

MEET THE EXPERT UNPLUGGED

Stimolazione leadless endocardica ventricolare sinistra (Sistema WiSE): Tecnica di impianto, casi clinici e applicazioni cliniche future

Dott. Giovanni Rovaris
Direttore S.S. Elettrofisiologia Interventistica
Fondazione IRCCS San Gerardo dei Tintori, Monza



Traditional CRT systems are suboptimal

Traditional CRT systems use leads to deliver energy to the heart, which can lead to many issues.



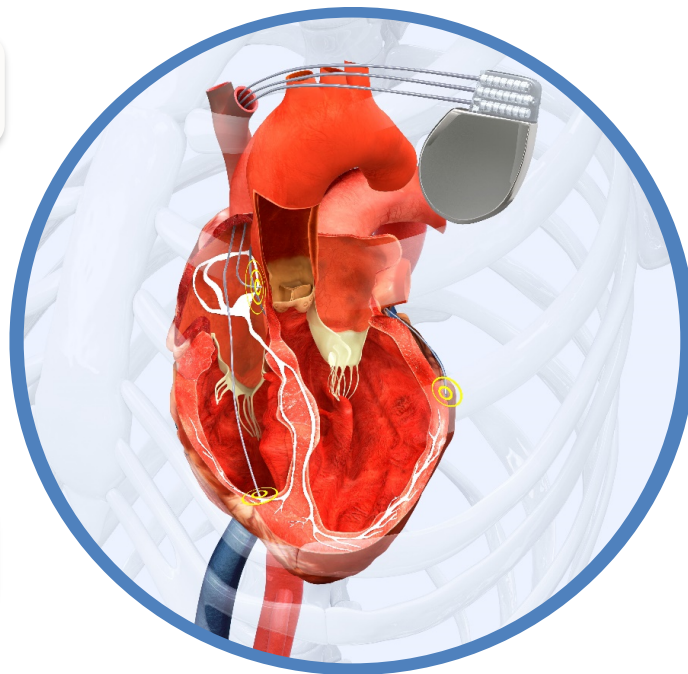
Leads can migrate and sometimes fracture



Leads can become a way for pathogens to reach the myocardium



Difficult to place



LV lead must be placed outside the heart to avoid blood clots



Coronary Sinus limits Left Ventricle (LV) lead placement locations



Leads can be associated with phrenic nerve stimulation



WiSE® System for Heart Failure Patients

Designed to overcome the limitations of conventional CRT and is the only leadless left ventricular endocardial pacing (LVEP) device.



Leadless

Un dispositivo ultracompatto elimina i vincoli dei sistemi di pacing basati sui cateteri



Versatile

La piattaforma aperta consente la sincronizzazione con una serie di dispositivi esistenti



LV Endocardial

Approccio più fisiologico per CRT

Left ventricle



WiSE Electrode
95% smaller than
Aveir or Micra

Right ventricle/atrium

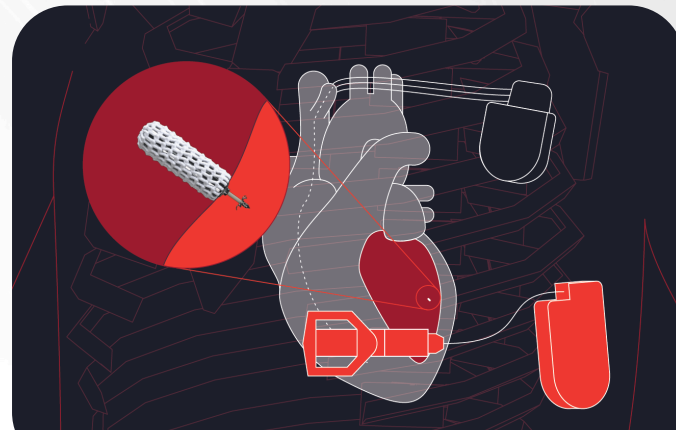


**Medtronic
Micra®**



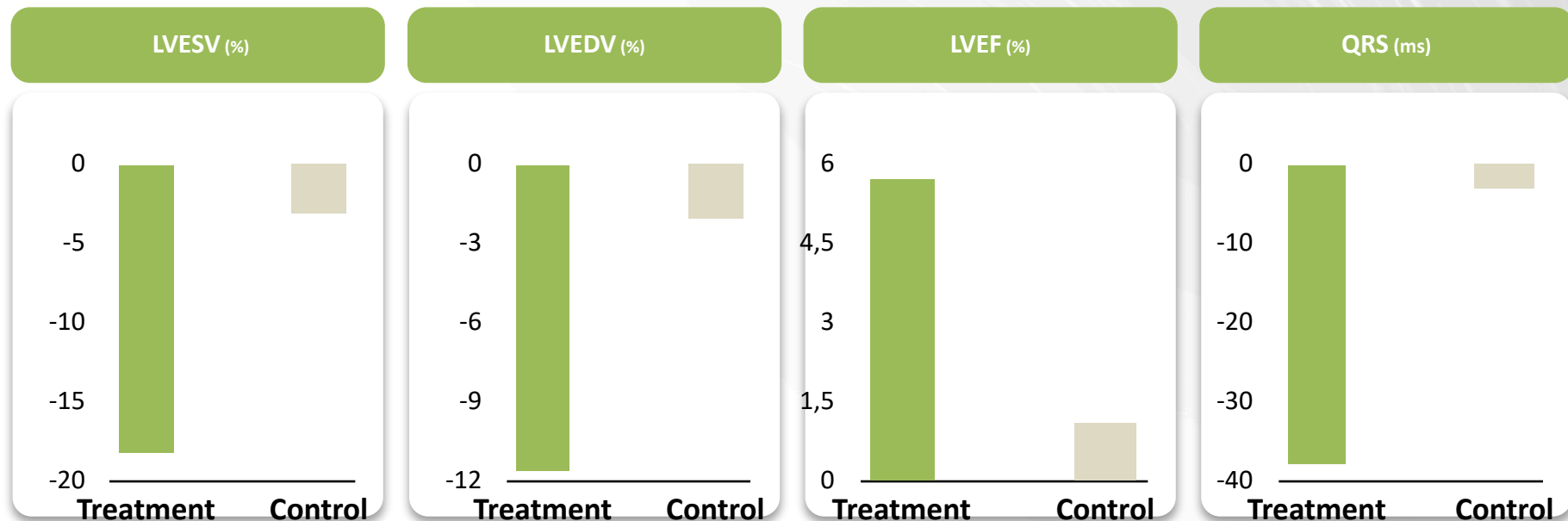
**Abbott
Aveir®**

Not to scale



• SOLVE-CRT Sub-analysis of Randomized Data

Demonstrated clinical evidence of **reverse remodelling** within *previously untreatable*, and *high-risk* patients

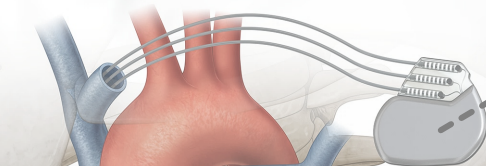


Control n = 25, Treatment n = 22

Seifert, M., Butter, C., Rinaldi, C. A., et al. Leadless ultrasound-based cardiac resynchronization system in heart failure: Results from the SOLVE-CRT randomised sub-study and the primary population patient cohort. EP Europace, 26 (Supplement_1), doi.org/10.1093/europace/ueae102.480



WiSE® System Overview



CO-IMPLANT DEVICE

Pre-existing device to provide RV pacing (PM, ICD, CRT or leadless PM)

TRANSMITTER

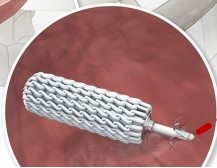
Phased array ultrasound Transmitter synchronizes with RV pacing pulse to transmit ultrasound energy to the Electrode

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



How It Works

1

DETECT

Il trasmettitore rileva l'impulso di stimolazione del RV proveniente dal dispositivo co-impianto.

2

LOCATE

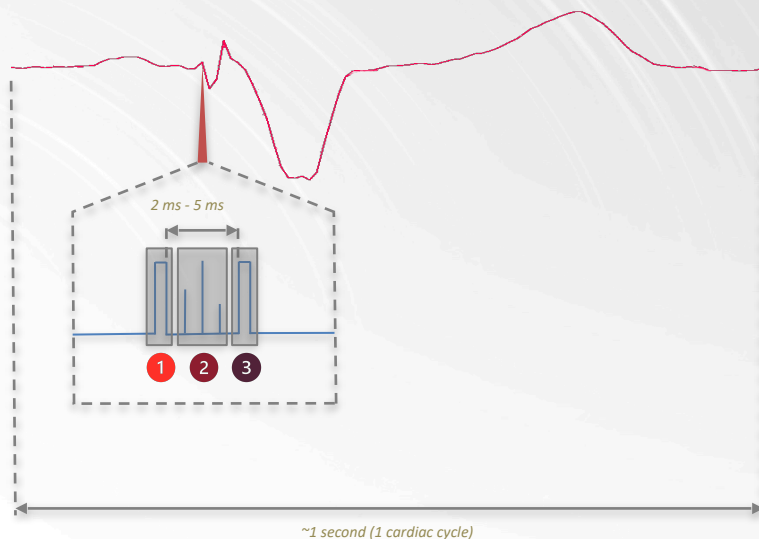
Il trasmettitore localizza l'elettrodo tramite diversi brevi "impulsi" a ultrasuoni. Questi impulsi brevi non sono sufficienti per far sì che il LV sia stimolato.

