# Endokardiální bezdrátová stimulace LK u nemocných indikovaných k CRT:

*multicentrická ověřovací studie - 12 měsíční sledování*

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# Deklarace konfliktu zájmů

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  - St Jude Medical Inc.
  - Medtronic Inc.
  - Boston Scientific Inc.

# Why We Need to Propose Endocardial LV Pacing ?

- *90-98% success rate with CS epicardial LV pacing but there are still implantation failures despite major improvements in the technology (*Failure of LV lead implantation (7%)[1]

- *Limitation due to the CS anatomy (small veins, tortuous veins, valves….)*
- *Limitation due to LV lead implantation complications*
  - CS dissection ( 1.3%) [1] coronary vein perforation (1.3%) [1]
  - High pacing threshold (acute and chronic)
  - Phrenic nerve stimulation (short and long terms)
  - LV lead dislodgement (short and long terms) (5.7%) [1]
  - Epicardial or non optimal pacing site ⟶ non response to CRT
  - X-rays exposure (patient, physician and staff)
  - In hospital-Death (0.3%) [1], 30-days mortality (0.7%) [1]

[1] *Van Rees. J Am Coll Cardiol 2011; 58: 995-1000*

# Endocardial LV Pacing
## *Benefits vs. Epicardial CS Pacing*

- No venous branch variability
- Flexibility in LV pacing site selection

**EFFICIENT IMPLANT**

- Lower capture thresholds
- No phrenic nerve stimulation
- Improved stability

**ADDRESSES COMPLICATIONS**

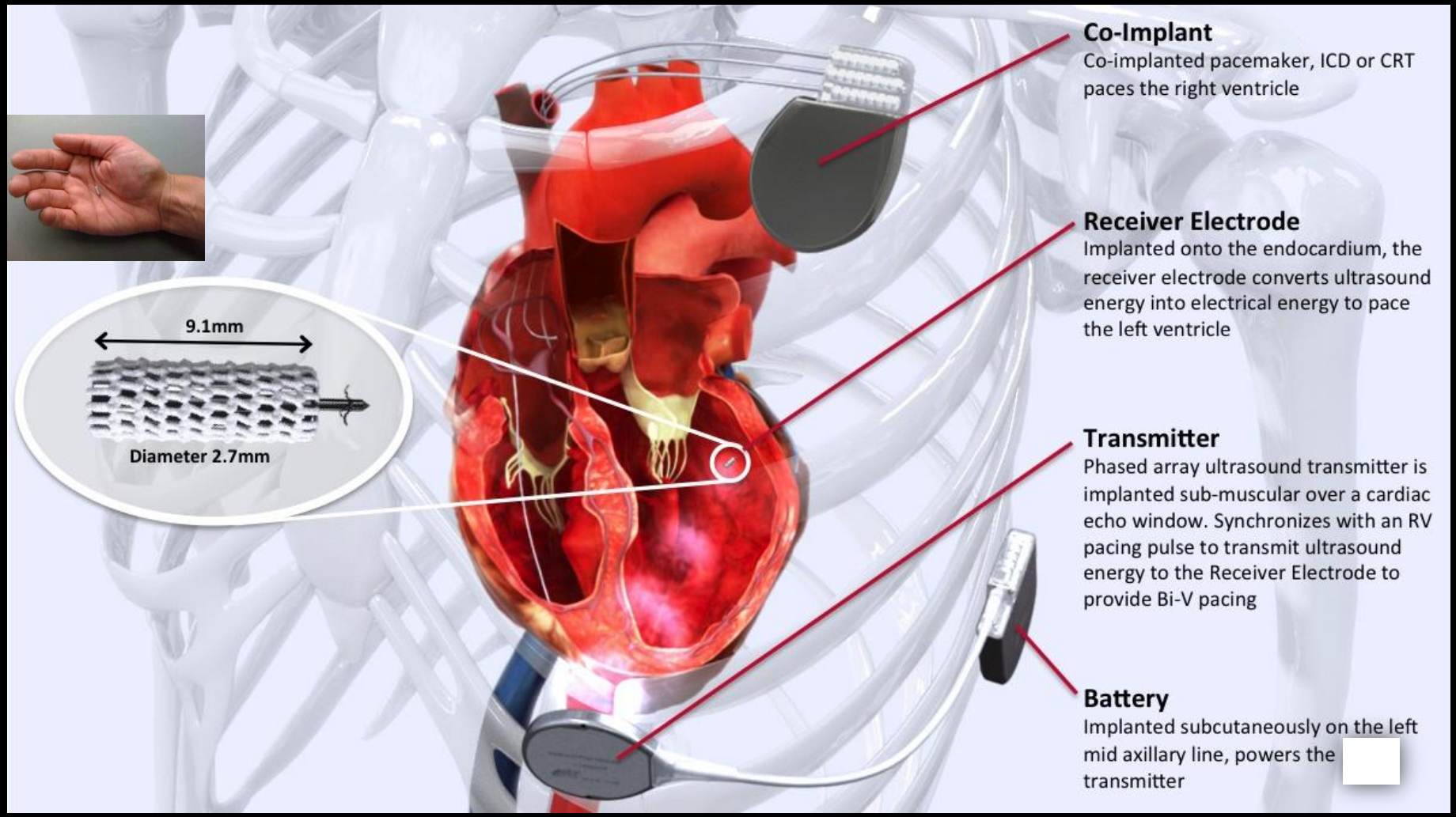
- More rapid activation of the LV myocardium
  - Physiological activation from endo- to epicardium
- Shorter QRS duration
- Improved haemodynamics

