Simposio:

Terapia Elettrica dello Scompenso Cardiaco

(Electrical Therapy for HF)

Anastomosi venose coronariche, un nuovo target per il pacing LV in CRT

Venous collaterals, a new target for LV pacing in CRT

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Friday, 30/Sep/2022

1994-2022: where are we after 28 yrs of CRT ?

Response to CRT is not uniform: a **reported 20%-40% of CRT pts** (depending on criteria) are considered **Non-Resp**.

Non-Response is often **multifactorial** and therefore requires a complete approach involving the entire pt's journey.

Effort to improve response includes careful consideration of selected patients, **optimal therapy delivery**, and comprehensive post-implant care

Troubleshooting CRT in Non-Responders
Dhesi S et al. Can J Cardiol 2017

*… […] … the **Non-Response" rate** to CRT is **around 30%**, remaining a major challenge that faces EPs and Researchers. … the etiology of CRT non-response is **multifactorial**, and it requires a multifaceted approach to address it.*

Naqvi SY ey al. Non-Response to CRT. Current Heart Failure Reports 2018

Still in the nightmare of Non-Response …

Common **causes of NR**:

- *Suboptimal LV lead site*
- *Insufficient V resynchr.*
- *Loss of LV capture*
- *Other minor factors*

Re-operations do increase the risk of **complications**

Table 1 Prevention of non-response to cardiac resynchronization therapy

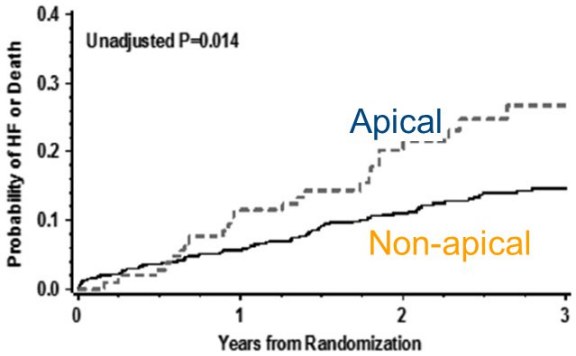
Non-response				
Prevention		**Detection**	**Management**[a]	
Pre-implant	Thoughtful patient selection Guidelines indications	Primary diagnosis Consensus definition Response/NR	Advanced heart failure	Treatment optimization continued Advanced care measures Mechanical circulatory support Cardiac transplantation
Implant	Optimal stimulation configuration Right ventricular lead LV lead: maximum delay Multipolar LV stimulation	Multidisciplinary approach Attending staff Heart failure team Heart failure status Electrophysiologists Device interrogations Cardiac imaging	Suboptimal device programming	Device re-programming Atrioventricular/interventricular intervals Stimulation Mode Rate Output
	Device settings Nominal Automatic Individual		Lead(s) Failure Improper position	Reoperation[a] for lead(s) Revision(s) Repositioning Addition → MSP
Post-implant	Remote monitoring—optimization of care Uptitration of pharmaceuticals Non-pharmacological interventions: Education Exercise training Heart failure monitoring	Concomitant disorders Arrhythmias Atrial fibrillation Atrial tachycardia Ventricular Mitral regurgitation Myocardial ischaemia	Antiarrhythmic drugs Catheter ablation[a] Atrial fibrillation Atrioventricular node Ventricular extrasystoles Treatment of MR[a] Revascularization[a]	

AVOIDING NR TO CRT: A PRACTICAL GUIDE
DAUBERT C ET AL. EUR HEART J 2017.

Site of Latest Activation

In the MADID-CRT Sub-Study, at a **population level**, basal pacing resulted in better outcomes than apical pacing.

MADIT-CRT
SUB-STUDY ON
LV Lead Position[1]



Conclusion:

"LV leads positioned in the apical region were associated with an unfavorable outcome, suggesting that this lead location should be avoided in cardiac resynchronization therapy."[1]

This outcome could have been due to the fact that the site of latest activation is often located in the mid-lateral or base of the LV. ***But is it for every patient?***

[1] Singh JP, et al. Left Ventricular Lead Position and Clinical Outcome in the Multicenter Automatic Defibrillator Implantation Trial–Cardiac Resynchronization Therapy (MADIT-CRT) Trial. Circulation 2011; 123: 1159-1166

Site of Latest Activation

For **almost all patients** in this study, the site of latest activation had a high correlation with improved response.

Determination of the longest intrapatient Left Ventricular Electrical Delay may predict acute hemodynamic improvement in patients after Cardiac Resynchronization Therapy (N = 32)

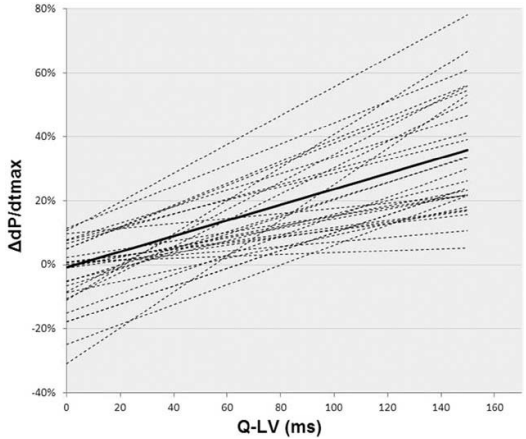


Figure 4:

Individual regression lines to depict variability. Dotted line indicates single regression; and dashed line, median regression for all patients.

"Pacing the LV at the site of the latest activation yielded the greatest increase in cardiac contractility in 31 of 32 patients."[1]

[1] Zanon F, et al. Determination of the Longest Intrapatient Left Ventricular Electrical Delay May Predict Acute Hemodynamic Improvement in Patients After Cardiac Resynchronization Therapy. Circ Arrhythm Electrophysiol, 2014;7:377-383.

Site of Latest Activation

For an **individual**, basal pacing may not always produce the best outcomes.

Electrical delay in apically positioned left ventricular leads and clinical outcomes after cardiac resynchronization therapy (N=31)

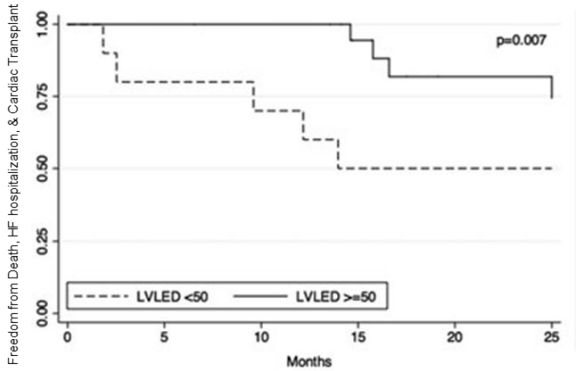


Figure 2:

Freedom from the primary composite endpoint of all-cause death, cardiac transplantation, or HF hospitalization at 2 years stratified by LVLED group.

LVLED = left ventricular lead electrical delay.

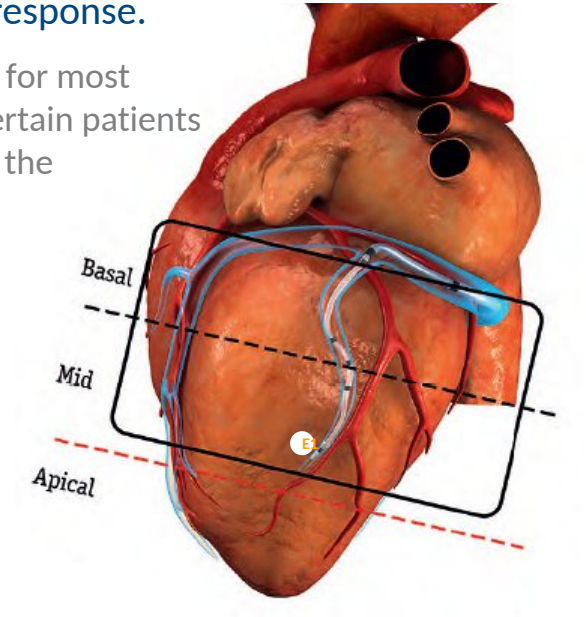
"It is possible that an apical position may work reasonably well for a subset of the patients where the apex is activated further into the depolarization wave front."[1]

[1] Kandala J, et al. Electrical Delay in Apically Positioned Left Ventricular Leads and Clinical Outcome After Cardiac Resynchronization Therapy. Journal of Cardiovascular Electrophysiology Vol. 24, No. 2, February 2013

Site of Latest Activation

For an **individual patient**, the site of latest activation is most important for attaining positive CRT outcomes and response.

- Although mid or basal pacing is best for most patients, studies have shown that certain patients benefit from apical pacing[1] and that the site of latest activation may predict improved CRT response.[2]
- E1 electrode is often located in the mid location, not apical.
- Every patient's electrical conduction pathway is unique.

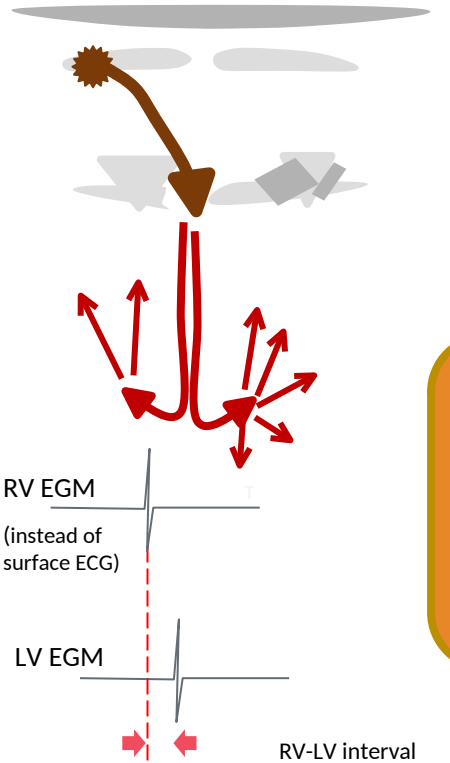


[1] Kandala J, et al. Electrical Delay in Apically Positioned Left Ventricular Leads and Clinical Outcome After Cardiac Resynchronization Therapy. Journal of Cardiovascular Electrophysiology Vol. 24, No. 2, February 2013

[2] Zanon F, et al. Determination of the Longest Intrapatient Left Ventricular Electrical Delay May Predict Acute Hemodynamic Improvement in Patients After Cardiac Resynchronization Therapy. Circ Arrhythm Electrophysiol, 2014;7:377-383.

Site of Latest Activation

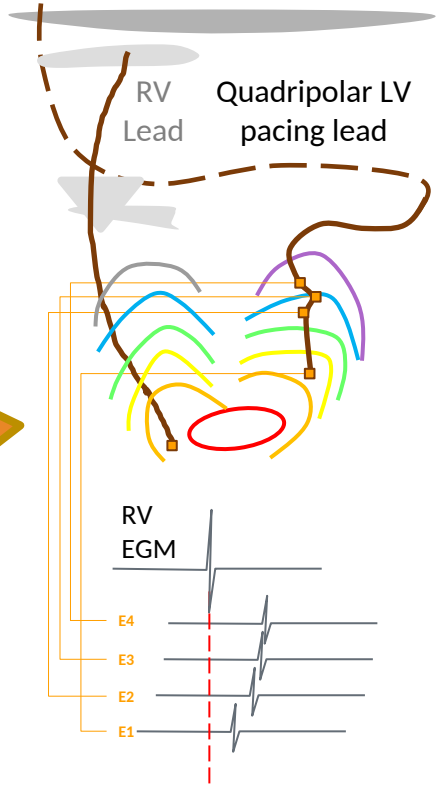
Measuring Electrical Delay: RV-LV



RV-LV is another measure of electrical delay, but is determined in a slightly different fashion than QLV.

By measuring the difference in activation between the RV and LV, we can determine the RV-LV interval.

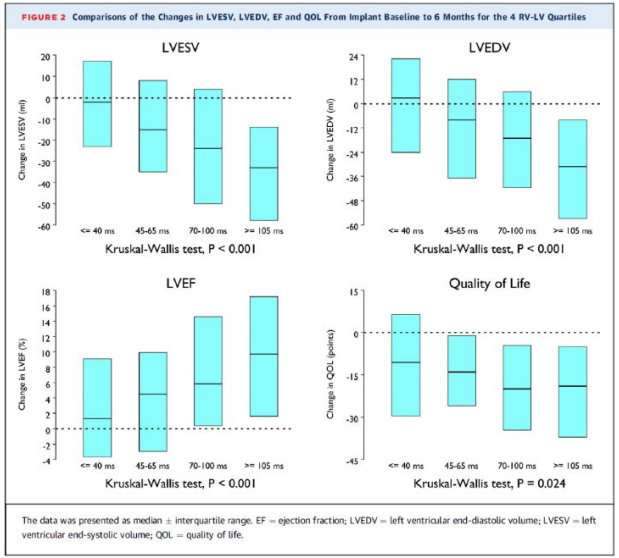
For a quadripolar lead, this would also result in four RV-LV values.