3

TRANSMIT & PACE

Il trasmettitore trasmette energia a ultrasuoni all'elettrodo, che la converte in un impulso elettrico di stimolazione sincrono con la stimolazione VD.

BiV Pacing with WiSE System

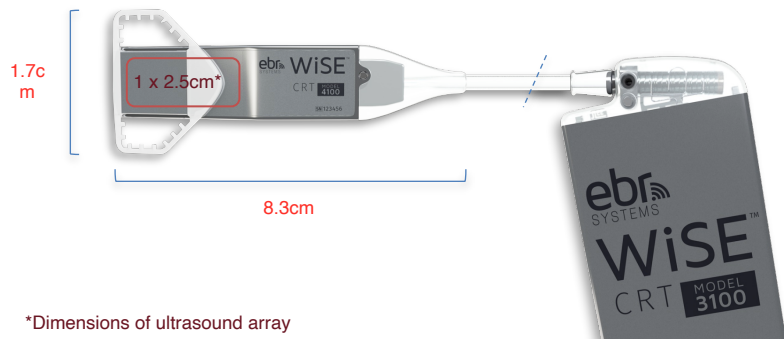


Timing from co-implant RV spike detection to
Electrode capture takes ~2-5 ms

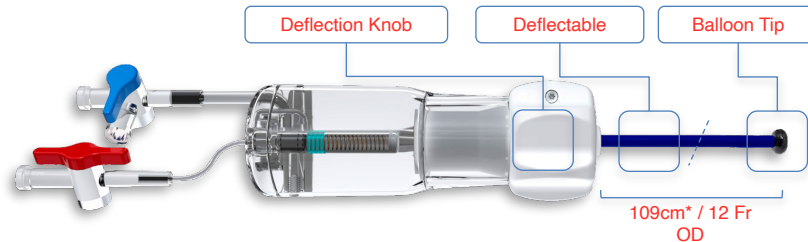


WiSE® Components

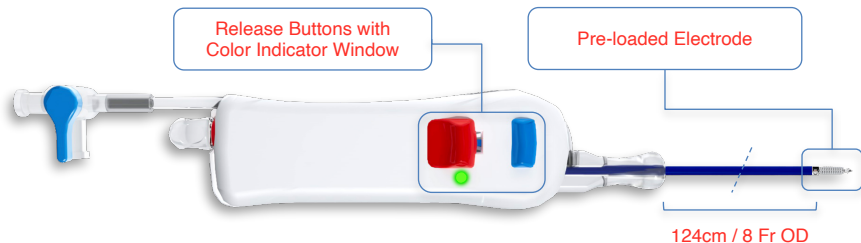
Transmitter (M4100) & Battery (M3100)



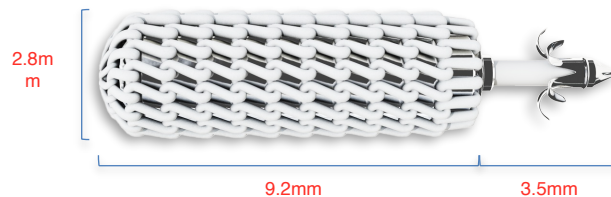
Delivery Sheath (M2000)



Electrode Catheter (M1000)



Electrode



WiSE® Electrode

Ultra-compact and capable

WiSE 0.05cc



Micra VR2 1.00cc



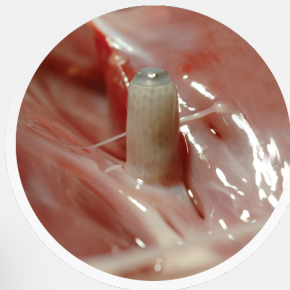
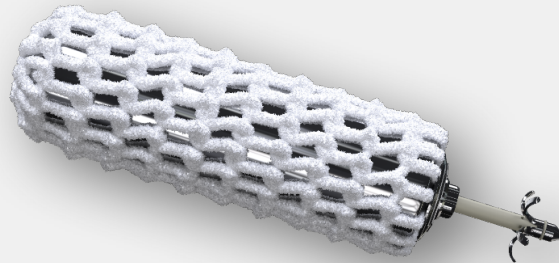
Aveir VR 1.10cc



Actual Relative Device Volume Comparison



Intracardiac



No need for **chronic anticoagulation**

Polyester jacket design



Standard DAPT post-implant



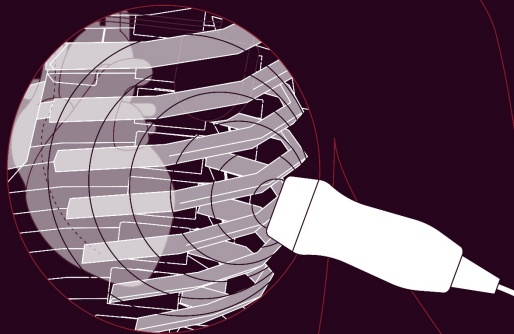
Rapid endothelialization
in 30-45 days

Medtronic Micra VR2 IFU
Abbott Aveir VR IFU

Echt DS, Moore D, Cowan M, Valli VE, Whitehair, JG, Willis NP. Chronic implantation of leadless pacing electrodes in the left ventricle of a goat model. Heart Rhythm 2010;7:S451 -2

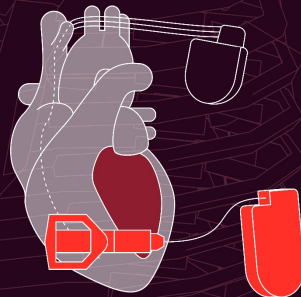


• WiSE[®] Procedure Overview



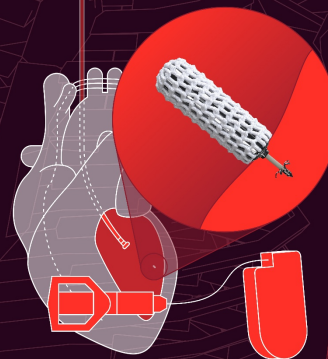
1. Pre-assessment

Transthoracic ultrasound
for anatomical screening



2. Extravascular Implant

Battery & Transmitter
implant



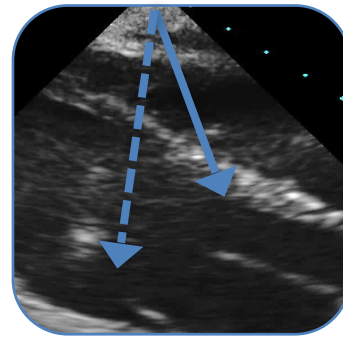
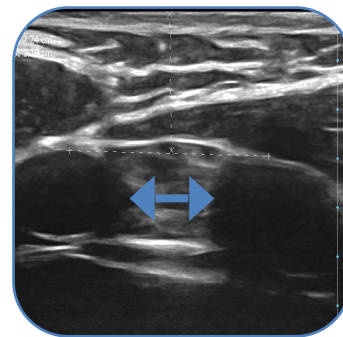
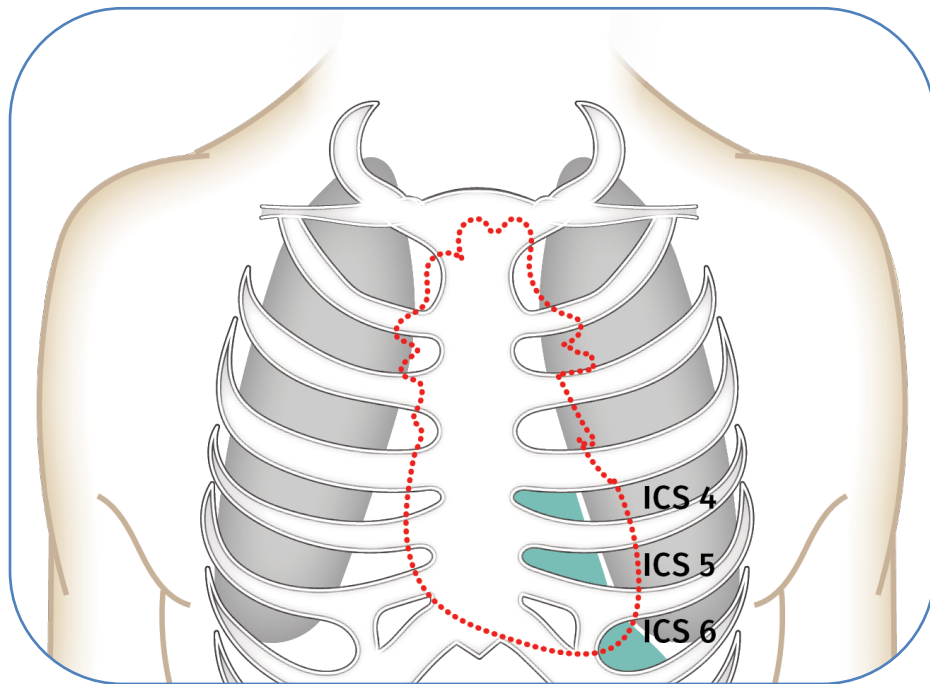
3. Transcatheter Implant

Electrode mapping and
anchoring





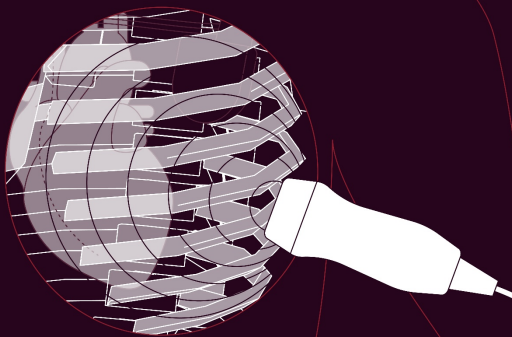
STEP 1: Pre-Assessment, Acoustic Window Screening



- Transthoracic ultrasound for anatomical screening.
- Assess intercostal spaces and cardiac images for optimal Transmitter Implant location.