**IMPROVES OUTCOME**

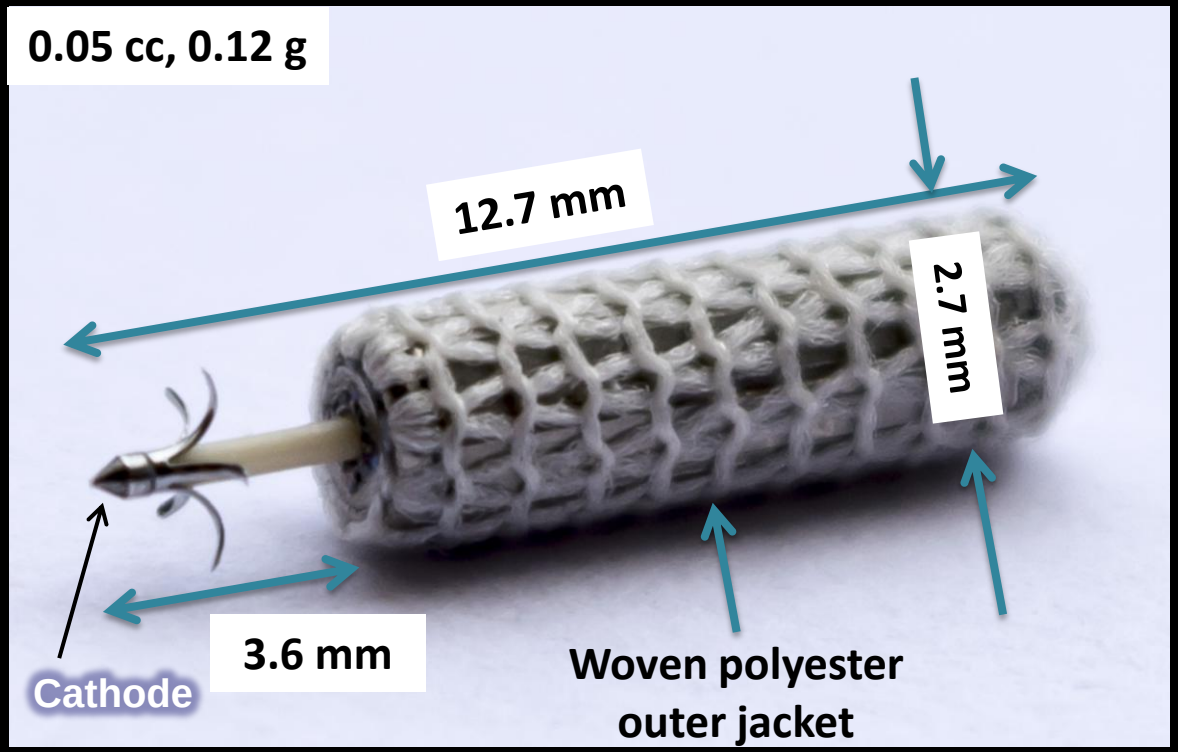
*Bordachar P et al:J Am Coll Cardiol. 2010; 56: 747-753.*

# WiSE CRT System

- Wireless, left ventricular, endocardial pacing system as alternative to conventional epicardial CS pacing



# WiSE CRT System
## *Electrode*





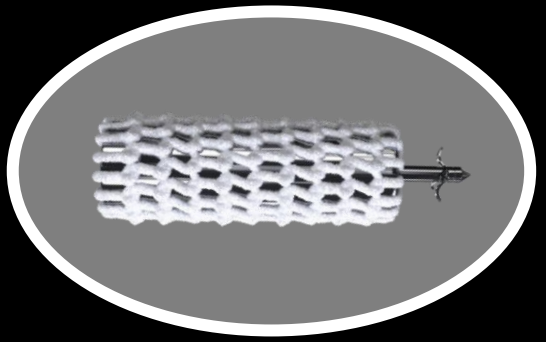
- Attached to LV endocardium with 5 barb fixation anchor
- Woven polyester outer jacket
  - Enhanced endothelialisation
  - Minimised risk of thromboembolic events

# WiSE CRT System
## *Electrode*

## Small Size

Designed for LV placement while avoiding need for chronic anticoagulation

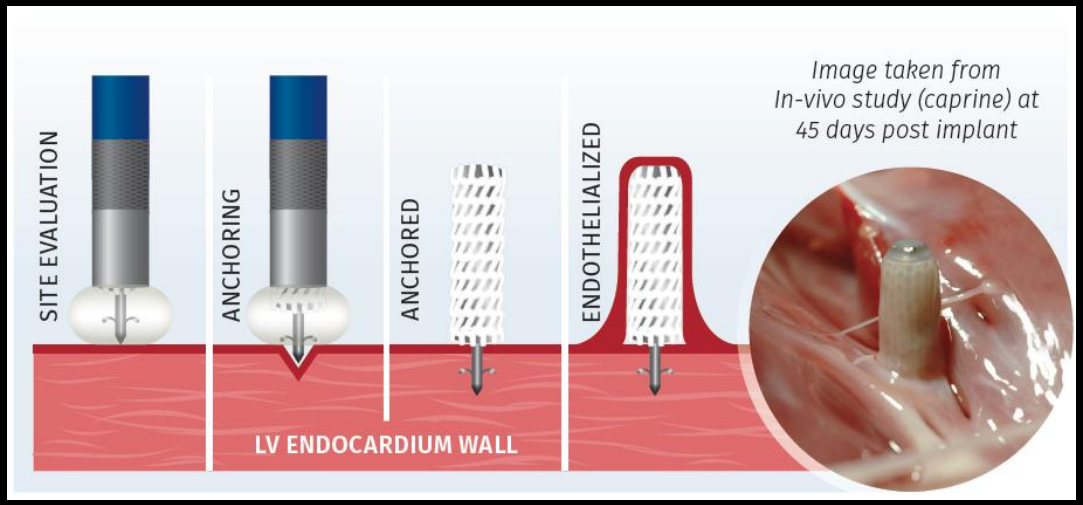
LENGTH OF BODY: **9.1mm**
DIAMETER: **2.7mm**
WEIGHT: **0.12 g**
VOLUME: **0.05 cc**



## Secure Attachment

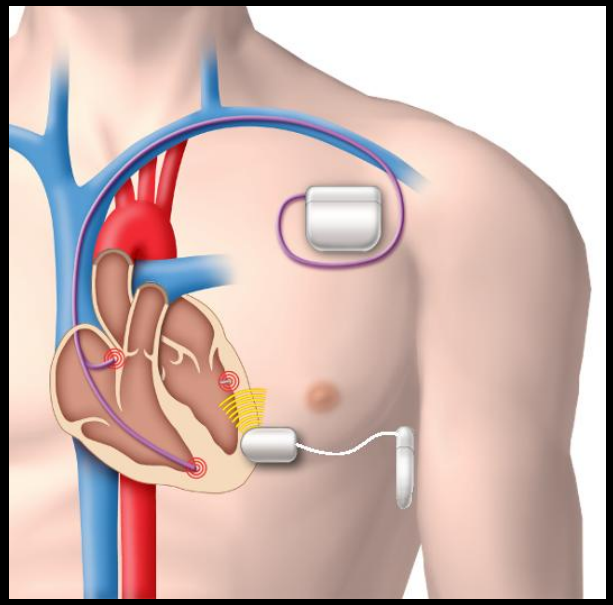
Endothelialises for a low risk of thromboembolic events

- Anchors onto endocardial wall with 5 nitinol tines
- Passive device with no need for replacement
- Full endothelialisation in animal testing at 30 to 45 days [11]

