

Cateteri per LBBA-D: a che punto siamo?

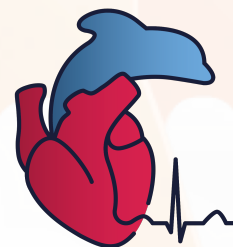
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P.O.C. «SS. Annunziata»

ASL Taranto



Elettrofisiologia
SS. Annunziata | Taranto



20° CONGRESSO NAZIONALE AIAC

Bologna
18-20 settembre 2024
Bologna Congress Center



If CSP is like marriage, LBBA-D is like adultery...



Patient:

Female, 62, FE 35%, NICD, LBBB, OMT, RV lead dislodgement during LV lead positioning attempt

A) SINGLE CHAMBER ICD

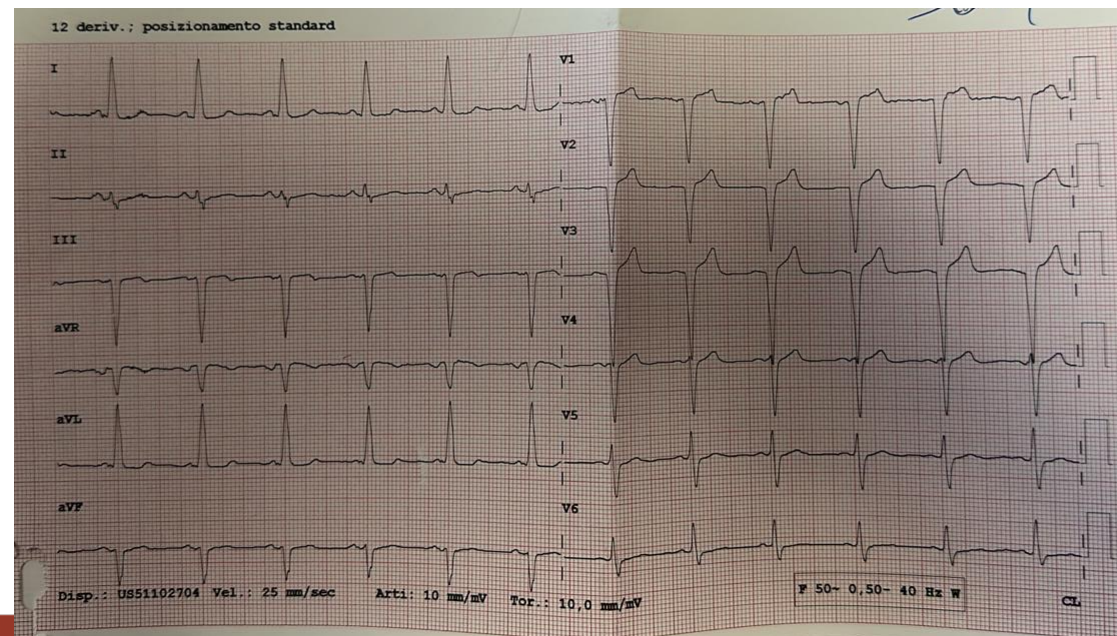
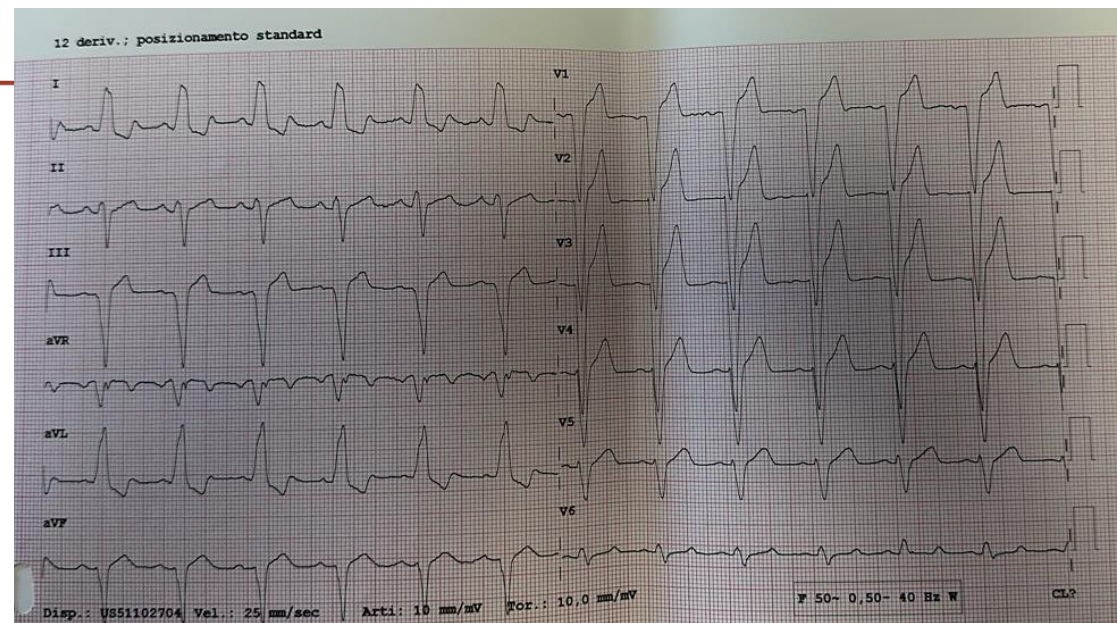
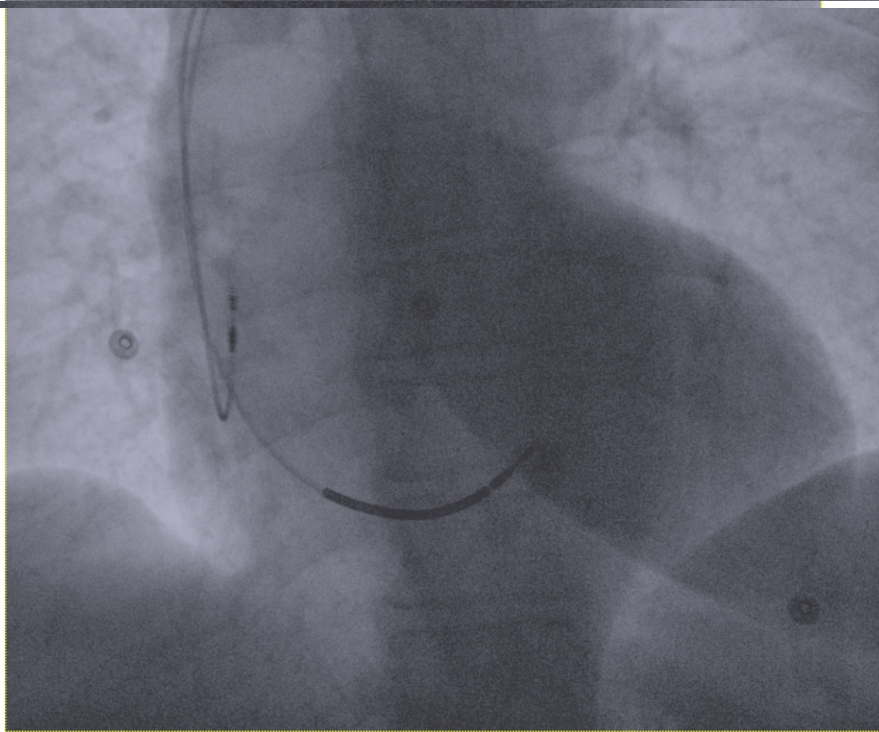
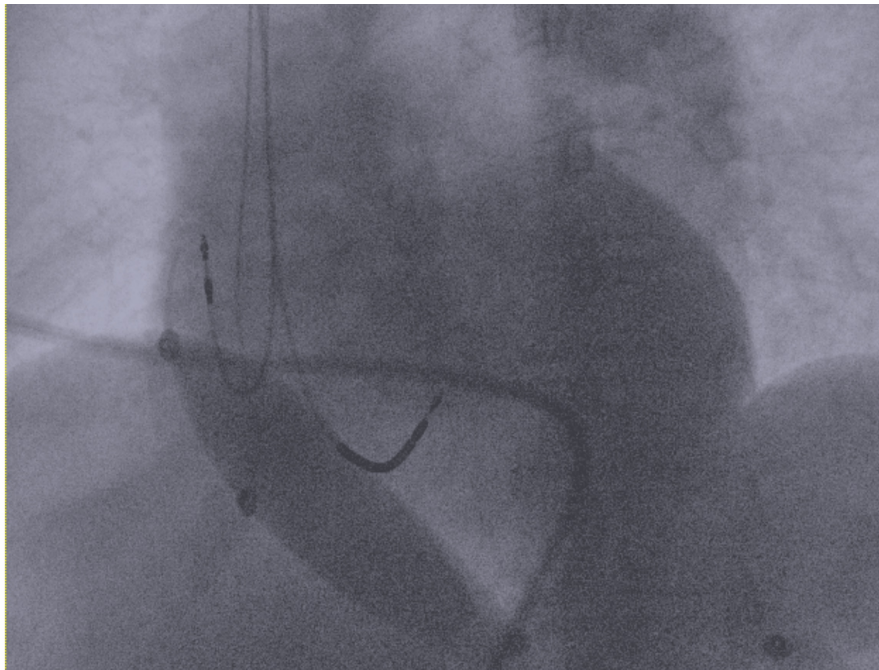
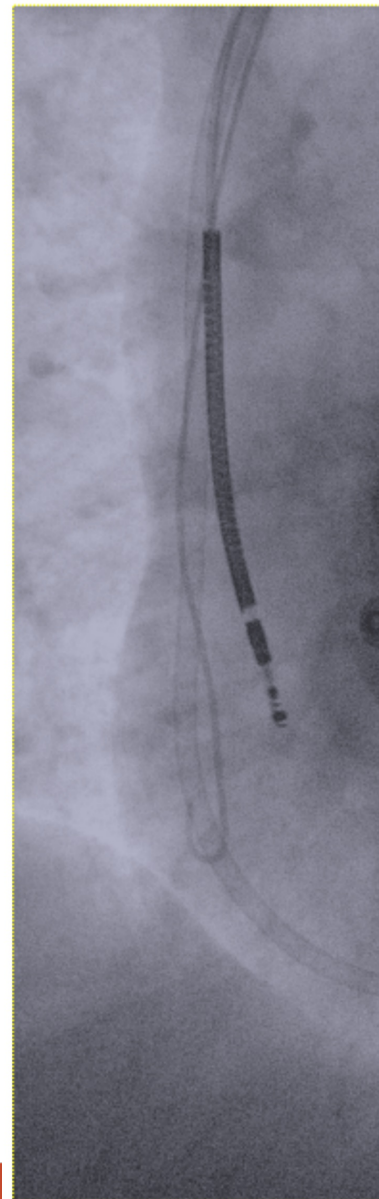
B) DUAL CHAMBER ICD

C) CRT-D w suboptimal LV positioning

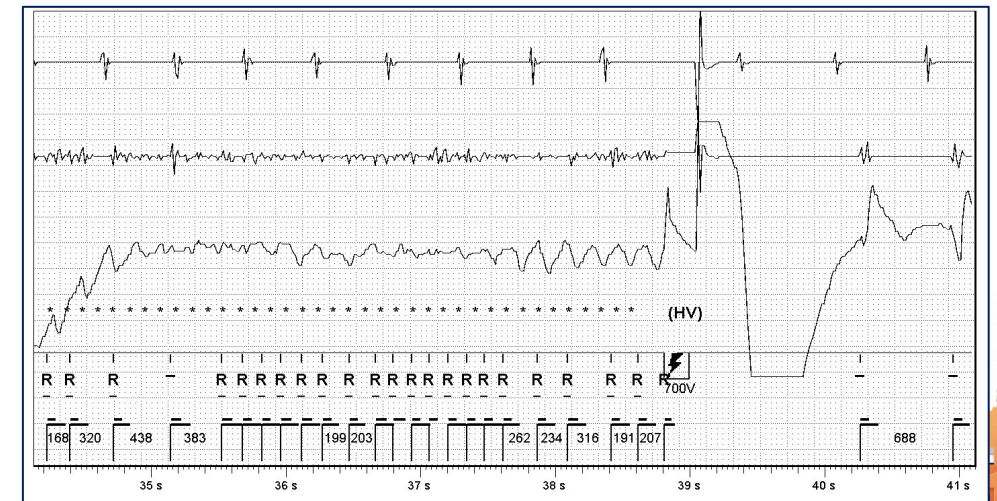
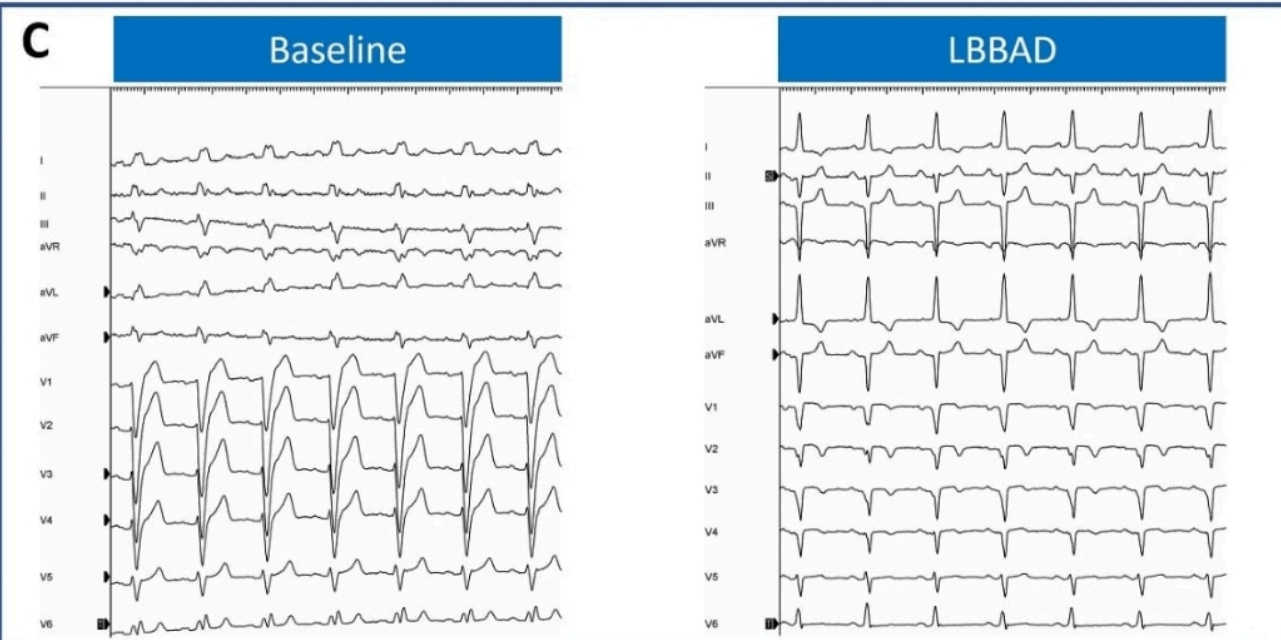
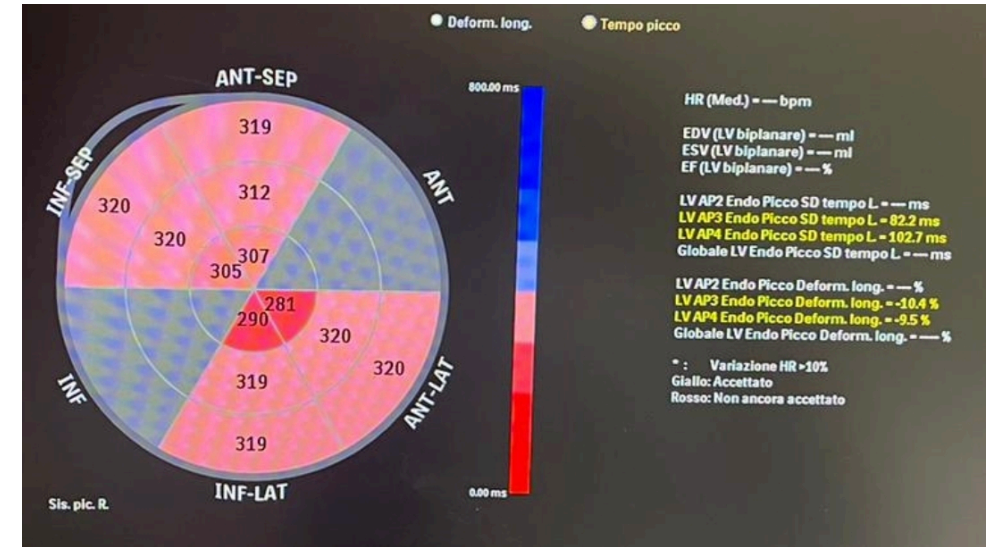
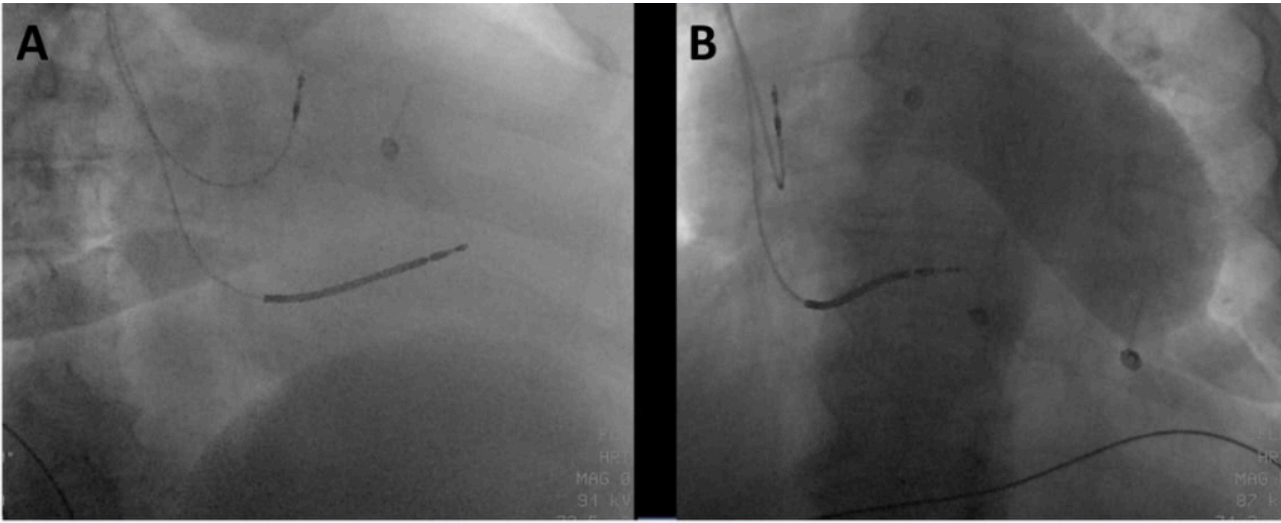
D) EPICARDIAL LATERAL ELECTRODE

E) LBBA...D





LBBA... Defibrillation Lead Implant result:



Performance at mid-term follow-up of traditional high voltage leads implanted in the left bundle branch area

C. Mandurino, M. Scolletta, A. Angelini, L. Di Gregorio, G. Luzzi

«SS. Annunziata» Hospital, Taranto, Italy

Background

Conduction system pacing (CSP) is emerging as a cardiac pacing technique alternative to conventional cardiac resynchronization therapy (CRT) to treat ventricular dyssynchrony. At this very moment, only a few data are available about the implantation of a **traditional high voltage (HV) lead** to perform **left bundle branch area (LBBA) pacing**, and follow-up is very short.

Purpose

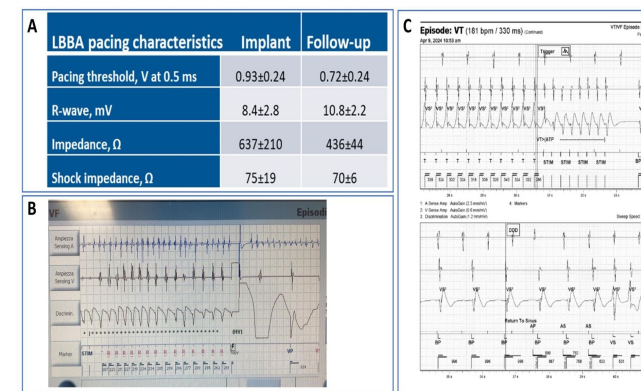
The aim of our study is to evaluate the **electrical performances, pacing, and defibrillator efficiency** of traditional HV leads implanted in the LBBA at **mid-term follow-up (up to 1 year)**.

Methods

14 patients (10 males, 68.8 ± 10.5 yo), with the indication for ICD/CRT-D, were enrolled and **implanted with a traditional DF-4 HV lead (6.8F) in the LBBA** (via a preshaped three-dimensional delivery sheath). **CSP verification and defibrillation tests were performed at implantation**. **Patient follow-ups were performed** at one week, one month, three months, six months, and **twelve months**, reporting **electrical parameters, consistency, ventricular synchrony, and efficacy of antitachycardia therapy**.

Results

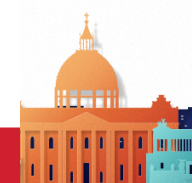
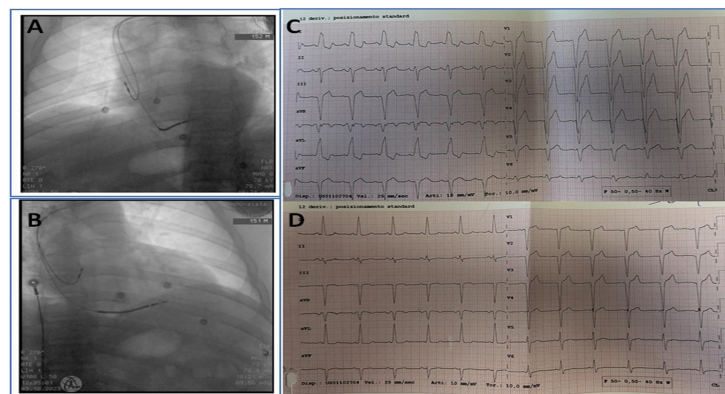
All 14 patients reported, at 1-year follow-up, **no change in ECG and ventricular synchrony echo parameters** (Peak Strain Dispersion <60ms). **Electrical parameters were also stable** (mean R-wave amplitude 10.8 ± 2.2 mV; pacing impedance 436 ± 44 ohm, shock impedance 70 ± 6 ohm, and pacing threshold 0.72 ± 0.24 V@0.4ms) with improving trend of R-wave amplitude and pacing threshold (with effective automatic capture management in 12 of 14 patients) and a significant reduction of pacing impedance, in comparison to acute post-implantation values. **We do not report any over/undersensing or noise issues**



and in two patients we observed **in vivo ICD effective ventricular arrhythmias termination both by antitachycardia pacing (ATP) and shock**. One patient underwent pocket revision due to significant weight loss, with no further issues. **No lead-related complications are reported**.