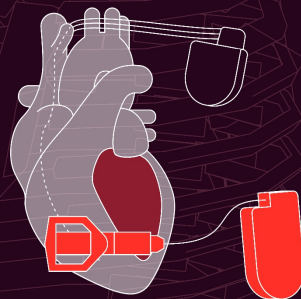


● WiSE® Procedure Overview



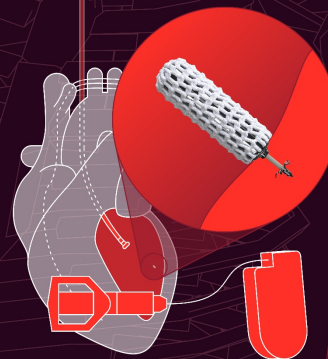
1. Pre-assessment

Transthoracic ultrasound
for anatomical screening



2. Extravascular Implant**

Implant for Battery and
Transmitter

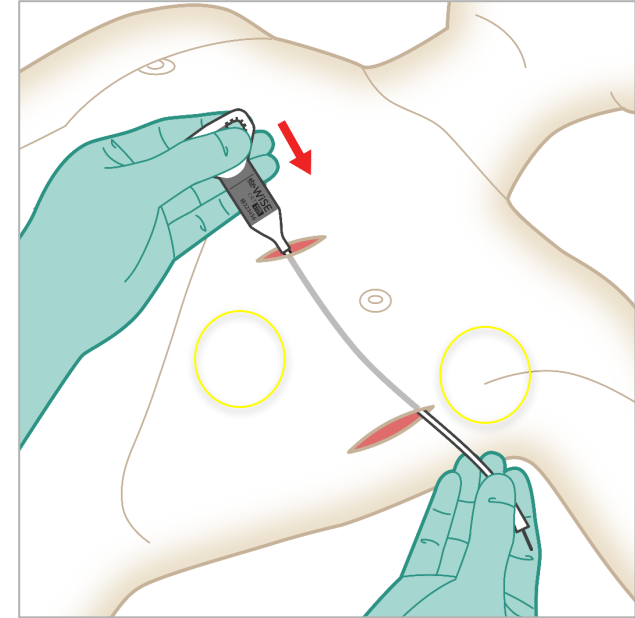
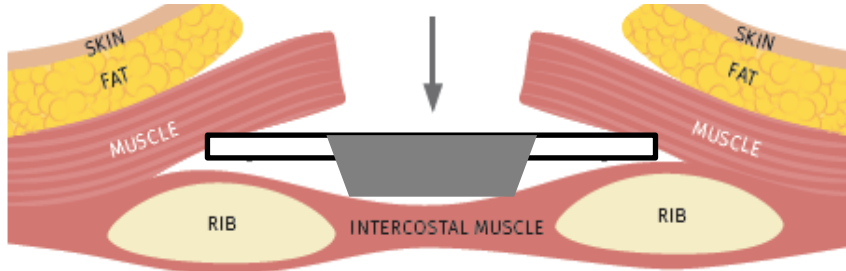


3. Transcatheter Implant

Electrode mapping and
anchoring



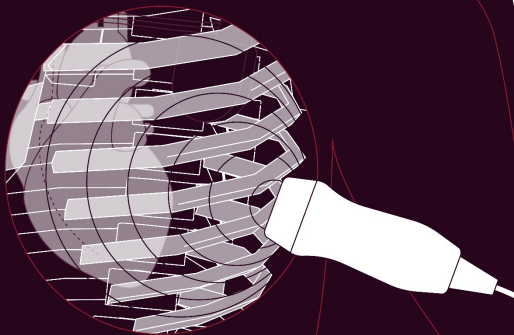
STEP 2: Implantation of Transmitter & Battery



*Transmitter implantation with
tunneled cable to Battery pocket*

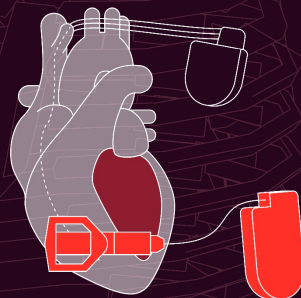


• WiSE® Procedure Overview



1. Pre-assessment

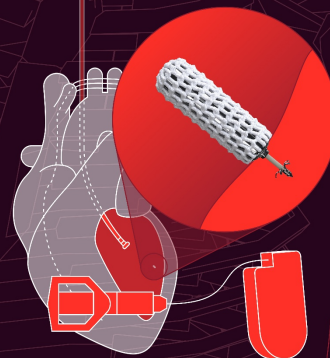
Transthoracic ultrasound
for anatomical screening



2. Extracardiac Implant**

**

Implant for Battery and
Transmitter



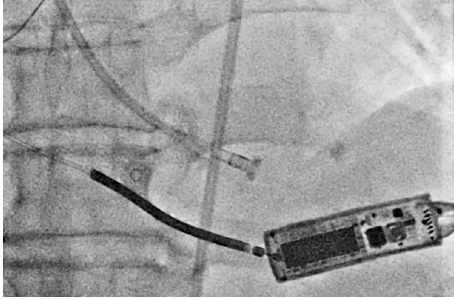
3. Transcatheter Implant

Electrode mapping and
anchoring

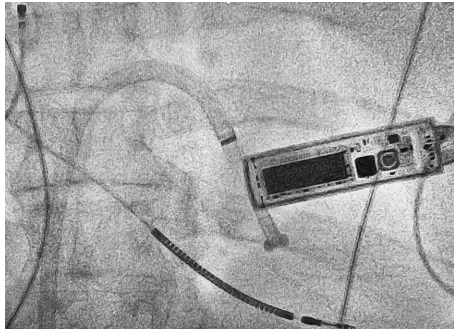


Step 3: WiSE[®] Electrode Implant Procedure

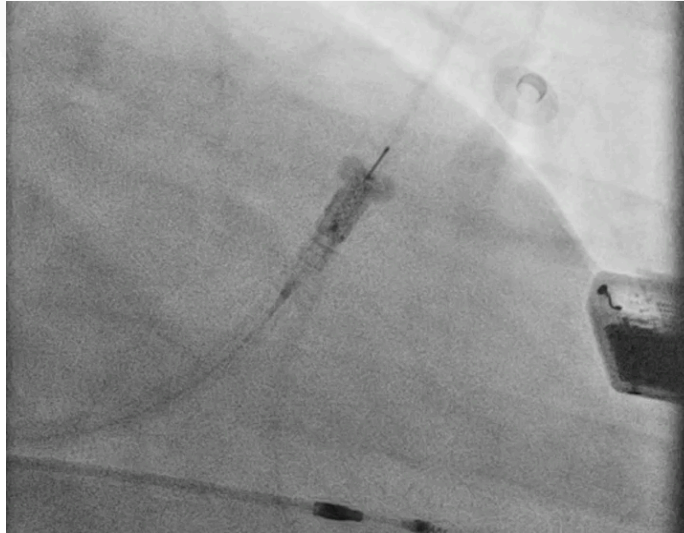
Retrograde Aortic Approach



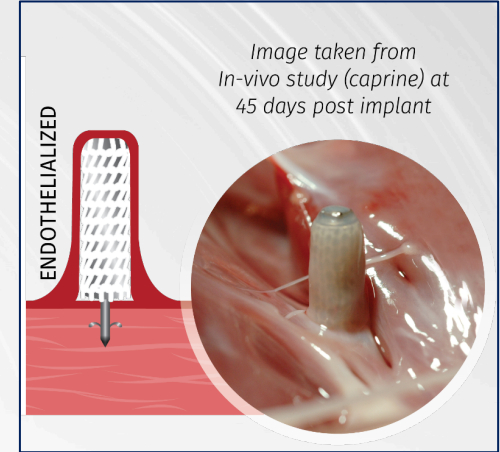
Transseptal Approach



Anchoring Sequence



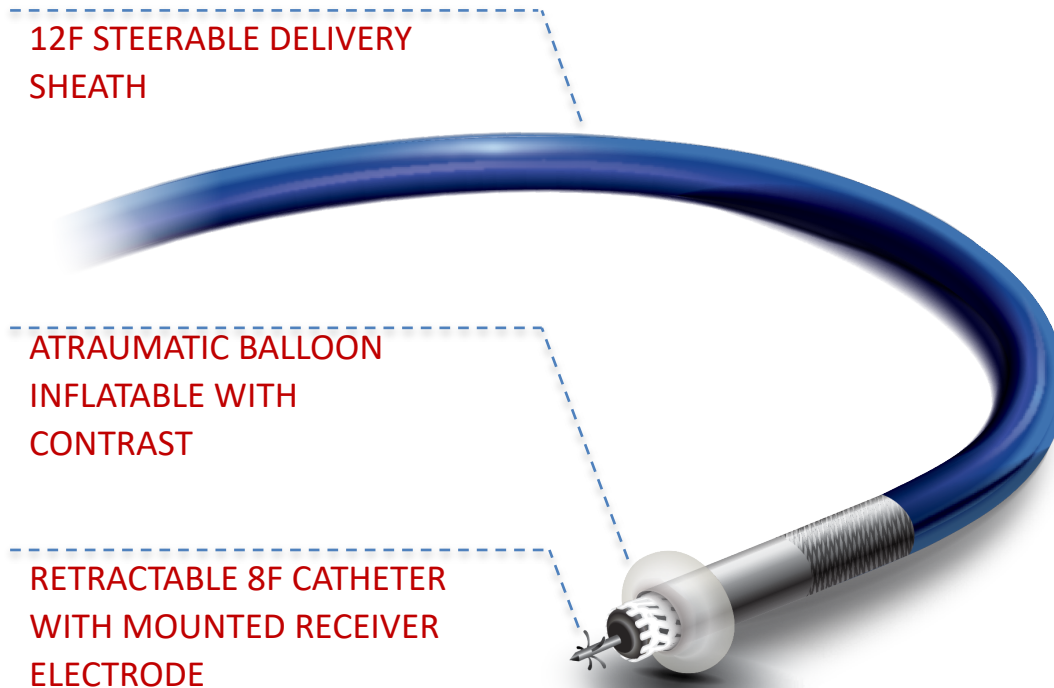
Secure attachment



- Endothelializes within 4-6 weeks
- No need for chronic anticoagulation
- No need for extraction
- No endocarditis to date