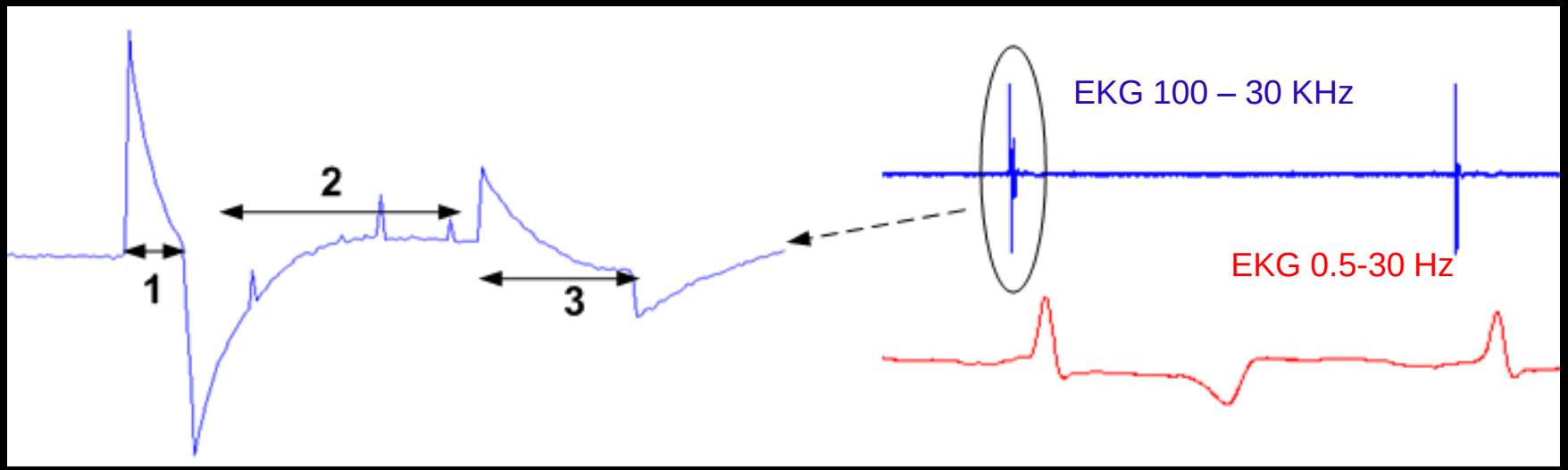



*Echt DS, Moore D, Cowan M, Valli VE, Whitehair JG, Willis NP. Heart Rhythm 2010; S451-2.*

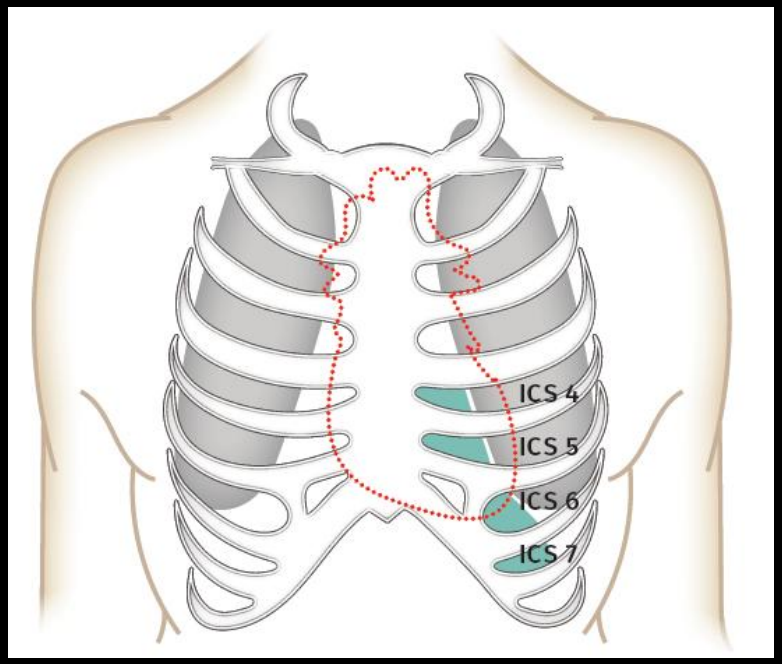
# WiSE-LV System
## Synchronization & Timing for CRT



1. Detect Co-implant RV output
   - Pacemaker, ICD, or CRT
   - Pulse-width measured to discriminate RV vs. RA
2. Locate/Target Electrode – “search”
   - 16 µs ultrasound pulses
   - sensed amplitude response discriminates position
3. Send pacing energy
   - Programmable PW 0.1-2.0ms and Transmit level
   - Typically 3ms after RV pulse, max ~12ms



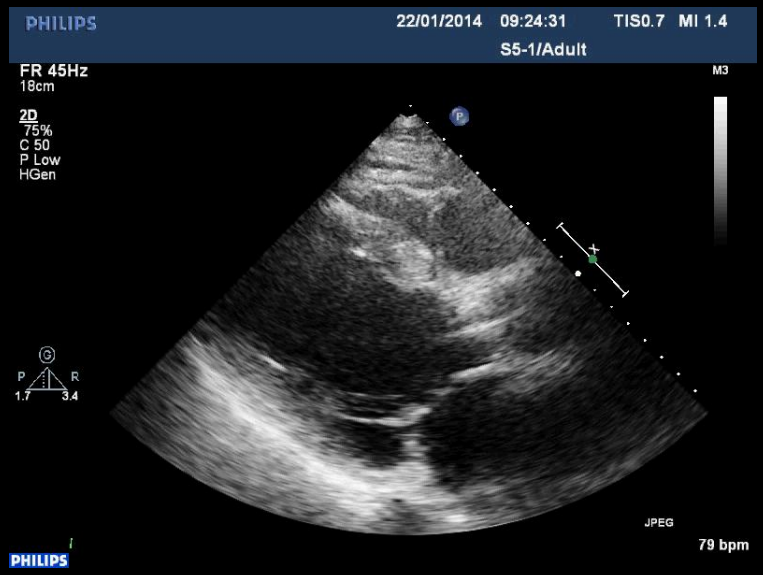
# Transthoracic Echocardiography: Examples of acustic window detection