Conclusions

Traditional DF-4 HV leads could not only be safely and effectively implanted in the LBBA but are also showing excellent pacing and defibrillation performances in mid-term (up to 1 year) follow-up. Further investigations are ongoing with prolonged follow-up.



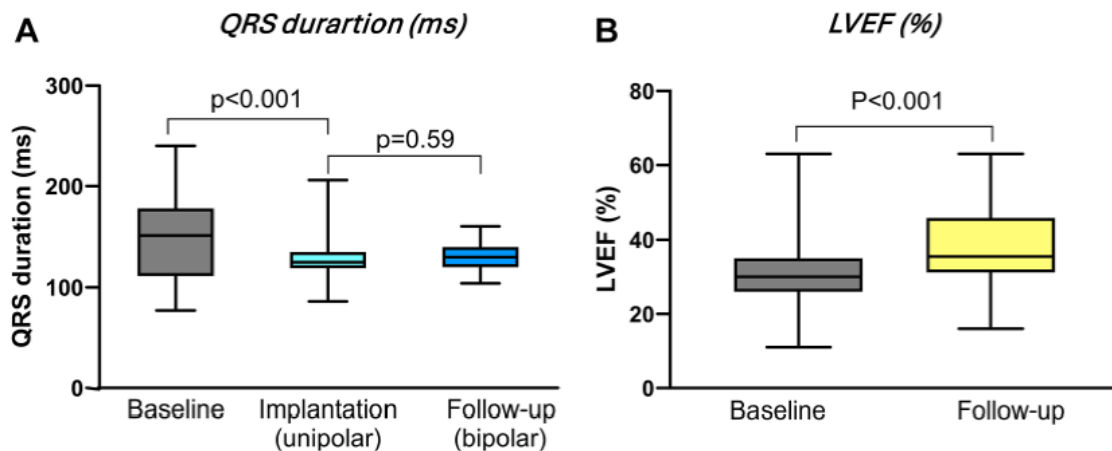
Implantation of standard defibrillator leads in the left bundle branch area: Experience from an international cohort ^e

Guram Imnadze, MD, FESC, FEHRA,^{1,2} Cosimo Mandurino, MD,³ Ana Briski, MD,⁴ Ulhas Pandurangi, MD,⁵ Anindya Ghosh, MD,⁵ Shunmuga Sundaram Ponnusamy, MD,⁶ Francesca Notarangelo, MD,⁷ Antonio Crocamo, MD,⁷ Ehsan Berenjkoub, MD,⁸ Brian Vezzi, MD,⁹ Kerstin Bode, MD, FEHRA, FESC,¹⁰ Christian Meyer, MD, FESC, FEHRA,⁴ Philipp Sommer, MD, FESC, FEHRA, FHRS,² Oscar Cano, MD,¹¹ Pugazhendhi Vijayaraman, MD, FHRS,¹² Haran Burri, MD, FESC, FEHRA¹³

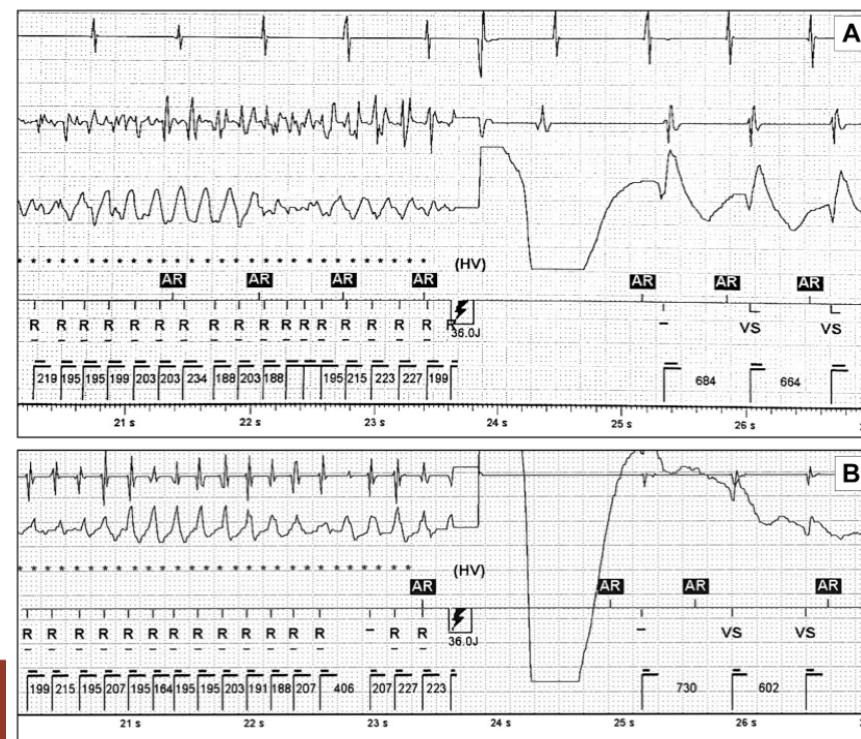
Table 3 ECG and electrical parameters at implantation and after a follow-up of 8 months (3–13)

ECG and electrical parameters	Implantation	Follow-up	P value
r/R in V1 (%)	80	72	.14
V6 R-wave peak time (ms)	76 (70–85)	79 (69–86)	.55
V6–V1 interpeak interval (ms)	44 (45–54)	41 (34–51)	.34
QRS duration from onset (ms)	125 (119–135)	130 (120–140)	.59
Capture threshold (V/0.4 ms)	0.8 (0.5–1.1)	0.75 (0.5–0.75)	<.001
Sensing amplitude (mV)	9.0 (6.2–12)	11 (6.0–12.0)	.29
Pacing impedance (Ω)	580 (493–650)	430 (398–470)	<.001
High-voltage impedance (Ω)	66 (60–75)	63 (57–70)	.04

ECG = electrocardiogram.

**Table 2** Device and procedural characteristics

Device and lead type	
ICD: VR/DR/CRTD (%)	10/50/40
Abbott Durata / Medtronic Sprint Quattro / MicroPort Invicta	161/1/1
DF-4/DF-1 (%)	84/16
Single coil/dual coil (%)	99/1
Procedural data	
Success (%)	88
De novo/upgrade (%)	82/18
Left/right side (%)	94/6
LOT-CRT (%)	28
Number of screw-in attempts	2 (1–3)
Total procedure duration (min)	100 (59–140)
Fluoroscopy duration (min)	16 (9–27)
Defibrillation test performed*	85
Defibrillation test success (%)	100
Successful shock energy (J)	30 (25–30)
Fascicular potential (%)	3
QRS transition (%)	34

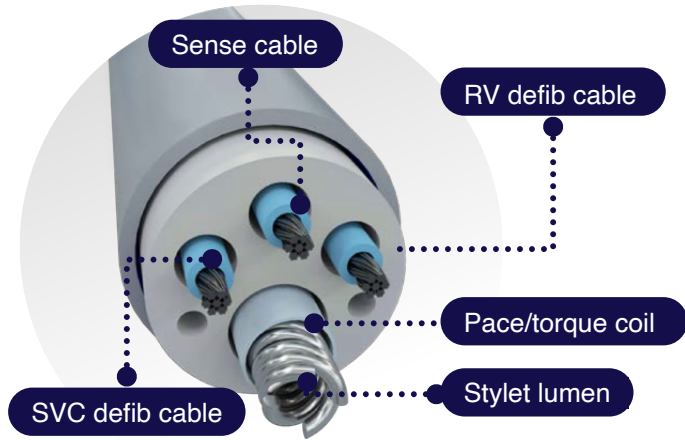




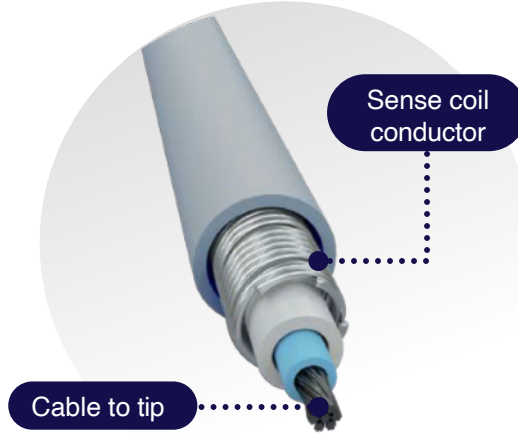
Great Scott!...How about dedicated tools???



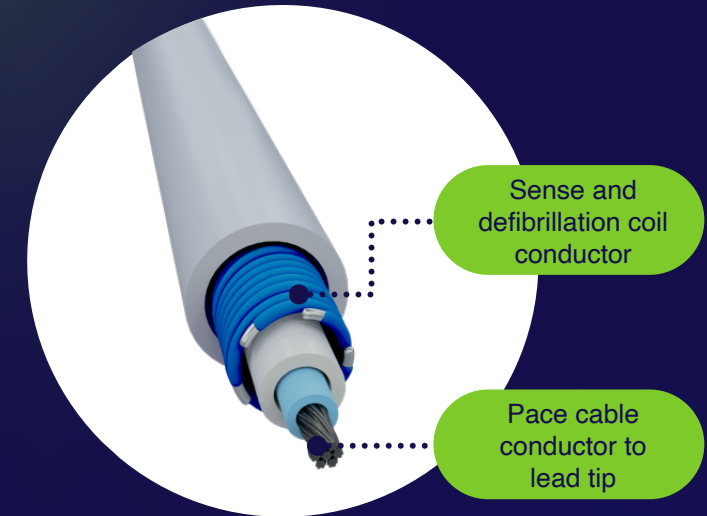
The small size of the OmniaSecure™ lead is enabled by fewer components and a reconfigured design



Sprint Quattro Secure™ 6947M
defibrillation lead



SelectSecure™ MRI SureScan™
Model 3830 pacing lead



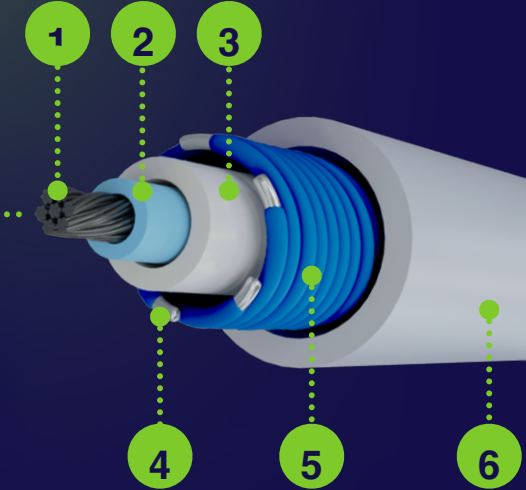
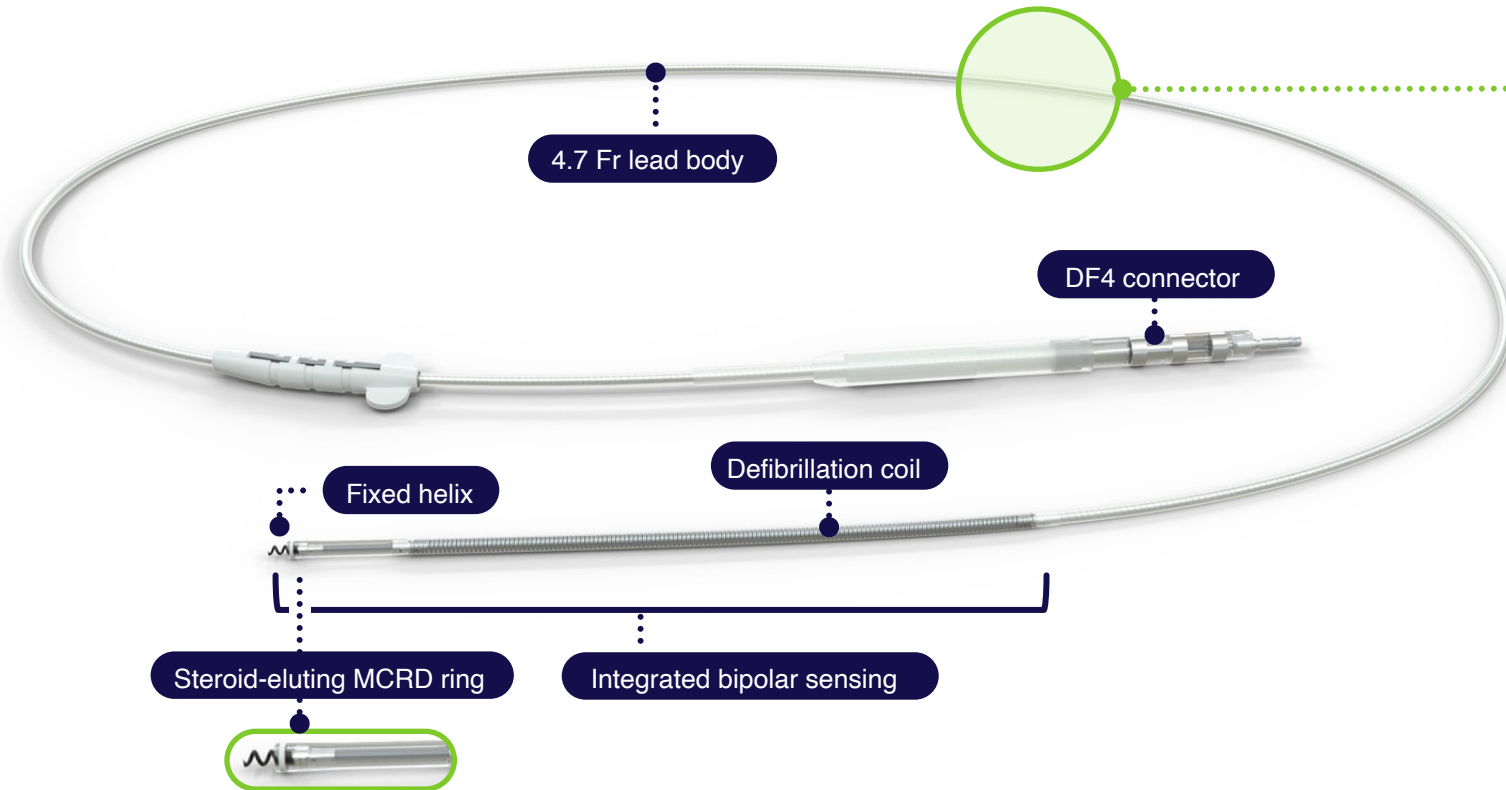
OmniaSecure 3930M
defibrillation lead†

Upsize from 4,1 fr to 4,7 fr

† OmniaSecure is 64% smaller than Sprint Quattro,¹ as depicted in the proportionally representative figures
1. Medtronic data on file. SecureD Lead Cross-Sectional Area and Volume Calculations. Filed September 2021.



OmniaSecure™ defibrillation lead construction



- 1 Conductor cable: MP35N
- 2 Inner insulation: ETFE
- 3 Inner insulation: silicone
- 4 Conductor coil: silver-cored MP35N
- 5 Conductor coil insulation: SI polyimide
- 6 Outer insulation: 55D polyurethane



Lead design comparisons

	OmniaSecure™ 3930M lead	Sprint Quattro™ 6935M lead	SelectSecure™ 3830 lead
Lead body diameter	4.7 Fr	8.6 Fr	4.1 Fr
Sensing polarity	Integrated bipolar	True bipolar Integrated bipolar	Unipolar True bipolar
Tip to RV Coil spacing	12mm	12mm (8 mm Tip to Ring)	9mm (Tip to Ring)
RV coil electrode surface area	371mm²	614mm²	N/A
Coil length	6.1 cm	5.7 cm	N/A

OmniaSecure MRI SureScan Model
3930M defibrillation lead will be available
in the following MR conditional lengths:



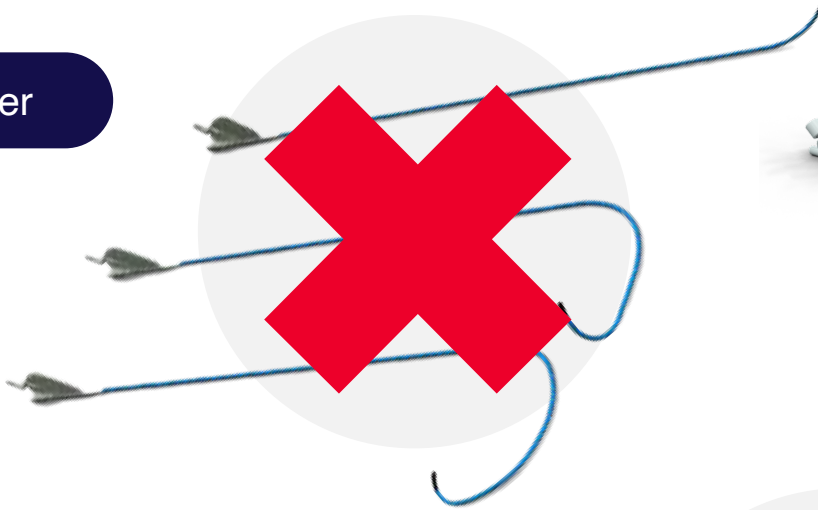
Catheters compatible with OmniaSecure™ lead

C315 delivery catheter

H40 40cm

S10 40cm

HIS 43cm



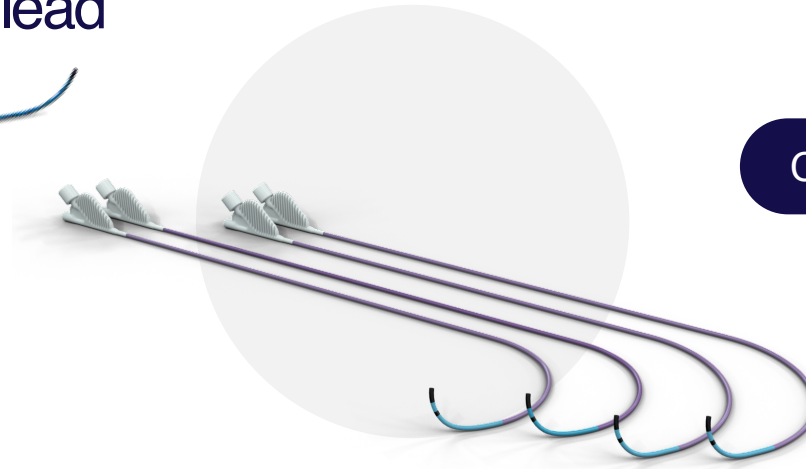
C320LBB delivery catheter

L 45cm

L 48cm

S 45cm

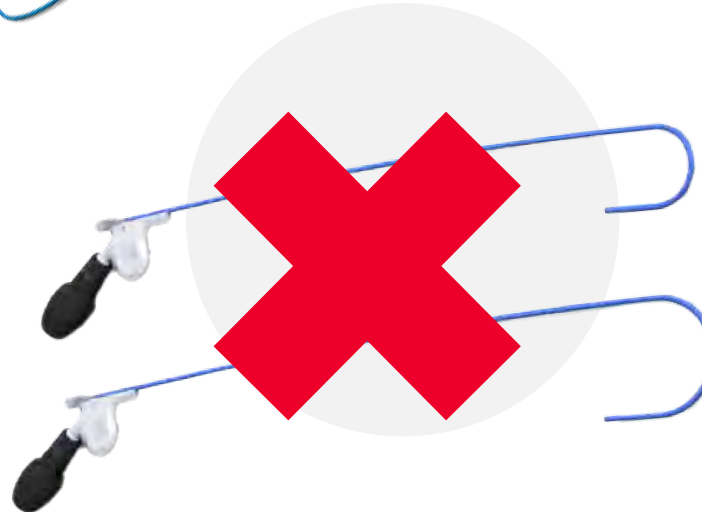
S 48cm



C304 deflectable catheter

C304-L 40cm

C304-XL 45cm

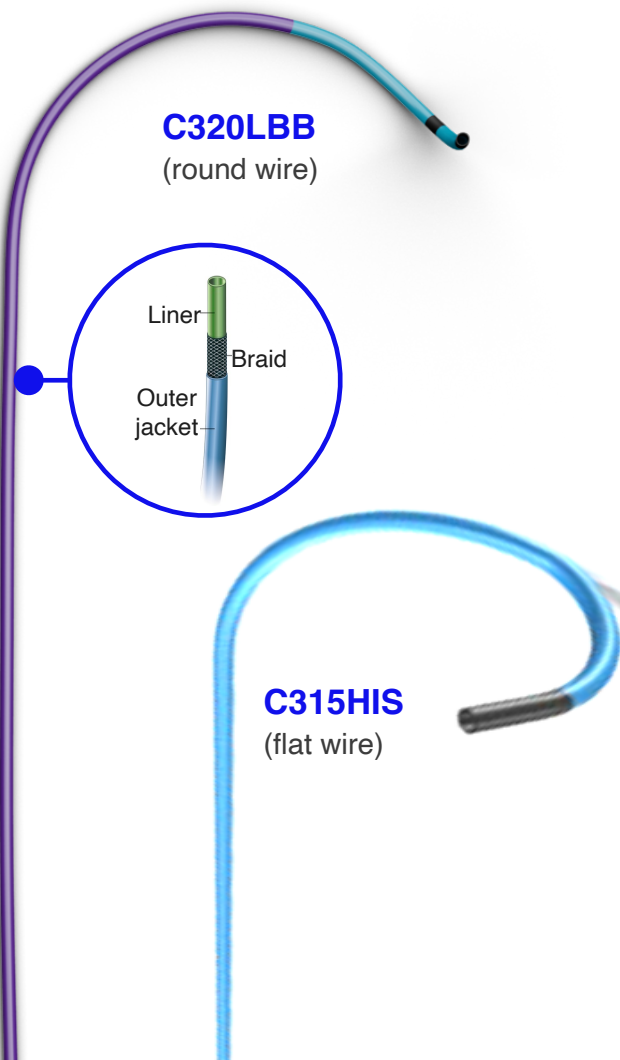


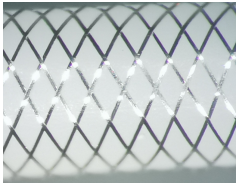
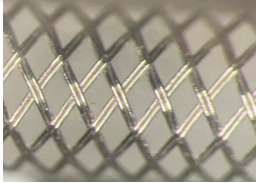
OmniaSecure lead is compatible with all C315, Attain Command™ + SureValve™ and Attain Select™ II + SureValve™ guide catheters.