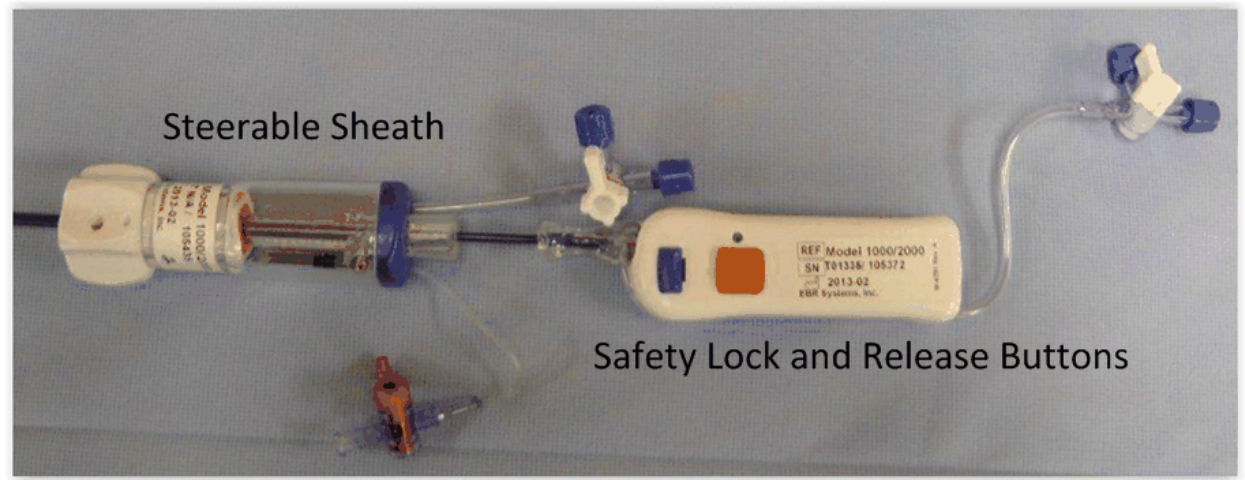
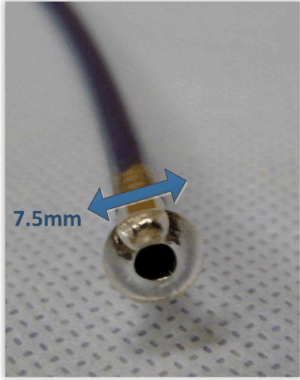
WiSE CRT System: Delivery Sheath & Electrode catheter



^Results from the SELECT-LV trial confirm all Receiver Electrode devices were safely placed without pericardial effusion events (N=34)



WiSE CRT System: Delivery Sheath & Electrode catheter



Clinical case 1

Caso 1

Paziente con CMD idiopatica, CRTD in prevenzione primaria (2010); FE 33% al 44%.

Luglio 2012: Revisione della tasca per il decubito. Tamponi positivi per staphylococcus.

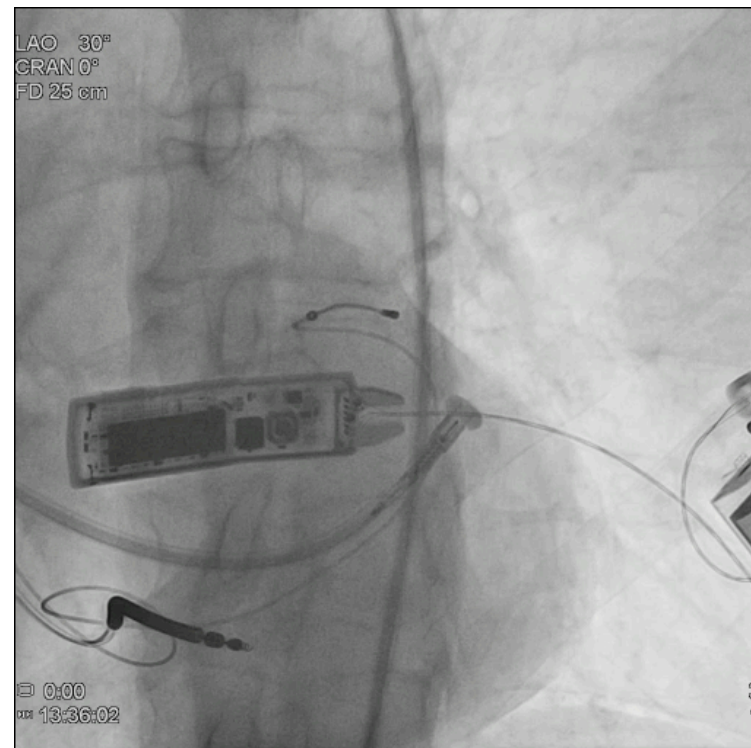
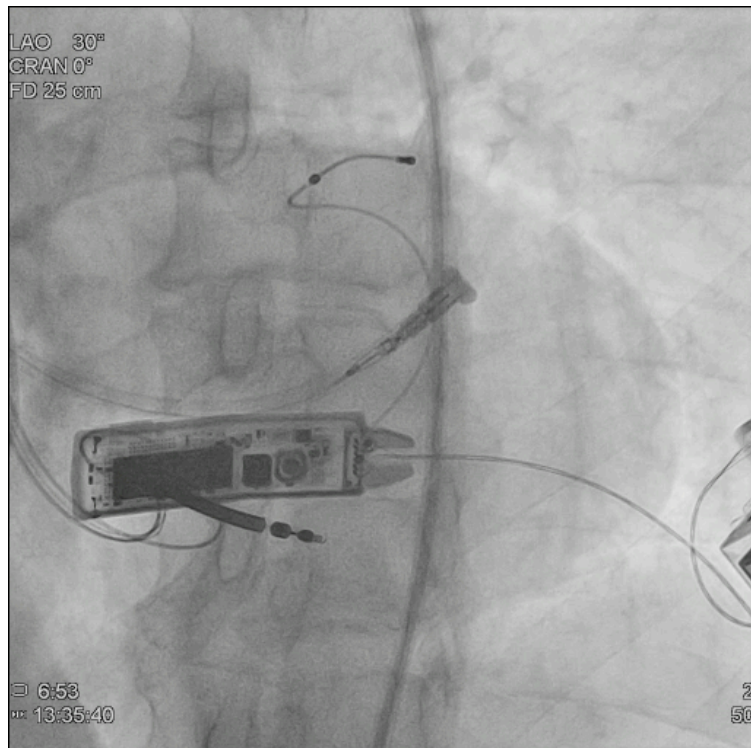
Agosto 2012: Espianto di dispositivi e cateteri e successivo reimpianto prepettorale destra.

Settembre 2018: Elevata soglia di stimolazione e stimolazione diaframmatica.

Ottobre 2018: impianto del sistema CRT WISE.

