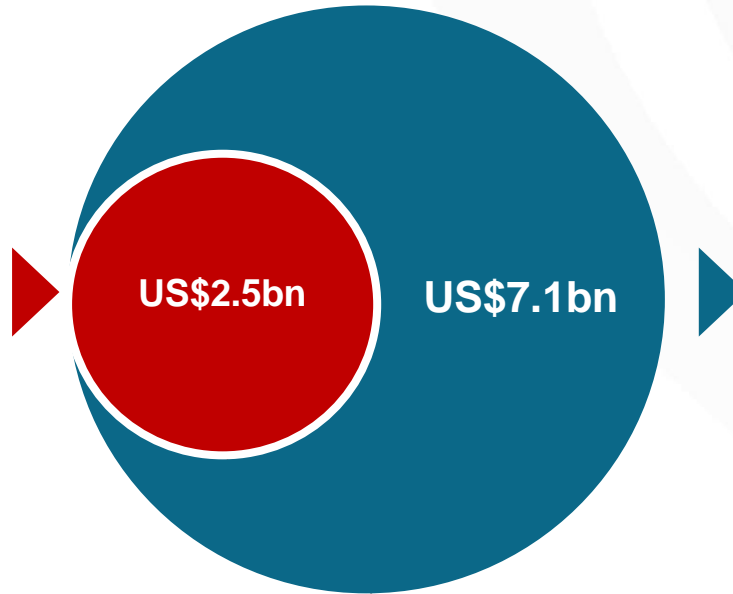
Market opportunity

EBR estimates to have an initial addressable market of ~US\$2.5bn at commercial launch, with further opportunities to expand WiSE into other patient groups

Initial Addressable Market

Target Patient Groups:

- Acute lead failure
- High risk upgrades
- Chronic lead failure
- Leadless upgrades



Expansion Opportunity

New patient groups, indications and geographies:

- First-line CRT treatment with Totally Leadless CRT (with existing technology)
- Conduction system pacing
- De novo implants for bradycardia
- International expansion

Rapid adoption of wireless devices supports strong market growth

Attractive investment opportunity

EBR is focused on executing its clear and targeted commercialisation strategy to deliver shareholder value

De-risked pathways to market



Positive results

Safety and efficacy endpoints met for SOLVE-CRT trial and Breakthrough Device Designation granted



Well funded

Funding flexibility to progress regulatory and commercial objectives



Large markets

Targeting initial addressable market of US\$2.5bn with significant upside



Unique solution

No competition as WiSE® is complementary to other leadless devices



Re-rate potential

Value upside exists as EBR continues progress towards first sales / revenues



Appendix

HRS conference
presentation

Safety and Efficacy of a Leadless Ultrasound-Based Cardiac Resynchronization System in Heart Failure

The SOLVE-CRT Study Results



HEART RHYTHM

BRINGING THE WORLD OF EP TOGETHER

MAY 19 - 21, 2023 • NEW ORLEANS

Jagmeet P. Singh MD, DPhil; Christopher A. Rinaldi MBBS, MRCP;

Prashanthan Sanders MBBS, PhD; Spencer H. Kubo MD; Simon James MD;

Imran K. Niazi MD; Tim R Betts MBChB; Christian Butter MD; Toshimasa Okabe MD;

Matthew Latacha MD; Ryan Cunnane MD; Emad Aziz MD; Mauro Biffi MD; Amir Zaidi MD;

Jeffrey Alison MD; Angelo Aurichio MD, PhD; Michael R. Gold MD, PhD;