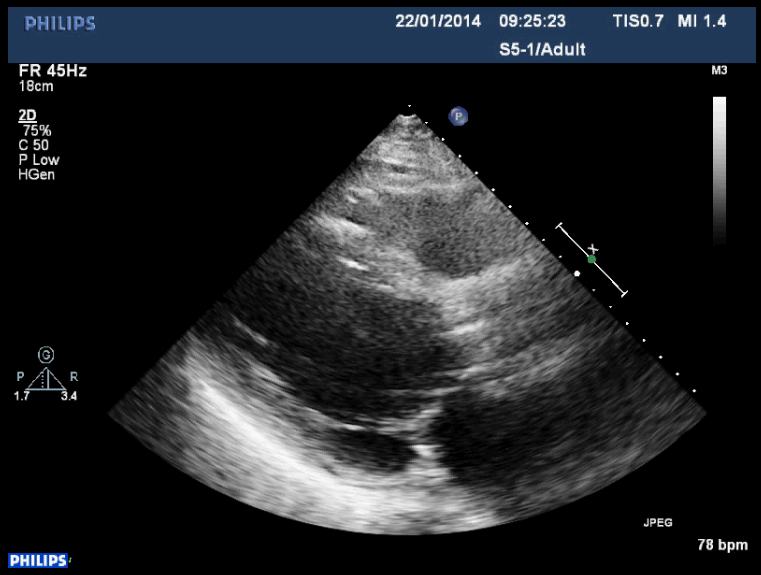


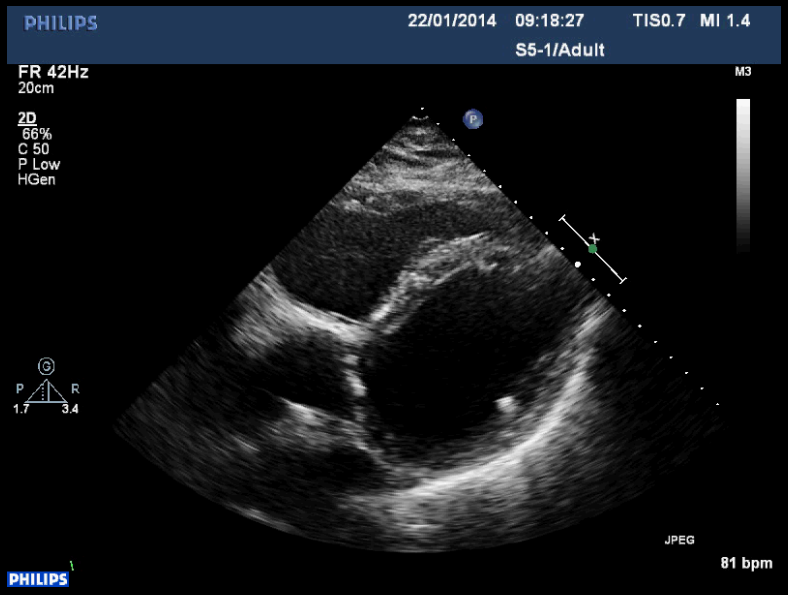

*Transmitter is most commonly placed in a patient's 6th intercostal space (ICS)*

- Identify optimal transmitter position, acoustic window, AW
  - Assess intercostal space 4-7 with TTE
  - Ensure no lung or rib obstruction preventing ultrasound transmission to potential receiver electrode site
  - Minimum 1 x 3.5cm window
- Additional assessment of:
  - LV wall thickness
  - Areas of ischemia
  - Potential electrode placement

# Transthoracic Echocardiography:
# Examples of acustic window detection



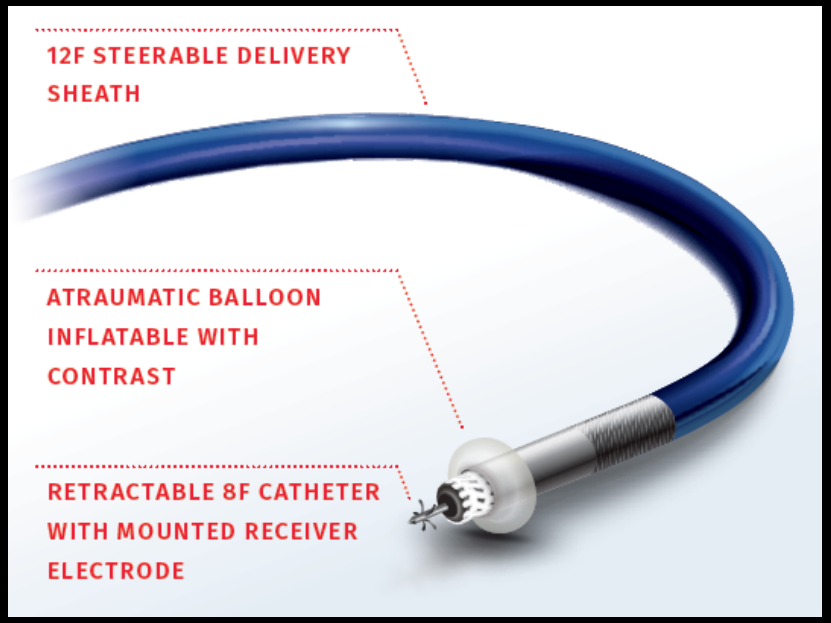
# WiSE – Transmitter and Battery
## Surgical Part of the Procedure