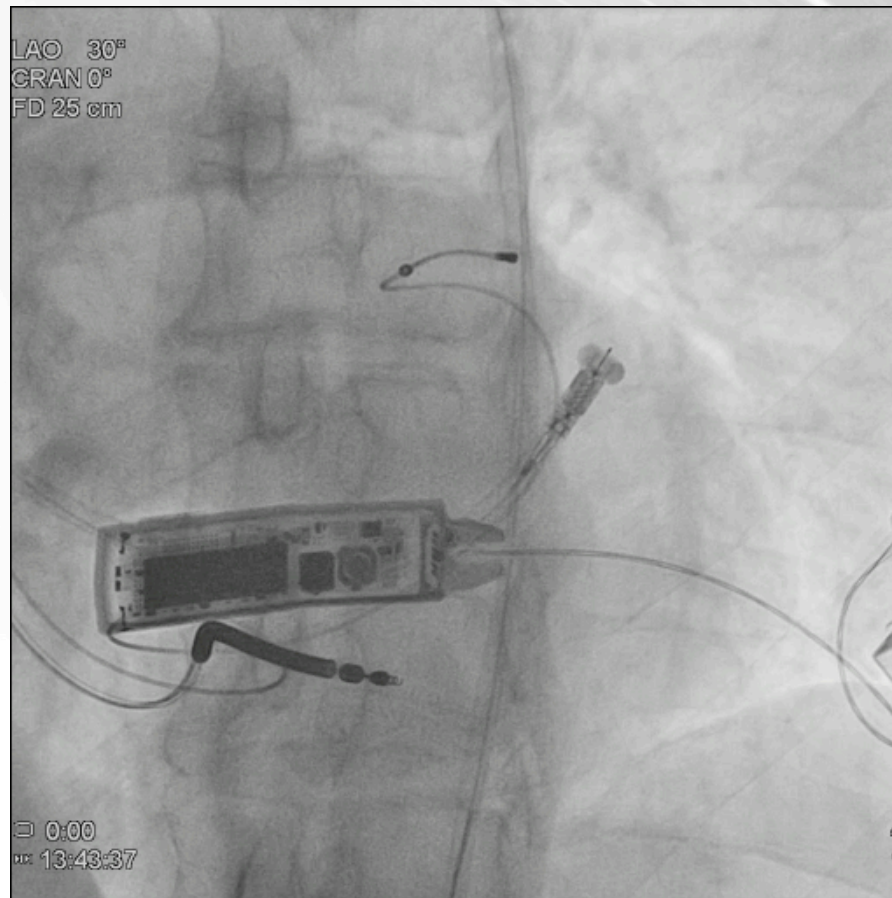


IMPLANTATION PHASE 1: Approaching the sidewall LV

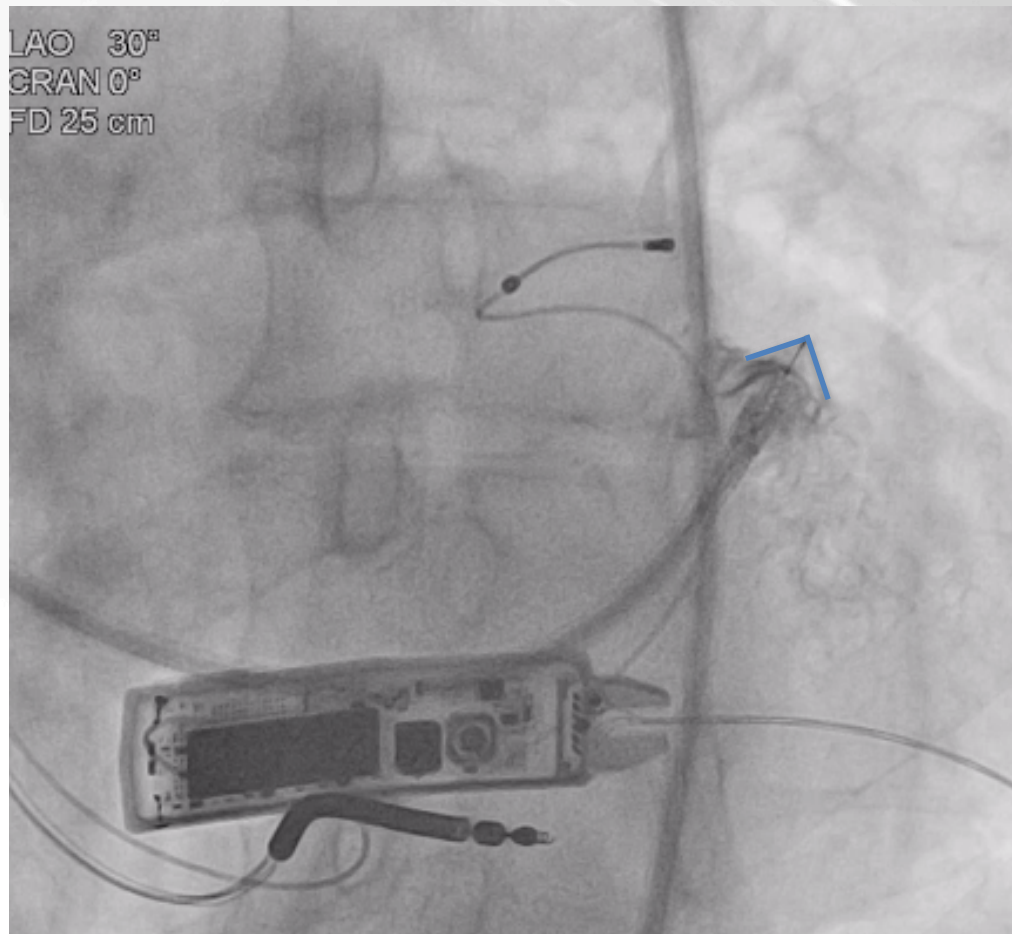


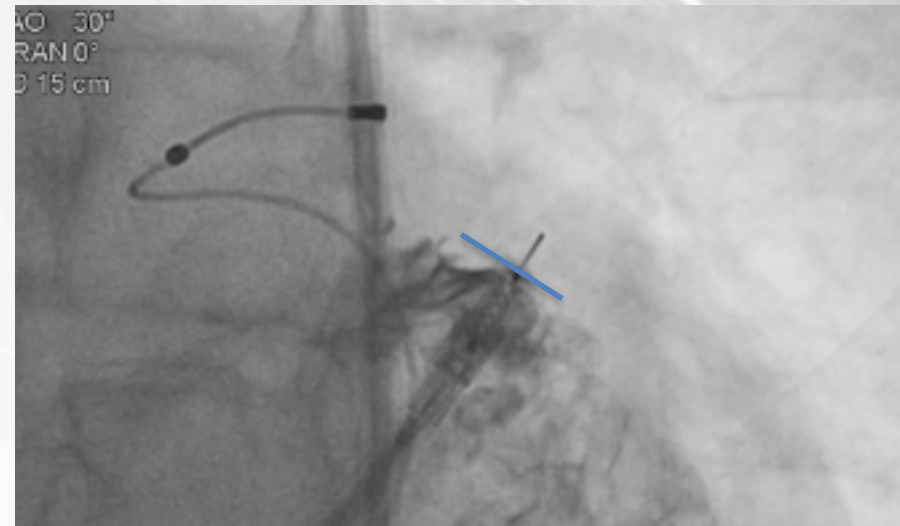
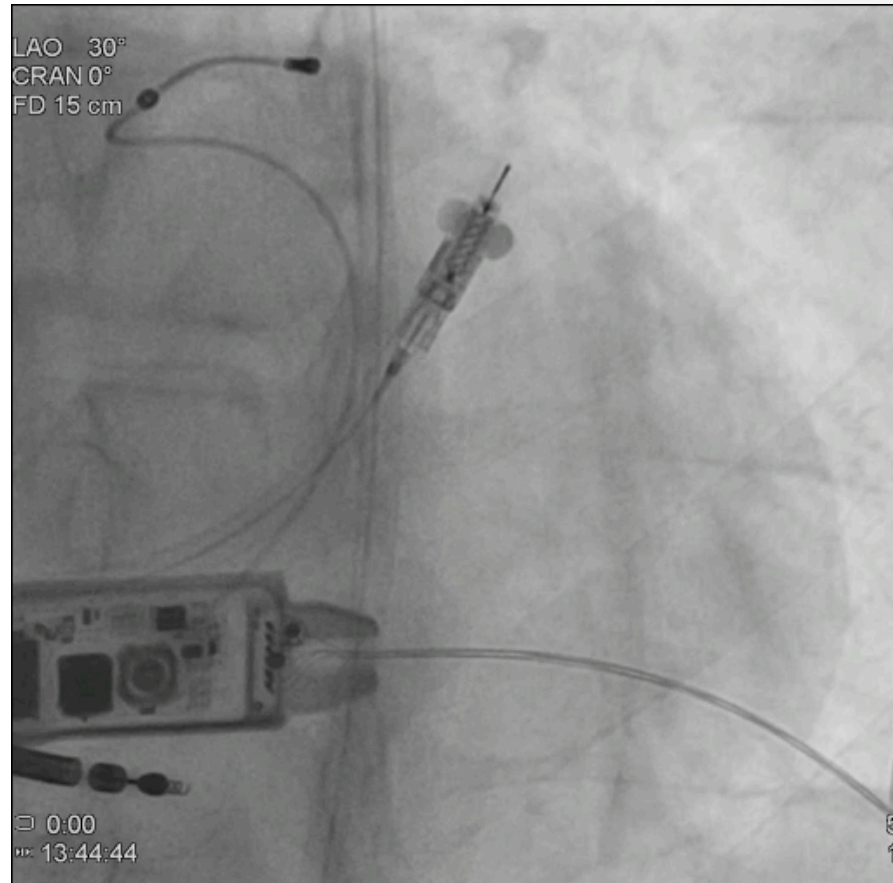
IMPLANTATION PHASE

2: Advancement of the electrode in the wall of the LV



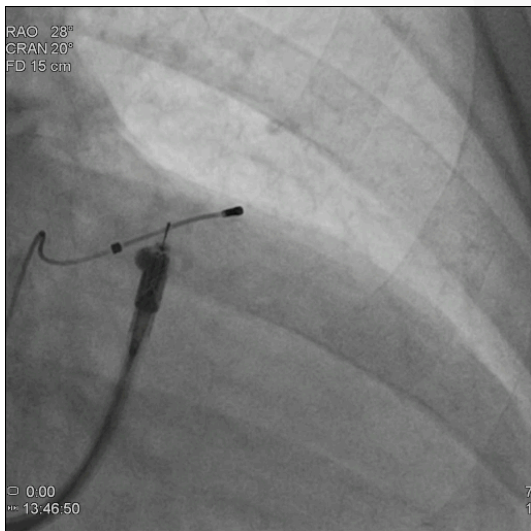
**Display with
contrast: partial
insertion**