RV-LV Clinical Data

For an **individual**, basal pacing may not always produce the best outcomes.

Interventricular Electrical Delay is predictive of response to Cardiac Resynchronization Therapy (N=419)



Study Conclusions

"The RV-LV interval is a strong and independent predictor of remodeling with CRT.

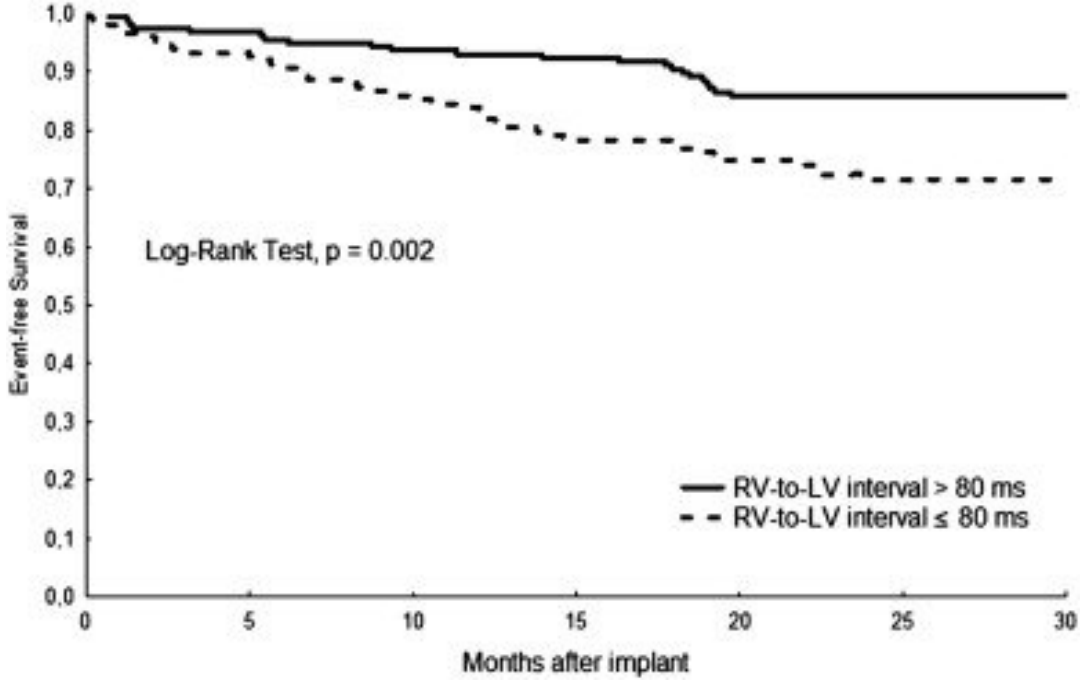
This parameter predicted reverse remodeling even in subgroups traditionally associated with low response rates.

Based on these results, measuring RV-LV time at implantation may help to identify optimal pacing sites."[1]

Key takeaway: the RV-LV interval is an important measure to be considered at the time of LV lead implant.

[1] Gold M, et al. Interventricular Electrical Delay Is Predictive of Response to Cardiac Resynchronization Therapy. JACC Clin Electrophysiol Vol. 2, No. 4, August 2016

RV-LV Clinical Data

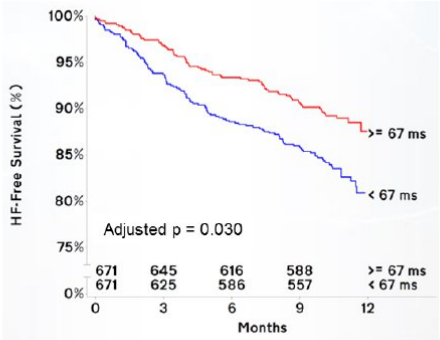


D'Onofrio A et al, Int J Cardiol Volume 168, Issue 5, 12 October 2013, Pages 5067-5068

RV-LV Clinical Data

Clinical data showed longer RV-LV was associated with improved CRT **outcomes** and **response**

30% reduction of risk of HF hospitalization or death associated with longer RVS-VS delay[1]



Kaplan-Meier curves of HF-Free Survival for the short and long RV-LV groups

82% response rate achieved when RV-LV ⊗ 105 ms[2]

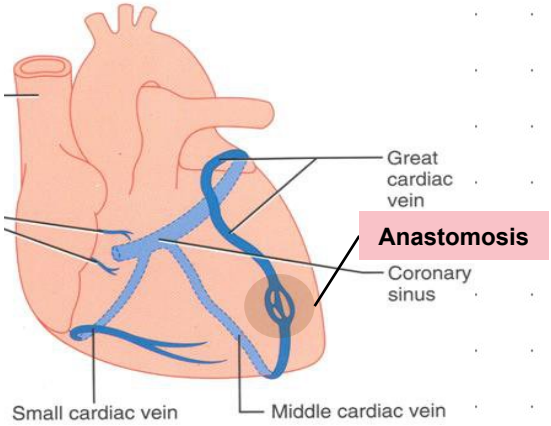
RV-LV	% Responders
≤ 40 ms	33%
45-65 ms	58%
70-100 ms	63%
≥ 105 ms	82%

[1] Gold M, et al. ESC 2014 (N=1342)

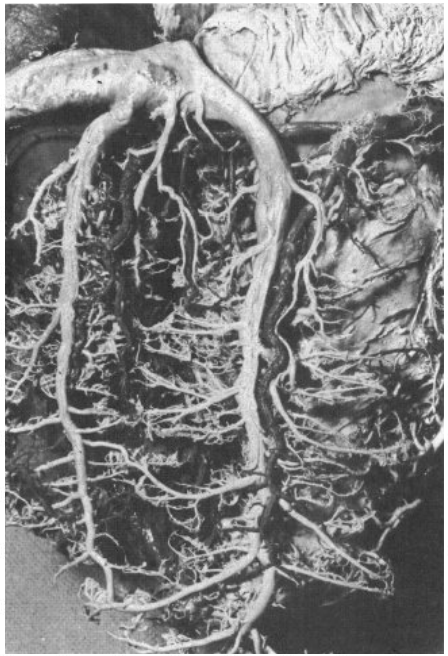
[2] Gold M, et al. AHA 2016 (N=419)

Venous collaterals (VCs)

ANATOMY BACKGROUND



PAKALSKA, MINN MED 1980



From clinical experience, anatomical studies and reviews of angiographies we know that **USUALLY Coronary Veins interconnect**

* Retrosp. review of angiographies
* Prosp. data on VC in CRT candidates

(coronary venograms in RAO / LAO from 4 University Hospitals - France)

Do venous collaterals (VC) exist? In how many «typical CRT» pts?

RETROSPECTIVE (R) PTS
Unselected pts who underwent CRT 2008-2012 at Rouen Hosp (Fr)

PROSPECTIVE (P) PTS:
CRT pts from the Axone Acute Pilot study in Y-2018

Evaluable venograms: n = 36 pts
(R: 21/65 - P: 15/20)

Aiming to identify VCs with an estimated diameter > 0.5mm:

VCs were found in all the evaluable n = 36 pts

Circulation Journal
Circ J 2021; **85:** 283–290
doi:10.1253/circj.CJ-20-0266

ORIGINAL ARTICLE
Devices

Exploring a New Systematic Route for Left Ventricular Pacing in Cardiac Resynchronization Therapy

Frédéric Anselme, MD, PhD; Mohammad Albatat, BSc; Christelle Marquié, MD; Christophe Leclercq, MD, PhD; Philippe Ritter, MD; Jean-François Ollivier, BSc; Nicolas Shan, BSc; Filippo Ziglio, BSc; Delphine Feuerstein, PhD

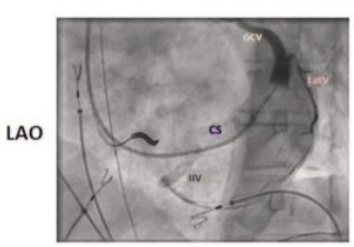
Background: Frequency and distribution of left ventricular (LV) venous collaterals were studied in vivo to evaluate the ease and feasibility of implanting a new ultra-thin LV quadripolar microlead for cardiac resynchronization therapy (CRT).

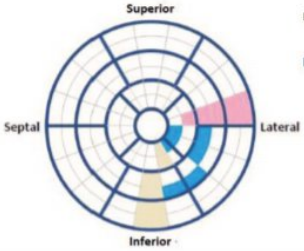
Methods and Results: Evaluable venograms were analyzed to define the prevalence of venous collaterals (>0.5 mm diameter) between: (1) different LV segments; and (2) different major LV veins in: unselected patients who underwent CRT from 2008 to 2012 at Rouen Hospital, France (retrospective); and CRT patients from the Axone Acute pilot study in 2018 (prospective). In prospective patients with evaluable venograms, LV microlead implantation was attempted. Thirty-six (21/65 retrospective, 15/20 prospective) patients had evaluable venograms with ≥1 visible venous collaterals. Collaterals were found between LV veins in all CRT patients with evaluable venograms. Regionally, prevalence was highest between: the apical inferior and apical lateral (42%); and mid inferior and mid inferolateral (42%) segments. Collateral connections were most prevalent between: the inferior interventricular vein (IIV) and lateral vein (64% [23/36]); and IIV and infero-lateral vein (36% [13/36]). Cross-vein microlead implantation was possible in 18 patients (90%), and single-vein implantation was conducted in the other 2 patients (10%).

Conclusions: Venous collaterals were found in vivo between LV veins in all CRT patients with evaluable venograms, making this network an option for accessing multiple LV sites using a single LV microlead.

Anselme F et al. Circ J 2021; 85: 283-90

Where are VCs mainly located?





Inferior interventricular vein (middle cardiac vein)

Collaterals

Figure 1. X-ray images showing LV venous network next to corresponding 17-segment bullseye and 3×3 grid representations of the LV. CS, coronary sinus; GCV, great cardiac vein; LAO, left anterior oblique; LatV, lateral vein; LV, left ventricle; IIV, inferior interventricular vein (middle cardiac vein); RAO, right anterior oblique.

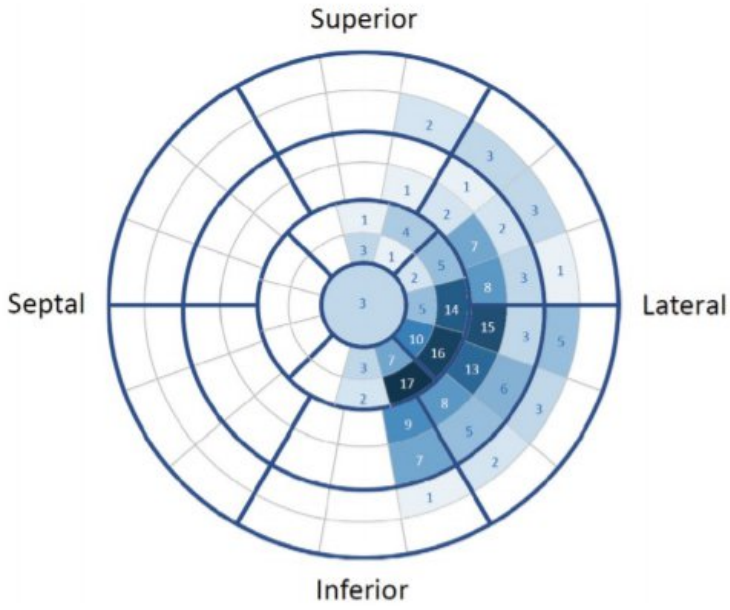


Figure 3. Bullseye representation of venous collateral density in the left ventricle in the overall population. Numbers in the sub-segments represent the number of times a venous collateral was detected in each sub-segment.