# WiSE – Transmitter and Battery
## Surgical Part of the Procedure

# WiSE – LV Lead
## *Delivery System*

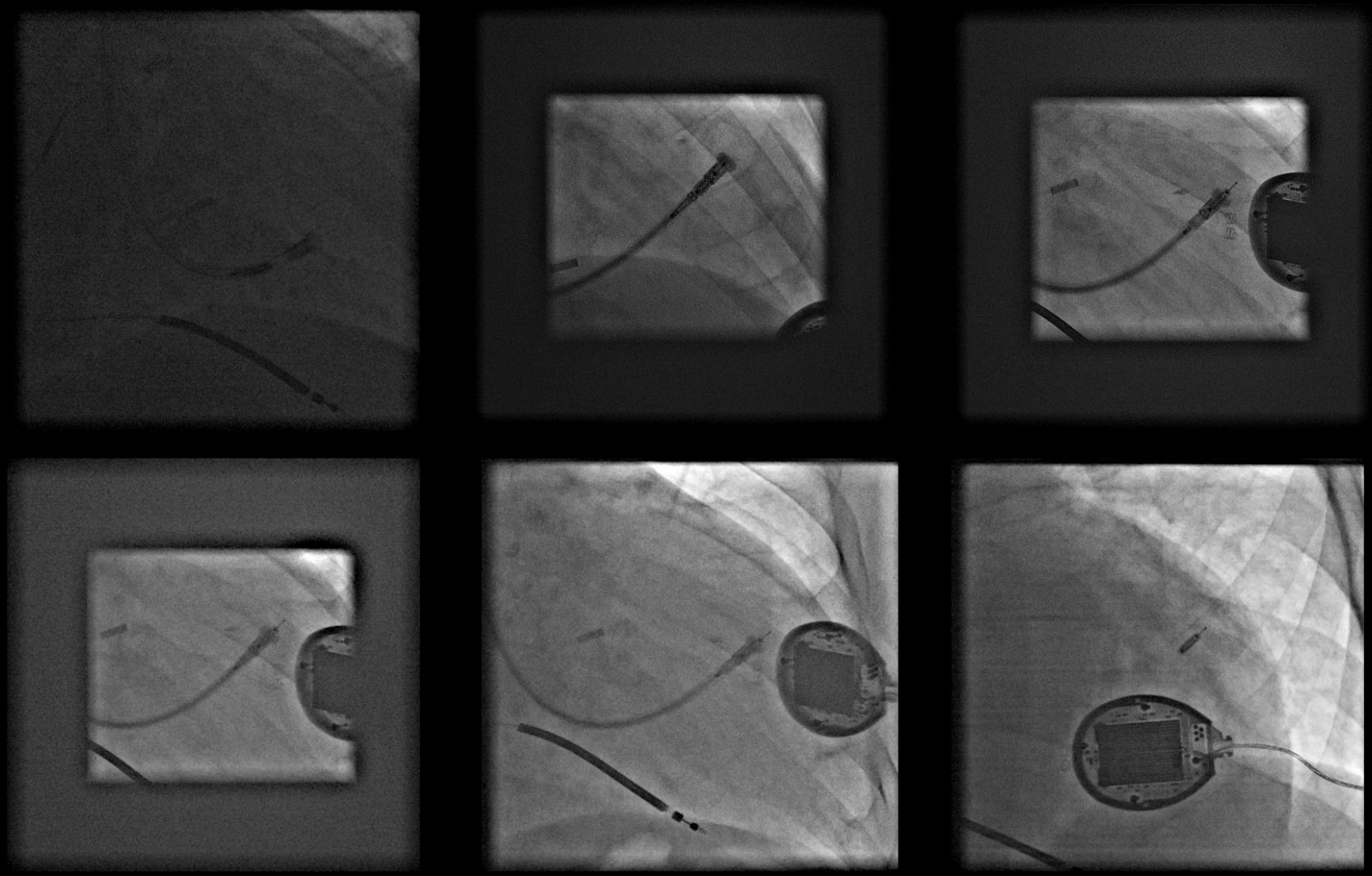
## Designed for Safety

- Innovative inflatable polyester balloon
  - Atraumatic tip
- Radiopaque markers
  - Clear visualisation of position
- Direct connection of the cathode tip to EP recording systems
  - Analysis of EGM signals, pacing & threshold testing

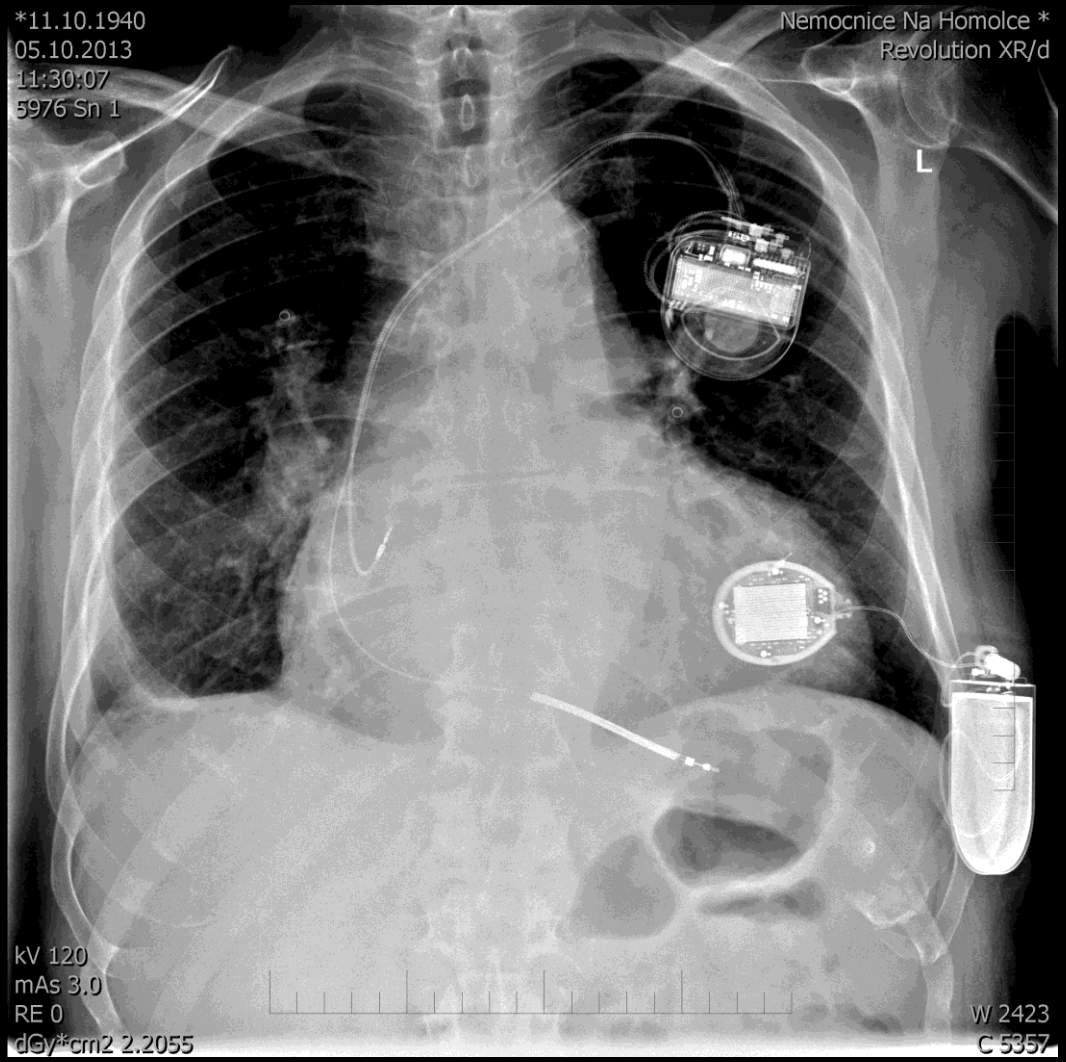


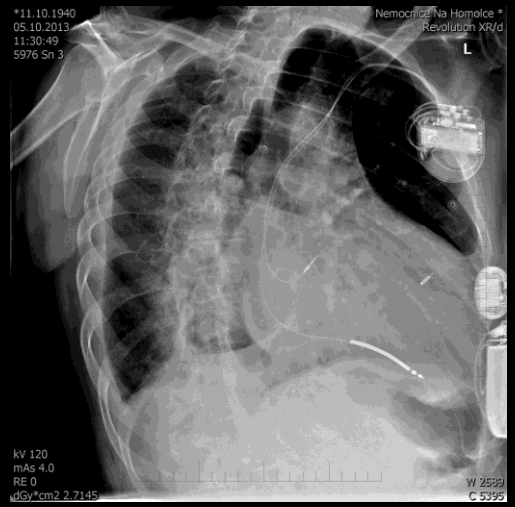

^ Results from the SELECT-LV trial confirm all devices were placed without issue (n=39)

