

LBBAP: TECNICHE E NUOVE TECNOLOGIE...

LBBAP: Nuovi strumenti a supporto delle procedure di impianto

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Disclosure

- Proctoring and speaker activities: **Boston Scientific** and **Medtronic**.





conduction system pacing



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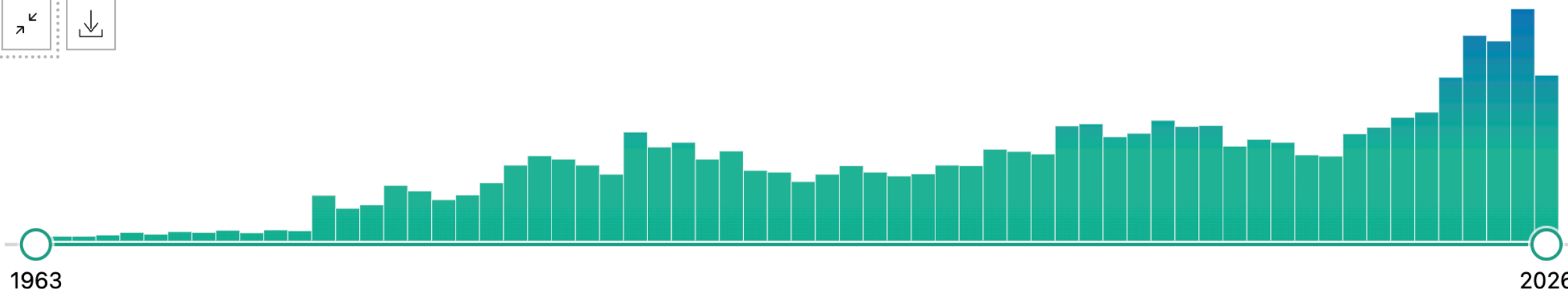
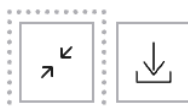


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RESULTS BY YEAR

9,946 results

⏪ ⏩ Page 1 of 995



CONDUCTION SYSTEM PACING: L'EVOLUZIONE CONTINUA



HIS BUNDLE PACING 2000-2010

Le prime esperienze
Istmo/His bundle
Pacing selettivo

LBBAP: LE PRIME ESPERIENZE 2010-2017

Descrizione della LBBAP
Proof of concept
Casi e piccole serie

CRESCITA E STANDARDIZZAZIONE 2018-2023

Aumentano i dati
Definizione dei criteri
Consensus e linee guida

FASE DI CONSOLIDAMENTO 2024-2026

Migliori conoscenze
Materiali dedicati
Strumenti di misurazione
Diffusione globale

LBBAP 2026: PERCHÉ OGGI IMPIANTIAMO MEGLIO?

1. CONOSCENZE "CULTURA"

- Conoscenza dell'anatomia
- Criteri ECG e di capture
- Cosa fare e cosa NON fare
- Troubleshooting
- Quando fermarsi
- Evidence e linee guida



CONOSCERE PER DECIDERE

2. MATERIALI "HARDWARE"

LEAD



DELIVERY SYSTEM



LBBAP

Medtronic

Boston
Scientific

Abbott

BIOTRONIK
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MicroPort

MIGLIORI MATERIALI, MIGLIORE ACCESSO,
MAGGIORE STABILITÀ

3. STRUMENTI DI MISURAZIONE "FEEDBACK"

- Fluoroscopia e proiezioni dedicate
- EGM unipolare
- Impedance drop
- Current of Injury
- Fixation beat
- Peak LVAT / V6 RWPT
- ECG criteria di capture



MISURARE PER CONFERMARE

LA PRIMA FASE È STATA TROVARE LA BRANCA.
LA SECONDA IMPARARE A CATTURARLA.