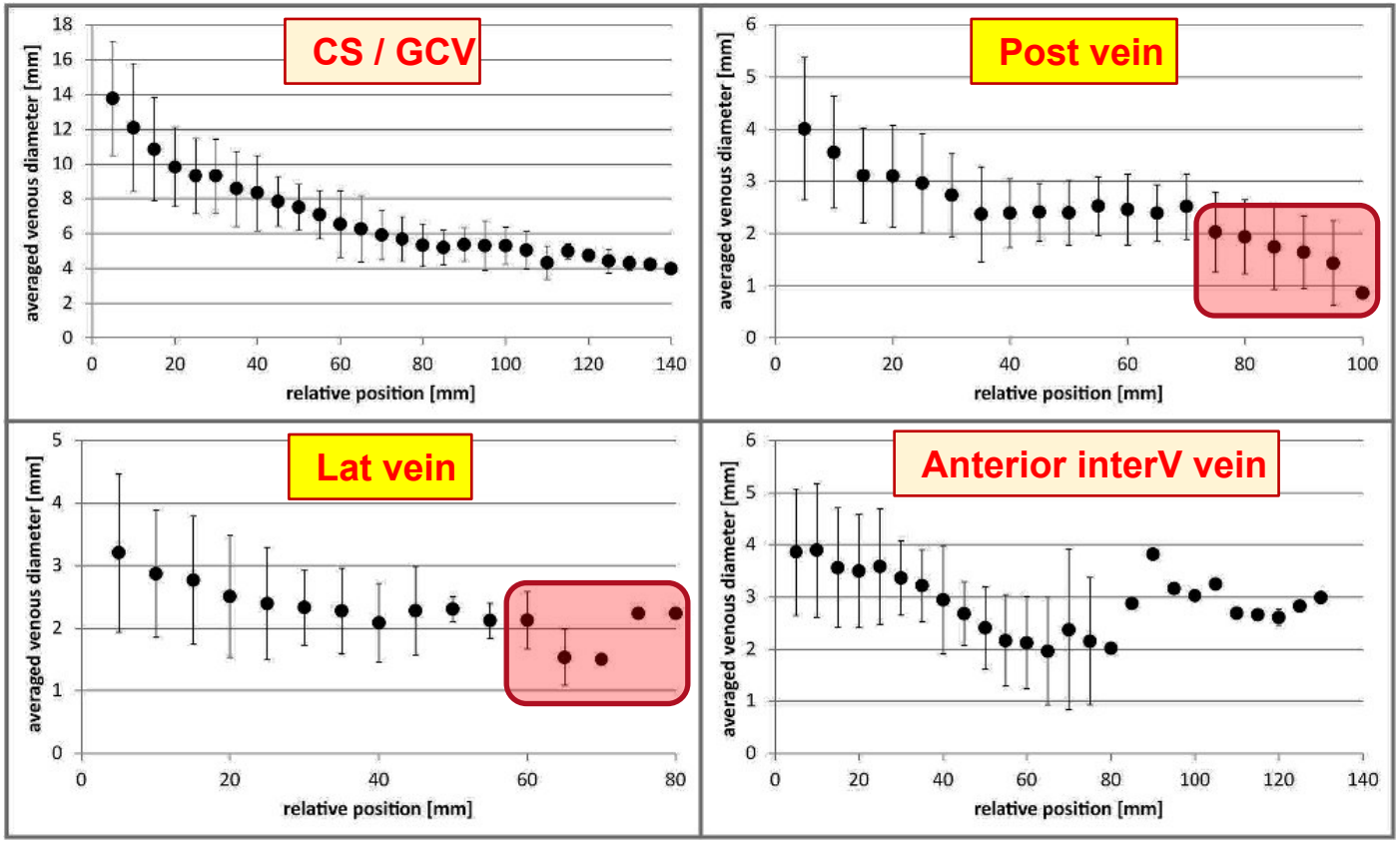
	MCV	PLV	LV	ALV	GCV
MCV		13 (36%)	23 (64%)	5 (14%)	6 (17%)
PLV			11 (31%)	4 (11%)	1 (3%)
LV				2 (6%)	5 (14%)
ALV					0*
GCV					

Abbreviations:

MCV	mid cardiac vein
PLV	posterolateral vein
LV	lateral vein
ALV	anterolateral vein
GCV	great cardiac vein
* None seen	

Anselme F et al. Circ J 2021; 85: 283-90

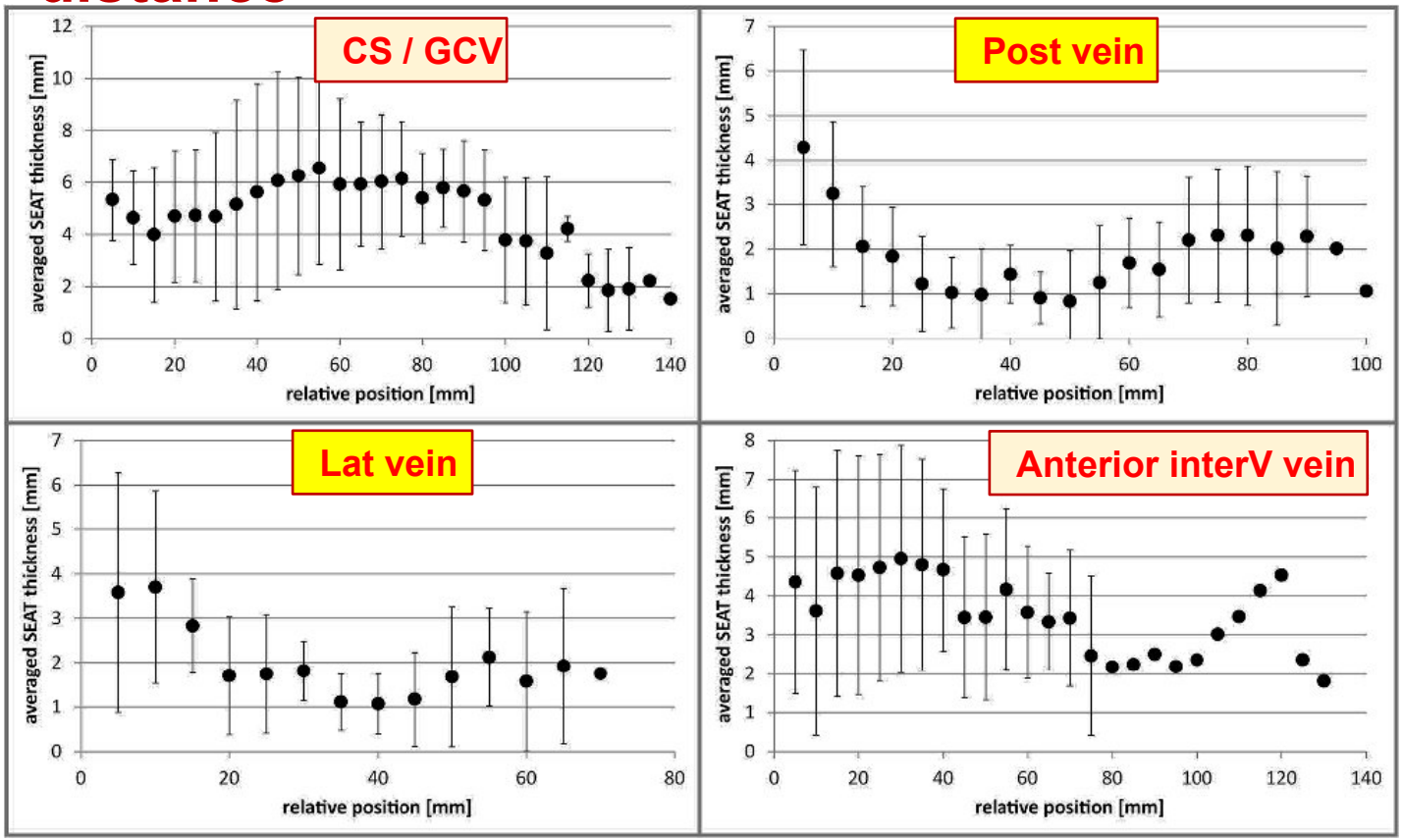
DIAMETER (mm) of coronary veins along the distance



In most cases the **diameter** of the **DISTAL** PORTIONS of the coronary veins is **around 1mm (3Fr)**

Keiler J et al. Frontiers in CV Medicine 2020

SEAT* thickness (mm) of coronary veins along the distance



Inferior SEAT thickness in Post. and Lat. veins vs. ANT. interV vein

In POST and LAT veins:

- better Signal/Noise ratios
- thinner “insulation” layer

This data reinforces the preference for LAT and POST LV regions as optimal pacing areas for most CRT

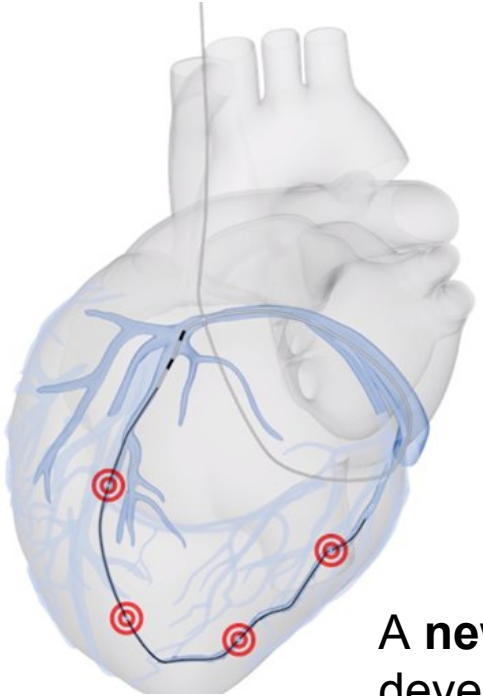
(in line with the majority of recent clinical studies on LV lead position)

Keiler J et al. Frontiers in CV Medicine 2020

** SEAT: sub-venous epicardial **adipose tissue***

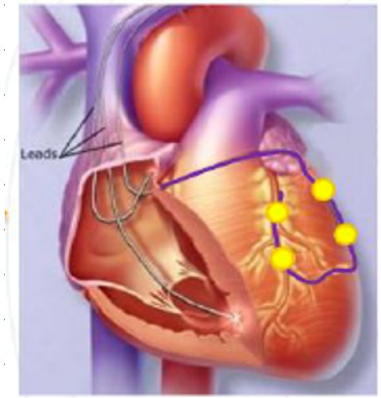
The AXONE technology: a new route for LV pacing

A new technology consisting of an **ULTRA-THIN 4P LV lead** (MICRO-LEAD) able to navigate **through collaterals** between veins and very thin veins



The Axone micro-lead has been developed to:

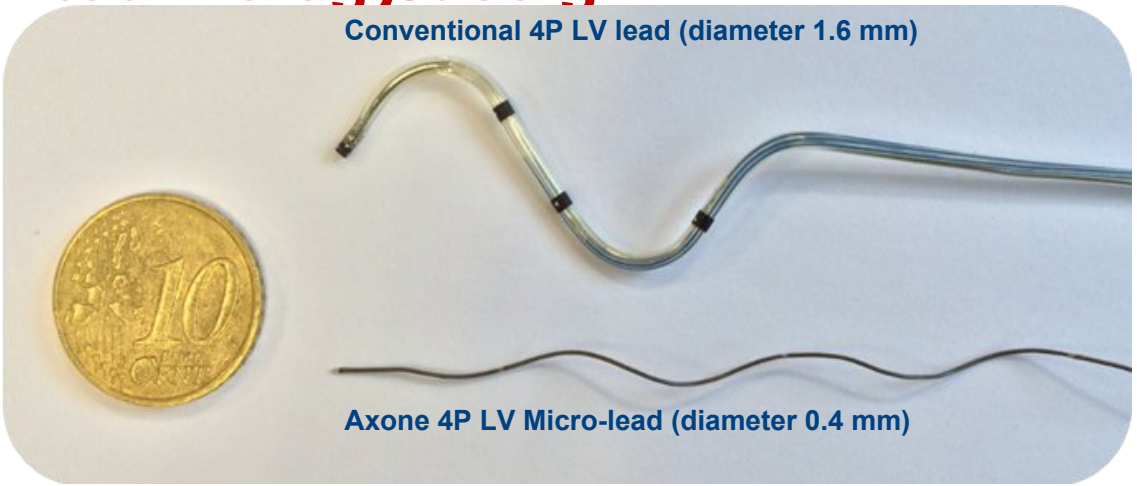
1. reach **more pacing sites**
2. reach **new pacing sites** not accessible with std 4P LV leads
3. perform **true "distant" pacing** *(BZP, "Bi-Zone Pacing")*



A **new implantation technique** has been developed to deploy this LV Micro-Lead

MicroPort™ CRM

AXONE 4P micro-lead: an innovative technology/design

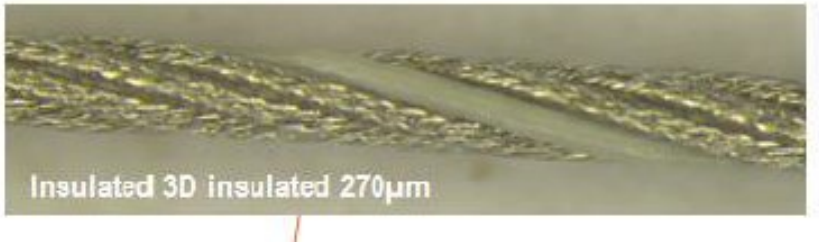


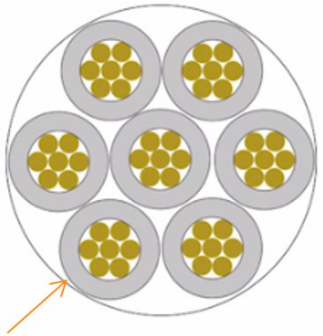
N = 20 CRTD pts from the **Axone Acute-1** Pilot study (Y-2018)