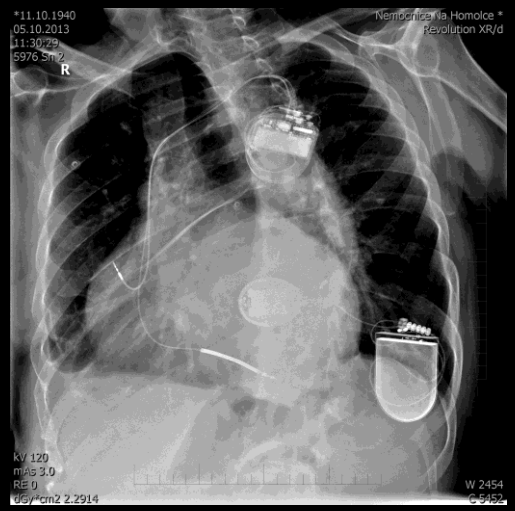
# LV Electrode
## Percutaneous Transaortic Implantation



# WiSE – System Insertion
## Fluoroscopy in Different Projections

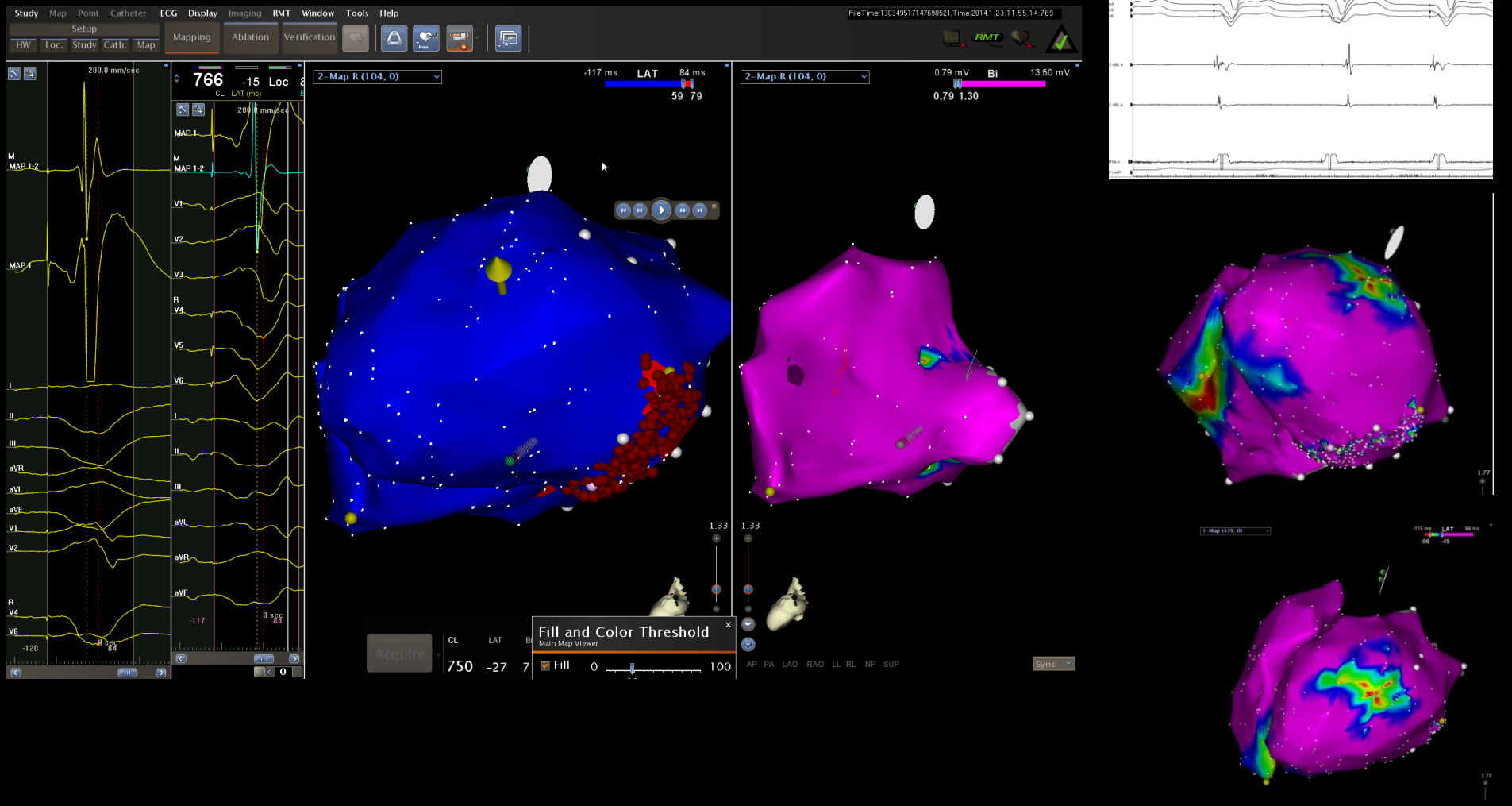


# CARTO Electroanatomical Mapping

## *8 months after Implantation*



# SELECT-LV Study
## Centres and Investigators

| Centre | Investigators |
|---|---|
| Na Homolce Hospital,<br>Prague, Czech Republic | Professor Petr Neuzil<br>Dr. Vivek Reddy |
| Aalborg University Hospital,<br>Aalborg, Denmark | Dr. Sam Riahi<br>Professor Peter Søgaard |
| Isala Ziekenhuis,<br>Zwolle, Netherlands | Dr. Peter Paul Delnoy |
| Heart Center,<br>Bernau bei Berlin, Germany | Dr. Christian Butter<br>Dr. Martin Seifert |
| LUMC,<br>Leiden, Netherlands | Dr. Lieselot van Erven<br>Professor Martin Schalij |
| St. Antonius Ziekenhuis,<br>Nieuwegein, Netherlands | Dr. Lucas Boersma |

# SELECT-LV Study Results

- 39 pts completed enrollment and screening
  - 3 pts failed acoustic window screening
  - 1 pt withdrew consent
- 34 (97.1%) of 35 attempted implants successful
- **25 pts followed for >12m**

# SELECT-LV pts reaching12m: Demographics

| Demographics | Mean ± SD |
|---|---|
| Age, years | 65.8 ± 8.6 |
| BMI | 29.7 ± 4.8 |
| Ejection fraction,% | 27.4 ± 5.4 |
| NYHA | 2.7 ± 0.6 |
| Intrinsic pre-imp QRS duration, ms | 163 ± 32 |
| Gender, male | |
| ICM / NICM / Both | **10 (40%)** / 12 (48%) / 3 (12%) |
| Untreated / Non responder / Upgrade | 19 (76%) / 4 (16%) / 2 (8%) |
| Pts with anticoagulant pre-implant | 13 (52%) |
| Implant duration, days | 571 ± 136 |