LA TERZA, CHE STIAMO VIVENDO OGGI, È RENDERLA **SEMPLICE, RIPRODUCIBILE E SOLIDA NEL TEMPO.**

Solia CSP S

Progettato esclusivamente per la CSP

Il primo e unico elettrocatetere al mondo progettato specificatamente per la stimolazione del sistema di conduzione (CSP), che unisce i vantaggi di una vite fissa a quelli di un elettrocatetere stilettabile.¹

Design innovativo a vite fissa

Solia CSP S è progettato in modo esclusivo per consentire una penetrazione del tessuto settale facilitata, controllata e fluida², oltre a favorire un agevole riposizionamento dell'elettrocatetere.²

ProMRI

Approvato
CE

- Vite fissa
- La vite più lunga del settore per la CSP, con una lunghezza di 2,2 mm¹
- Passo della vite esteso di 1,3 mm

Geometria innovativa della vite con punta affilata a doppio taglio

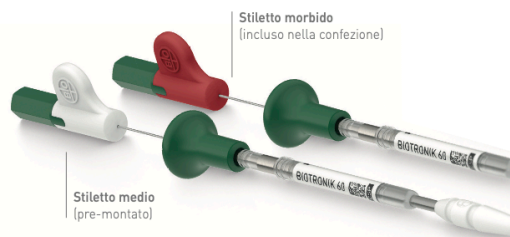
Inserimento profondo dello stiletto

Stilettabile

Solia CSP S è un elettrocatetere stilettabile, con l'estremità dello stiletto posizionata in profondità nella punta dell'elettrocatetere. Questo design è pensato per migliorare la manovrabilità e la facilità di spinta, per una migliore penetrazione nei tessuti e un controllo ottimale della punta.

Lo stiletto consente di effettuare misure elettriche continue durante l'avvitamento.

Le due varianti dello stiletto offrono la flessibilità di poter scegliere la rigidità del catetere e di regolarne la curvatura.



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Utilizzo semplificato dell'elettrocatetere

Solia CSP S è creato per rendere efficiente la stimolazione dell'area della branca sinistra (LBBAP), consentendo procedure più rapide con esposizione ridotta alla fluoroscopia.

A differenza di altri elettrocateri stilettabili utilizzati per la LBBAP:

- Non è necessaria alcuna preparazione per utilizzare l'elettrocatetere.
- Non è richiesta la verifica fluoroscopica dell'estensione dell'elica.
- Non è necessario alcuno strumento di bloccaggio per l'ancoraggio dell'elettrocatetere.

Lunga durata

Solia CSP S presenta un'estremità distale ottimizzata per garantire una lunga durata³, offrendo al contempo un design della punta flessibile che contribuisce a ridurre il pericolo di perforazione.⁴

Alte prestazioni e sicurezza²

97%

Livello di successo dell'impianto LBBAP

100%

Tasso SADE*-free



400 milioni di cicli
Durata di servizio di 10 anni



Solia CSP S dimostra la capacità di sopportare un carico operativo pari a **6 volte** quello tipico sperimentato nella posizione LBB.⁵

Test di laboratorio e modellazione del comportamento a lungo termine

¹ Manuale tecnico BIOTRONIK Solia CSP S; Manuale tecnico Medtronic SelectSecure 3830; Manuale dell'elettrocatetere destinato al medico Boston Scientific INGEVITY;

Manuale utente Abbott UniPace.

² Protocollo clinico provvisori BIOIMASTER CSP. Dati in archivio.

³ Test interno BIOTRONIK. Dati in archivio.

⁴ Test interno BIOTRONIK. Dati in archivio.

⁵ Protocollo di indagine interna BIOTRONIK. Dati in archivio.

* Eventi avversi gravi correlati al dispositivo.

Esclusione di responsabilità: Solia CSP S non è attualmente approvato negli Stati Uniti. Contenuto non destinato agli operatori sanitari USA. L'approvazione a livello normativo locale può variare a seconda del Paese.