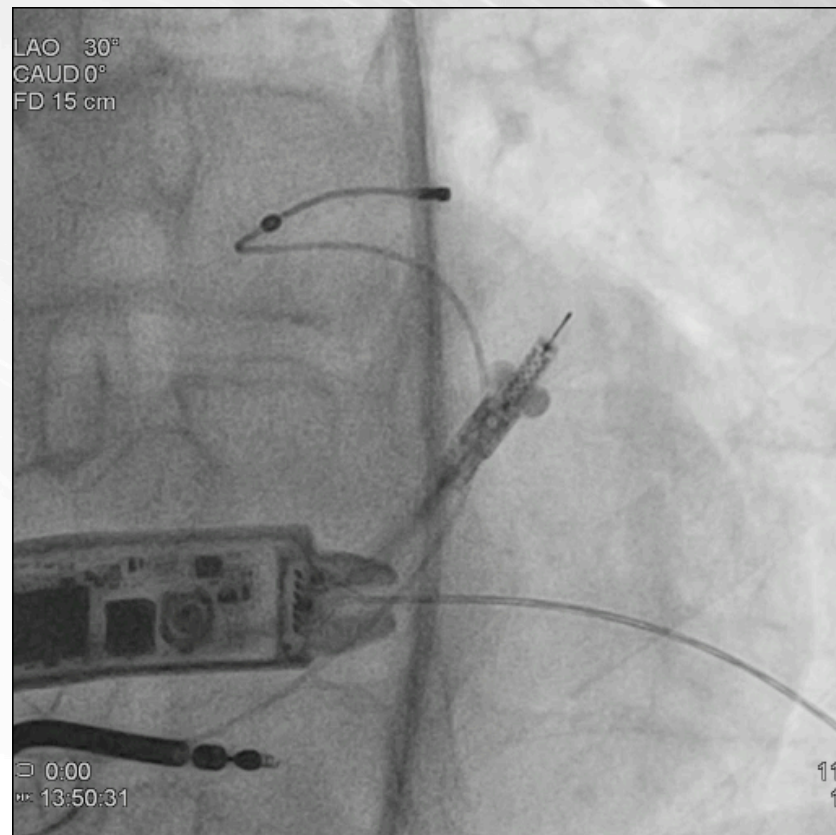


**Display with
contrast: full input**

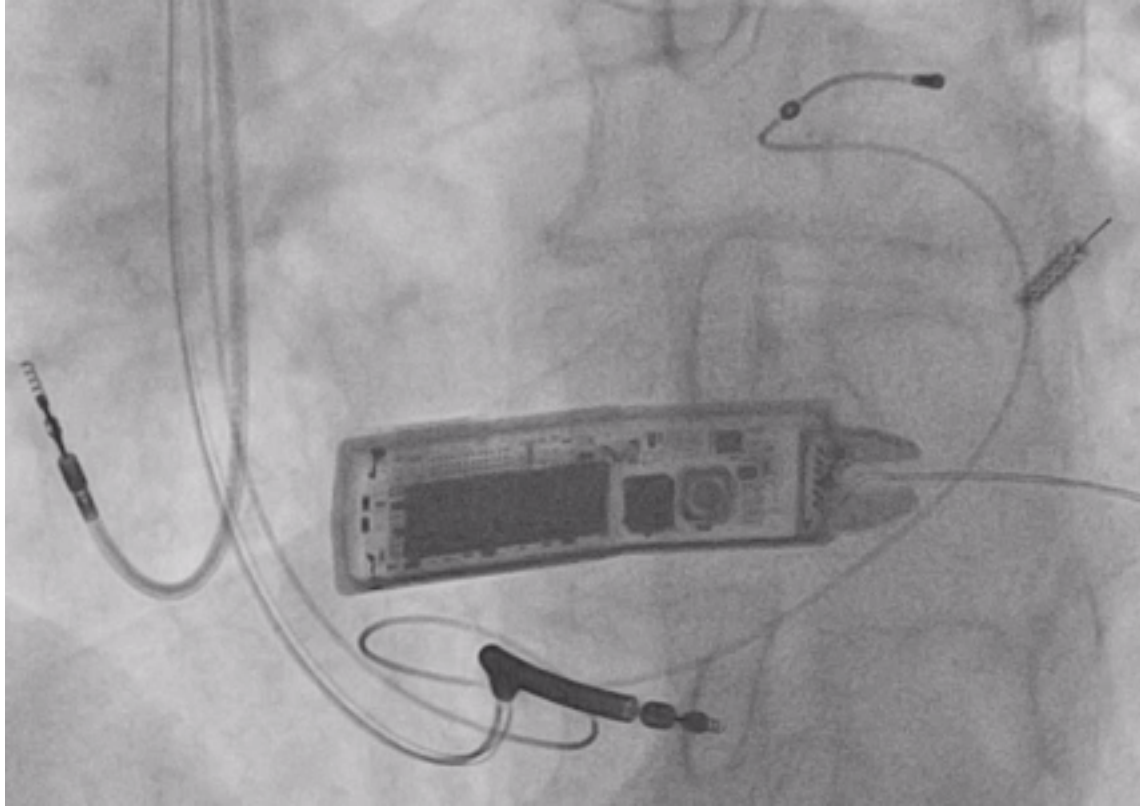




IMPLANTING PHASE 3: Electrode detachment



FINAL RESULT



Clinical case 2

Case 2

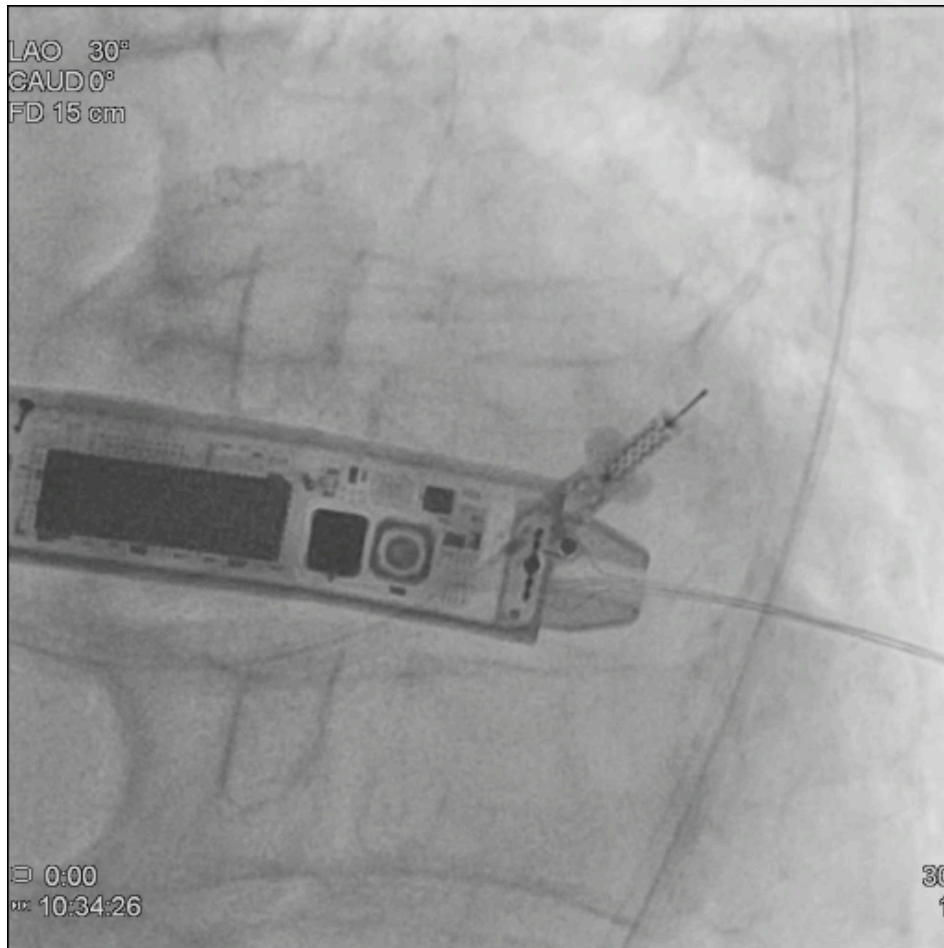
Paziente con CMD ipocinetica secondaria a mutazione del gene LMNA (EF 35%) con aritmie ventricolari + blocco AV totale.

CRTD dal 2010, con necessità successiva di revisioni dovute a un malfunzionamento dell'elettrodo.

Espianto dell'intero sistema CRTD nel maggio 2018.

Reimpianto d ICD monocamerale, RV in VD con dipolo flottante in atrio destro e impianto del sistema WiSE CRT (giugno 2018).