JoAnn Lindenfeld MD; Tyson Rogers MS; and Mary Norine Walsh MD

on behalf of the SOLVE-CRT Investigators

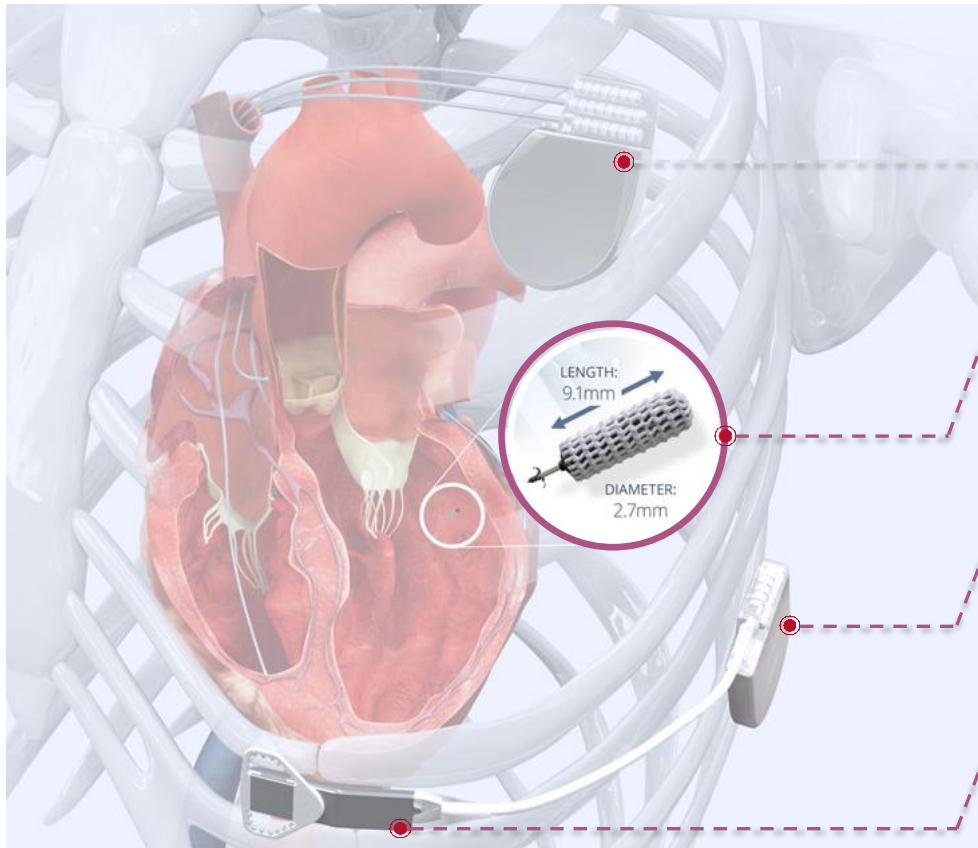
Background

- Despite the well-established role of CRT in heart failure, major limitations of CRT include:
 - High incidence of unsuccessful coronary sinus (CS) lead placement
 - Upgrading ICDs in high-risk patients
 - High rates of CRT non-responders (30-50%)
- The WiSE[®] CRT System is designed to overcome the limitations of traditional CRT pacing by providing wireless, left ventricular (LV) endocardial pacing as an alternative to the epicardial CS lead
- Prior non-randomized studies with the WiSE CRT System have shown high implant success rates and improvement in LV remodeling and heart failure symptoms^{1,2,3}

CAUTION: WiSE CRT System is an investigational device. Limited by Federal (US) law to investigational use only.

¹Delnoy, et al. (2014) – Europace, ²Reddy, et al. (2017) – JACC, ³Okabe T, et al. (2021), Heart Rhythm

The WiSE[®] CRT System



CO-IMPLANT DEVICE

Existing pacemaker, ICD or CRT provides RV pacing

RECEIVER ELECTRODE

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

BATTERY

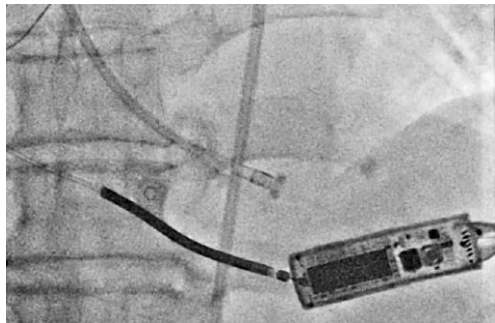
Implanted subcutaneously at the left mid-axillary line, powers the Transmitter.

TRANSMITTER

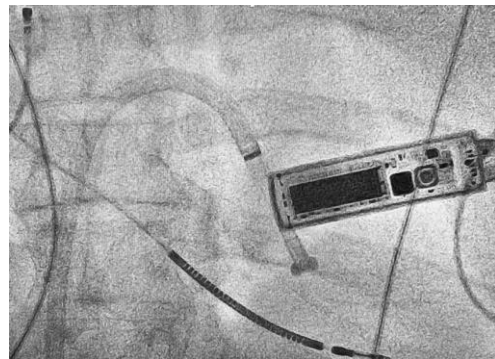
Phased array ultrasound Transmitter synchronizes with RV pacing pulse to transmit ultrasound energy to the Receiver Electrode.