CE 0123

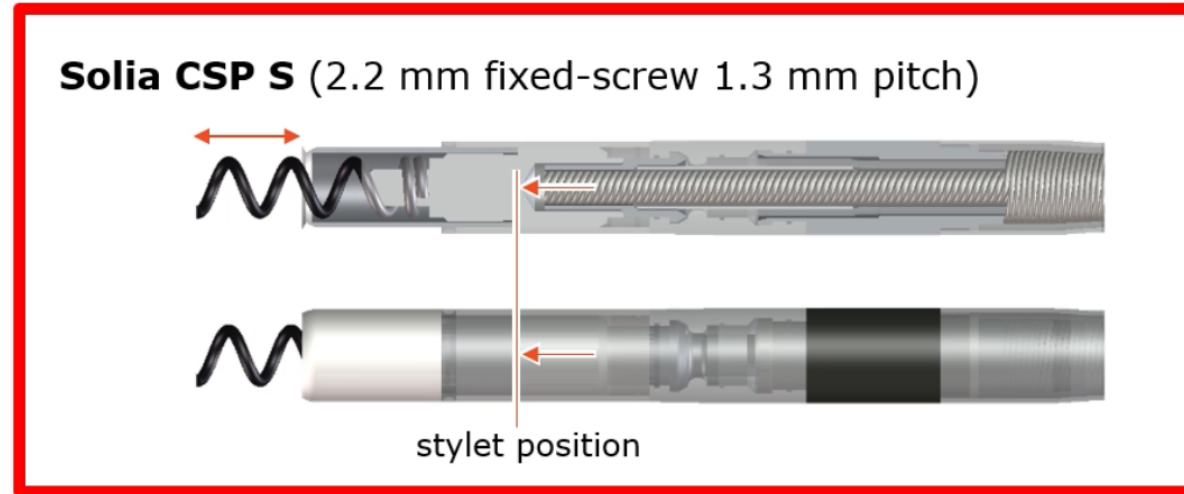
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Solia CSP S: **stylet-driven, fixed helix** lead design