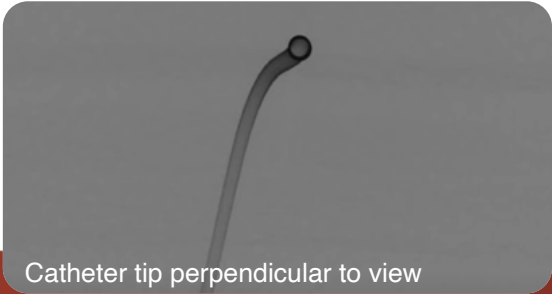


C320LBB delivery system – engineered for LBBAP

Comparison with C315 catheter



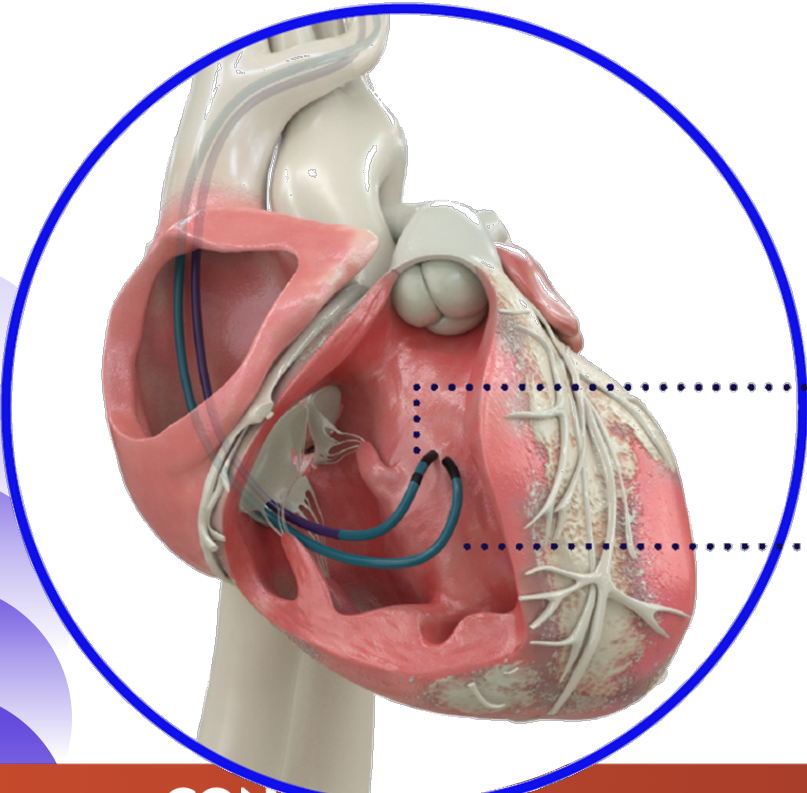
Items	C315HIS Catheter	C320LBB Catheter
Liner	Hydrophilic Liner	Hydrophilic Liner
Braid	Flat wire 0.001“*0.002” 	Round wire OD: 0.002” 
Usable length	43cm	45 and 48cm
Curve	His	S curve & L curve
Marker	One marker	Two markers



C320LBB delivery system – engineered for LBBAP

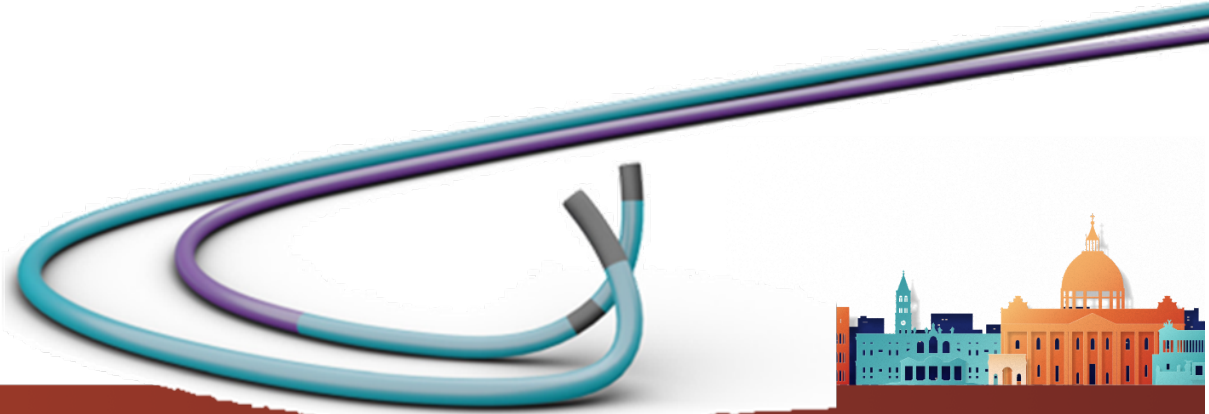
Comparison with C315 catheter

Items	C315HIS Catheter	C320LBB Catheter
ID	5,5 Fr	5,4 Fr
OD	7 Fr	7 Fr
Outer Jacket	C315	C320
	Distal 45D 11mm 55D 10mm 63D 10mm 72D 399 mm for 430mm catheter Proximal	Distal 45D 7mm 55D 5mm 45D 3mm 55D 6mm 63D 7mm 72D 23mm Vestamid 399 mm for 450mm catheter; 429 mm for 480mm catheter Proximal
	Two markers	



C320LBB catheter

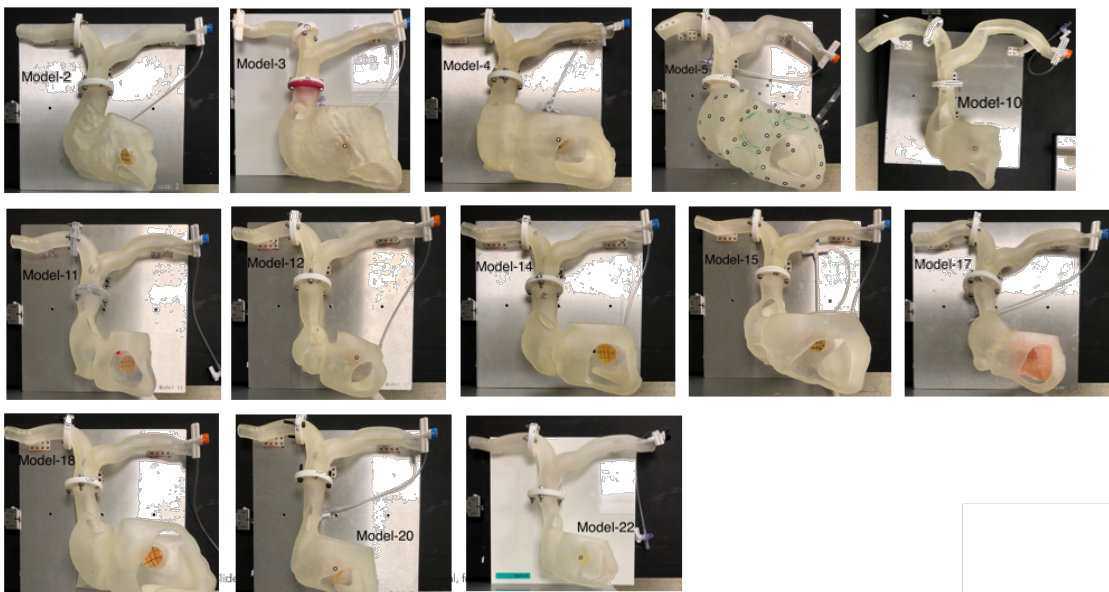
C315HIS catheter



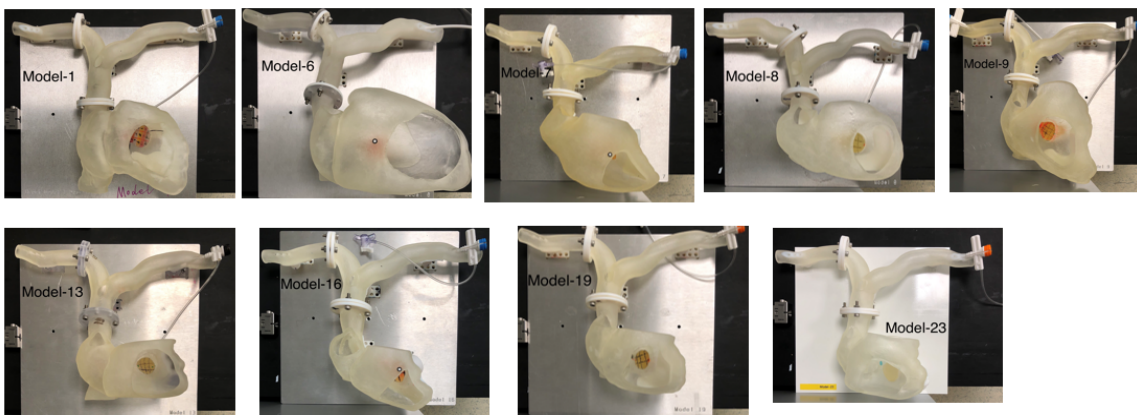
Engineering study comparing **C320LBB** shapes and C315His

on 22 anatomical bench models developed using clinical CT scans of patients

Group 1 models_ Large curve



Group 2 models_ Small curve



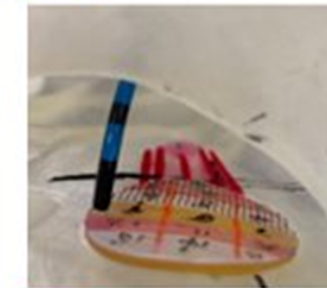
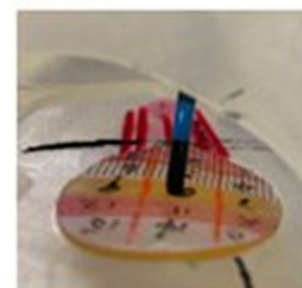
- Anatomies selected to represent a wide range of heart size, orientation, and disease state/indications
- Catheter performance was evaluated based on ability to reach the LBBP target, and perpendicularity of the tip at the target



In the center



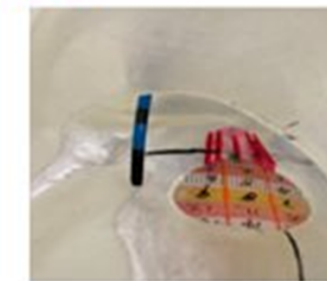
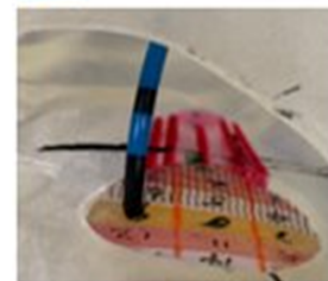
On the Edge



On the Side



Can't Reach



IFU Recommendations

Model number	C320LBBS45	C320LBBL45	C320LBBS48	C320LBBL48
Guide-catheter usable length	45 cm (17.7 in)	45 cm (17.7 in)	48 cm (18.9 in)	48 cm (18.9 in)
Guide-catheter dilator usable length	56.5 cm (22.2 in)	56.5 cm (22.2 in)	56.5 cm (22.2 in)	56.5 cm (22.2 in)
Compatible leads length	69 cm (27.165 in) or greater		74 cm (29.134 in) or greater	



Why 74 cm Model 3830 lead?

- It provides enough slack for slitting.
- A 3830-69cm lead w/C320LBBx48cm only leaves ~2-3 cm of slack with the slitter in place.

Why 79 cm Model 3930M lead?

- A 79cm OmniaSecure lead is needed with 48cm catheter to allow exposure of entire defib coil for checking electrical efficacy and allow adequate draping of coil before slitting



OmniaSecure impact on tricuspid regurgitation

Smaller defibrillation lead diameter is associated with less tricuspid regurgitation: a computational modeling study

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Methods: We developed a physics-based computational model to evaluate the global effect of lead and moderate TR loads on the integrated office area (IOA). Additionally, we simulated three commercial transverse loads, with discharges of 4.7 N, 6.8 N and 8.8 N, and evaluated the induced IOA. These jaw-position baseline conditions were considered to allow no TR, mild TR and moderate TR.

Results: Load disorder exhibited a predominant effect on IOA compared to material properties, in mild and moderate TR levels. The IOA loads resulted in exponential increases in IOA. The 4.7 N load increased significantly below clinically relevant increases in IOA. In contrast, the 6.8 N and 8.8 N loads induced a transition from mild to moderate TR.

Conclusions: Coronal implantable electronic denture permanent prostheses, removable partials, and complete dentures designed with deformational, occlusal differentiation, lead release and occlusal dysfunction.

1. Introduction

2.1. Methods

2.1.1. Vahro model

To model the TV we used the Solisite 3.5 fibre element 6 model, which is based on a healthy human donor has simulated leaflets, annulus and chordae tendineae, and was validated against echocardiographic data [13].

CONTRACT: Kevin L. Sack, Kevin.L.Sack@medtronic.com | Cordis, Rhythm Management, Medtronic, Inc., 6301 Cardiac Dr. NE, Minneapolis, MN, 55412, USA

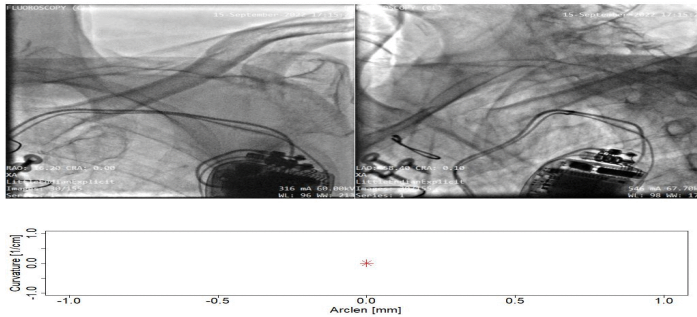
Modeling the impact of a smaller and more flexible lead on tricuspid regurgitation

Continued evidence generation, including the LEADR post approval study

OmniaSecure™ defibrillation lead predicted to be highly durable with an overall 98.2% fracture-free rate at 10 years

Understand in-vivo use conditions

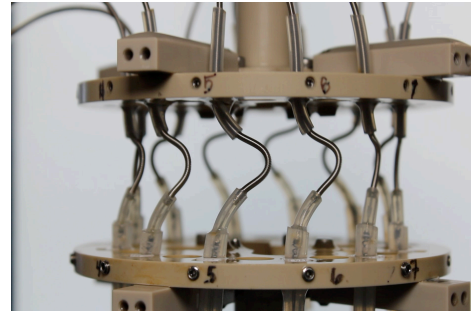
- OmniaSecure LEADR substudy imaged patients during full range of arm motion to assess and quantify in-vivo bending
- Inclusion of cyclic use conditions based on patient activity



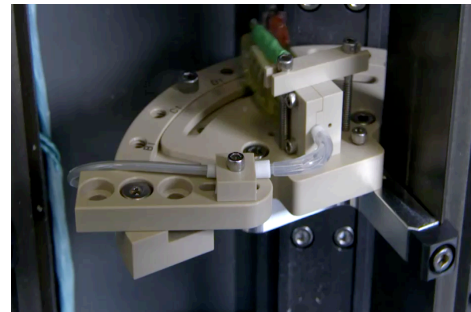
Clinically relevant bench testing and test to failure¹

Benchtop fatigue tests designed to mimic in-vivo use conditions and reflect extreme levels of stress, taking into consideration:

- Patient anatomy and lead interaction in different zones of the body
- Implant techniques



Distal fatigue test



Proximal connector fatigue test

Massive tests to look at the lead durability at 10 years:

- 400 million cycles for cardiac motion
- 5 million cycles of arm motions.
- 50.000.000 patients
- 5.000 cohorts

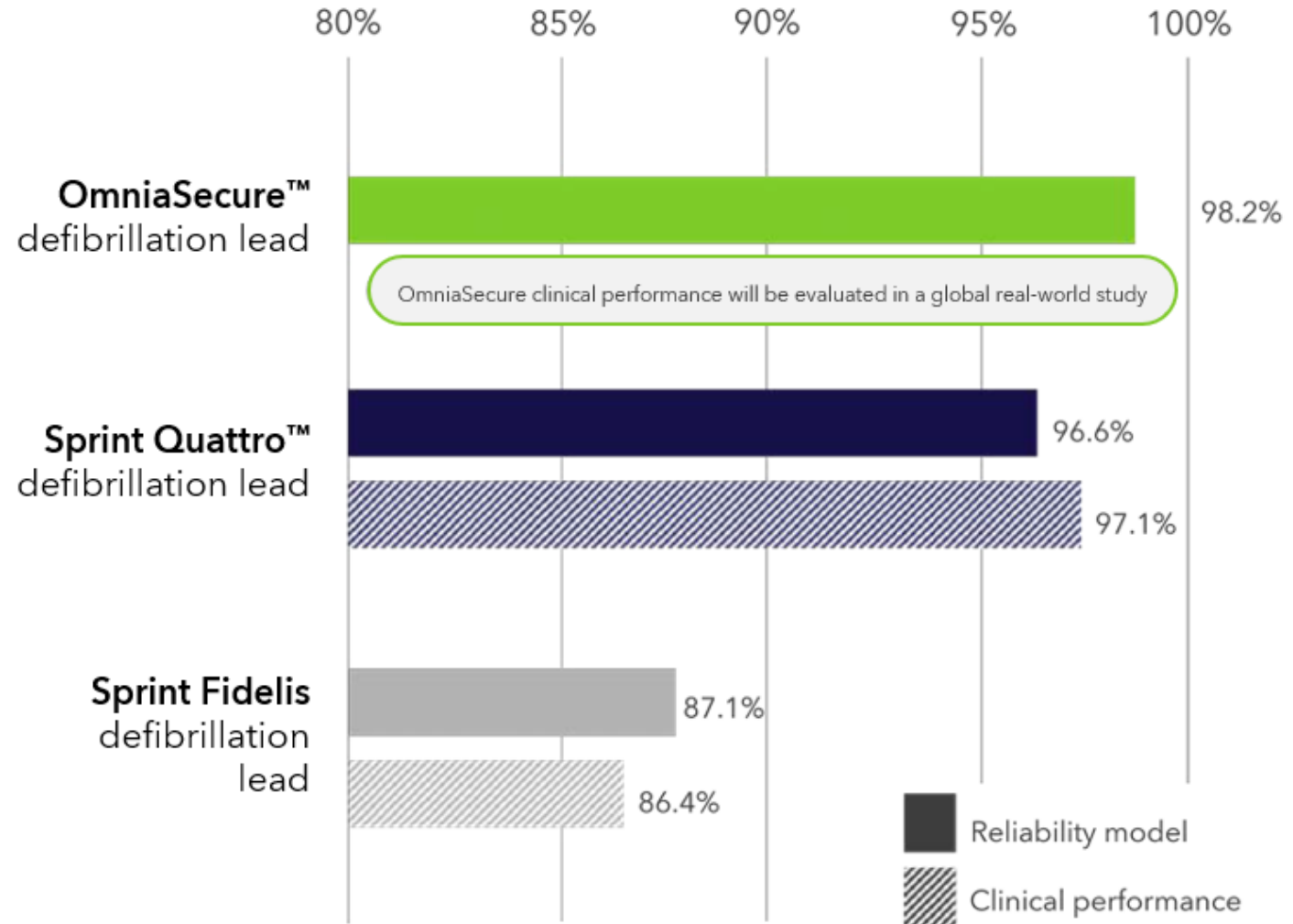
1. Crossley GH, et al. *Heart Rhythm*. 2025;22:302–310.
2. Wilkoff BL, et al. *Heart Rhythm*. 2021;18:1605–1612.