Receiver Electrode Implant Procedure

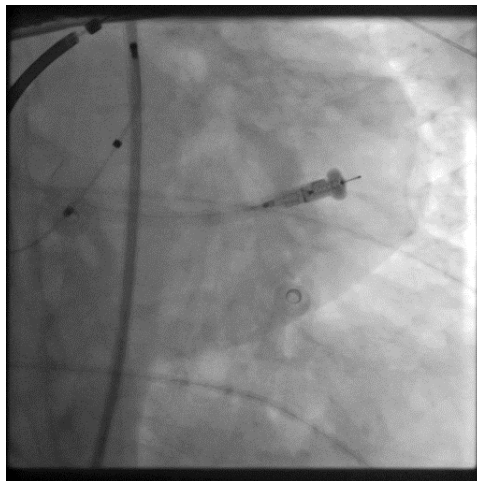
Retrograde Aortic Approach



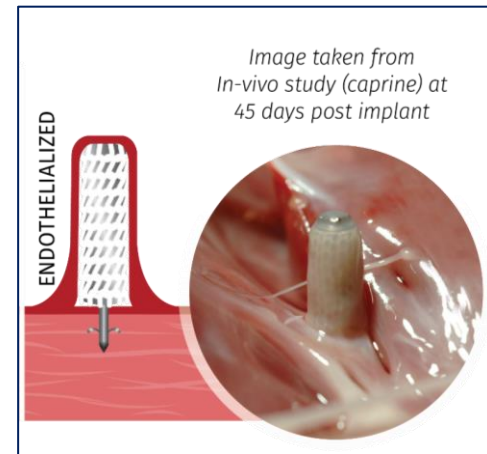
Transseptal Approach



Anchoring



Secure Attachment



Endothelializes for a low risk of thromboembolic events

SOLVE-CRT Study

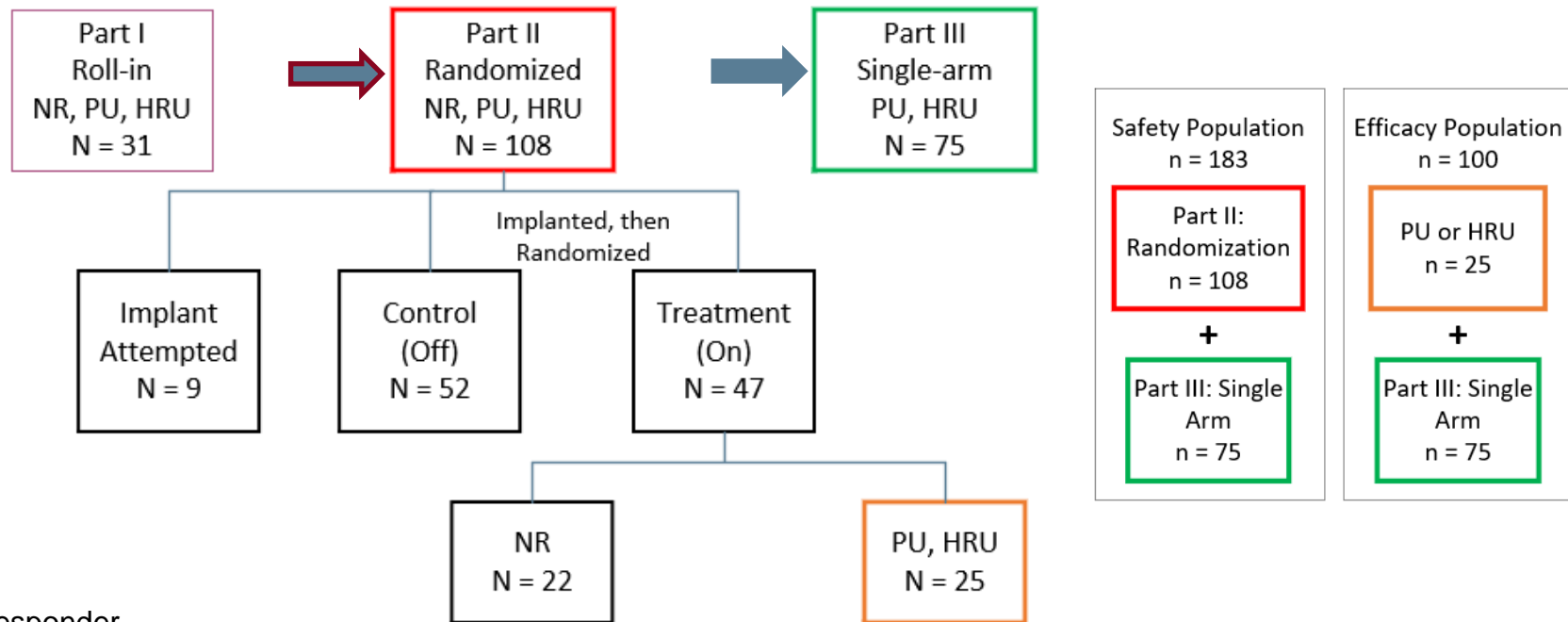
Objective: Pivotal study to assess the safety and effectiveness of the WiSE[®] CRT System