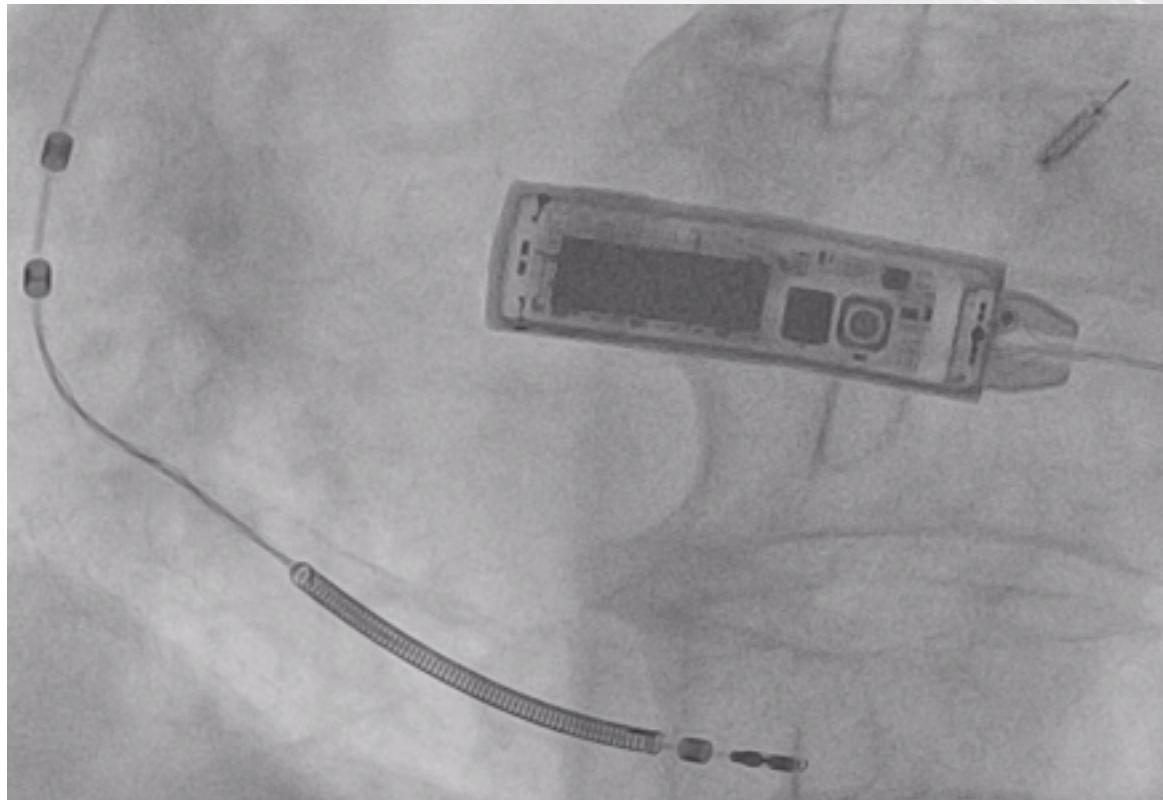




IMPLANTING PHASE 3: Electrode detachment



FINAL RESULT



Clinical case 3

Case 3

Paziente con CMD ipocinetica post-ischemica e grave disfunzione del VS (EF 25%).

CMD valvolare in SVAO meccanica + annuloplastica mitralica e FA cronica.

Impianto di CRTD nel 2006.

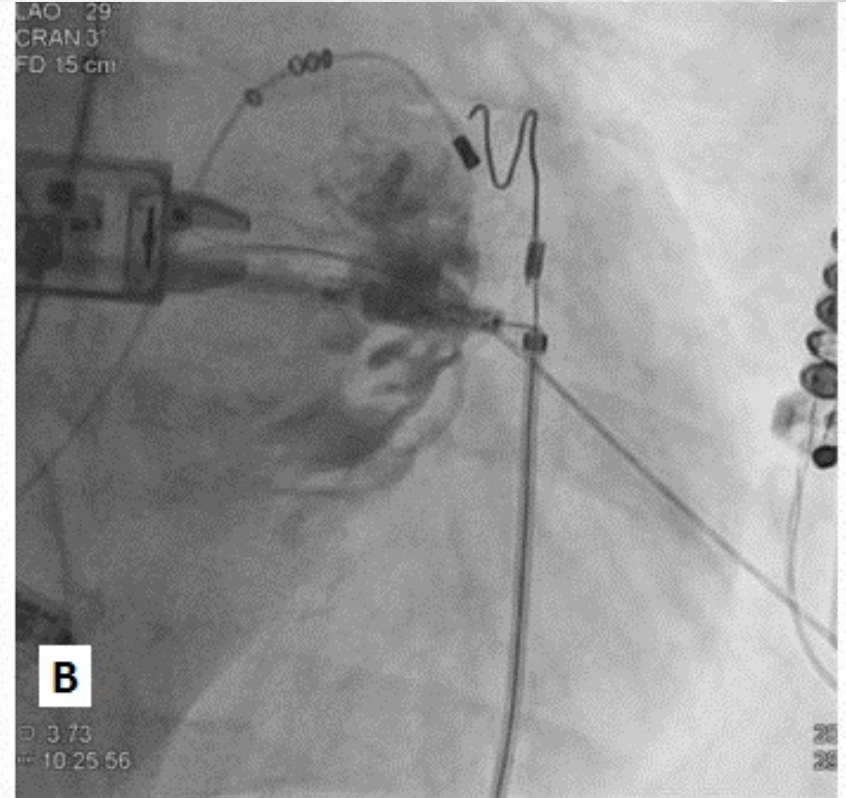
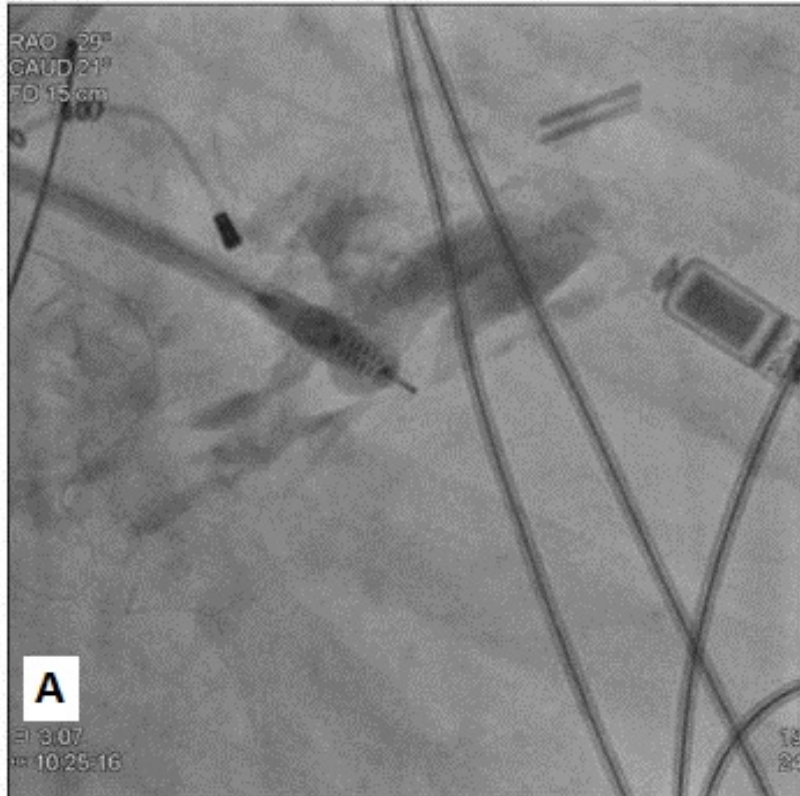
2018 Primo espianto per storia di infezioni di tasca per S. Epidermidis.

2019 Secondo espianto per decubito e segni di infezione sistemica da Staph. epidermidis.

Reimpianto di Micra VR + sistema CRT WiSE sottocutaneo con approccio trasettale (first in Human).



WISE IN VS ELECTRODE IMPLANT



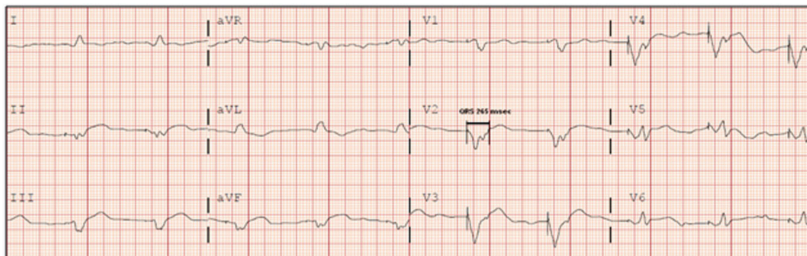
CASE REPORT

First-in-man fully leadless transvenous CRT-P with a transeptal implant of WISE-CRT® system and Micra® PM

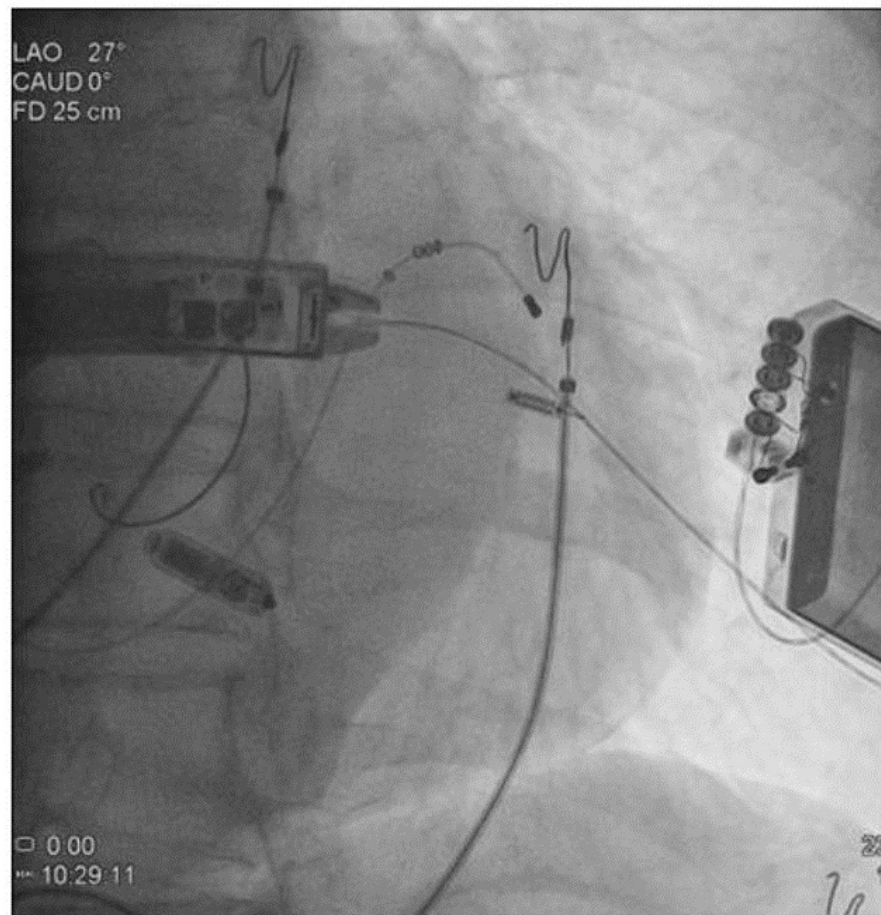
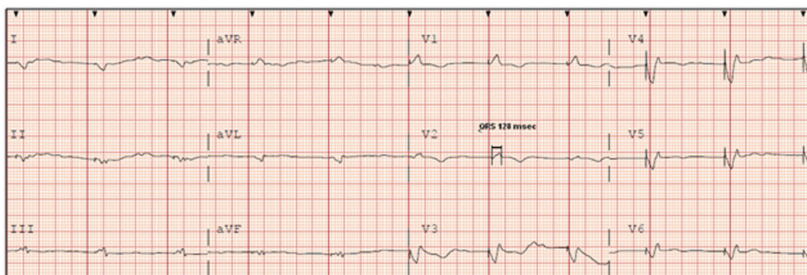
Elisabetta Montemerlo MD  | Mattia Pozzi MD | Sergio De Ceglia MD |