OmniaSecure™ defibrillation lead predicted to be highly durable with an overall 98.2% fracture-free rate at 10 years

Validated fatigue survival model²

The reliability model accurately predicted 10-year real-world performance of Medtronic commercialized leads²



1. Crossley GH, et al. *Heart Rhythm*. 2025;22:302–310.

2. Wilkoff BL, et al. *Heart Rhythm*. 2021;18:1605–1612.



OmniaSecure™ defibrillation lead predicted to be highly durable also for adolescents population at 10 years: 97,9%

Validated fatigue survival model²

The reliability model accurately predicted 10-year real-world performance of Medtronic commercialized leads²

Table 4 Ten-year fracture-free survival results for OmniaSecure and controls (Sprint Quattro and Sprint Fidelis)

Lead model	Mean estimate (95% CI)		
	Whole population	Adults (age ≥22 y only)	Adolescents (age ≥12 y and <22 y)
OmniaSecure	98.2% (96.4%–99.7%)	98.3% (96.5%–99.8%)	97.9% (95.9%–99.5%)
Sprint Quattro 6947	96.6% (93.2%–99.0%)	96.7% (93.2%–99.0%)	93.0% (86.6%–97.8%)
Sprint Fidelis 6949	87.1% (80.6%–92.6%)	87.1% (80.6%–92.7%)	77.4% (67.2%–85.9%)

The only High Power lead to receive U.S. FDA approval for >12 years and 30Kg weight

In LEADR study, no fractures, 100% implant success

1. Crossley GH, et al. *Heart Rhythm*. 2025;22:302–310.
2. Wilkoff BL, et al. *Heart Rhythm*. 2021;18:1605–1612.



The OmniaSecure™ LEADR Global Pivotal Trial



Study objective: To assess the **safety, efficacy, and reliability** of the Omnia Secure defibrillation lead

657

patients indicated for de novo ICD/CRT-D with implant attempt

45

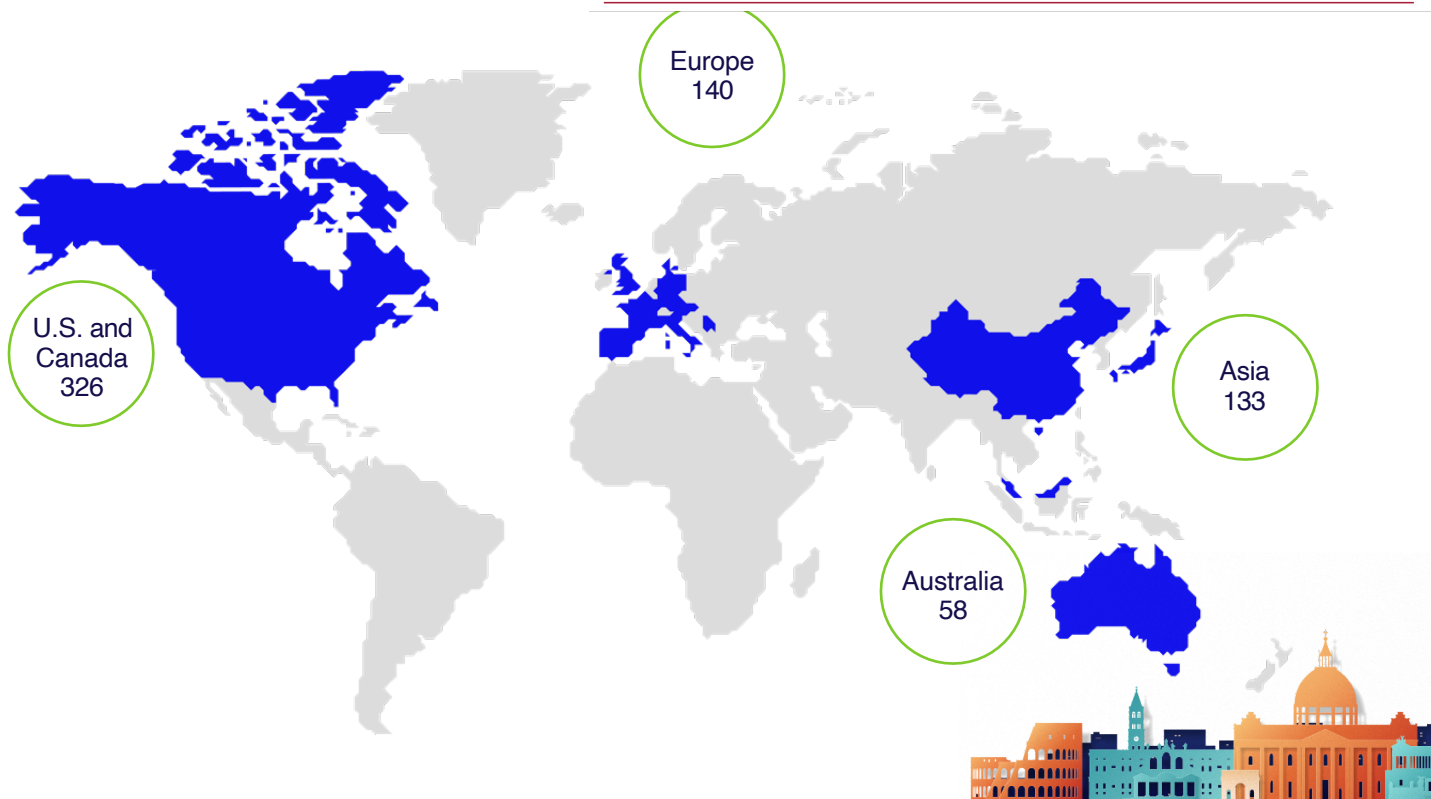
centers

96

physicians

17

countries



Safety, efficacy, and reliability evaluation of a novel small-diameter defibrillation lead: Global LEADR pivotal trial results

George H. Crossley III, MD, FHRS, CCDS,¹ Prashanthan Sanders, MBBS, PhD, FHRS,² Bert Hansky, MD,³ Paolo De Filippo, MD,⁴ Maully J. Shah, MBBS, FHRS, CCDS, CEPS-P,⁵ Morio Shoda, MD, PhD,⁶ Surinder Kaur Khelae, MBBS, FHRS,⁷ Travis D. Richardson, MD,¹ François Philippon, MD, FHRS,⁸ John S. Zakaib, MD,⁹ Hung-Fat Tse, MD, PhD,¹⁰ Darius P. Sholevar, MD,¹¹ Christoph Stellbrink, MD,¹² Rajeev K. Pathak, MBBS, PhD, FHRS,¹³ Goran Milasinović, MD,¹⁴ Jason S. Chinitz, MD, FHRS,¹⁵ Bernice Tsang, MD,¹⁶ Michael B. West, MD,¹⁷ Brian M. Ramza, MD, PhD,¹⁸ Xuebin Han, MD,¹⁹ Babak Bozorgnia, MD,²⁰ Roberto Carta, PhD,²¹ Tessa Geelen, PhD,²² Adam K. Himes, MS,²¹ Megan L. Platner, BS,²¹ Amy E. Thompson, MS,²¹ Pamela K. Mason, MD, FHRS,²³ for the Lead Evaluation for Defibrillation and Reliability Trial Investigators

Efficacy: Catheter delivery for targeted lead placement



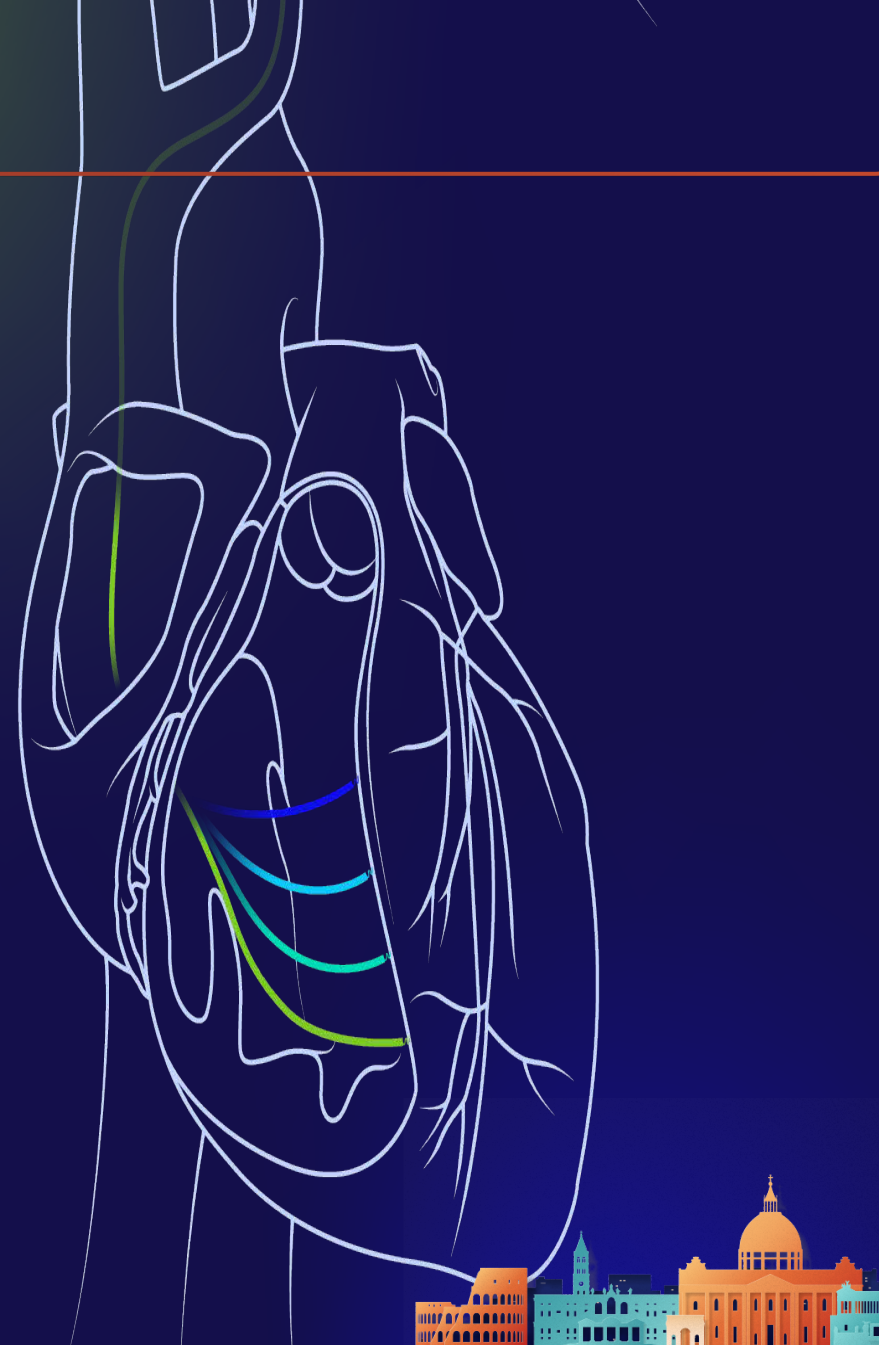
8.2% High septum

31.9% Mid septum

33.1% Low septum

20.1% Apex

6.7% Other



[†] This lead was not evaluated in conduction system pacing locations in the LEADER Global Pivotal Trial

96.5% freedom from lead-related major complications through three years¹

OmniaSecure™ LEADR Global Pivotal Trial

Primary safety objective met at 6 months with 97.1% (638/657) subjects free from lead-related major complications, exceeding performance goal.[†]

• Industry leads: 95.7% to 97.5%²⁻⁷

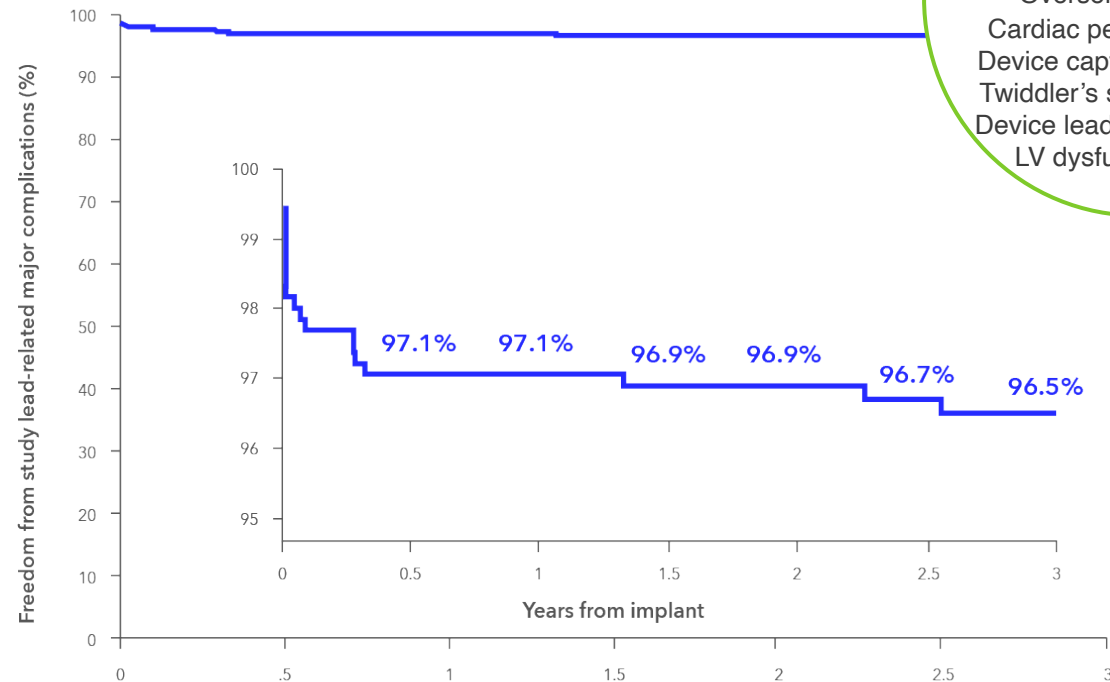
There were no deaths causally related to the OmniaSecure lead. There were **zero complications** associated with the tricuspid valve.

[†] The lower bound of the credible interval exceeded the prespecified performance threshold of 90%, hence the objective was passed.

[‡] Among the four PWOS events, none resulted in inappropriate shock, one was resolved with programming changes after hospitalization, and three resulted in replacement with non-study leads.

[§] The event coded as device lead damage was a lead fracture.

1. Crossley GH, et al. *Circ Arrhythm Electrophysiol*. Published online November 12, 2025.
2. Crossley GH, et al. *J Cardiovasc Electrophysiol*. 2023;34:257–267.
3. Curtis AB, et al. *N Engl J Med*. 2013;368:1585–1593.
4. Linde C, et al. *J Am Coll Cardiol* 2008;52:1834–1843.
5. Gold MR, et al. *J Am Coll Cardiol* 2015;65:2581–2588.
6. Auricchio A, et al. *Heart Rhythm*. 2015;12:926–936.
7. Crossley GH, et al. *Heart Rhythm*. 2024;21(10):1914–1922.



Major complications:
Lead dislodgement (N=11)
Oversensing (N=5)[‡]
Cardiac perforation (N=2)
Device capture issue (N=1)
Twiddler's syndrome (N=1)
Device lead damage (N=1)[§]
LV dysfunction (N=1)

No. at risk	657	604	593	577	546	517	209
No. of events	4	19	19	20	20	21	22

Reliable performance demonstrated with stable electricals through three years¹

OmniaSecure™ LEADR Global Pivotal Trial

Stable electrical performance

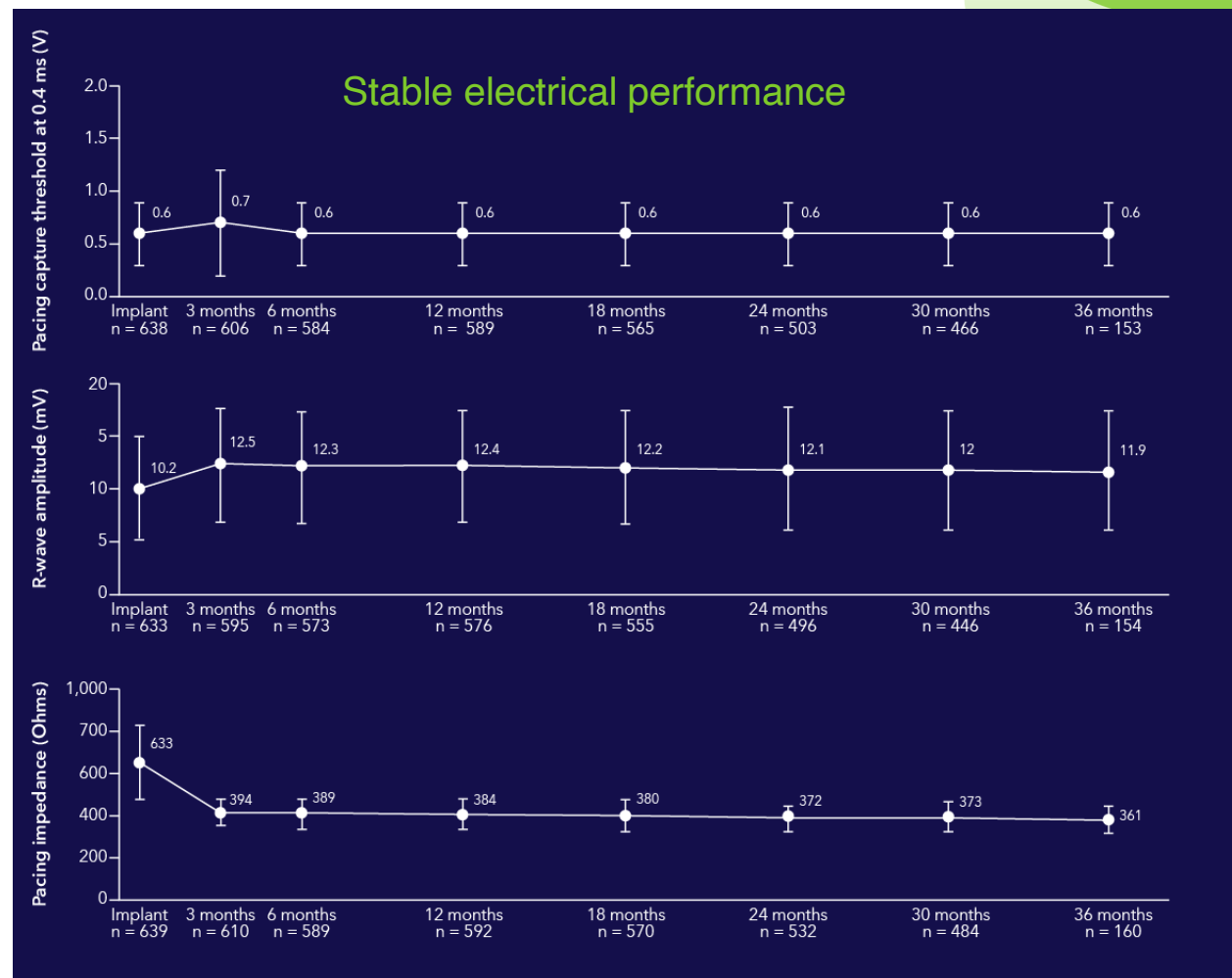
(sensing, pacing, impedance) through three years

Implant procedure²

97.9% implant success rate

99.5% implanted in desired RV location

- Low septum, 33.1%
- Mid septum, 31.9%
- Apex, 20.1%
- High septum, 8.2%
- Other, 6.2%
- Outflow tract, 0.5%



1. Crossley GH, et al. *Circ Arrhythm Electrophysiol*. Published online November 12, 2025.

2. Crossley GH III, et al. *Heart Rhythm*. 2024;21:1914–1922.

OmniaSecure™ LEADR Global Pivotal Trial

97.5% defibrillation efficacy at implant through three years¹

Overall defibrillation efficacy at implant was **97.5% (116/119)**

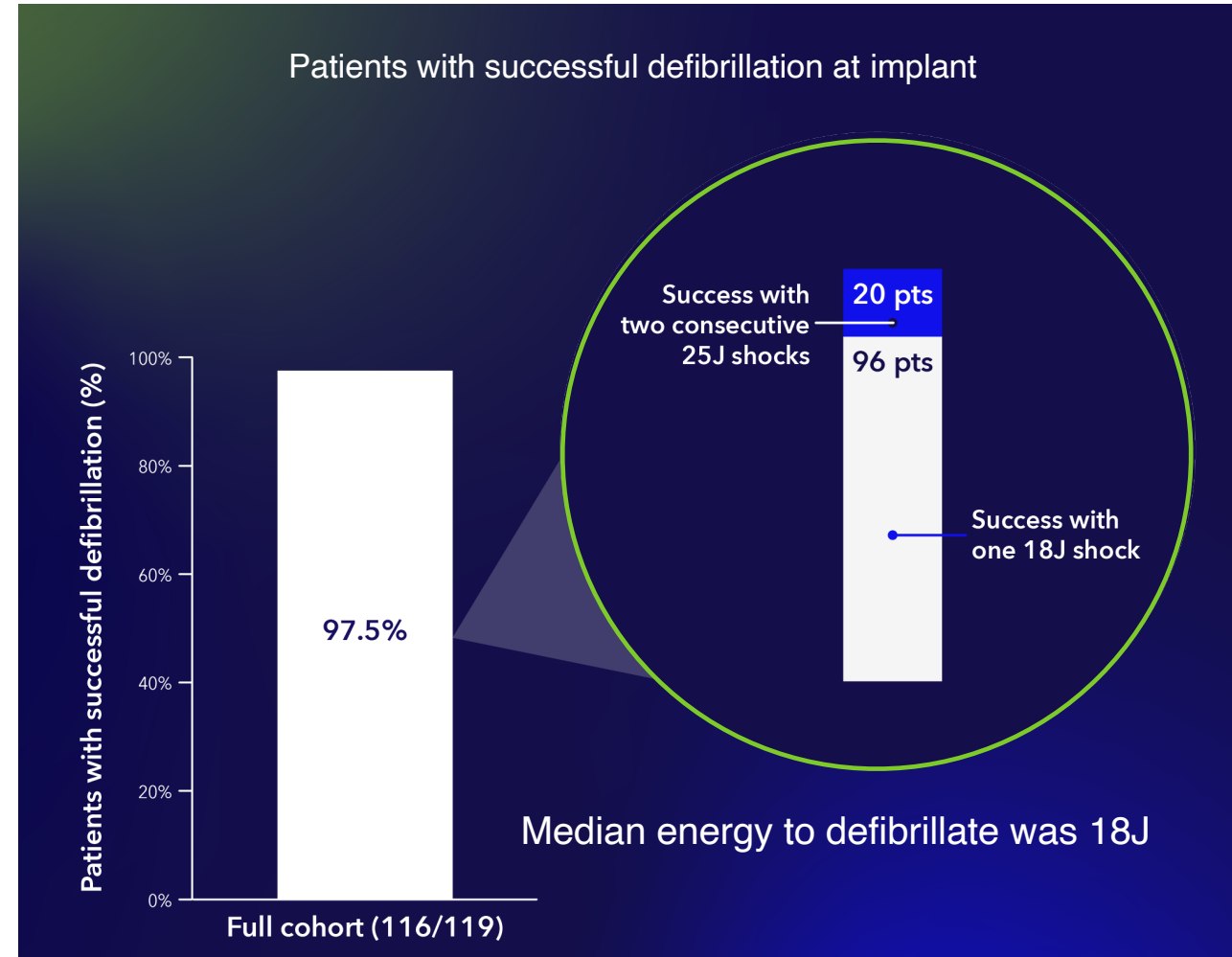
- Industry leads: 77% to 93%^{†,2-5}

Primary objective passed with **94/97** first consecutive patients having successful defibrillation, exceeding performance goal.[‡]

[†] two of three patients that did not pass the defibrillation testing protocol remained in the study at physician discretion after demonstrating ≥ 1 successful conversion at 25J.

[‡] The lower bound of the credible interval exceeded the prespecified performance threshold of 88%, hence the objective was passed.