VCs found in all the 20 pts *(diameter > 0.5mm)*

Axone acutely attempted in all n = 20 pts:
- ***90% final position in VCs*** *(18 pts)*
- *10% std single-vein positioning* *(2 pts)*

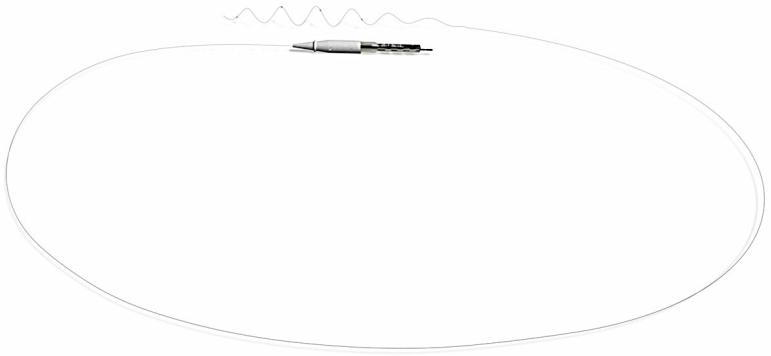
Anselme F et al. Circ J 2021; 85: 283-90





Microwire 20 mm (7 x 7) structure

The Axone System



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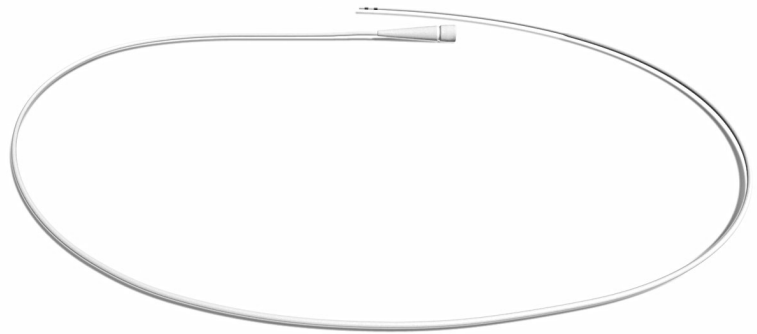


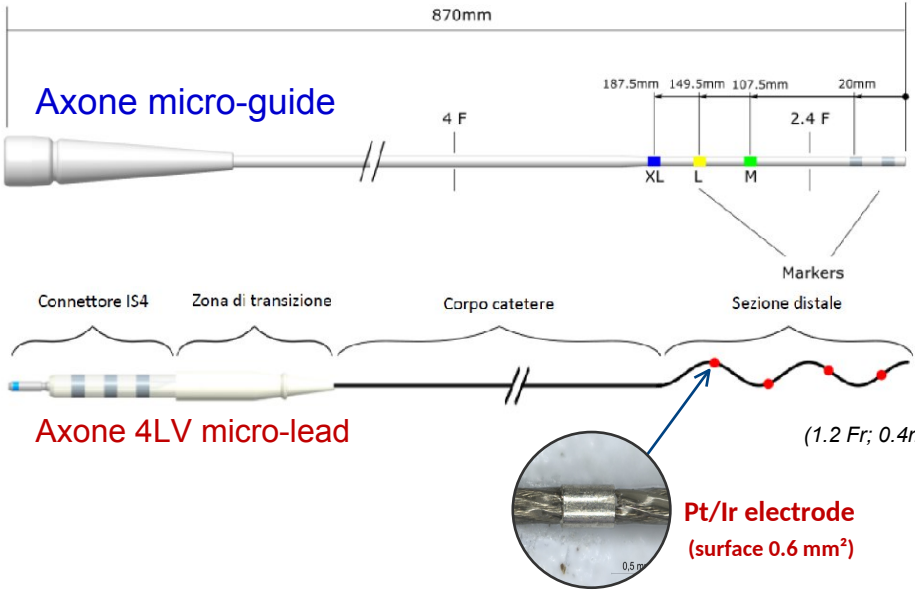
Axone 4LV, ultra-thin LV lead:

- **1.2Fr** with distal spiral shape
- Lumenless
- IS4 connector
- Low surface electrodes

Axone µGuide, permanently implantable catheter:

- **2.4Fr** (distal) to 3.9Fr (proximal)
- Distal hydrophilic coating
- Radiopaque markers
- Acts as delivery tool, then providing mechanical support / insulation on the long term

Implantation Technique: the « AXONE system »

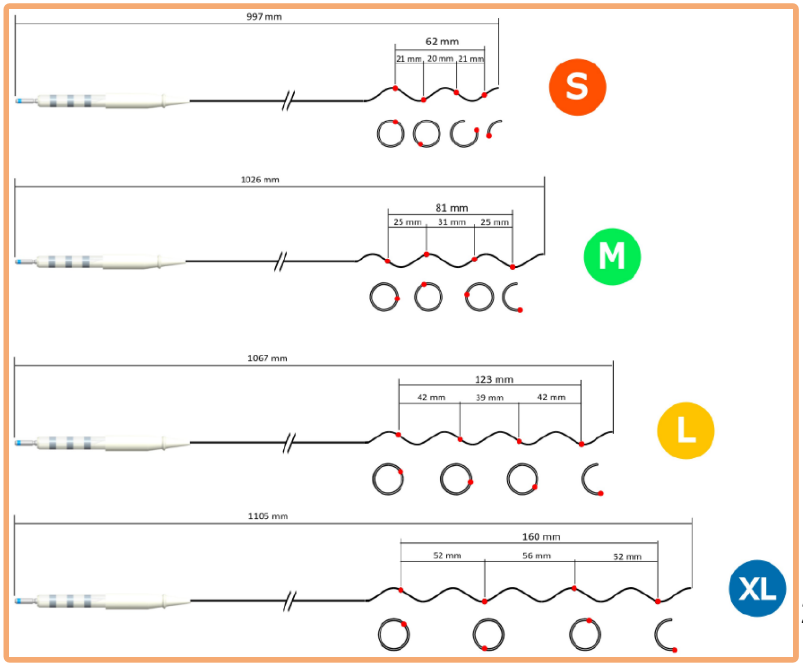


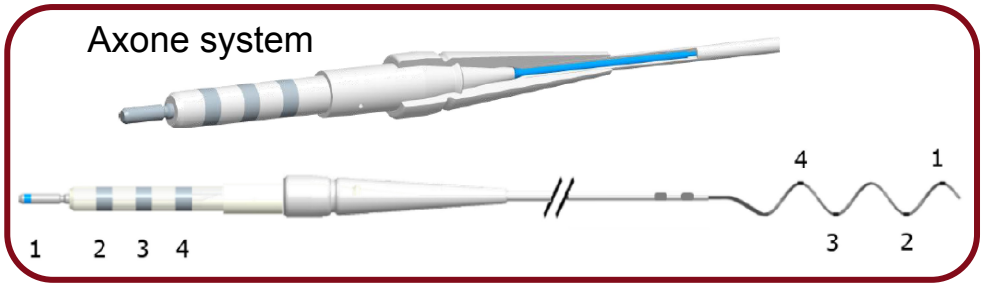
AIMs:

1. reaching the target site
2. selecting the appropriate micro-Lead model (S-M-L-XL)
3. providing extra-insulation + robustness

Axone 4LV lead models:

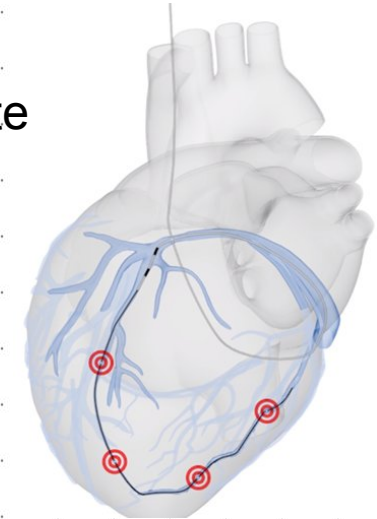
- S ☾ single-vein positioning
- M-L-XL ☾ cross-vein positioning (i.e. VC)





Implanting Axone 4LV: main steps

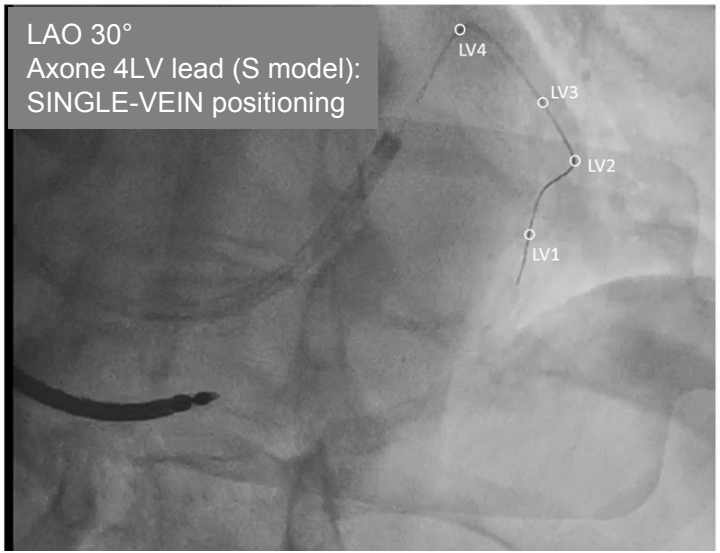
1. Std **guidewire** insertion (0.014”)
2. Navigation with **Axone µGuide** over the guidewire ☾ **target** site
3. **Selection** of Axone lead **model**
4. Guidewire removed ☾ Axone 4LV lead introduced
5. Axone µGuide slightly retracted to uncover lead electrodes
6. If electrical measures OK, Axone µGuide fully retracted
7. Axone µGuide remains <u>permanently implanted</u> with lead
8. Finishing the **« IS4 Axone system »** *(blocking µGuide onto lead)*

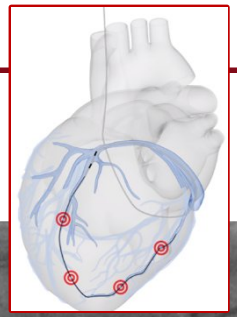


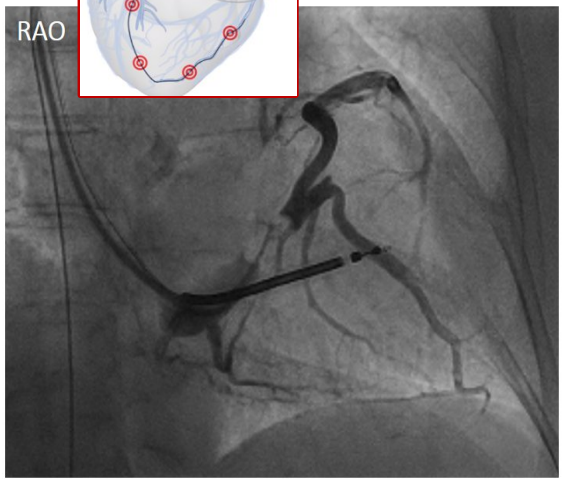
AXONE: single-vein vs. cross-vein (VC) positioning

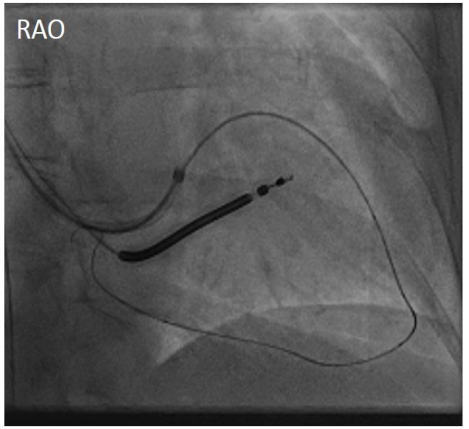
Axone

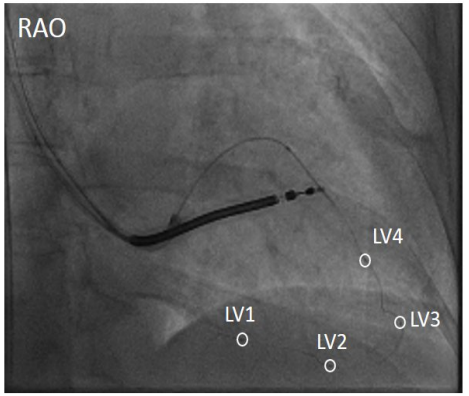
The *smallest* quadripolar
left ventricular lead