Design: International, multi-center, 3-part study: (i) Roll-in, (ii) Randomized, and (iii) Single-arm

Study Population: Patients indicated for CRT and

- Previously untreatable (PU), or
 - Considered a high-risk upgrade (HRU) to conventional CRT, or
 - Non-responders (NR) to CRT – Randomized part only

SOLVE-CRT Study Design



NR = Non responder
PU = Previously untreatable
HRU = High risk upgrade

Primary and Secondary Endpoints

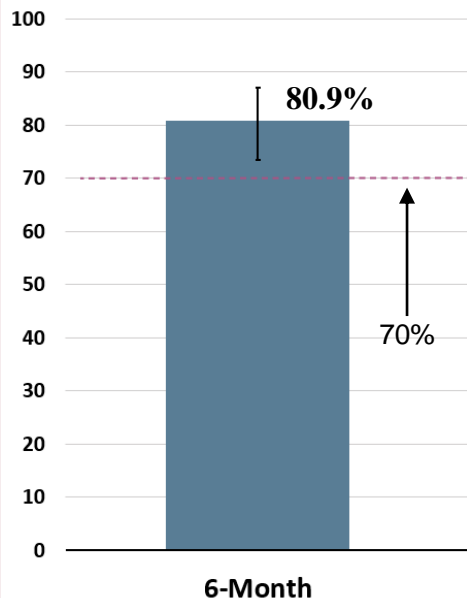
- **Primary Safety Endpoint:** Freedom from Type I complications at 6 months compared to a Performance Goal of 70%
 - Type I: Device or procedure-related complications
- **Primary Efficacy Endpoint:** Decrease in LVESV at 6 months compared to a Performance Goal of 9.3%
- **Secondary Endpoints:** Proportion of participants with
 - KCCQ improvement ≥ 5 points
 - LVEF improvement $\geq 5\%$
 - Acoustic Pacing Capture Threshold (APCT) < 2.9 mJ
 - Stable APCT ($< 3\times$ increase from baseline), and
 - Mean BiVP %

Baseline Characteristics

Safety Population	n/N (%) or Mean \pm SD
Female	42/183 (23.0)
Age at enrollment (Years)	68.1 \pm 10.28
Left ventricular ejection fraction	30.0 \pm 8.3
Co-implant device:	
-CRT-D	113/183 (61.7)
-CRT-P	9/183 (4.9)
-ICD	42/183 (23.0)
-Pacemaker	15/183 (8.2)
Prior Myocardial Infarction	74/183 (40.4)
Prior PCI or CABG	108/183 (59.0)
Renal dysfunction	51/183 (27.9)
Hypertension	99/183 (54.1)
Diabetes	64/183 (35.0)
NYHA Class II	63/182 (34.6)
NYHA Class III	119/182 (65.4)
ACEI, ARB, or ARNI use	178/183 (97.3)
SGLT2 inhibitor	6/183 (3.3)
Beta-blocker use	174/183 (95.1)
Aldosterone Antagonist	115/183 (62.8)
Loop diuretic use	145/183 (79.2)