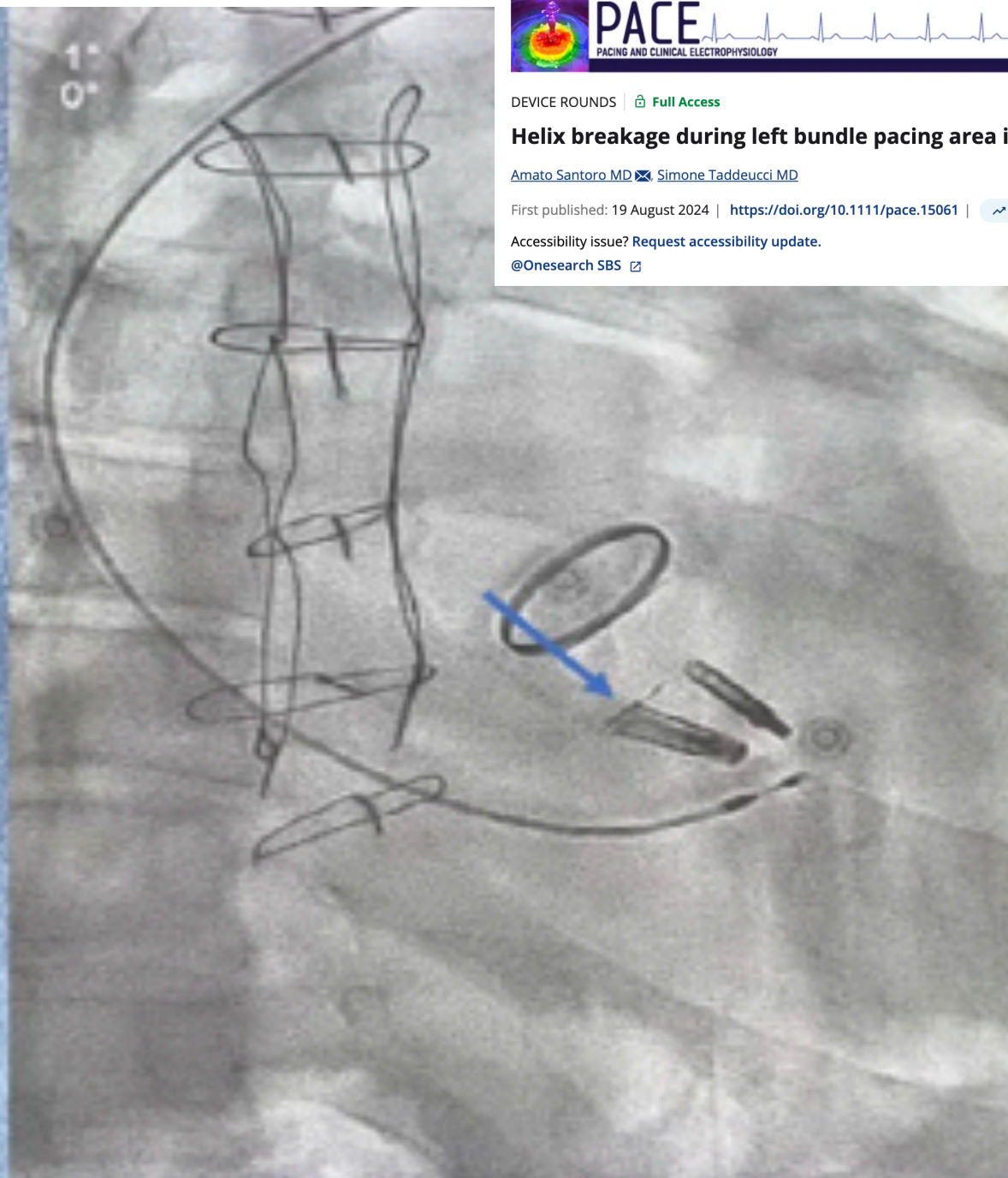
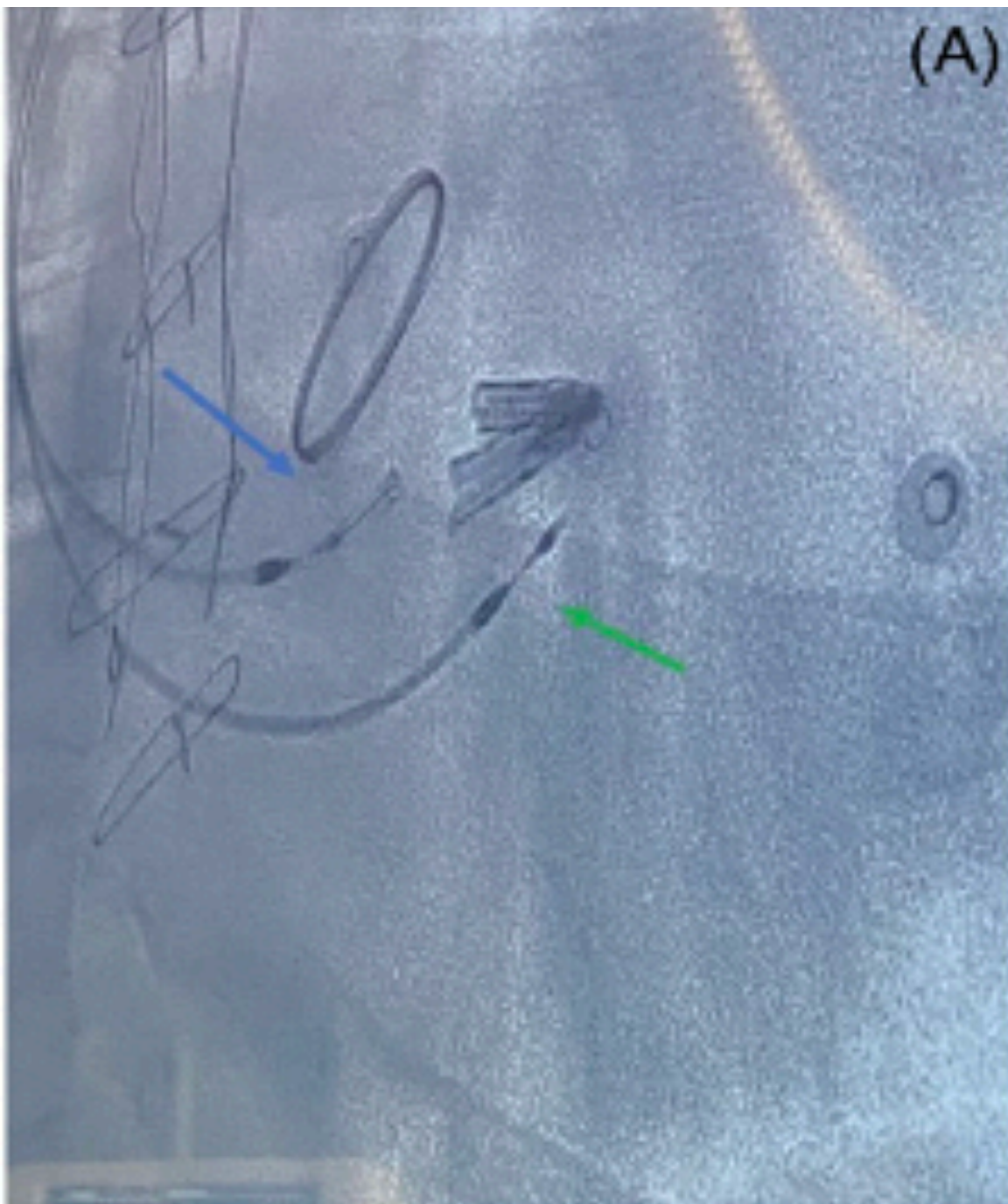
➤ Modifications in helix design