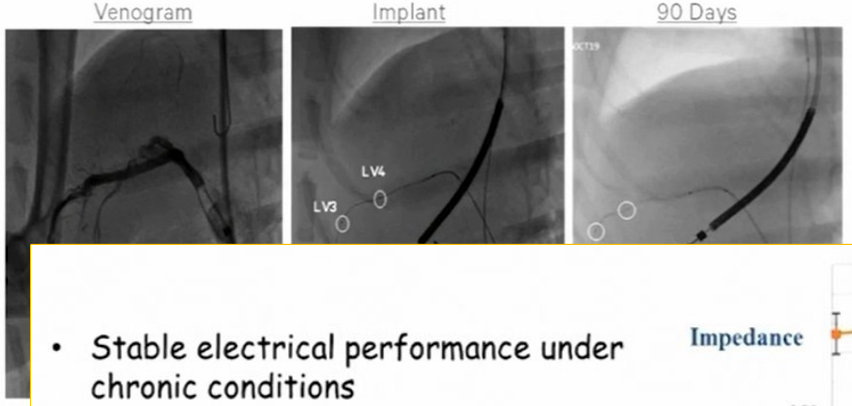


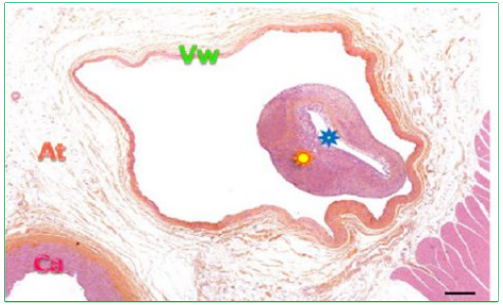


Axone 4LV lead (L model):
CROSS-VEIN positioning

Axone: chronic pre-clinical evaluation *(dogs)*

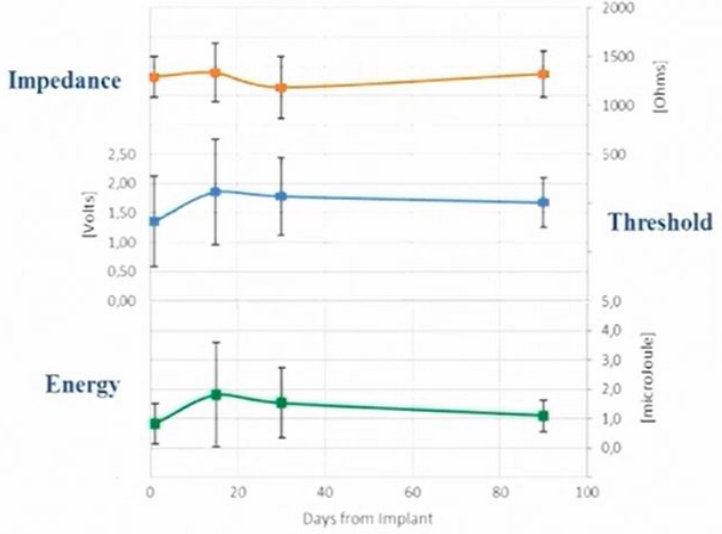
- 7 healthy adult dogs
- Chronic implant up to 3 months (1, 15, 30, 90 days follow-up)
- 100% implant success rate In 5/7 across collaterals
- Lead position checked via fluoroscopy at each follow-up and stable in all cases
- Excellent local tissue tolerance by microscopic evaluation 3 months after implant





F. Anselme, MD, PhD; F. Ziglio, MSc; N. Shan, MSc; L.I
left ventricular quadripolar pacing lead". E-poster EHR

- Stable electrical performance under chronic conditions
- High pacing impedance (x 2-3 vs. conventional LV lead)
- At 90 days post-implant, pacing energy < 2µJ in all cases



Mean pacing threshold, impedance and pacing energy at each follow-up visit (there are no significant differences in electrical performance for any parameter vs day 1)

2 µJ ≈ 1.4 V @500 Ω, 0.5 ms

Axone in-man: Acute Pilot II results

FIRST IN MAN (ACUTE): N = 28 PTS

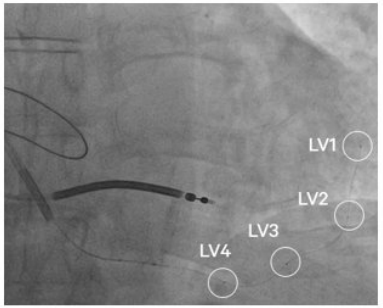
- Acute testing of Axone (max 30min from µGuide insertion) during a standard CRT procedure:

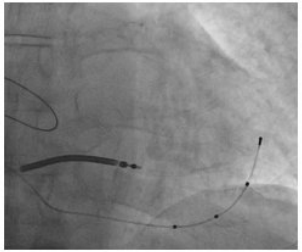
LV Pacing success
% pts with 1 vector with PT ≤ 3.5V/0.5ms
82.1% (23/28)
IC95 [63.1% to 93.9%]

Bizone LVp success
% pts with 2 distant vectors with PT ≤ 3.5V/0.5ms
60.7% (17/28)
IC95 [40.6% to 78.5%]

- Standard LV 4P lead subsequently implanted → LVp success 85.7% (24/28)
- **Mean PT: 1.57 ± 0.96 V**

- Safety: n=1 eps of VF during guidewire navigation, successfully treated (no sequelae)





Axone in-man *(case #1 - Axone Acute Pilot study)*

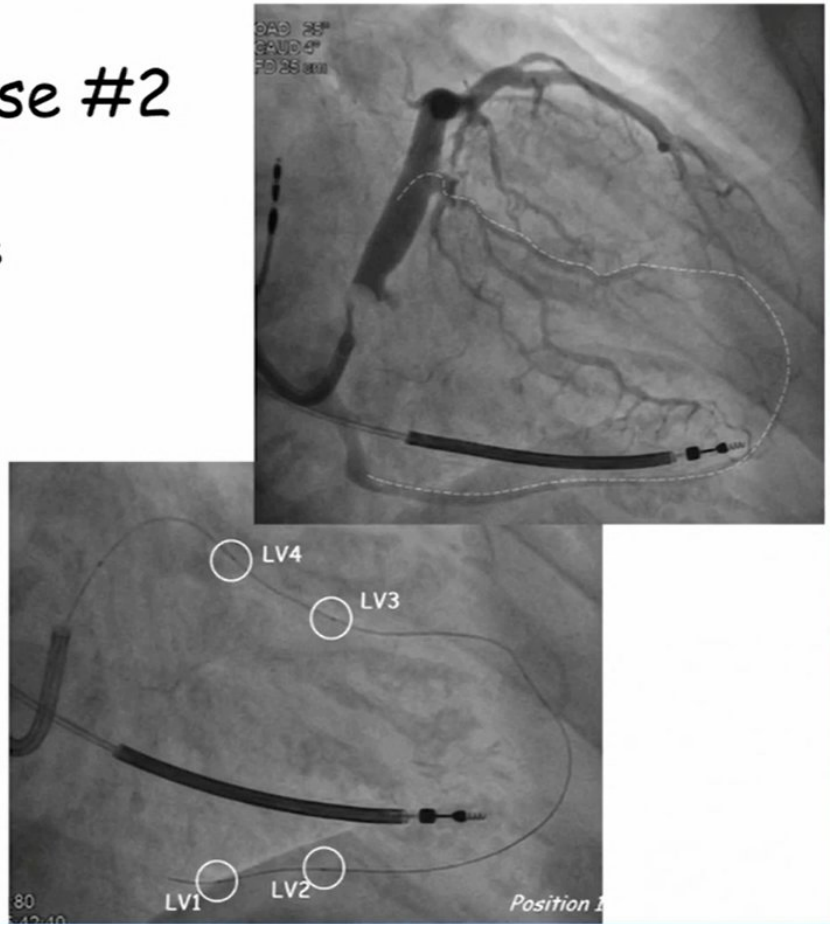
AXONE – Acute clinical case #2

- Female, 60y, BMI 28
- Dilated, EF=35%, QRS 152ms, thin and tortuous CS veins

- Axone lead (model XL) **placed in a cross-vein position**: lateral to postero-lateral

- Two distant pacing zones:
  - LV2-RVCoil: threshold 3.2V/0.5ms – 1475 Ω
  - LV3-RVCoil: threshold 3.0V/0.5ms – 1448 Ω

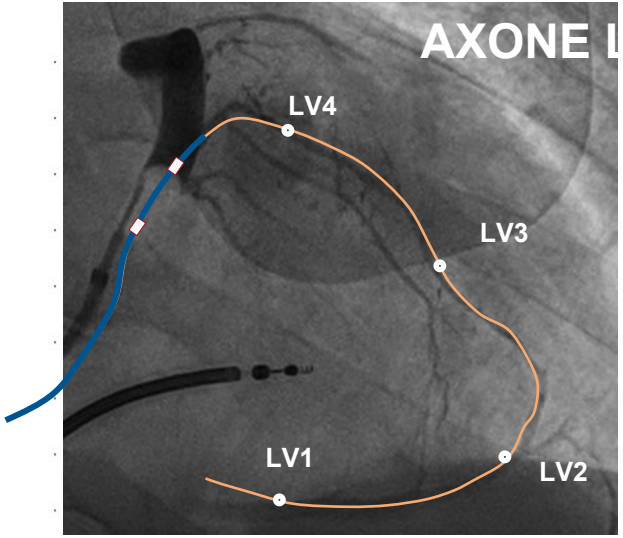
- Standard LV lead **could not be implanted** despite one additional hour of procedure.

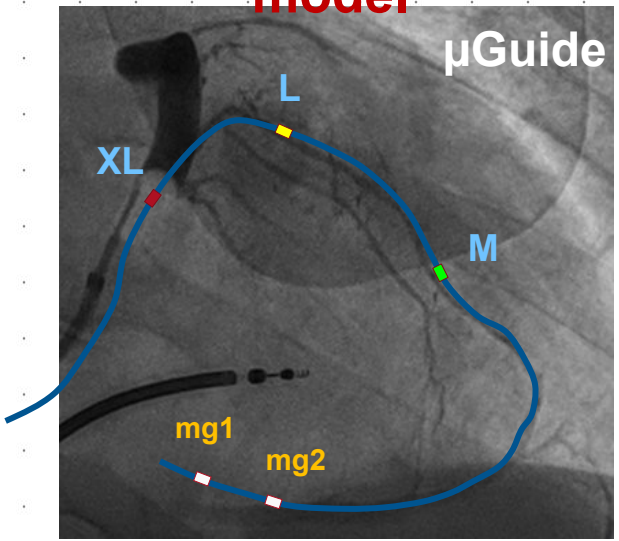


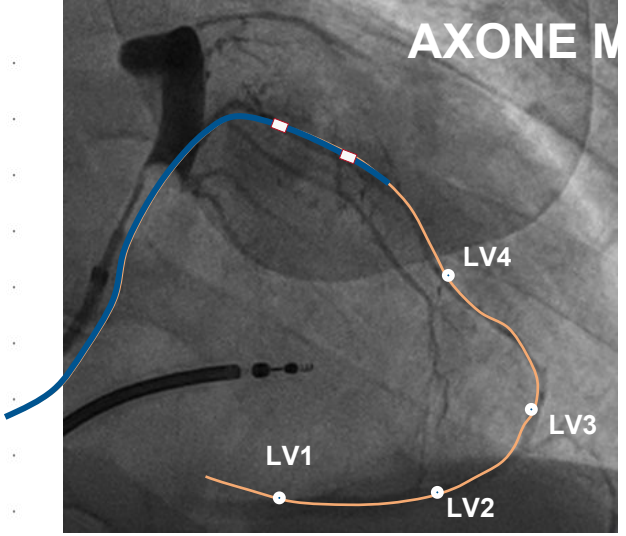
LVp OPTIONS with Axone:

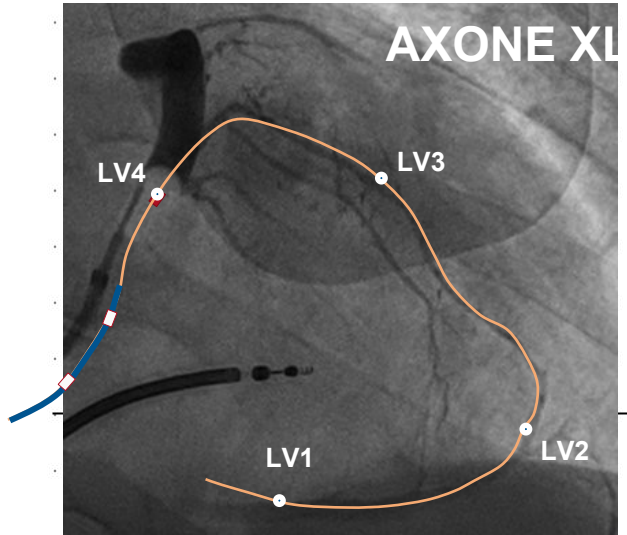
- single-vector from LATERAL (LV3)
- single-vector from POSTERIOR (LV2)
- MPP Bi-Zone ("LV2-RVc" + "LV3-RVc")