Primary Safety Endpoint

Freedom from
Type I Complications
(%)
 $p < 0.001^\dagger$



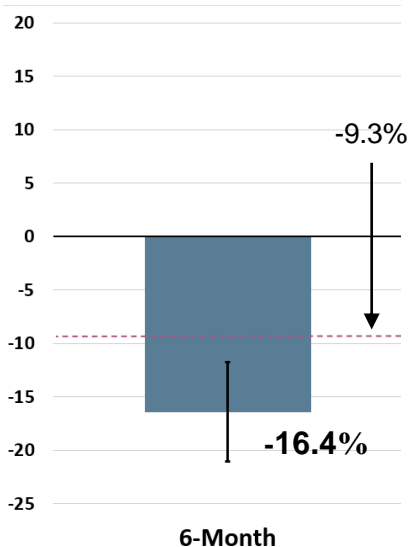
Type I Complications	Participants, n (%)
Type I	35 (19.1%)
Study device system event	12 (6.6%)
Receiver Electrode not anchored	7 (3.8%)
No BiV capture	3 (1.6%)
Transmitter revision	1 (0.5%)
Ventricular tachycardia	1 (0.5%)
Vascular event	5 (2.7%)
Groin hematoma	2 (1.1%)
Ischemic leg	1 (0.5%)
Retroperitoneal bleed	2 (1.1%)
Stroke and other thromboembolic events (e.g., TIA)	3 (1.6%)
Cardiac perforation	7 (3.8%)
Surgically repaired	4 (2.2%)
Pericardiocentesis	3 (1.6%)
Pocket Events	12 (6.6%)
Hematoma	4 (2.2%)
Infection	4 (2.2%)
Transmitter revision	2 (1.1%)
Battery revision due to erosion	2 (1.1%)

[†]Clopper-Pearson
exact binomial test

Primary Efficacy Endpoint

Primary Endpoint

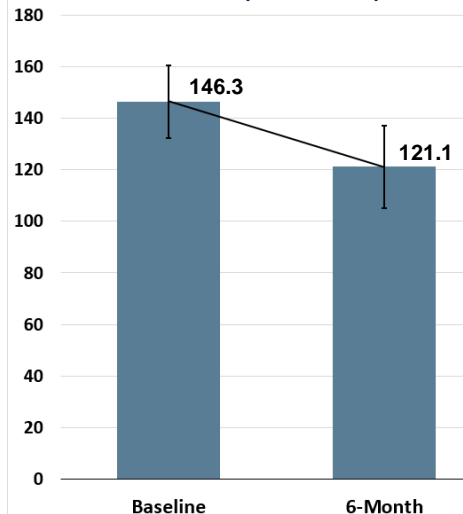
% Δ LVESV
p = 0.003[†]



Additional Evidence of Reverse Remodeling

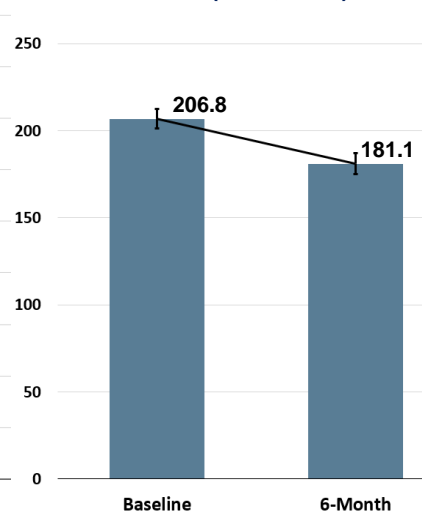
LVESV (ml)
p < 0.001[‡]

Mean Δ = -25.1
95% CI (-32.4, -17.9)



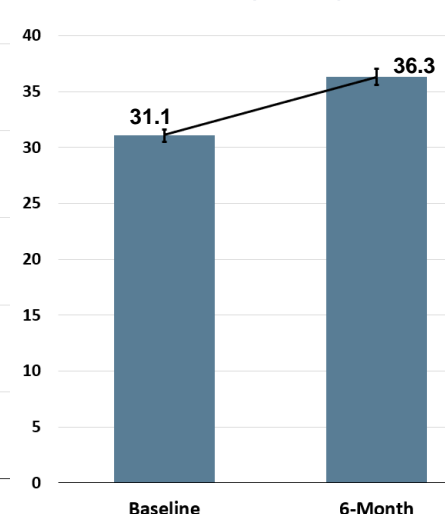
LVEDV (ml)
p < 0.001[‡]