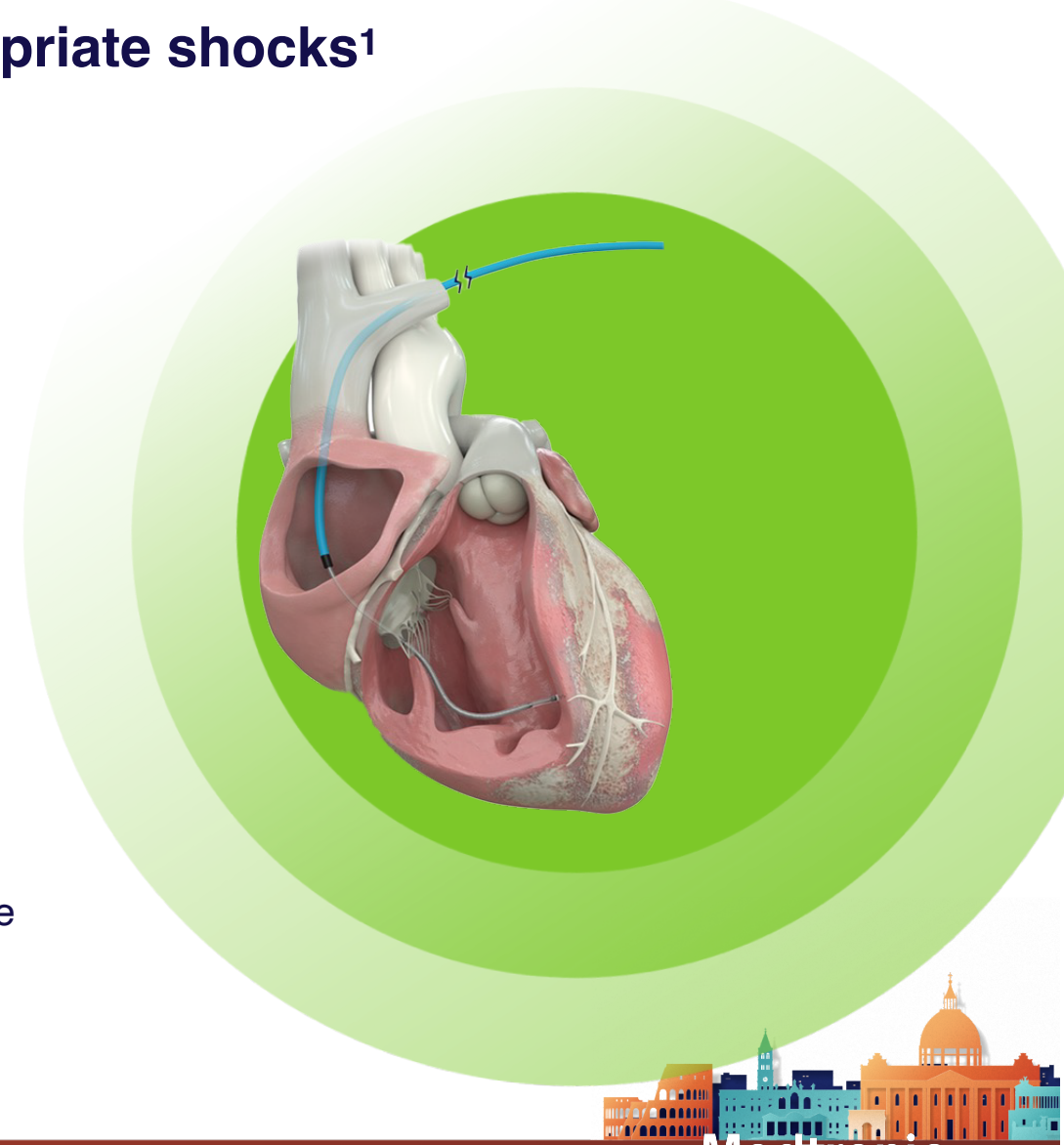
1. Crossley GH, et al. *Circ Arrhythm Electrophysiol*. Published online November 12, 2025.
2. Leong-Sit P, et al. *Am Heart J*. 2006;152:1104–1108.
3. Pires LA, et al. *J Cardiovasc Electrophysiol*. 2006;17:140–145.
4. Michowitz Y, et al. *Europace*. 2011;13:683–688.
5. Healey JS, et al. *Lancet*. 2015;385:785–791.



Termination of spontaneous arrhythmias, inappropriate shocks¹

OmniaSecure LEADR Global Pivotal Trial

- **22.3%** of patients received appropriate therapy for VT/VF through three years.
- **95.3% (181/190)** episodes treated with shock were successful.
 - 6 ATP terminated
 - 1 self terminated rhythm
 - 1 PVT/VF in patient with amyloidosis/scarring where all programmed shocks were unsuccessful
- **75.4% (826/1,095)** ATP or iATP successfully terminated episodes, preventing shock in 76 patients.
- **5.9% inappropriate shock rate** at 3 years, comparable to prior reports²⁻⁴
 - **Zero** inappropriate shocks due to P-wave oversensing, a few for T wave

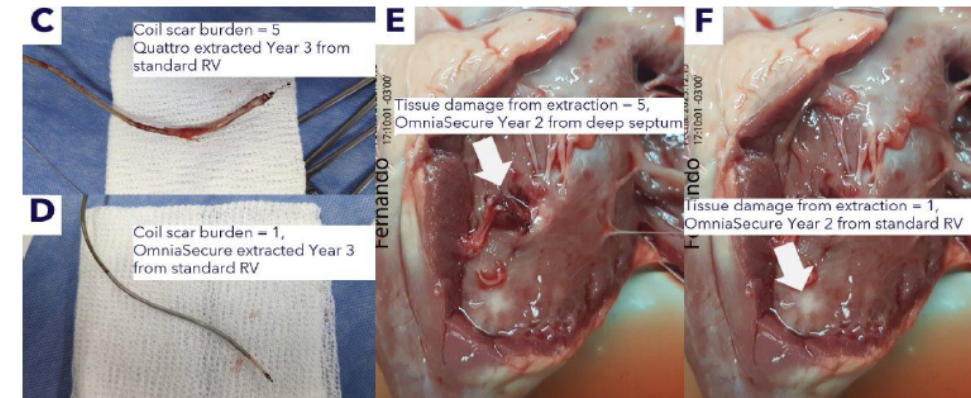
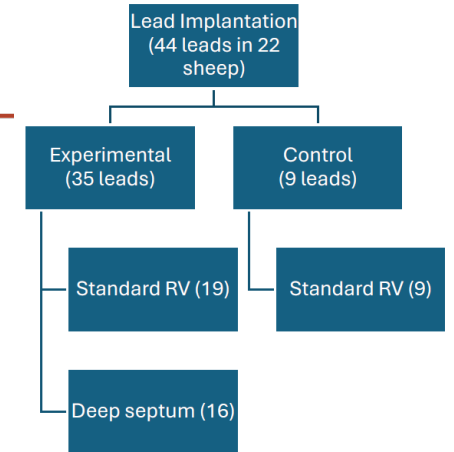
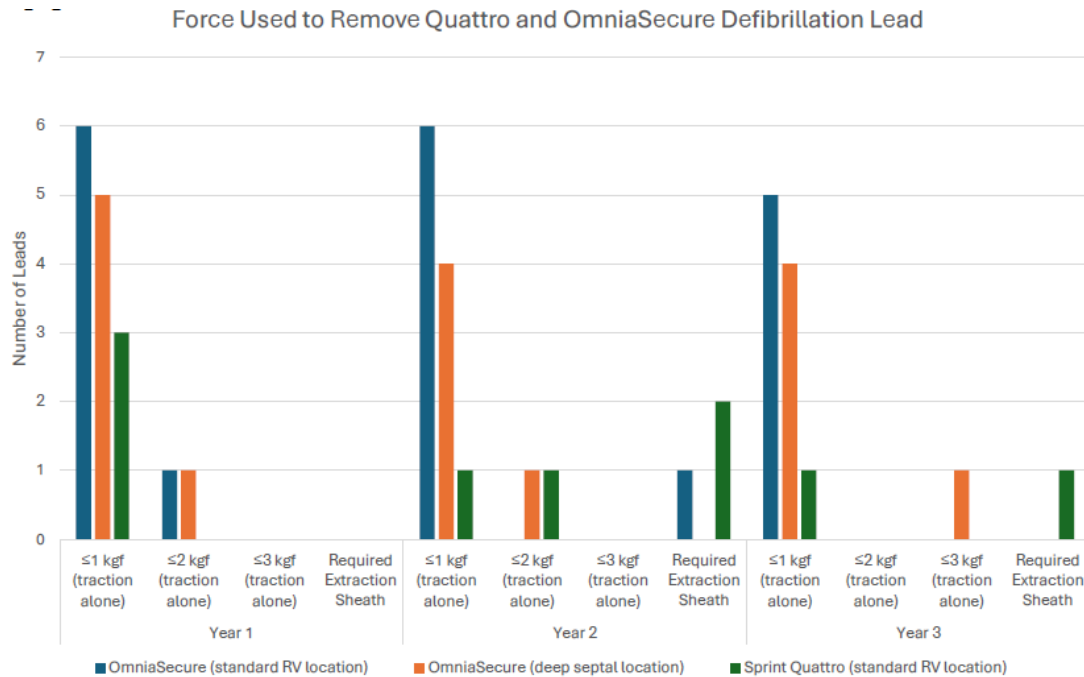


1. Crossley GH, et al. *Circ Arrhythm Electrophysiol*. Published online November 12, 2025.
2. Auricchio A, et al. *Heart Rhythm*. 2015;12:926–936.
3. Auricchio A, et al. *Int J Cardiol*. 2022;350:36–40.
4. van Rees JB, et al. *J Am Coll Cardiol*. 2011;57:556–562.

Evaluation of the extractability of the OmniaSecure lead

Metrics recorded were

- Force required to remove lead
- Scar burden from coil to tip on extracted lead (1-low, 5-high burden)
- Images of the suspected lead implant location were taken at necropsy and evaluated for tissue damage.



These data demonstrate the extractability of OmniaSecure leads through 3 years in large animal models. ***OmniaSecure leads may offer advantages in clinical lead extraction, including lower lead removal forces and reduced scar burden.***



Clinical evidence of lead-induced TR

Evidence of lead-induced TR:

- RV lead implantation observed **predictor of TR progression**¹
- PM lead-associated TR observed **predictor of survival**¹
- 10% incidence of **increased TR** post-endocardial RV lead placement²
- In patients undergoing TV repair the presence of a transvenous lead was associated with an **increased risk of persistent or recurrent TR**³
- **Interference of pacing lead** with the TV reported in 7-45% of RV lead implantations⁴
- Incidence of **TV complications** of 13.1 per 1000 ICD-patient years⁵

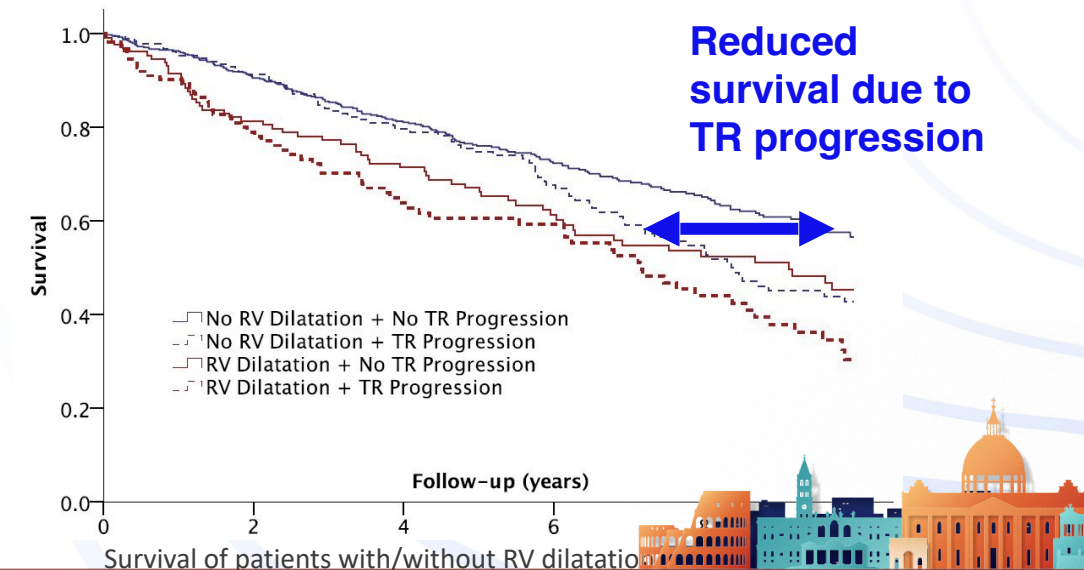
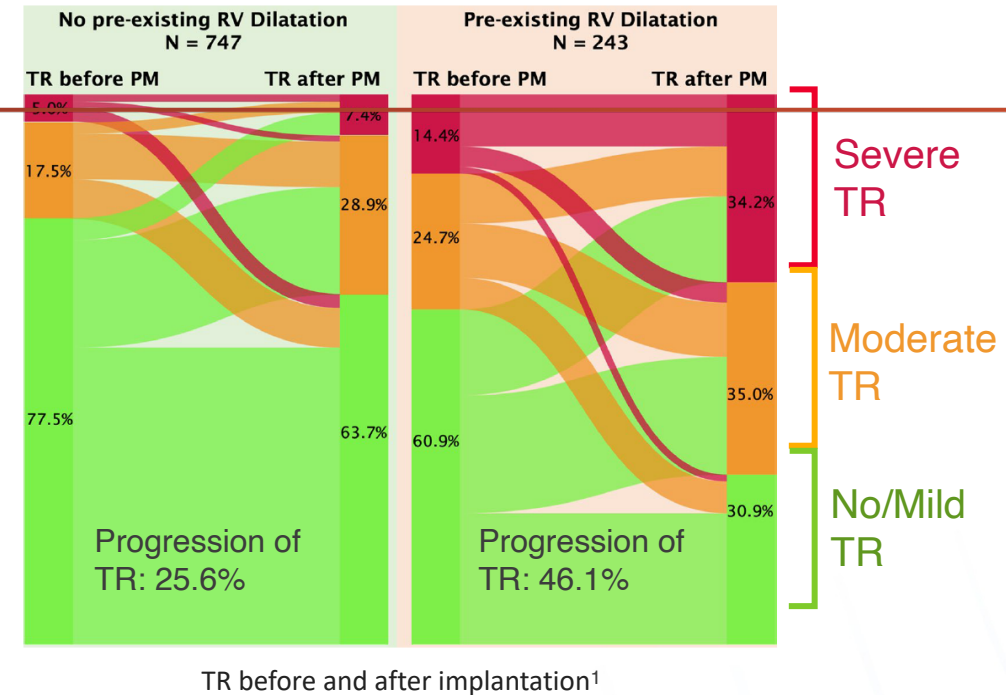
[1]: Riesenhuber, M. et al. *Clin Res Cardiol* 110, 884–894 (2021)

[2]: Lee, R.C. M.D. et al. *PACE* (2015)

[3]: Mazine, A. M.D. et al. *The Ann of Thor Surg* (2013)

[4]: Addetia, K. et al., *JACC Cardiovasc Imag* (2019)

[5]: Mason P.K. M.D. et al. *J of Cardiovasc Electrophys* (2024)



Clinical evidence on **Effect of lead size on TR**

Prospective study: patients with 9Fr vs. 7Fr leads ($N_{9Fr}=31$ & $N_{7Fr}=30$)

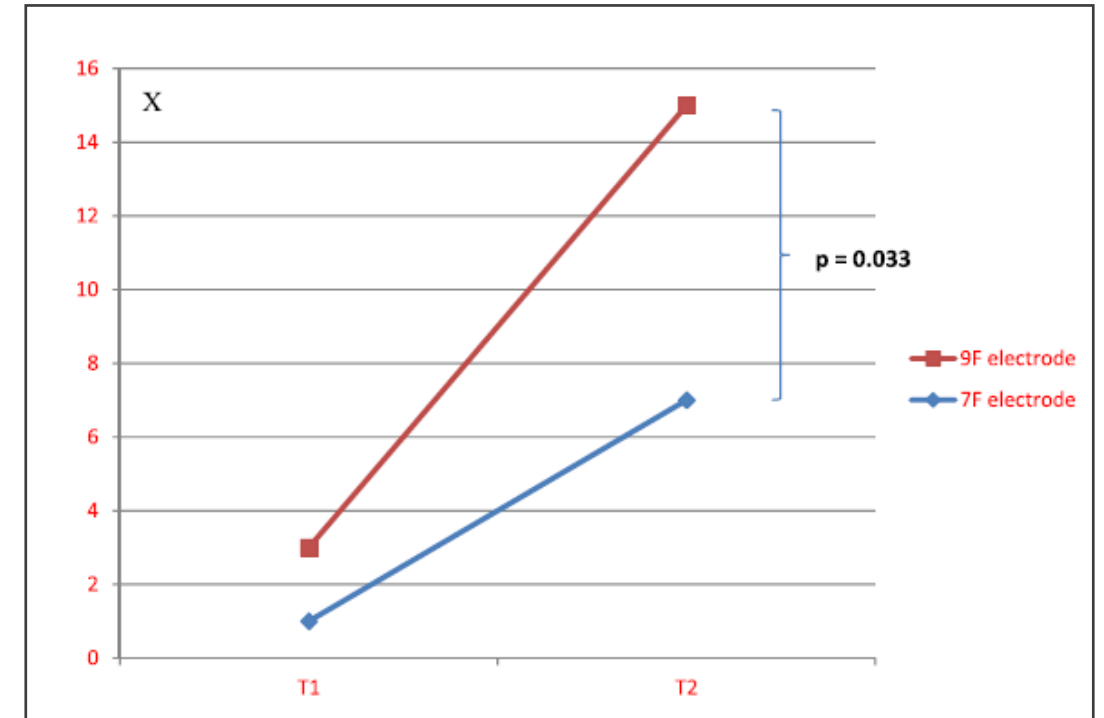
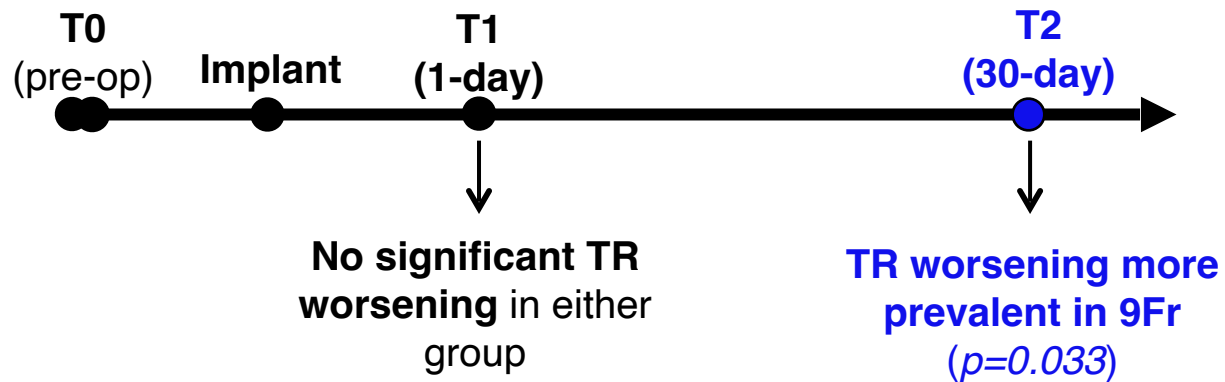
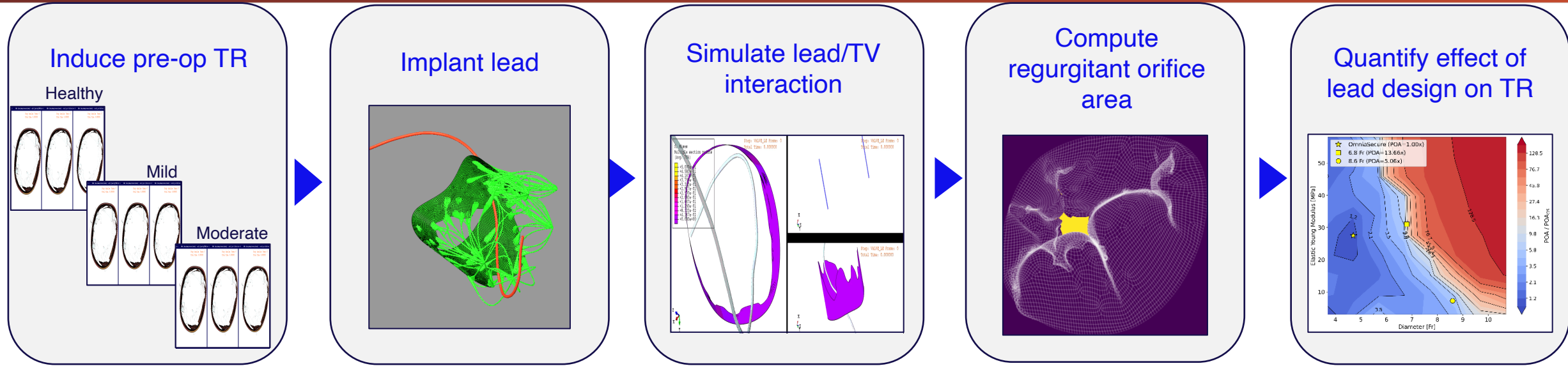


Fig. 1 - TR worsening for 9Fr and 7Fr groups at **T1** and **T2**.