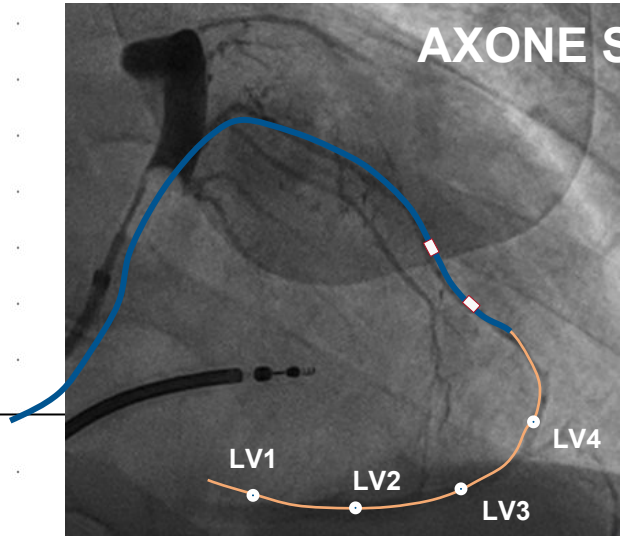
Choice of Axone lead model









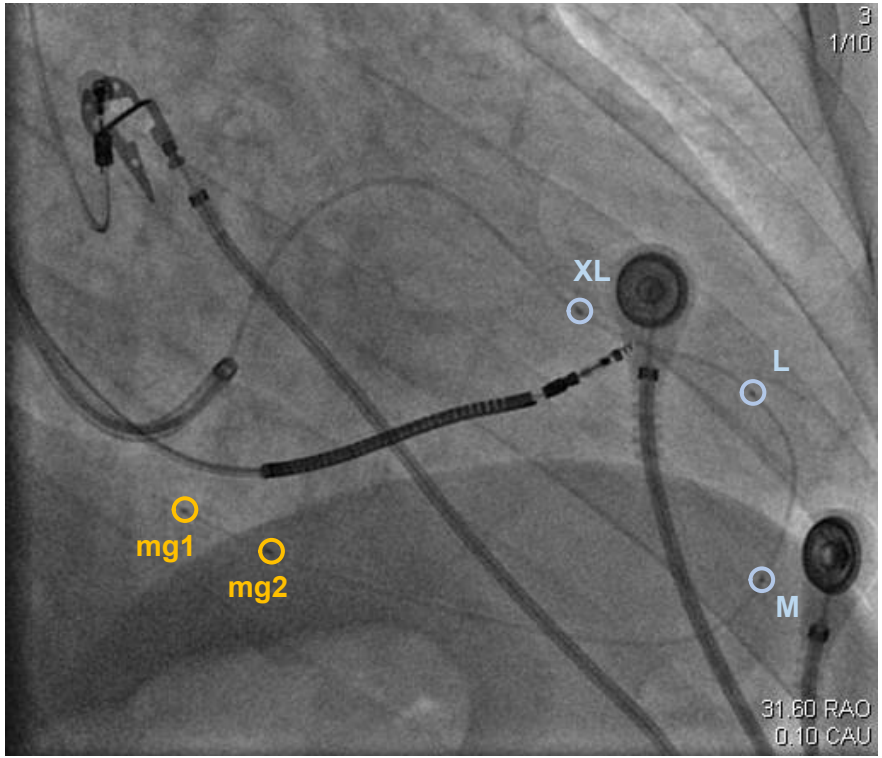


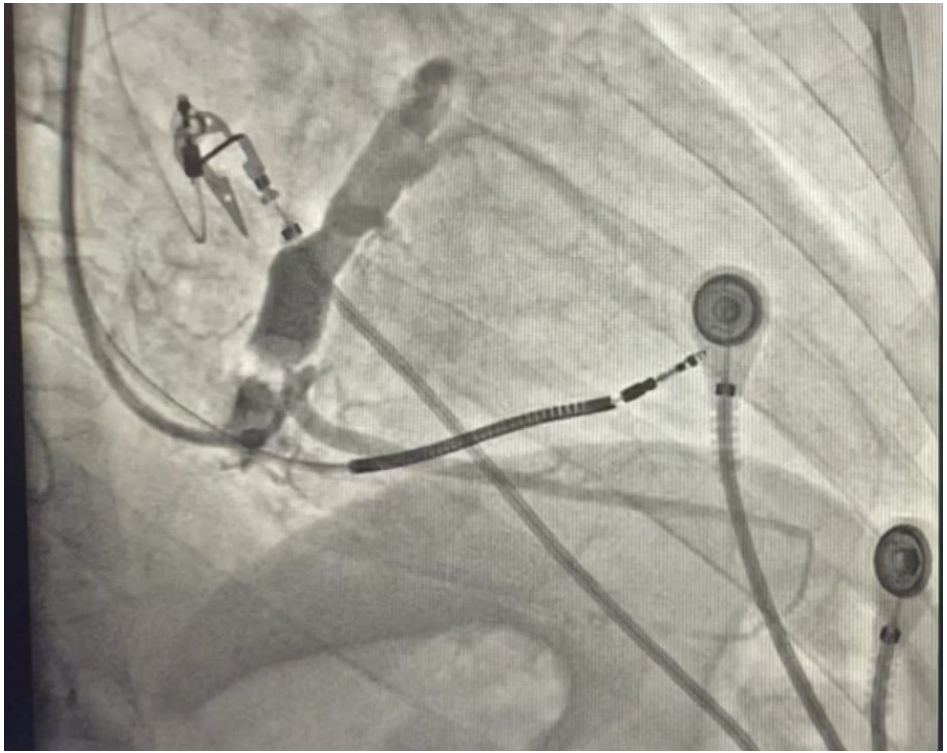
mg1-mg2 markers:
Position of **LV1** pole when Axone micro-lead implanted

M/L/XL markers:
Position of the **LV4** pole when Axone micro-lead implanted

Stability criterion:
the M marker must be located into a CS tributary vein

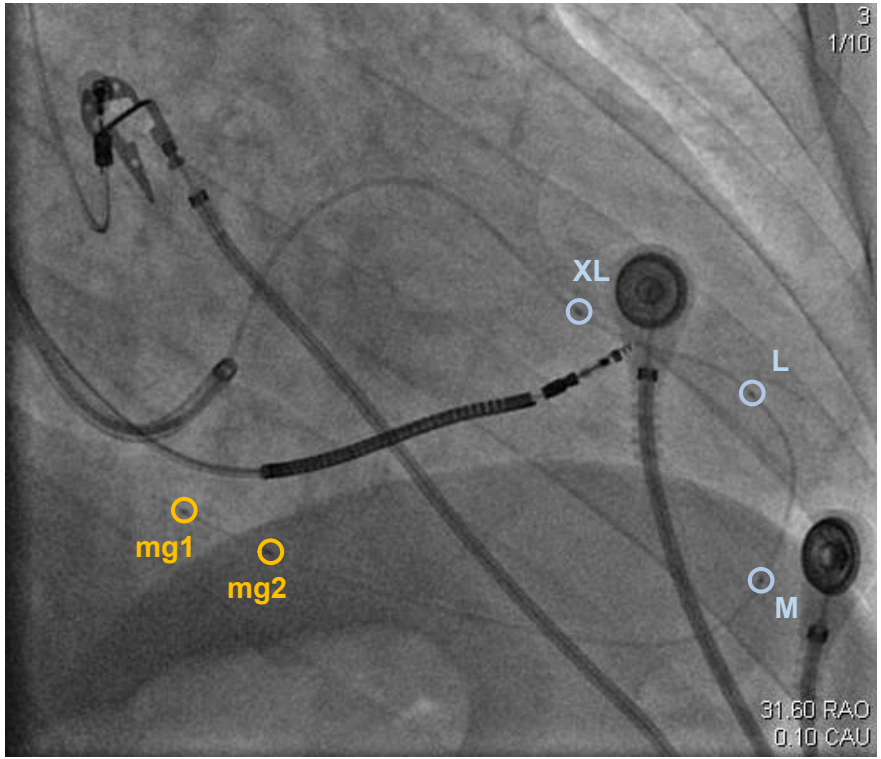
Pt #4 AXONE (RAO view) ☾ cross-vein: LAT to POST