Mean Δ = -25.4
95% CI (-28.4, -22.5)



LVEF (%)
p < 0.001[‡]

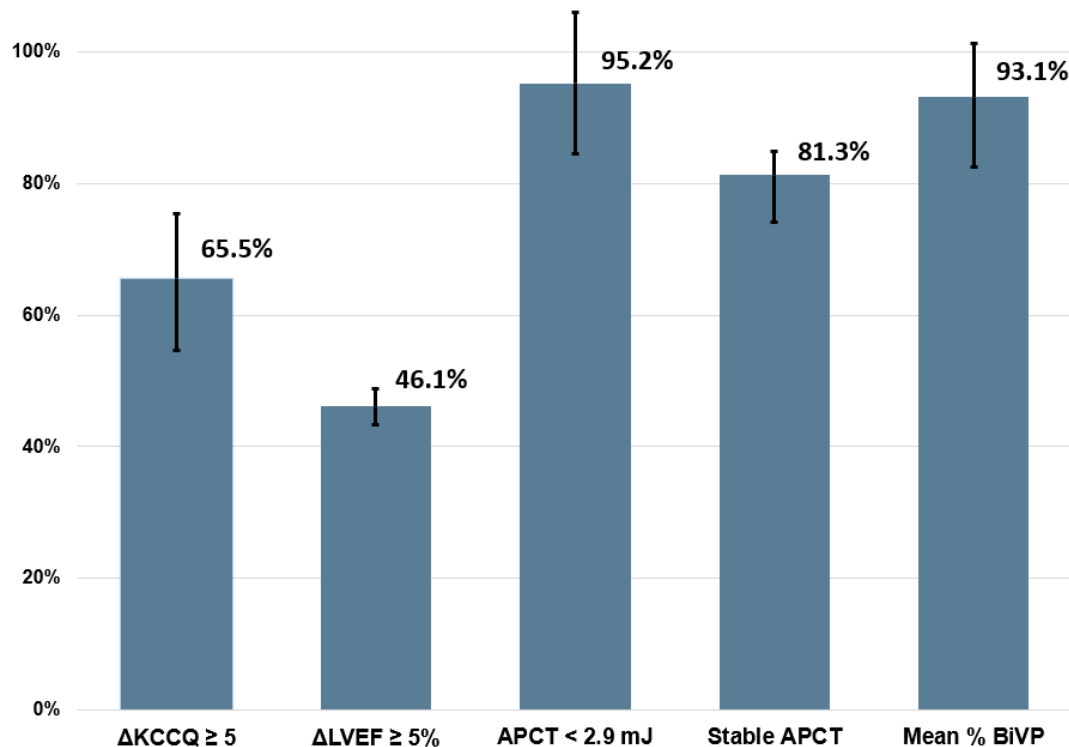
Mean Δ = 5.2
95% CI (4.7, 5.7)



[†]One-sample t-test

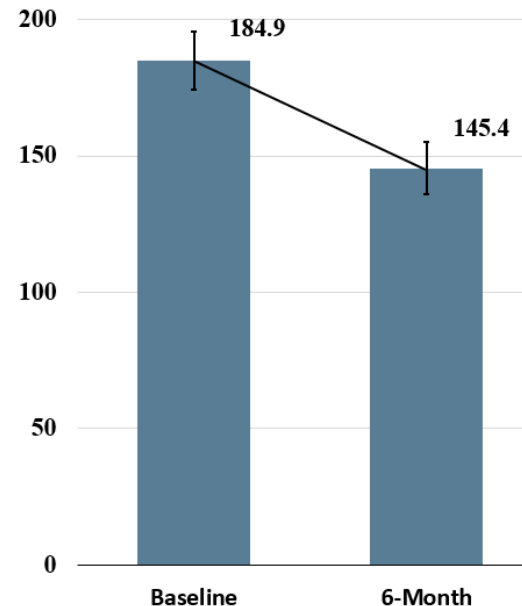
[‡]Paired t-test, nominal p-value

Secondary Endpoints



Change in QRS (ms)

Mean Δ = -39.3
95% CI (-44.5, -34.2)