[1] F. Gülçebi, A. et al. *Echocardiography* 42, no. 9 (2025): 42, e70275. <https://doi.org/10.1111/echo.70275>





- Physiologically realistic material models
- Patient-specific geometry, pressure and annulus motion
- TR induced in pre-op models by dilating tricuspid annulus
- Patient-specific lead path extracted from LBBAP 3830 study
- Orifice area calculated exactly using projection method



Combined effect of lead diameter and material stiffness on TR

OmniaSecure is below transition thresholds for clinically relevant TR progression

Pre-op: **Healthy** (POA: 0.0cm²)

Mild TR (0.14cm²)

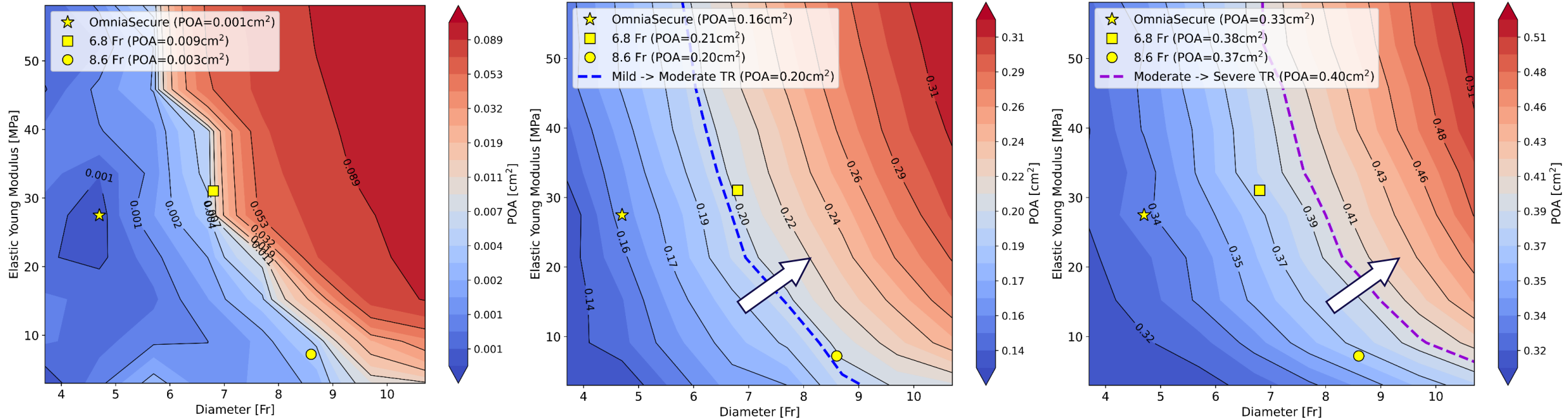
Moderate TR (0.31cm²)

Post-op: **No clinically relevant TR**

Mild → **Moderate TR** transition

Moderate → **Severe TR** transition

Mild TR	<0.2cm ²
Moderate TR	0.2 – 0.39cm ²
Severe TR	>0.40cm ²



*In mild and moderate TR baselines, **thicker leads resulted in exponential increases in ROA**. The 4.7 Fr lead remained significantly below clinically relevant increases in TR. In contrast, the 6.8 Fr and 8.6 Fr leads induced a transition from mild to moderate TR.*



LEADR LBBAP Clinical Trial Design

Scope

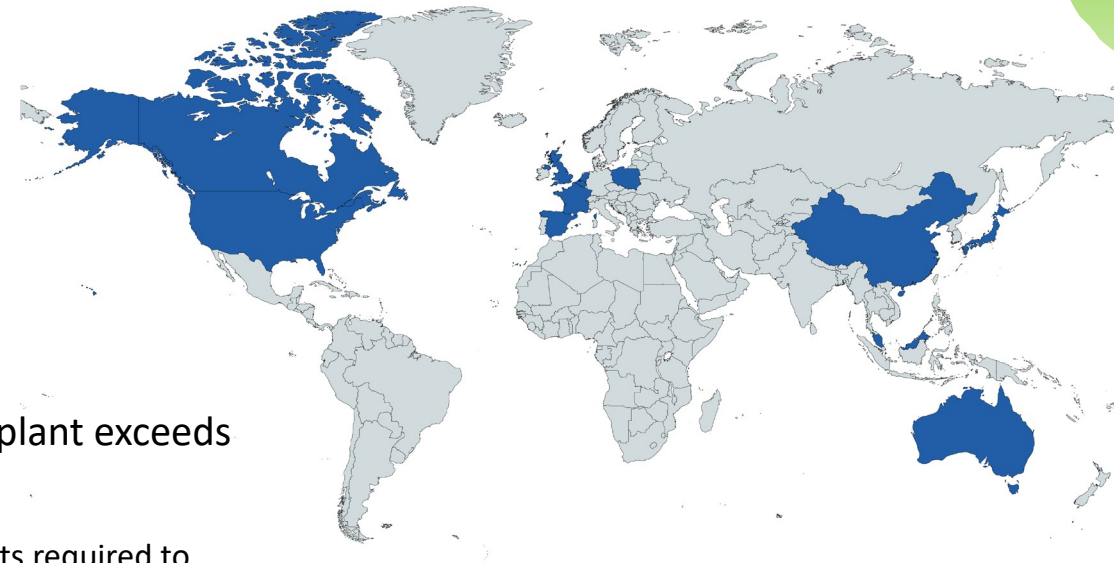
- To confirm the safety and defibrillation efficacy of the OmniaSecure lead when placed in the LBBAP location in an ICD or CRT-D patient population

Study population

- De novo ICD or CRT-D guideline indicated patients ≥ 12 years of age
- At least 300 patients enrolled and 150 LOT-CRT-D implant attempts

Study endpoints

- Primary efficacy: Percentage of patients successfully defibrillated at implant exceeds pre-specified threshold of 88% in at least 160 patients
 - Established based on historical defibrillation data and analysis of number of patients required to power analysis
- Primary safety: Estimate the OmniaSecure ICD Lead-related major complication rate at 3 months in 150 patients



The OmniaSecure lead demonstrated high defibrillation success and low complications when placed in the LBBAP location

Prospective, global study

Patients indicated for *de novo* implant of primary or secondary prevention ICD/CRT-D, including patients ≥ 12 years of age

Primary efficacy objective

Demonstrate percentage of subjects successfully defibrillated at implant (subset of subjects)

95.4% Physician reported implant success

307 patients with an implant attempt; 162 patients in defibrillation cohort

100% defibrillation efficacy at implant

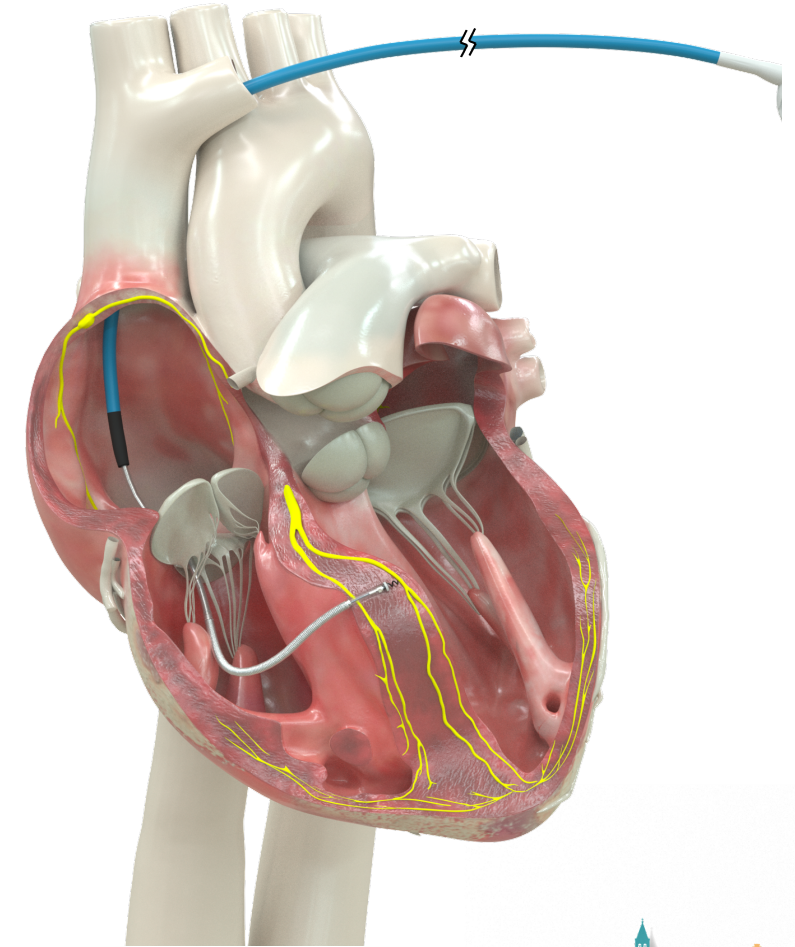
Primary objective passed, exceeding performance goal

97.9% freedom from OmniaSecure lead-related major complications

At 3 months

Vijayaraman, P., et al. HRS 2025 LBCT. Presented April 25, 2025.

Vijayaraman, P., et al. ESC 2025 Oral presentation. Presented August 29, 2025.



Procedural characteristics

OmniaSecure LEADR LBBAP Global Trial

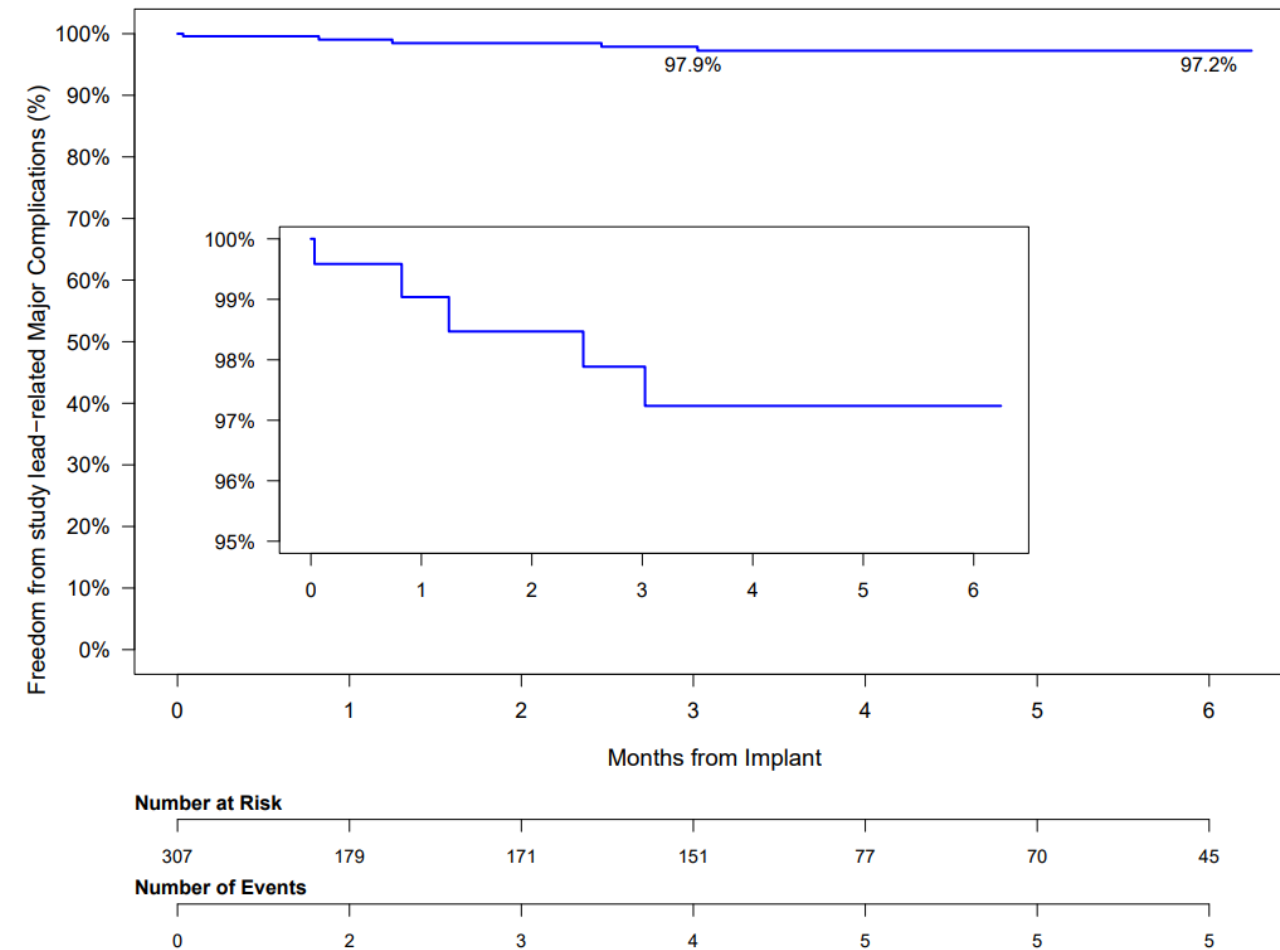
Procedural characteristics	Successful implant (n=183)	Defibrillation cohort (n=162)
Average repositions	2.9 ± 2.2	3.0 ± 2.1
Electrical performance at implant		
Pacing Capture Threshold (V)	0.62 ± 0.29 (n=182)	0.62 ± 0.29
R-wave (mV)	9.0 ± 4.9 (n=169)	9.2 ± 5.0 (n=151)
Impedance (Ω)	518.4 ± 113.2 (n=182)	521.4 ± 112.8

- Optimizing LBBA capture was primary reason for repositioning during implant
- No OmniaSecure procedural-related major complications
- No helix or lead fractures at implant
- No deaths related to system and/or procedure



Low OmniaSecure lead-related major complication rate at 3 months

Estimate the OmniaSecure defibrillation lead-related major complication rate at 3 months post-implant when the OmniaSecure defibrillation lead implant is attempted in the LBBAP location.



Complication type	LBBAP implant attempted (N=307)		
	Total	Within 90 days	After 90 days
Total major complication rate (N, %)	5 (5, 1.6%)	4 (4, 1.3%)	1 (1, 0.3%)
Device Connection Issue	1 (1, 0.3%)	1 (1, 0.3%)	0 (0, 0.0%)
Device Pacing Issue	1 (1, 0.3%)	0 (0, 0.0%)	1 (1, 0.3%)
Lead Dislodgement	2 (2, 0.7%)	2 (2, 0.7%)	0 (0, 0.0%)
Undersensing	1 (1, 0.3%)	1 (1, 0.3%)	0 (0, 0.0%)

- No helix or lead fractures at implant and during current follow-up
- No inappropriate shock adverse events relating to oversensing
- No deaths related to system and/or procedure



Limitations

Primary objectives were to understand acute lead defibrillation and 3 month OmniaSecure lead-related major complication rate

- Patients are in follow-up phase and future analyses will focus on appropriate therapy delivery, inappropriate shock and heart failure outcomes

Study did not require full or centralized adjudication of LBBA placement following physician reported confirmation

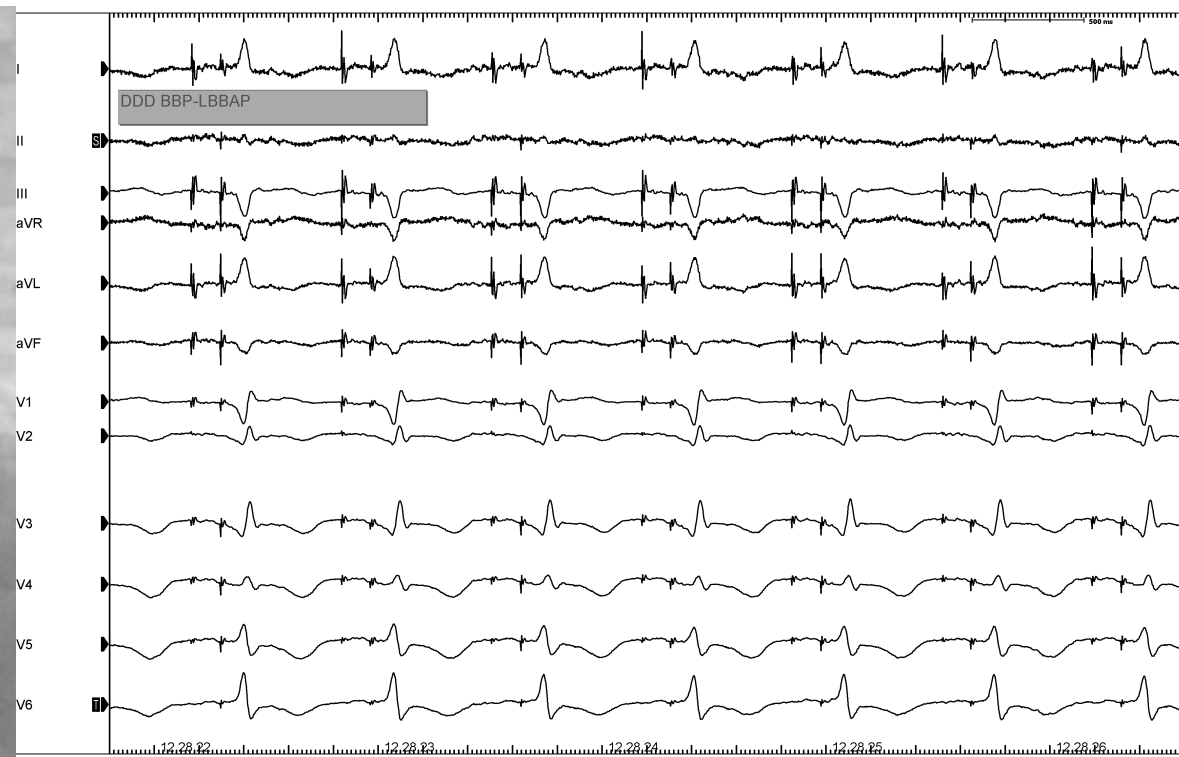
- Future exploratory analyses of long-term capture criteria and sensing pending

Conclusions

- High rate of defibrillation success at implant
 - Defibrillation performance exceeded (100%)
- Low complication rate at 3 months
 - 97.9% freedom from OmniaSecure lead-related major complications

**LEADR LBBAP trial enrollment
completed as of 21-
March-2025 (NCT04863664)**

**Follow-up in the trial is
ongoing**



11 cases

9 successful
LBBAP
(3LOT-CRT)

Pro:

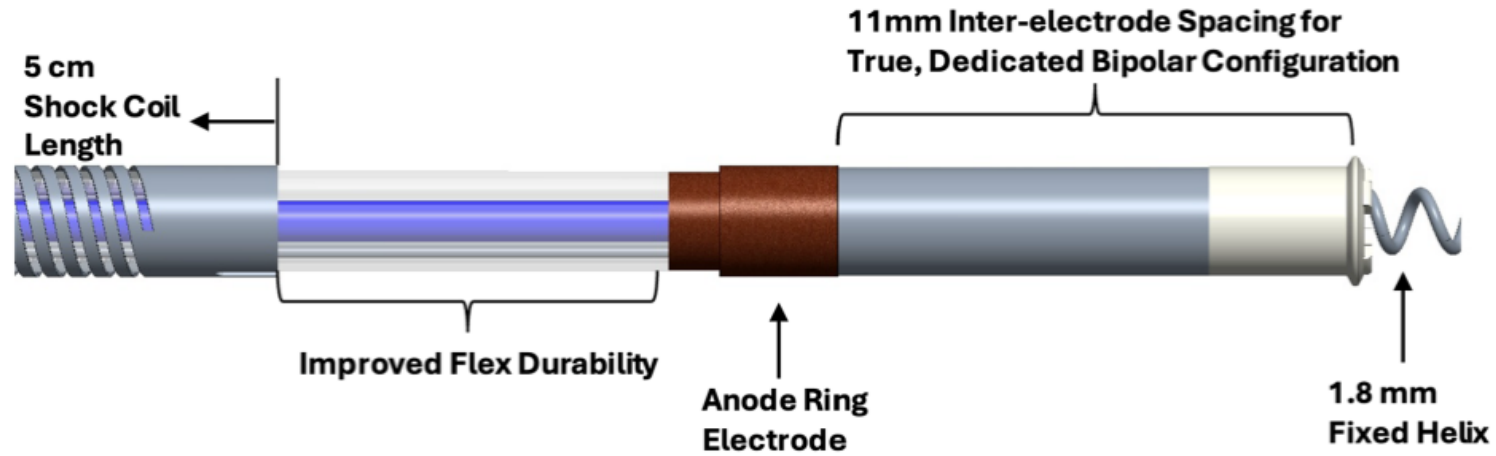
- Small diameter
- Lead durability
- Integrated bipolar (pacing)

Cons:

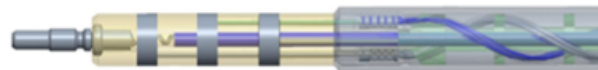
- Learning curve
- Integrated bipolar (sensing)
- Steroid on ring (lesion arousal)



UltiSynq ICD Lead



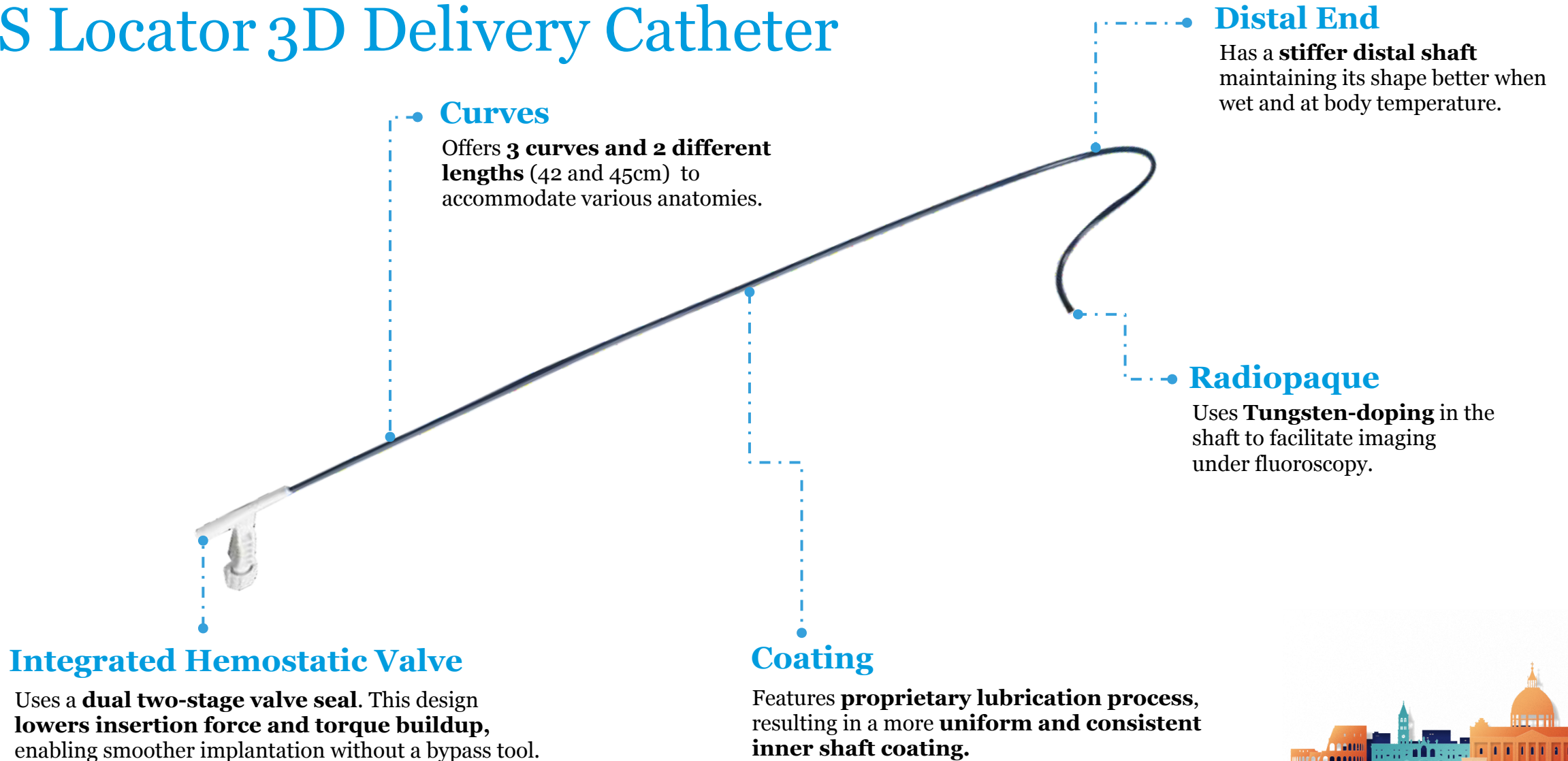
LDA1122Q (with DF4 Connector)



LDA1122 (with DF-1 and IS-1 connectors)