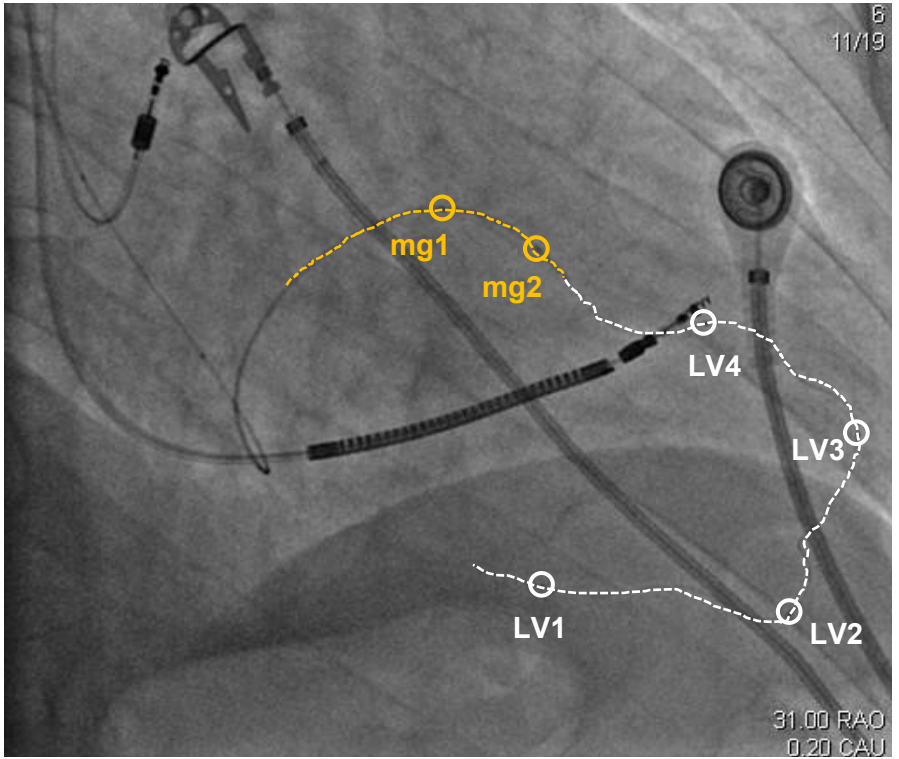




Choice of an **L Axone model**

Pt #4 AXONE (RAO view) ☾ cross-vein: LAT to POST

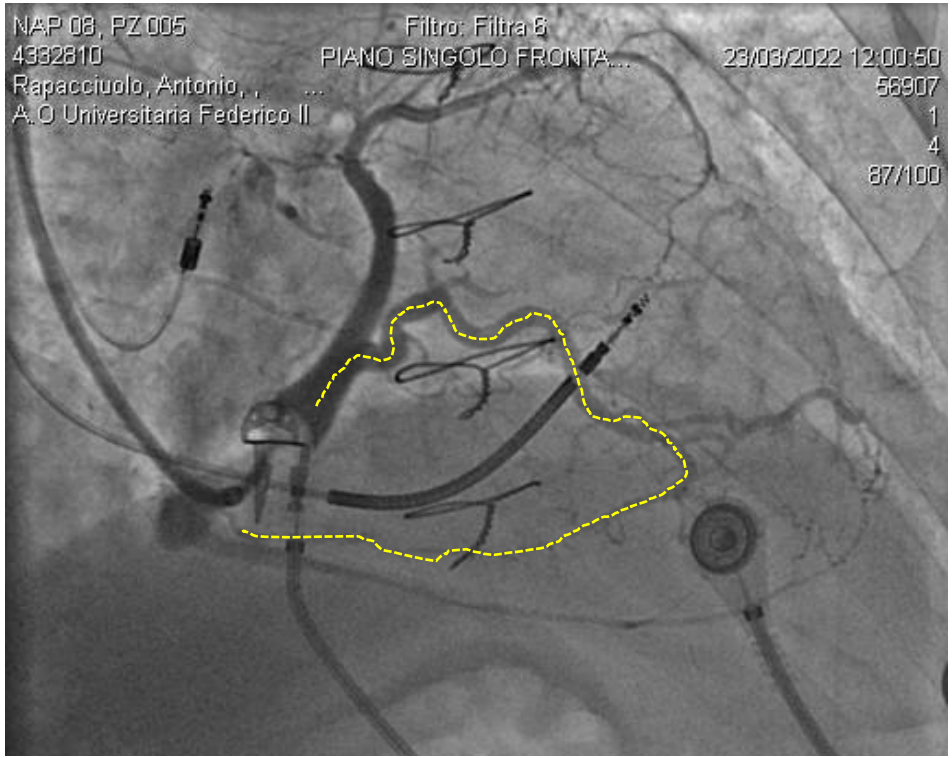


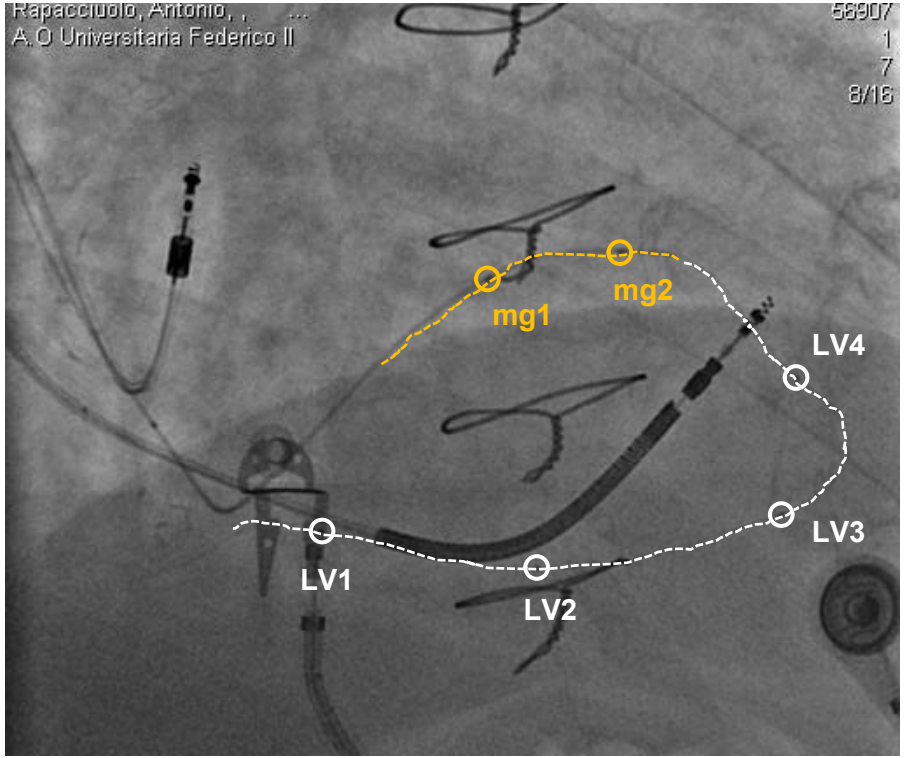


Axone lead L model (final position)

ASTRAL-4LV STUDY

Pt #5 AXONE (RAO view) ☾ cross-vein: PosteroLat to Posterior





Axone lead M model (final position)

ASTRAL-4LV STUDY

CONCLUSIONS: *AXONE technology, a new route for LVp*

POTENTIAL BENEFITS of MICROLEADS

- *Systematic **access of VCs** during lead implantation*
- *Better **flexibility** ☾ better navigation of acute **angles** and **tortuosity** in smaller veins*
- *Better **distal reach** via access to smaller veins*
- *Enhanced **myocardial penetration**, as collateral width decreases towards the endocardium.*

Any or all of these possibilities could **improve LV lead positioning** and thus **help optimize CRT**.

What about SAFETY? Does in the **LONG-TERM FU** a reduced LV lead body associate with increased lead **fragility** or an increase in implant- or **lead-related AEs** ?

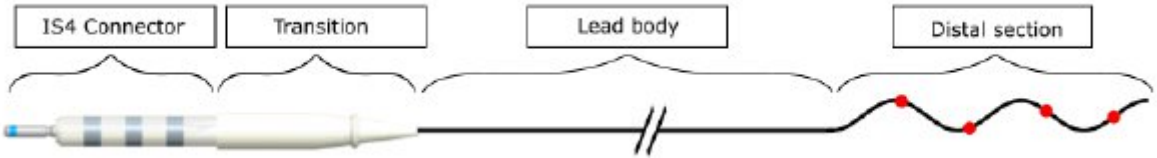
If long-term studies exclude these concerns and confirm the positive findings of our study, then **LV microleads could become a valuable tool** for extending access to **new LV pacing sites**.

Anselme F et al. Circ J 2021; 85: 283-90

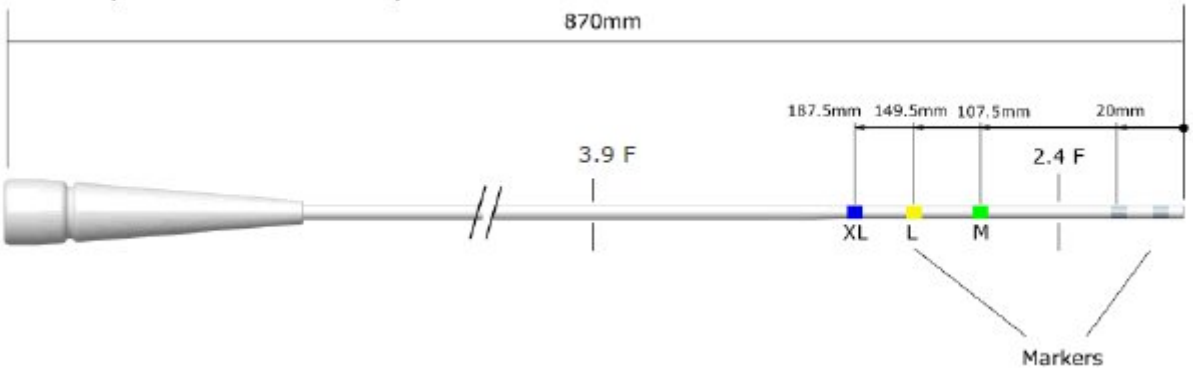
ASTRAL-4LV study (LAXI01) ongoing *(n = 78/152 pts successfully implanted)*
De-novo CRT-D pts, overall FU 4Y *(clinicaltrials.gov ID: NCT04463641)*
1-ary EP: **Chronic Safety / Performance [@ 6M FU]**

ASTRAL-4LV STUDY

For questions: device measurements



Diameter 4.0 Fr (proximal) to 1.2 Fr (distal)
Electrode surface 0,6mm^2



Minimal internal diameter 1.35 Fr
Coating on last 20 cm

LV implant Accessories

Guidewire

- Select a soft or medium support guidewire (avoid extra-support)
- Diameter dimension ≤ 0.014''

Subselection Catheter

- Minimum 4F inner diameter, peelable and shorter than 75 cm

Guiding Catheter / Delivery System

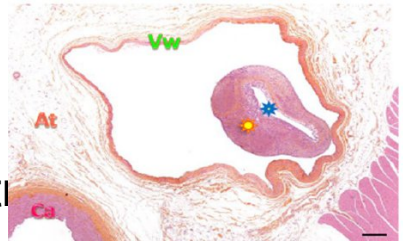
- No specific recommendation
- Worley can be used

Preclinical data

- 6 heathly dogs chronically implanted with CRT-D system (incl. Axone lead)
- Follow-up @1, 15, 30 and 90 days post implant
- 100% successfully implanted (S & M models), including 5/6 through a collateral
- No safety event during procedure
- Stable pacing thresholds at 3M (transitory elevation of PT @15d post implant), no PNS observed

Post-implant follow-up	Pacing threshold	Pacing impedance
1 day	2.2±1.3 V	1180±179 Ω
15 days	3.1±1.7 V*	1295±227 Ω*
30 days	2.2±0.9 V	1242±300 Ω
90 days	2.2±0.8 V	1334±279 Ω*

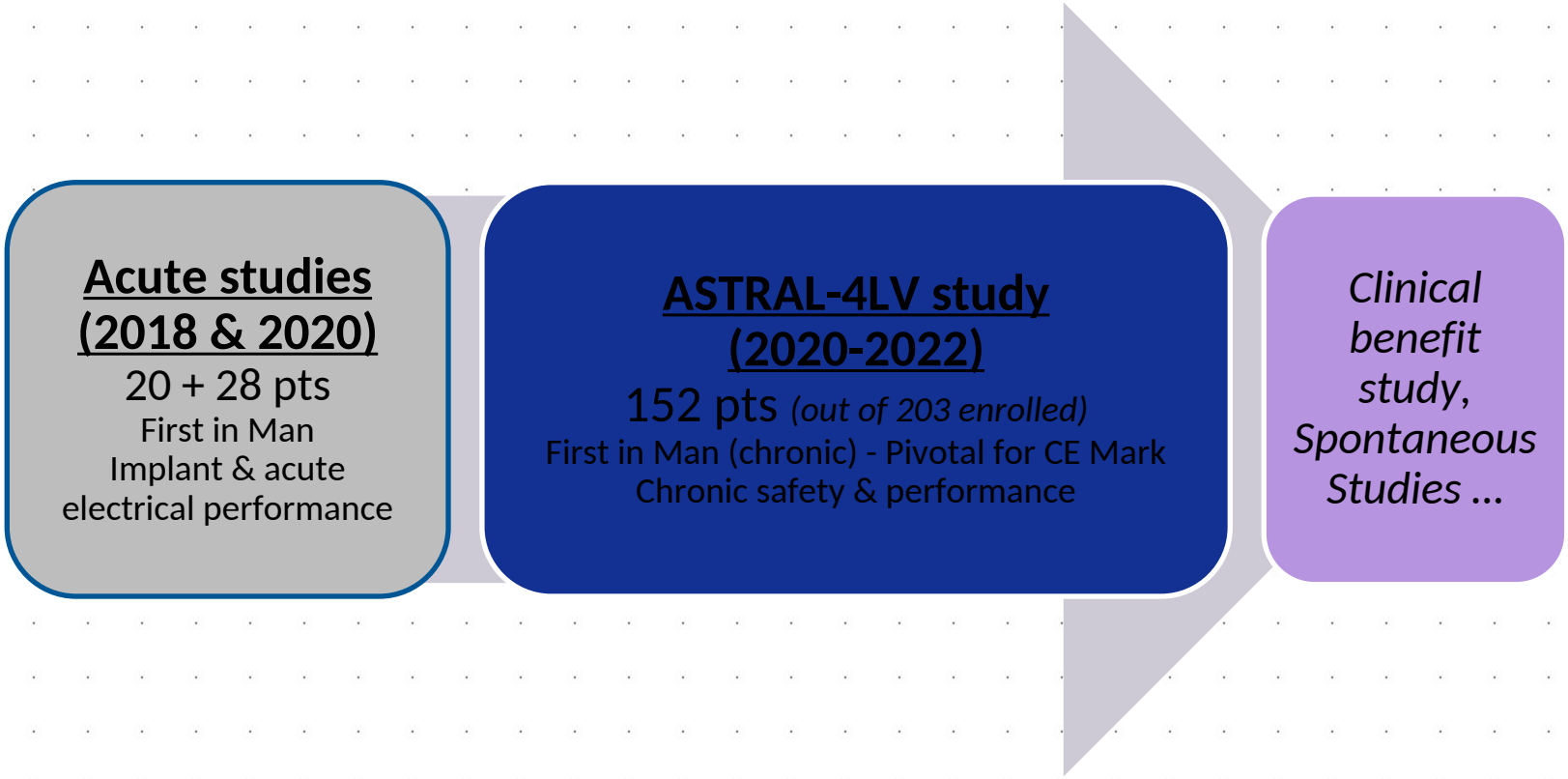
Mean Pacing Threshold and Impedance of Axone 4LV lead
(*p<0.05 compared to day 1)



- Stable lead position through follow-up (fluoroscopic cont
- Histology analysis: local bio-tolerance was excellent

Anselme et al. Acute and Chronic Performance Evaluation of a New Ultra-Thin LV Quadripolar Pacing Lead in a Canine Model (Poster Session HRS 2020)