Limitations & Strengths

Limitations

- COVID impact on protocol
- Non-randomized part was open-label with no control group
- Short follow-up duration

Strengths

- Multi-center
- Prospective
- Blinded Echo Core Lab
- Independent Clinical Events Committee

Conclusions

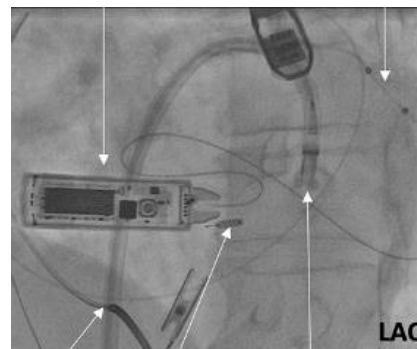
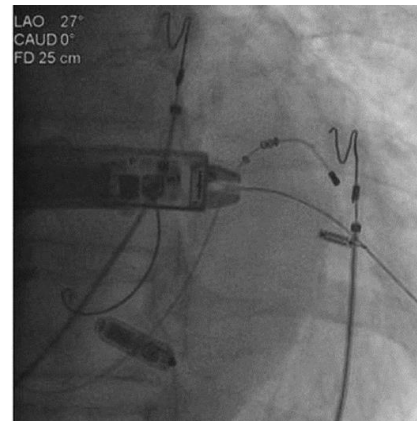
The pivotal SOLVE-CRT study has demonstrated that leadless, ultrasound-based endocardial pacing with the WiSE CRT System is:

- Feasible
- Safe
- Clinically efficacious, resulting in reverse remodeling and improvement in functional status

Clinical Implications

- **Totally Leadless CRT⁴**
 - Potential pairing with leadless pacemakers

- **Leadless LBBAP / Conduction System Pacing⁵**
 - Allows for refined targeting



⁴ Carabelli, et al. (2020) – Europace, ⁵Elliott, et al. (2022) – Heart Rhythm

Acknowledgements

- Participants
- Investigators & Teams
- Data and Safety Monitoring Board
- Penn State Echo Core Lab
- Clinical Event Committee
- Eligibility Review Committee
- Coordination and Data Management Teams
- EBR Clinical & Study Monitoring Teams

St. Thomas' Hosp, UK	Liverpool Heart and Chest Hosp, UK	Naples Community Hosp, US	Prince Charles Hosp, AU	UCSD, US
James Cook University Hosp, UK	Emory Univ, US	Centre Cardiologique du Nord, EU	Canberra Hosp, AU	Intermountain Heart Institute, US
Aurora St. Luke's Med Ctr., US	Penn State Hershey Med Ctr, US	Barts Heart Ctr, UK	United Heart and Vascular, US	Heart Center Research Huntsville, US
Immanuel Klinikum Bernau, EU	Isala Zwolle, EU	Fiona Stanley Hosp, AU	St. Vincent Indianapolis, US	St. Luke's Hosp Kansas City, US
John Radcliffe Hosp, UK	Fondazione IRCCS San Gerardo, EU	Prince of Wales Hosp, AU	UT Health, US	Atlanticare, US
Ohio State Univ, US	The Heart Hosp Baylor Plano, US	Baptist Health Lexington, US	Sydney Adventist Hosp, AU	KUMC, US
Methodist Physicians Clin, US	Stern Cardiovascular Ctr, US	Prairie Heart, US	Texas Heart Institute, US	Northside Hosp, US
Univ of Michigan, US	St. Vincent's Jacksonville, US	University of Iowa, US	MUSC, US	Minneapolis Heart Institute Foundation, US
Royal Adelaide Hosp, AU	Cleveland Clinic, US	University of Virginia, US	Houston Methodist, US	CHU Rennes Hosp, EU
Rutgers-New Jersey Med School, US	Broward Health, US	Sentara, US	Michigan Heart, US	University Erlangen, EU
Policlinico S. Orsola, EU	Piedmont Heart, US	Watson Clinic, US	University of Michigan, US	University Heart Center Hamburg, EU
Manchester Heart Center, UK	Ochsner, US	CHU Nord-Hospital Albert Michallan, EU	William Beaumont Hosp, US	Royal Melbourne Hosp, AU
Monash Heart, AU	Peace Health SHMC, US			#HRS2023

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