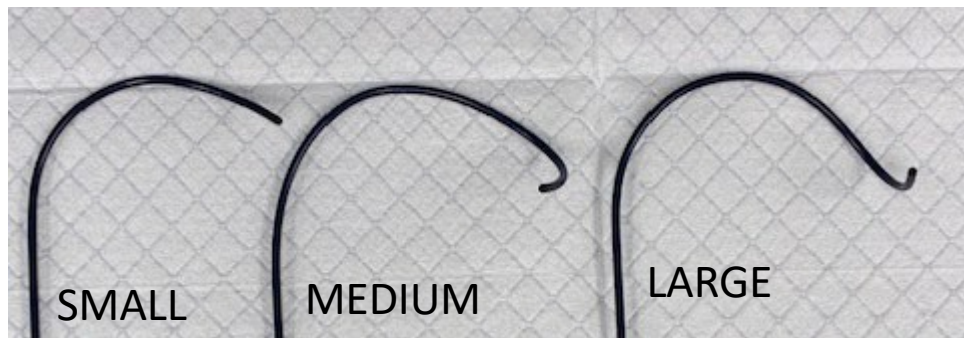


CPS Locator 3D Delivery Catheter

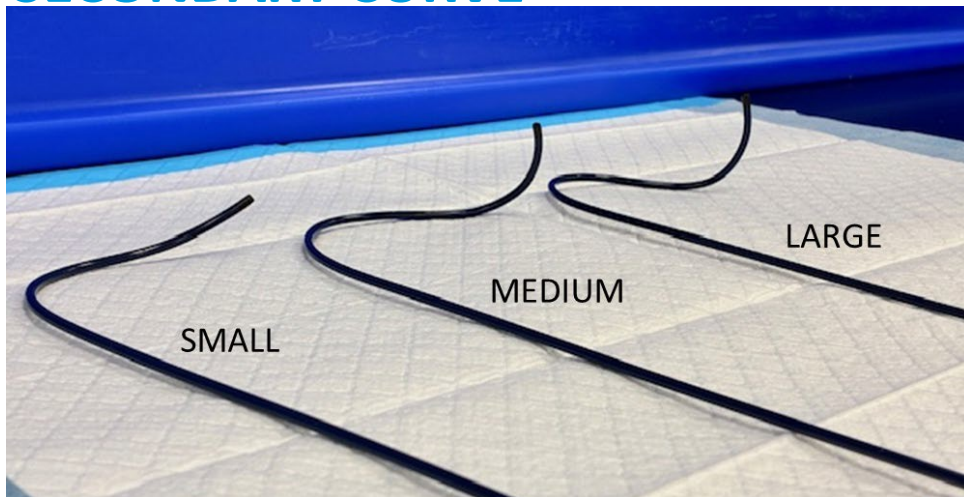


CPS Locator 3D curves comparison

PRIMARY CURVE

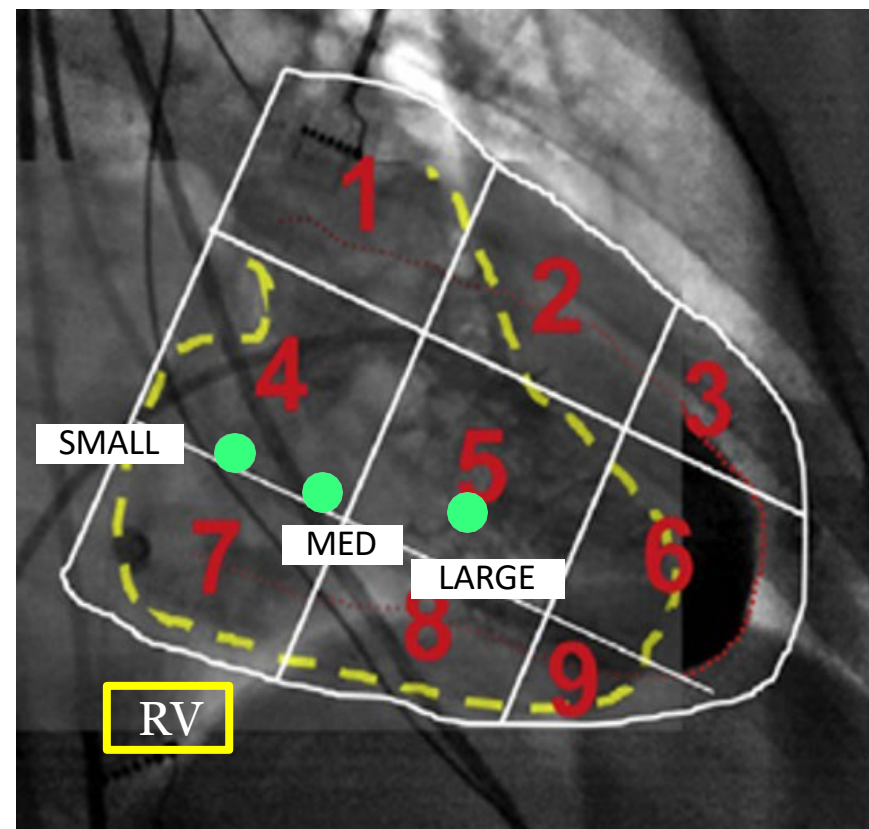


SECONDARY CURVE



Estimated RV septum landing

***dependent on RA and RV size**



ASCEND CSP Trial

Robert D. Schaller, Hospital of the University of Pennsylvania

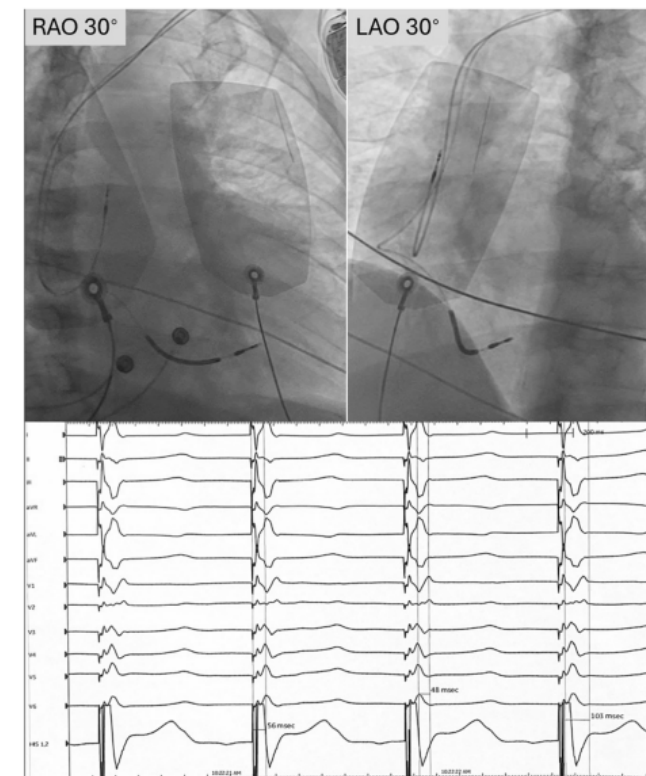
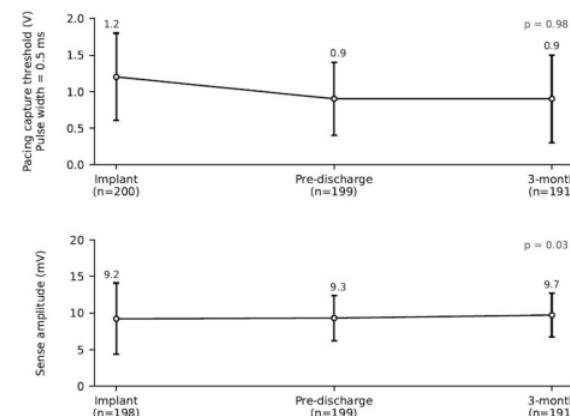
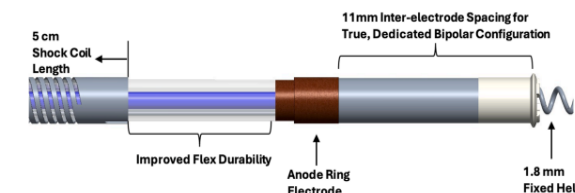
UltiSynq HV lead demonstrated high implant success, stable electrical performance, reliable defibrillation efficacy, and favorable short-term safety

KEY POINTS

- 98.5% lead implantation success with LBBAP criteria met in 99.0%.
 - a. LBBP or likely LBBP capture criteria were met in 86.0%.
- Primary effectiveness end point achieved in 94.6%
- Defibrillation testing was successful in 100%, with 92.5% defibrillated with a single 20 J shock.

Safety and performance of a novel ICD lead for left bundle branch area pacing: Results from the ASCEND CSP trial

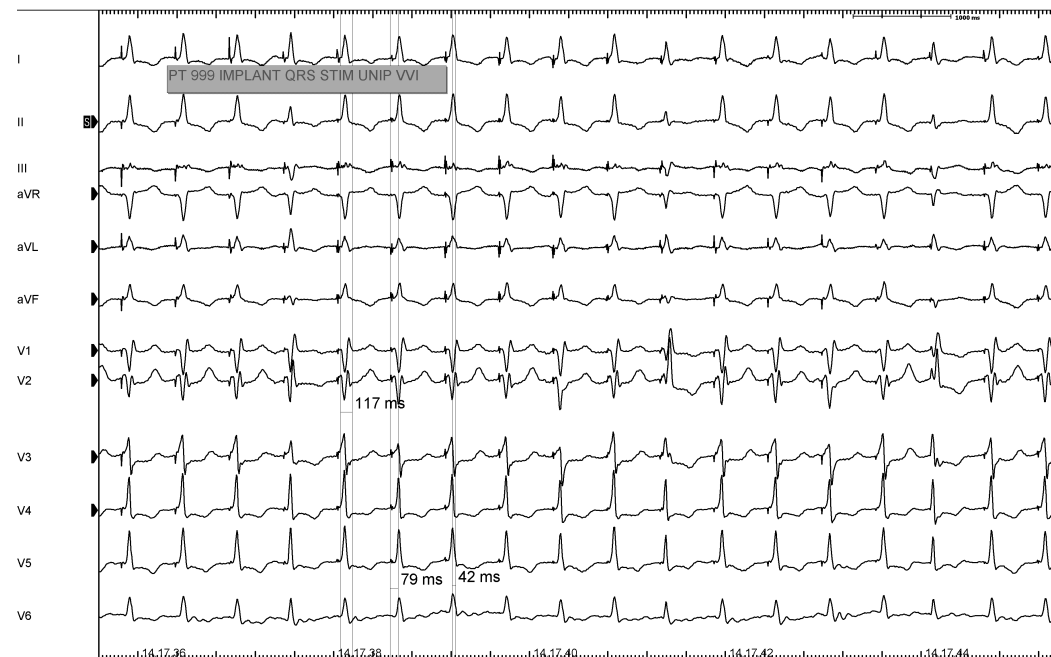
Robert D. Schaller, DO, FHRS,¹ Prashanthan Sanders, MBBS, PhD,² Jacqueline Joza, MD,³ Peter Zimetbaum, MD, FHRS,⁴ Ulrika Birgersdotter-Green, MD, FHRS,⁵ Roderick Tung, MD, FHRS,⁶ Balbir Singh, MD,⁷ Mark T.K. Tam, MBChB,⁸ Athanasios Thomaides, MD, FHRS,⁹ Devi Nair, MD, FHRS,¹⁰ Christophe Leclercq, MD,¹¹ Pugazhendhi Vijayaraman, MD, FHRS,¹² Cyrus A. Hadadi, MD,⁹ Jim Wiley, MS,¹³ Leonard Ganz, MD, FHRS,¹³ Lin Feng, PhD,¹³ Gayle Johnson, MPH,¹³ Kyungmoo Ryu, PhD,¹³ Robert Shaw, BS,¹³ Vishnu Charan, MS, MBA,¹³ Kwangdeok Lee, PhD,¹³ Haran Burri, MD,¹⁴ on behalf of the ASCEND CSP Investigators



Confronto ASCEND CSP e LEADR LBBAP

Parametro	ASCEND CSP (Abbott)	LEADR LBBAP – OmniaSecure (Medtronic)
Lead	CSP ICD dedicato, bipolare, stylet-driven	OmniaSecure 4.7F, lumenless, integrated
N arruolamenti	205	307
Successo impianto	98,5%	95,4%
Conferma LBBAP (overall)	99,0%	95,4%
Successo defibrillazione (totale)	100%	100%
Primo shock riuscito	92,5% a 20 J	82,7% a 18 J
Necessità riposizionamento per DFT	0%	1,2%
QRS paced (CRT-D)	137 ± 25 ms	156.6 ± 27 ms
Soglia di pacing a 3 mesi	0,9 ± 0,6 V @0,5 ms	0,6 ± 0,3 V @0,4 ms
R-wave a 3 mesi	9,7 ± 3,0 mV	10,9 ± 5,4 mV
R terminale / Qr-qR in V1	80,5%	51,2%
RWPT V5/V6 <85–100 ms	75% cumulativo (46% <85 ms + 29% <100 ms)	51,2%
Intervallo V6–V1 >33 ms	55,0%	6,5%
Potenziale di branca	6,0%	2,0%
Transizione QRS durante test di soglia o stimolazione programmata	22,0%	7,8%





26 cases

all successful
LBBAP (3
LSP)
(10 LOT-CRT)

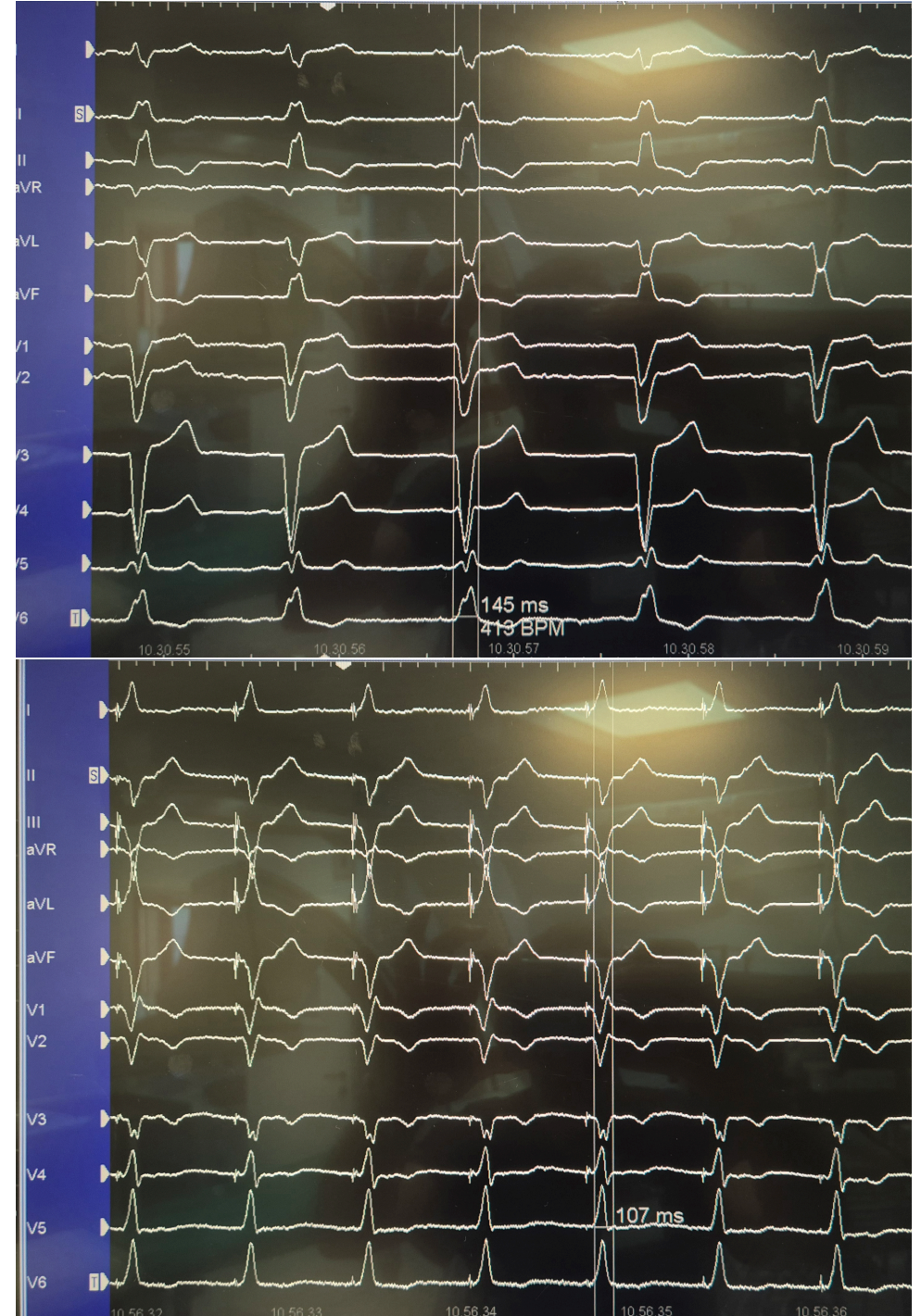
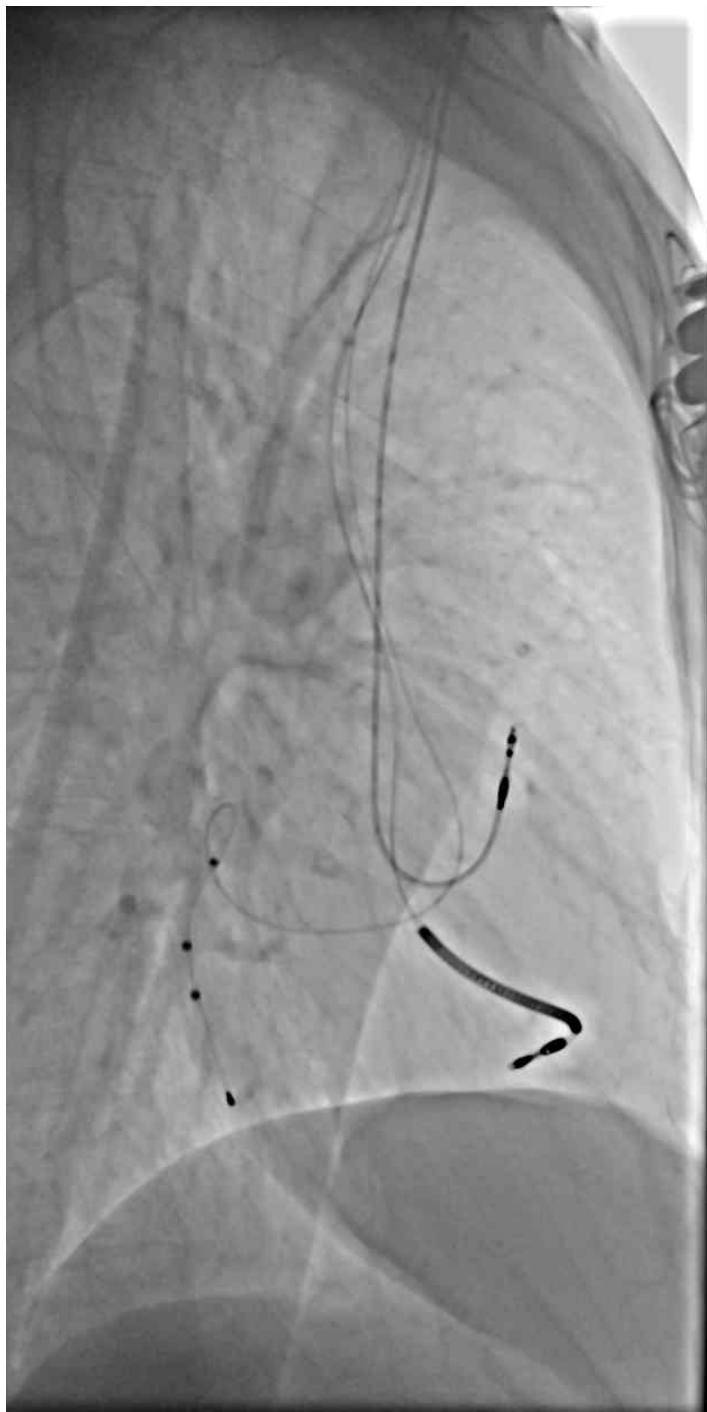
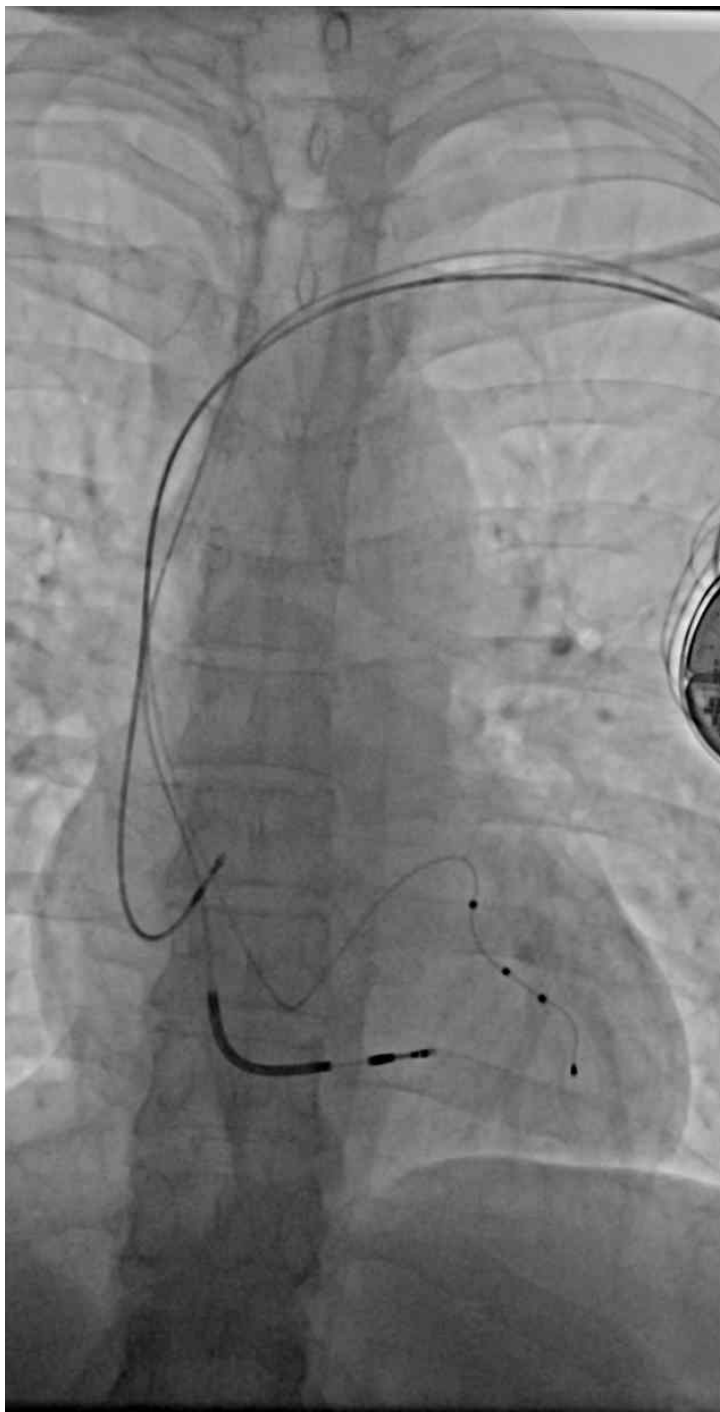
Pro:

- Easy implant
- Bipolar (sensing)
- Steroid on tip

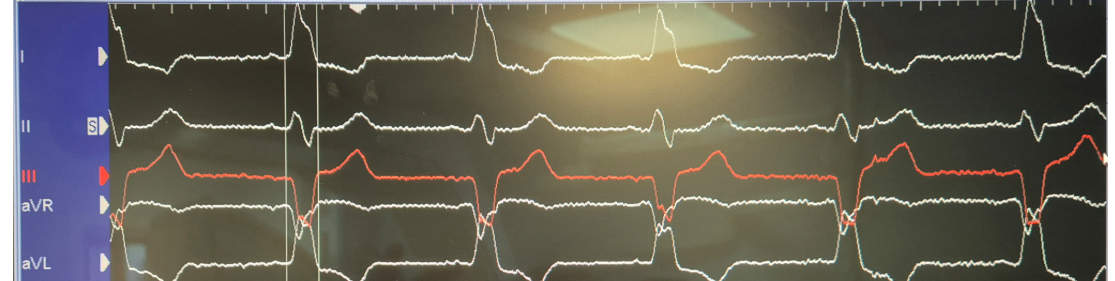
Cons:

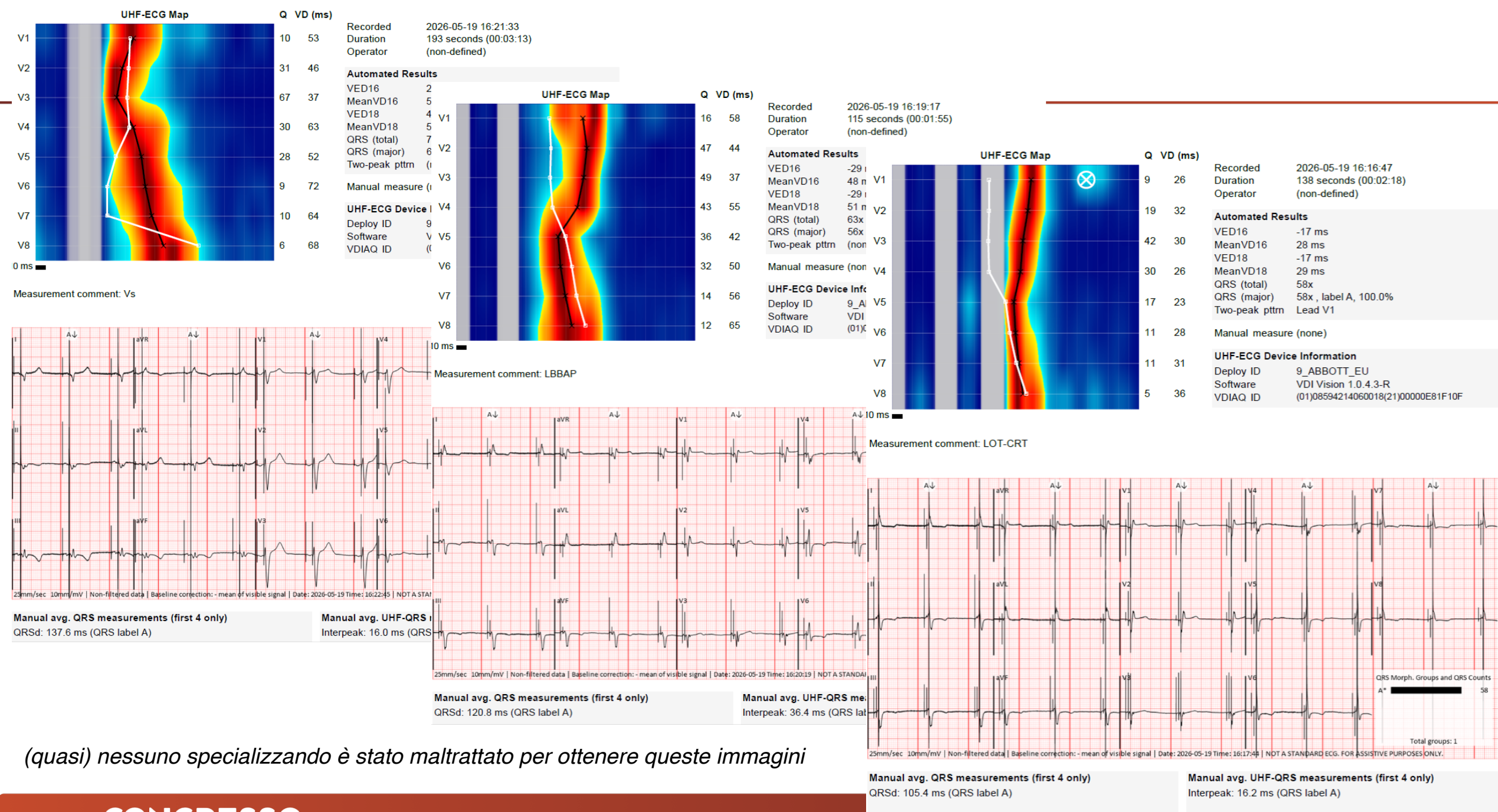
- Thicker
- Bipolar (anodal capture)
- Less data on durability





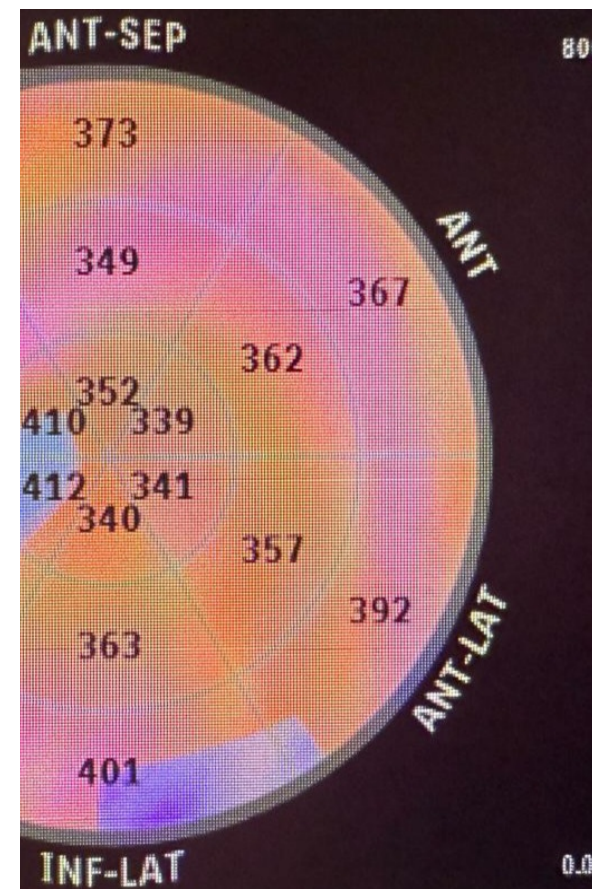
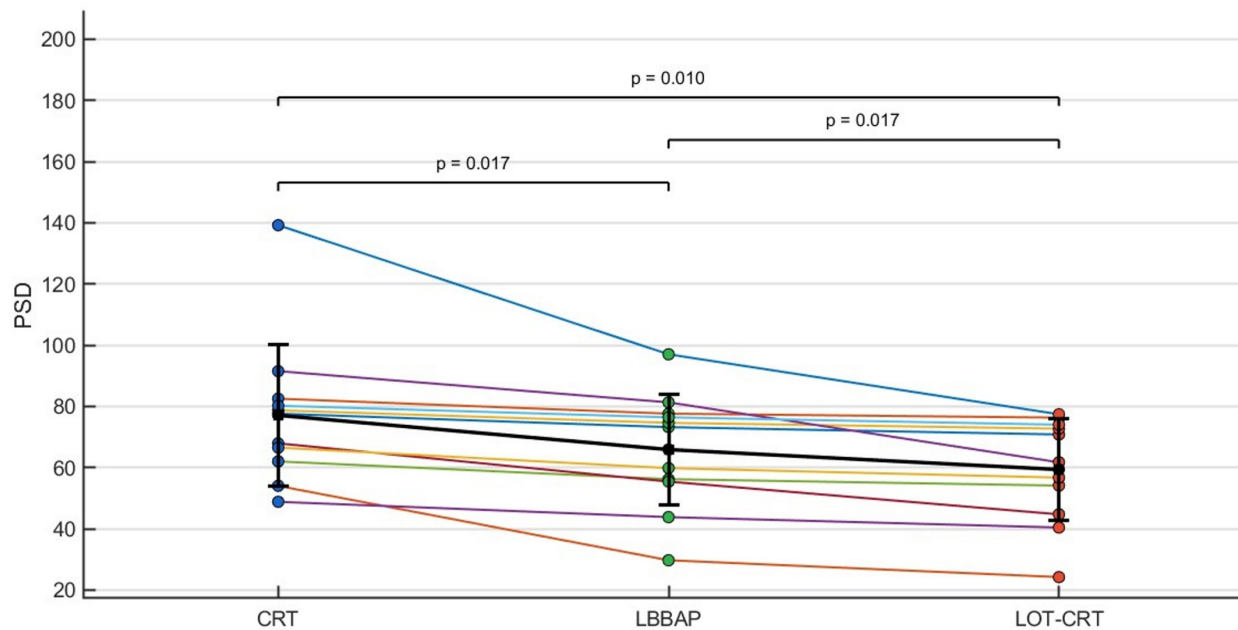
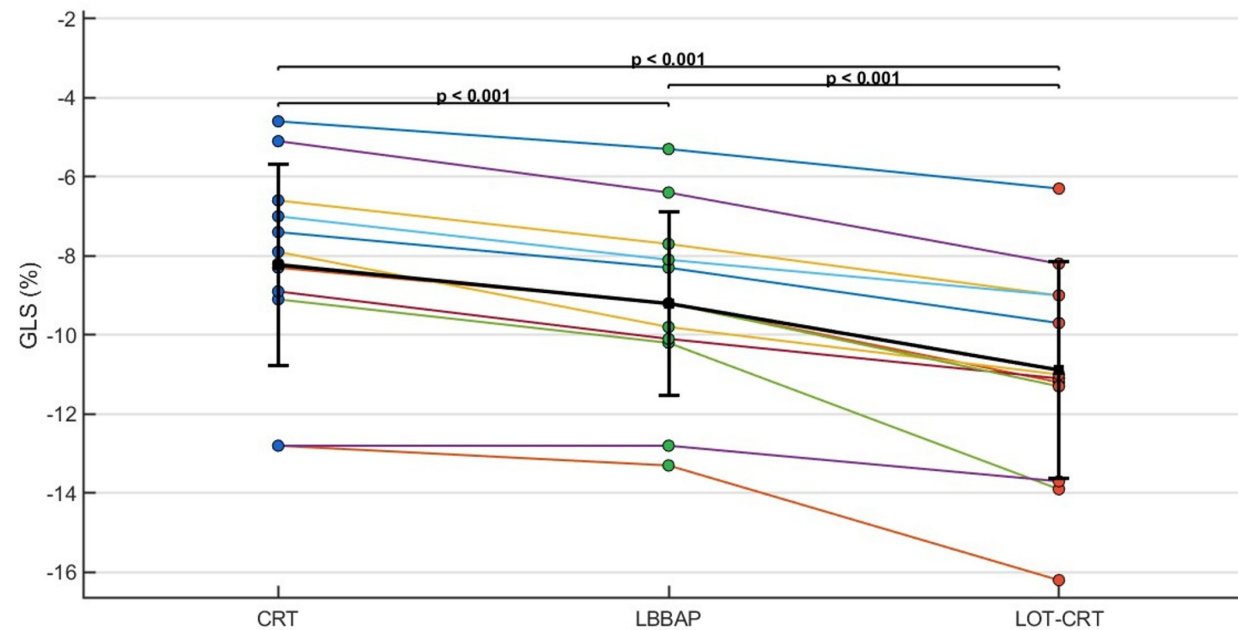
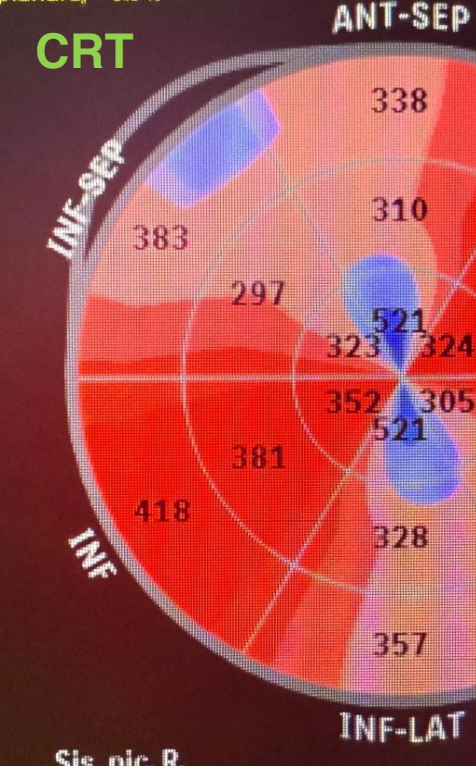
AX
VD12





(quasi) nessuno specializzando è stato maltrattato per ottenere queste immagini

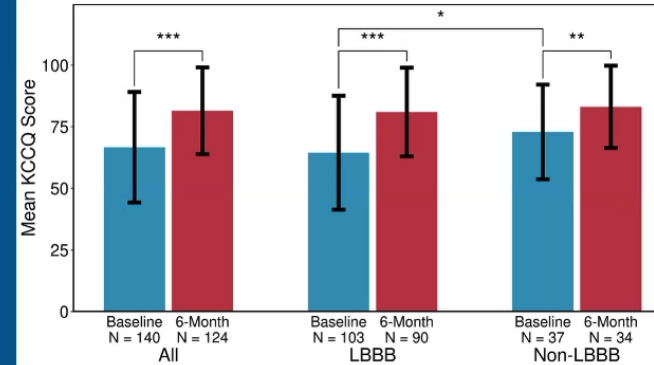
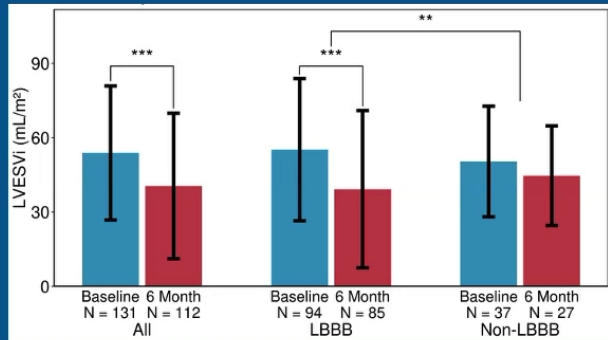
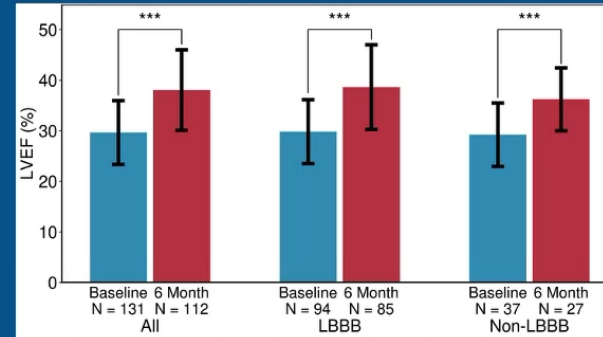
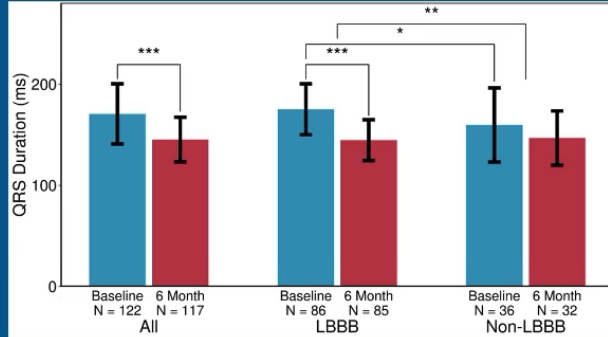
CRT



CONGRESS

LEADR LBBAP: Longer-term Safety, LOT-CRT

- 143 pts. LOT-CRT: 24.4ms reduction in QRS duration



*: p<0.05
**: p<0.01
***: p<0.001

Vijayaraman P. Presented as an abstract EN-527958-005 at the HRS congress 2026 in Chicago

Medtronic



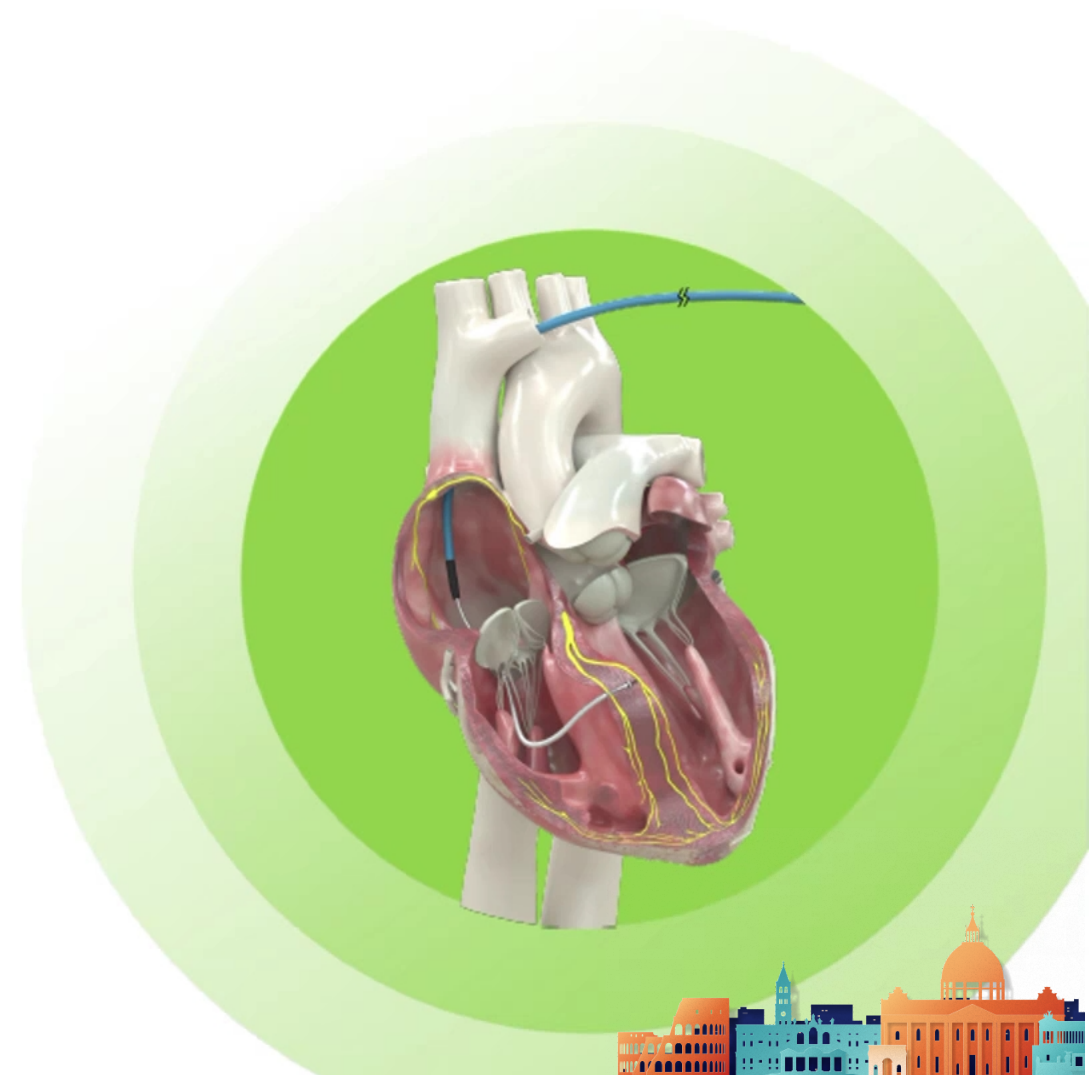
The OmniaSecure™ lead shows improvement in outcomes for heart failure patients receiving LOT-CRT

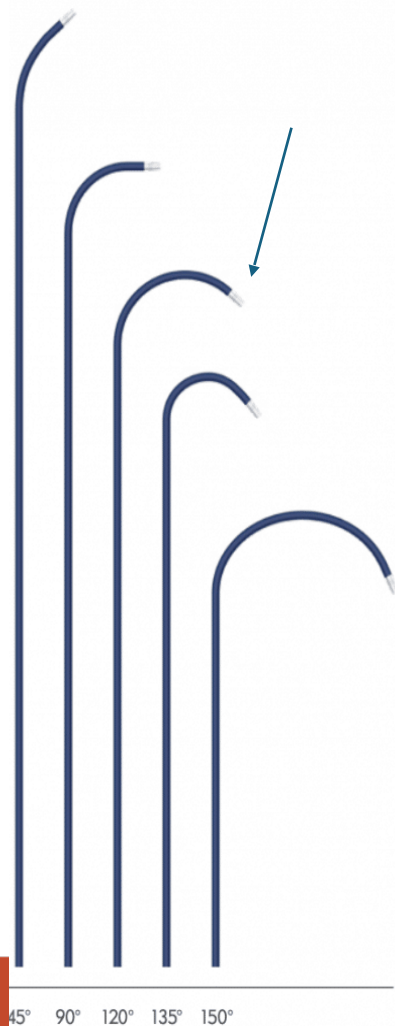
OmniaSecure™ LEADR LBBAP Global Trial

At six months, patients treated with the three-lead LOT-CRT configuration demonstrated¹

- A decrease in QRS duration
- A decrease in LVESVi
- An increase in LVEF

These results are consistent with previously published findings.
85% of patients receiving LOT-CRT either improved or maintained QOL scores.¹







Roads? Where we're going we don't need roads

(but dedicated tools could help!)