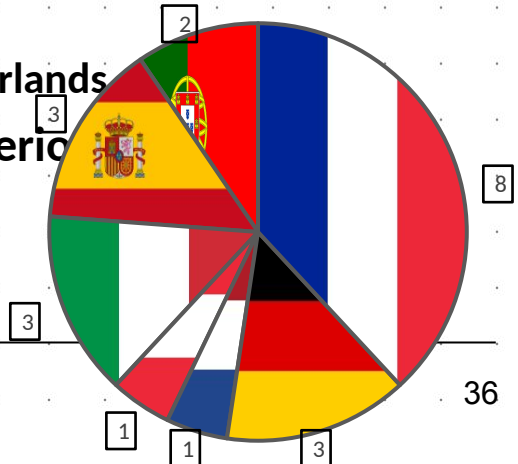
Axone Clinical Program



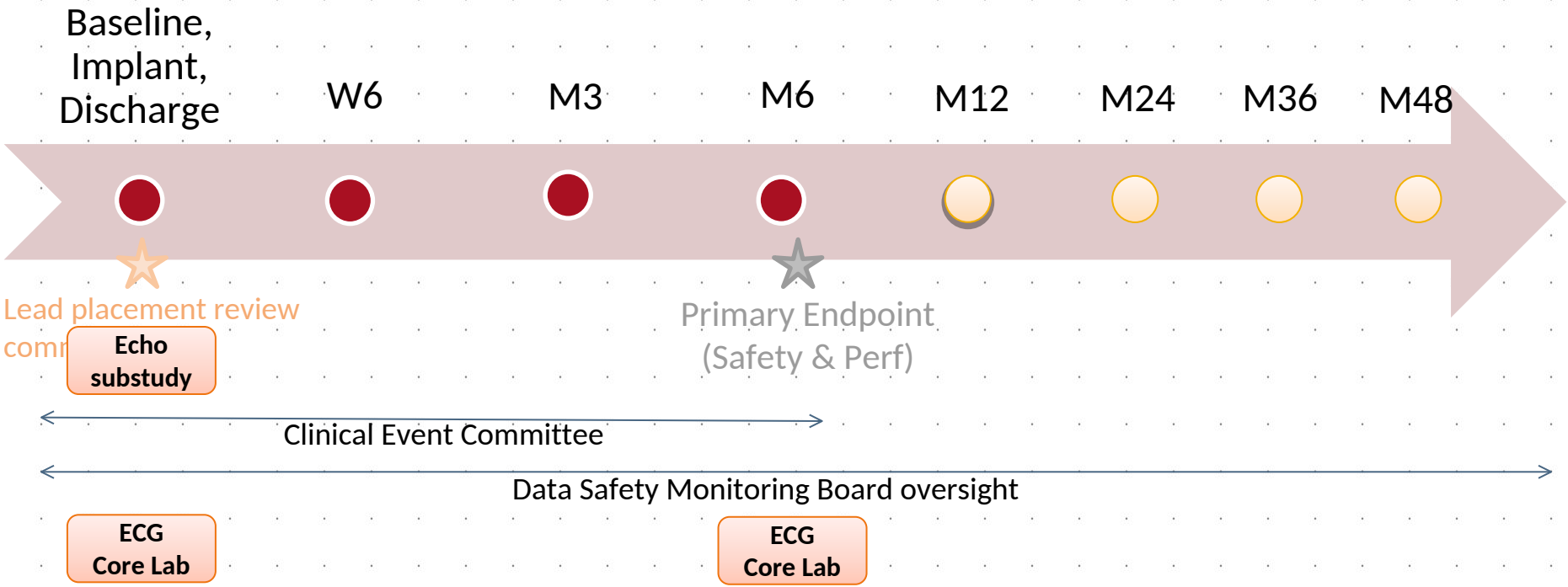
ASTRAL-4LV study: DESIGN

- **Study title**: Assessment of a micro multipolar lead for enhanced cardiac resynchronization therapy (ASTRAL-4LV)
- **Coordinating Principal Investigator** : F. Anselme (CHU de Rouen)
- **Device under investigation**: Axone System
- **Primary objective**: Assess the chronic safety and performance of the Axone LV micro-lead
- **Sample size**: 152 subjects implanted (max 203 subjects included [i.e. Axone µGuide inserted])
- **Sites**: 20 in Europe (France, Germany, Italy, Spain, Portugal, Netherlands
- **Duration**: 15-month inclusion period and 4 years follow-up perio

FPI : December 2020
Phase2: started Sept 2021
End of inclusion period expected for End Y2022



Study objectives & design



Primary Endpoints

❑ Safety Co-Primary Endpoint: **defined as Axone system related complication free rate at 6 months post implant.**
A complication is defined as any Serious Adverse Device Effect (SADE) resulting in death or requiring invasive intervention.
Endpoint will be based on independent event adjudication by a Clinical Event Committee (CEC).

❑ Performance Co-Primary Endpoint: **defined as LV pacing success rate at 6 months post implant.**
LV pacing success is defined as at least one LV pacing vector with:

- **Pacing Threshold (PT) ≤ 3.5V at 1ms pulse width, and**
- **No phrenic nerve stimulation at PT+2V / 1ms pulse width.**

The study will be considered successful if both co-primary endpoints are met.

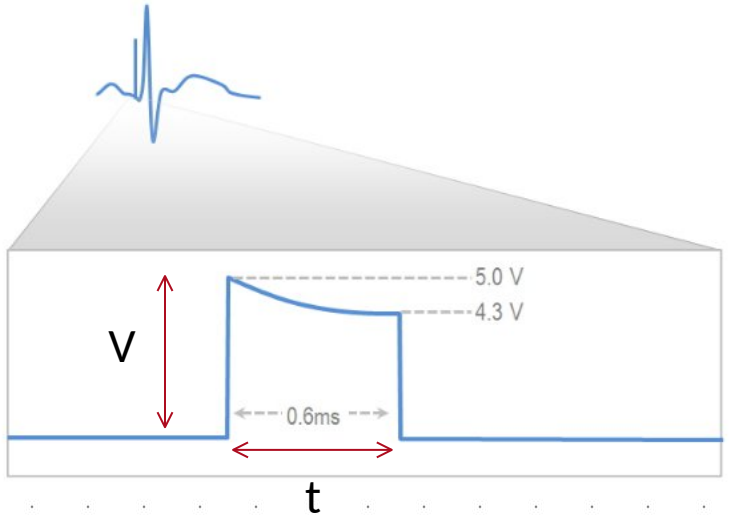
Impedance and energy

$$E = \frac{V^2 * t}{Z}$$

4 electrodes
Z=2000 Ohms
At 2V, 0,5ms

=

1 electrodes
Z=500 Ohms
At 2V, 0,5ms



Pacing Impedance

DUE TO THE SMALL SURFACE OF THE AXONE PACING ELECTRODES, PACING IMPEDANCE ARE HIGHER THAN STANDARD IS4 LEAD

Standard IS4 lead*	AXONE**
Pseudo-Bipolar: 400-1000 Ohm	Psudo-Bipolar: **1000-3000 Ohm**
Bipolar: 900-1500 Ohm	Bipolar: **2000-5000 Ohm**

** Data from NAVIGO at W10*

*** Data Animal studies at M3*

Pacing Energy Equivalence

2.5V @0.5ms – 700 Ohm STD IS4 lead

=

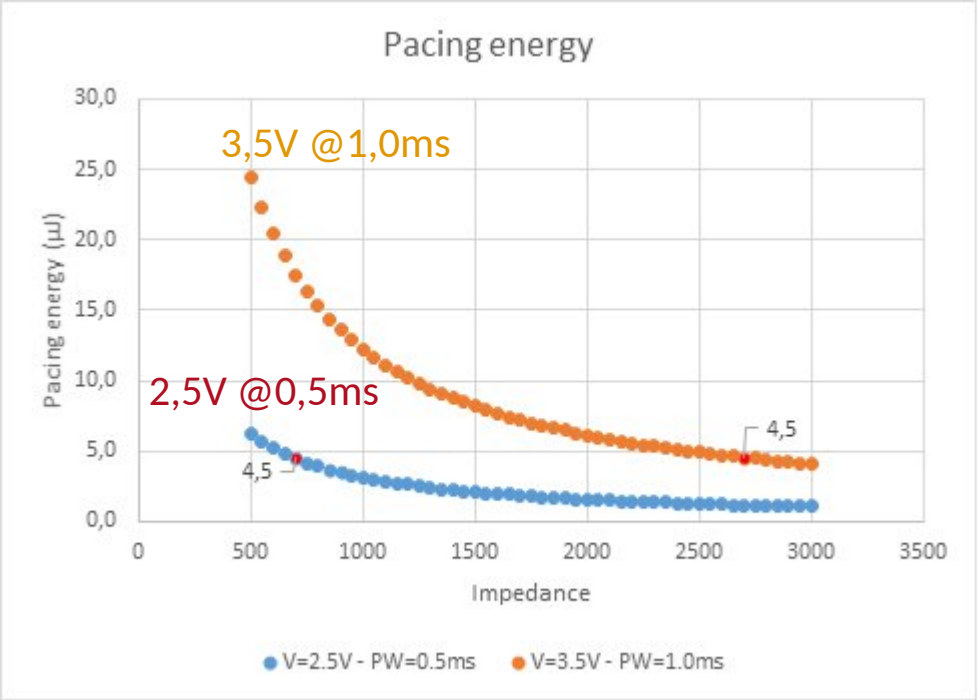
3.5V @0.5ms – 1400 Ohm

=

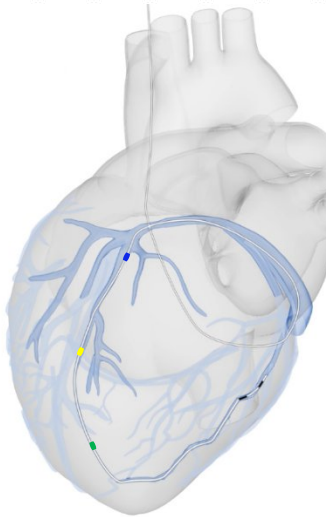
3.5V @1.0ms – 2700 Ohm AXONE lead

=

4.5 µJ

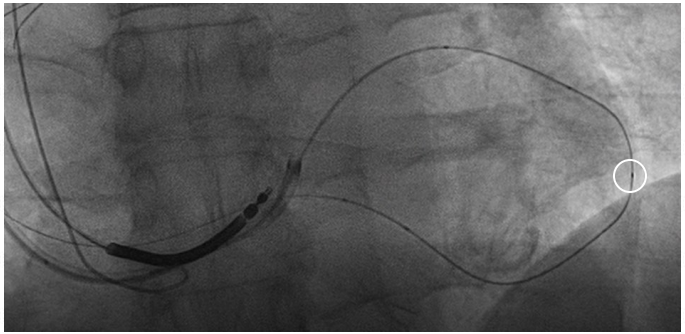


Axone µGuide placement (2)



- As per protocol, **it is recommended that Axone µGuide is advanced enough so that at least the M radiopaque marker is located inside a vein.**

  If not, implanter should not proceed with Axone system implantation.



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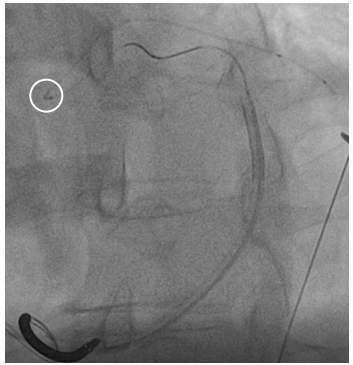
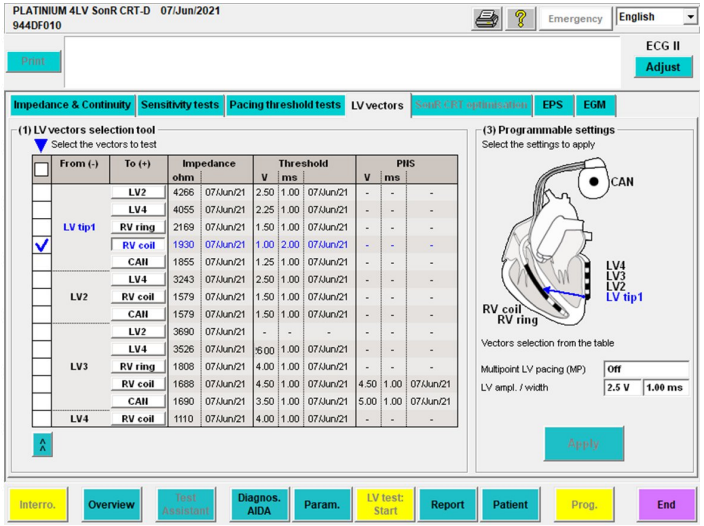


X

- While holding the Axone µGuide, slowly remove the guidewire.

Electrical Performance – Axone lead



- **Typical Axone lead impedances:**
  - 1500-2500 Ω in UNI / pseudo-BIP mode
  - 2000-5000 Ω in BIP mode
- **Typical Axone lead thresholds:**
  - 0.5V – 3.5V in UNI / pseudo-BIP mode
  - 1.5V – 5V in BIP mode
- **Same ENERGY consumption vs. convent. 4P leads**
- **Specific progr. sw to manage high LVp imped.**
  - tick box « high impedance lead » at implant
  - programmer values displayed up to 8000 Ω
  - extended range for LVp impedances “High Limit” alerts