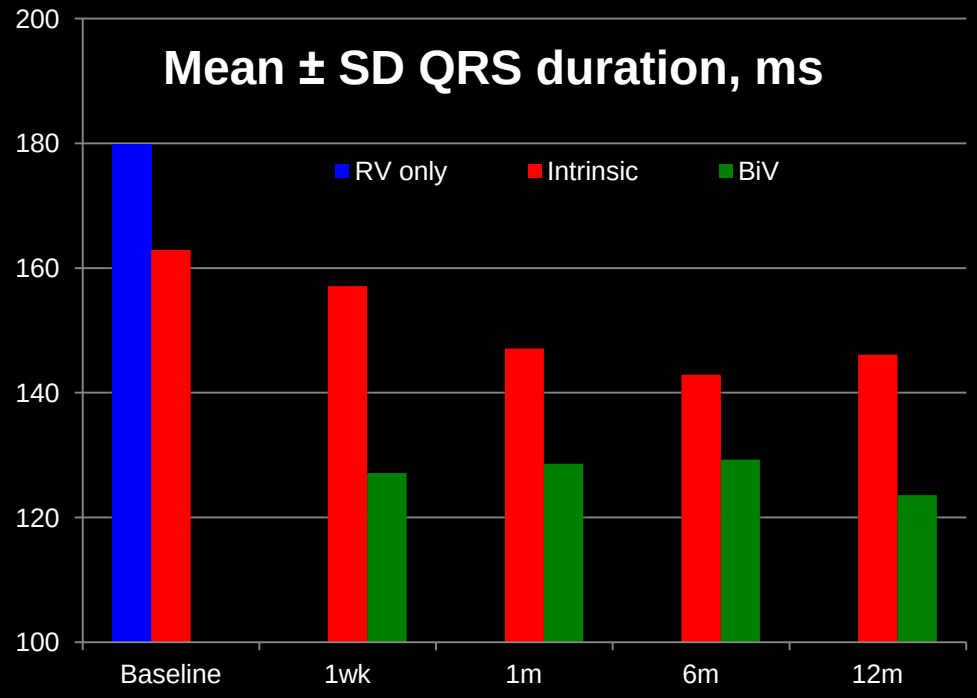
# SELECT-LV pts reaching12m: Clinical Events

| Clinical events | |
|---|---|
| Suspected infection | (3 patients) |
| Haematoma at pulse generator pocket | |
| Acute CVA - pt not compliant with anticoagulant regimen | |
| Pseudo aneurysm | |
| Heart failure hospitalisation | (Repeated in 1 patient) |
| Death, heart failure | (2 patients) |
| Premature battery depletion | (2 patients) |
| Arrhythmic storm | (2 patients) |
| VF and adequate ICD therapy | |

- No cardiac perforation
- No electrode dislodgments

# SELECT-LV pts reaching12m:
## Performance - BiV Pacing

- BiV pacing capture on 12 lead ECG at 1, 6 and 12m
  - 100%, 97% and 96% of evaluable pts

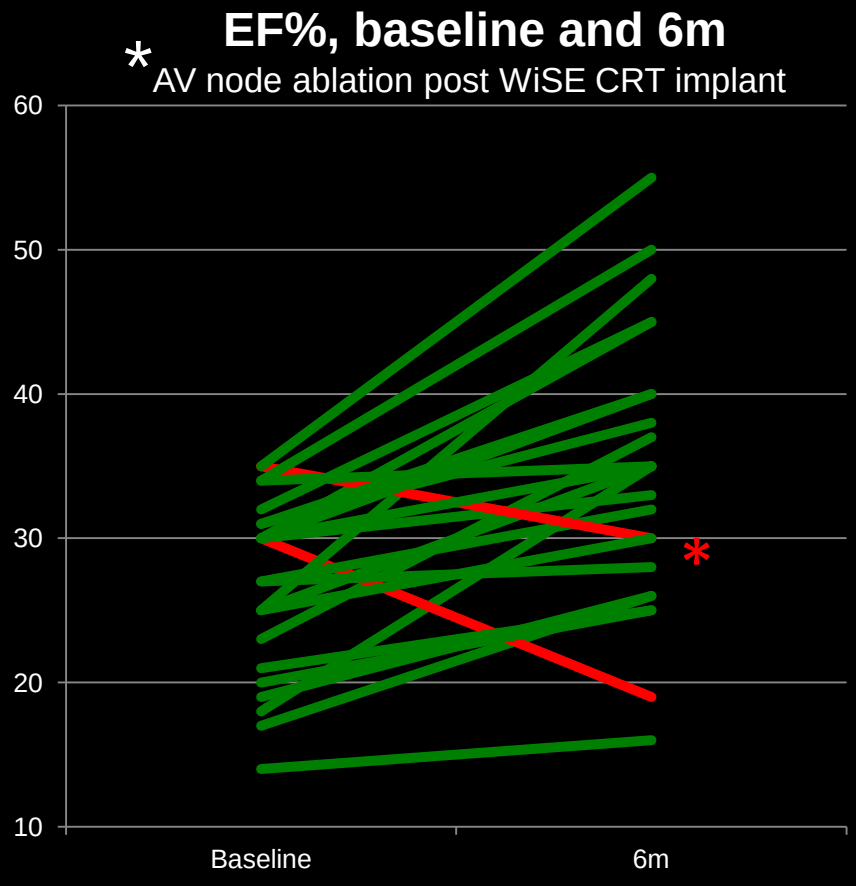



- ***Mean BiV QRS reduced at 1, 6 and 12m vs:***
  - ***Baseline RV:***

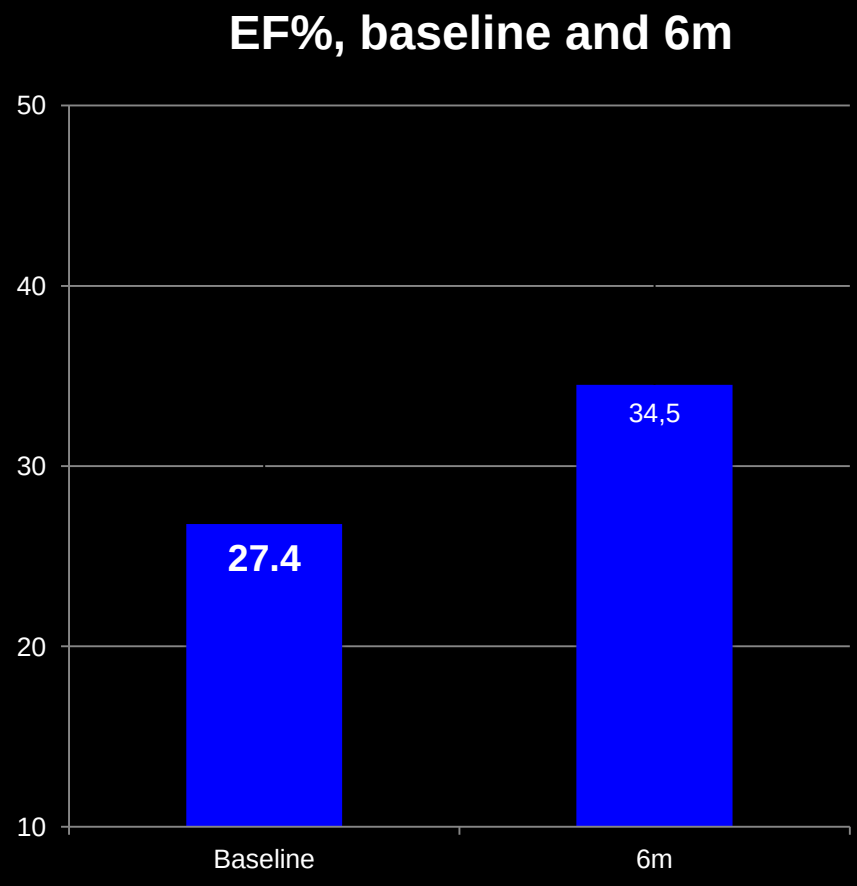
  ***51, 51 and 56 ms***
  - ***Intrinsic:***