Francesca Santini MD | Elena Piazzini MD | Giovanni Rovaris MD

(A)

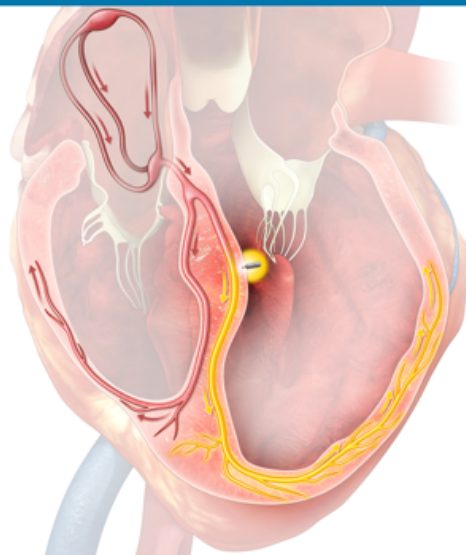


(B)



Additional Clinical Applications

Leadless left bundle branch pacing



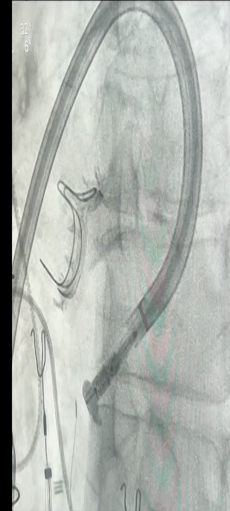
Potential advantages:

- Physiologic pacing
- Low pacing threshold
- No need for deep penetration into interventricular septum
- Negligible damage to conductive tissue
- Low risk of endocarditis

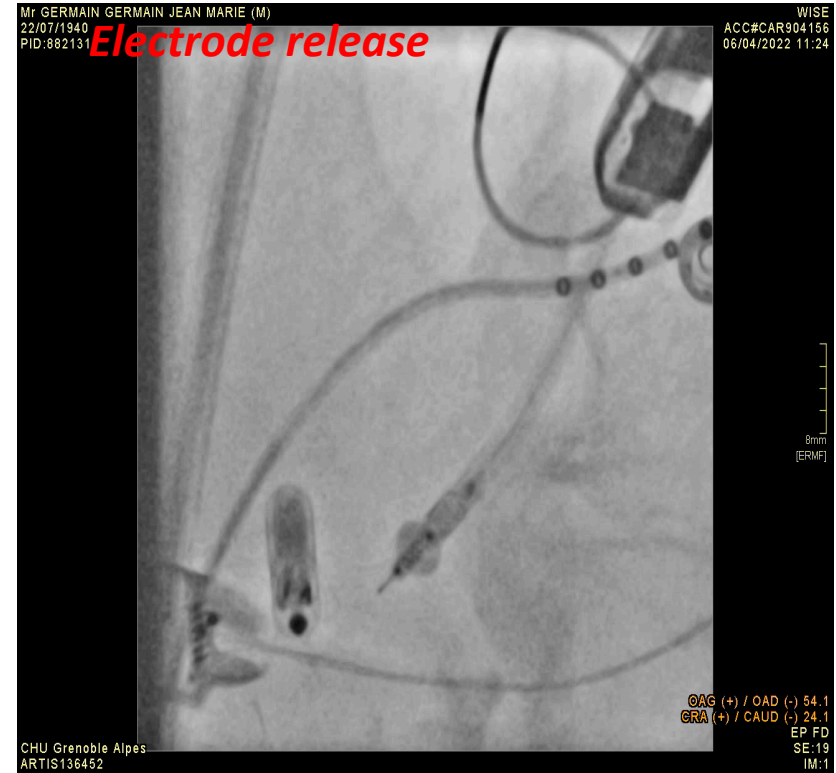
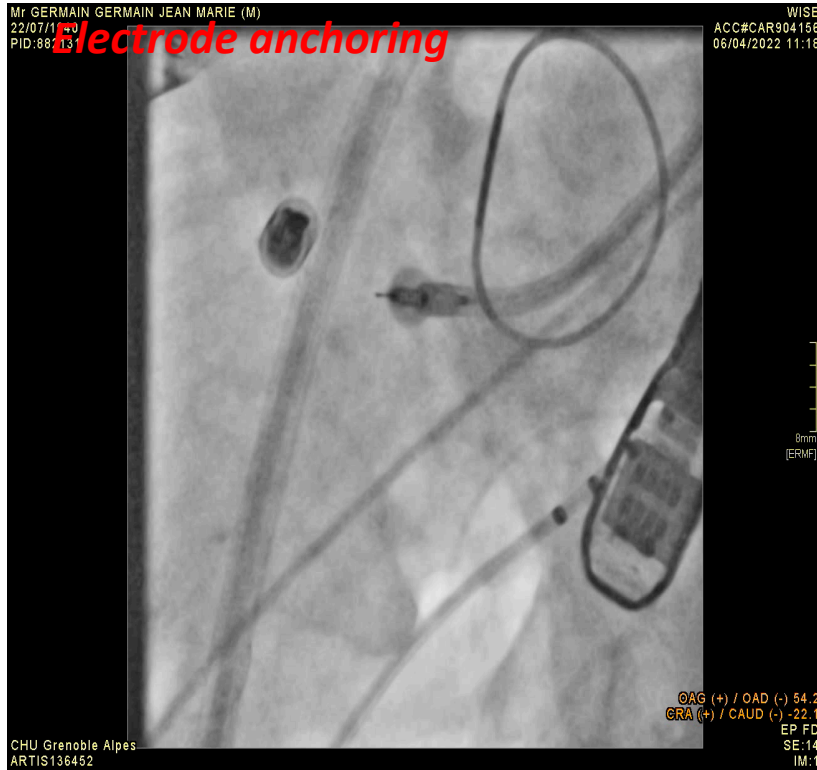


ADDITIONAL APPLICATION: LBBAP/CSP

4. Electrode anchoring in the LV septum
- Perpendicular view of Delivery Sheath balloon against septum
 - Electrode magnified
 - Electrode catheter advancement with continuous small puffs of contrast to evaluate stages of anchoring
 - Full tenting
 - Partial tenting
 - ZERO tenting



First WW totally leadless LBBAP (WiSE® + Micra VR) – APR 2022



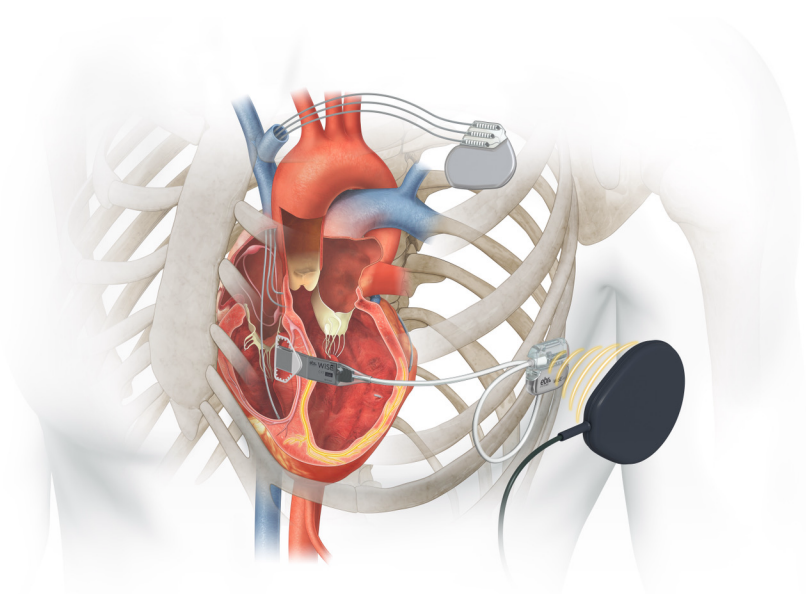
Future Development: Rechargeable Battery

EBR is developing a new rechargeable battery that will support the WiSE® CRT System in becoming a **first-line therapy option** and treat a **broader** suite of patients

Patient benefits

- Reduces need for future battery replacement surgery
- Recharge interval once per week¹
- 66% reduction in size from current battery

¹ 95% of patients will only need to recharge once per week



EBR's rechargeable battery will charge using a patch and external device to provide non-invasive, wireless charging



Thank you for
the attention