➤ **Fixed helix!**

- Longer helix (2,2 mm instead of 1,8 mm, +22%)
- Wider pitch of helix (1,3 mm vs 0,9 mm)
- Sharper helix (two sided grinded)

➤ Modifications in lead design

- Deeper insertion of stylet (+3,6 mm)
- Optimized distal part for high resilience



DEVICE ROUNDS | [Full Access](#)

Helix breakage during left bundle pacing area implantation

[Amato Santoro MD](#) | [Simone Taddeucci MD](#)

First published: 19 August 2024 | <https://doi.org/10.1111/pace.15061> | [VIEW METRICS](#)

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Lumenless and Stylet-Driven Leads for Left Bundle Branch Area Pacing: Materials, Techniques, Benefits, and Trade-Offs of the Two Approaches

Simone Taddeucci ¹, Gianluca Mirizzi ², Amato Santoro ³

Affiliations + expand

PMID: 39200900 PMCID: PMC11355410 DOI: 10.3390/jcm13164758

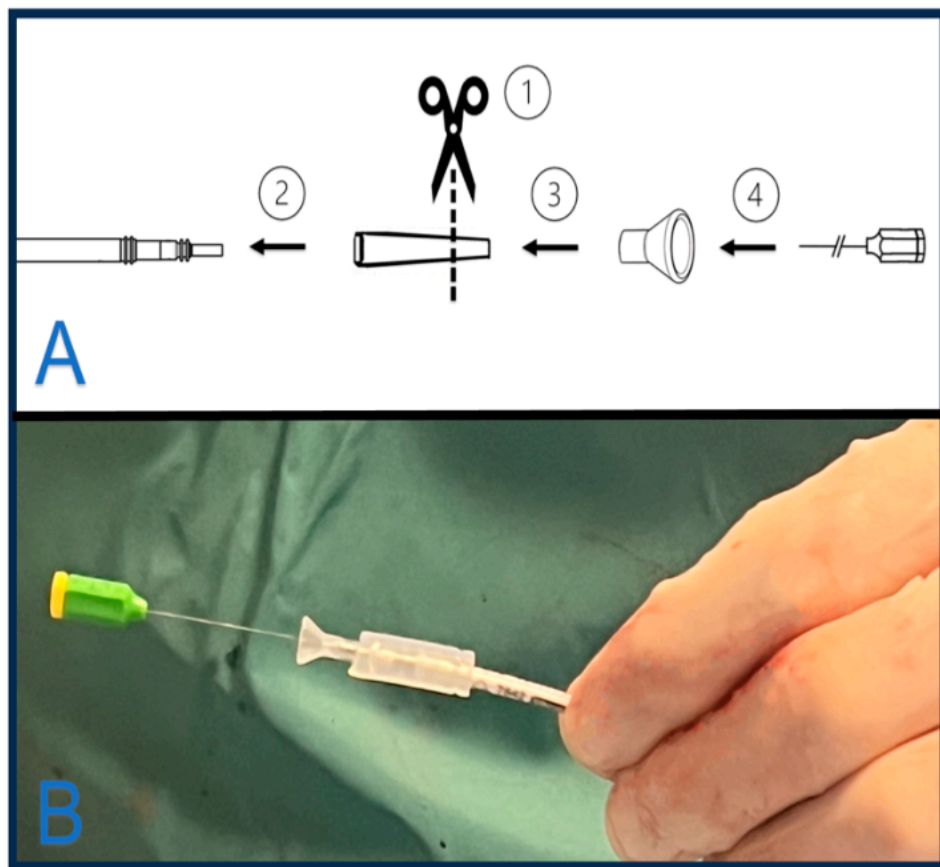


Figure 6. Panel (A) shows a customized locking tool for the Ingevity + catheter lead. Step 1: Cut the lead cap at $\frac{2}{3}$ of the longer tail, as shown in the figure. Step 2: Insert it into the lead. Step 3: The insert tool is pushed under the cut tail of the cap and over the IS1 tip. The customized sleeve locks the inner coil and prevents helix retraction. Step 4: Insert the desired stylet. Panel (B) shows an assembled lead with the customized locking tool.