  ***34, 34 and 39 ms***
- **Intrinsic QRS reduced over the time**

# SELECT-LV pts reaching12m: Preliminary Efficacy



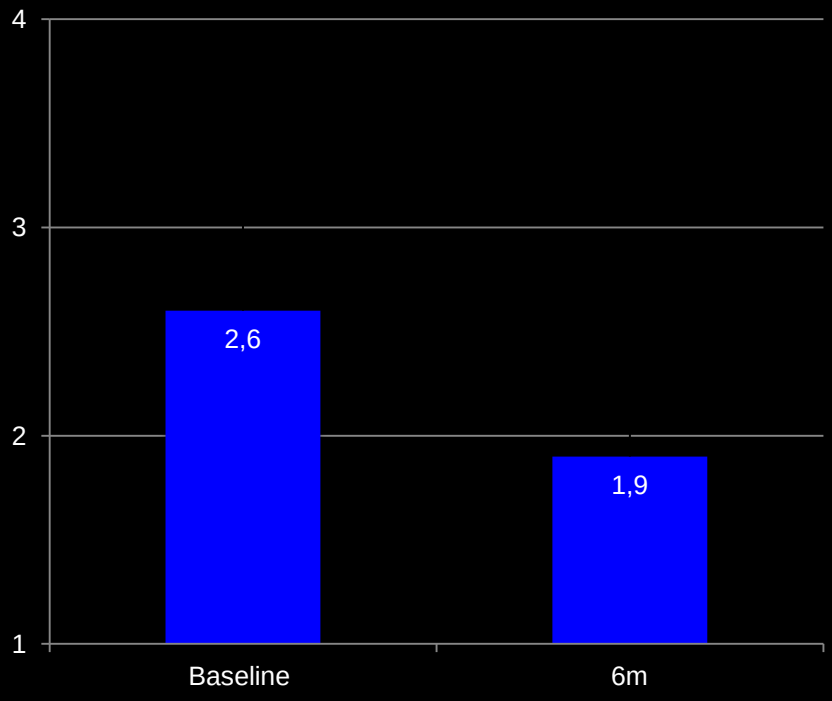

68% pts ≥5% increase




Mean ± SD difference at 6m = 7.1 ± 8.0

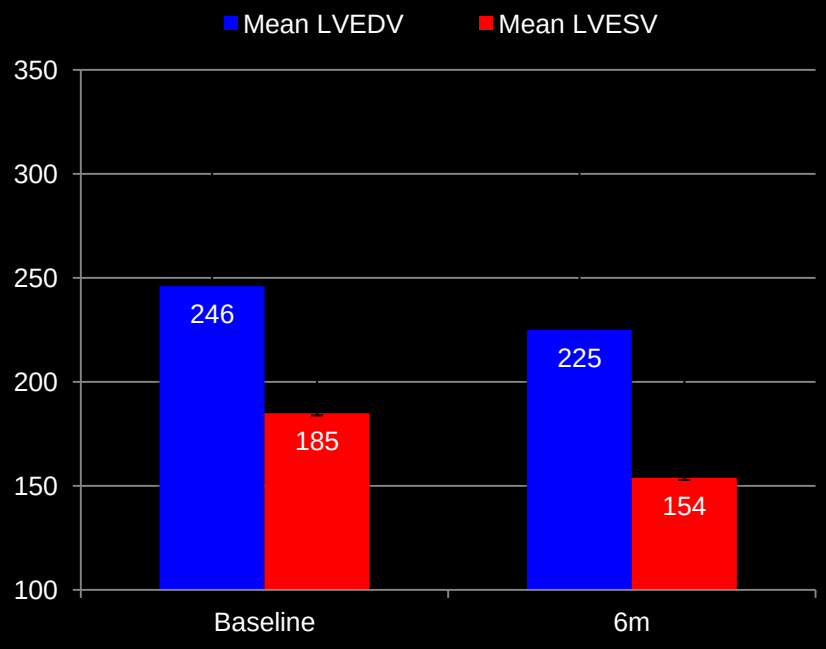
# SELECT-LV pts reaching12m: Preliminary Efficacy

**NYHA, Baseline and 6m**




52% pts ≥ 1 class improvement

**End systolic and diastolic volumes, ml, baseline and 6m**




53% pts ≥15% improvement in LVESV

# SELECT-LV pts reaching12m: Preliminary Efficacy - Clinical Composite Score

- 25 pts to date followed for 12m study duration
  - No pts died within study period
  - 1 pt hospitalised for HF on 2 occasions
  - NYHA mean ± SD decrease from 2.7 ± 0.6 →1.8 ± 0.7
  - Pt global assessment:

**Clinical composite score**

**76% (19) pts improved**

**16% (4) pts unchanged**

**8% (2) pts worsened**

*Packer M et al., J Cardiac Failure 2001; 7: 176-182.*

# SELECT-LV pts reaching12m: **Conclusion**

- WiSE CRT shows promising efficacy in pts unable to benefit from conventional CRT, non responders / upgrades
- Multi-centre experience in a small number of pts has demonstrated feasibility, utility and long term outcome of endocardial LV pacing to achieve CRT
  - BiV pacing achieved in 100, 100, 97 and 96% of pts at 1 week, 1, 6 and 12m
  - Mean BiV QRS duration reduced by 1 week and maintained at 12m
  - Intrinsic QRS duration reduced, demonstrating electrical reverse remodelling
  - Mean LV EF increased
  - Mean NYHA reduced
  - Mean end systolic / diastolic volumes reduced
  - Clinical composite score improved

# SELECT-LV pts reaching12m: **Conclusion**

- Chronic anticoagulation is not required
- Post-market surveillance registry underway for WiSE CRT
  - Consolidated experience in clinical practice, not clinical study
  - Site selection strategies for electrode investigated
- Improvement in battery longevity by
  - Programming
  - Transmitter development
  - Electrode development
  - Battery development