5. Potential Complications in LBBPa

- **Septal perforation.** Septal perforation is a common complication and is reported in up to 10.2% of LLL and 11.6% of SDL. The procedural outcome and follow-up of SDL compared with LLL for LBBPa can be diagnosed after a marked fall in the current of injury (COI) amplitude associated with a “QS” morphology, along with a drop in pacing impedance to $<450 \Omega$. In the case of perforation, the lead can be advanced in the left ventricle and can evoke left ventricular ectopy. Pacing thresholds can rise.
- **Macrodislodgment.** Macroscopic dislodgment of the lead should be addressed as a technical problem during lead implantation (i.e., drill effect during screwing) and may lead to loss of capture. Lead displacement can be both in the right ventricle or left ventricle in the case of concomitant septal perforation.
- **Microdislodgment.** Per-operative microdislodgments are diagnosed in case of a change in morphology at surface 12 lead ECG, with a loss of terminal R’/r’ deflection in V1 and/or widening of the QRS.
- **Lead rupture.** Subtricuspidal friction of the lead may lead to lead rupture. The most common point of rupture is between the lead body and the ring [18,19]. LLL can be affected, too, and fractured leads in atypical locations can suggest that multiple attempts during initial lead implantation may be at a higher risk of lead fracture [20].
- **Helix damage.** Endocardium entanglement or deep septal penetration in thick myocardium can hamper tissue advancement, and counterclock rotations to retract the helix can be ineffective. Repositioning maneuvers are often necessary during LBBPa and can be a source of possible complications. In rare cases, helix elongation can precede helix rupture into the interventricular septum [13].
- **Chest pain and ST elevation.** Acute coronary events are rare occurrences during LBBPa implants ($<1\%$ of implants). They generally present with intraprocedural chest pain and possible ST elevation. Helix and lead retraction usually leads to symptom resolution. Coronary angiography is negative when performed in these cases. However, persistent ST elevation should also prompt suspicion of coronary vasospasm.

Helix breakage during left bundle pacing area implantation

Amato Santoro MD¹  | Simone Taddeucci MD²¹Division of Interventional Cardiology, Azienda Ospedaliera Universitaria Senese, Siena, Italy²Cardiovascular Department, University of Siena, Siena, Italy**Correspondence**
Amato Santoro MD, Division of Interventional Cardiology, Azienda Ospedaliera Universitaria Senese, Viale Bracci 1, 53100 Siena, Italy.
Email: amato.santoro@gmail.com**Abstract**

A left bundle pacing stimulation pacemaker was implanted using stylet driver lead. The screw incarceration occurred after positioning of the lead. The screw rupture occurred during lead retraction; the distal portion of the screw remained incarcerated at the interventricular septum.

KEYWORDS

conduction system pacing, left bundle branch pacing area

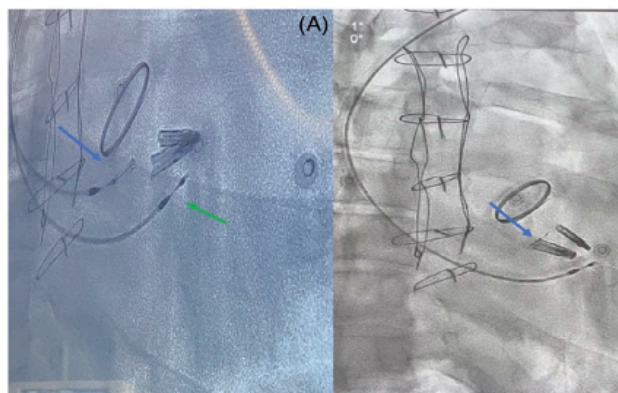


FIGURE 1 (a) The LBBPa lead show a helix stretch that demonstrate its entrapment in the septum (blue arrow). The (b) shows the back-up lead, temporary positioned on the septum LBBPa positioning. (b) The broken helix remained in the ventricular septum (blue arrow). [Color figure can be viewed at [wileyonlinelibrary.com](https://onlinelibrary.wiley.com)]



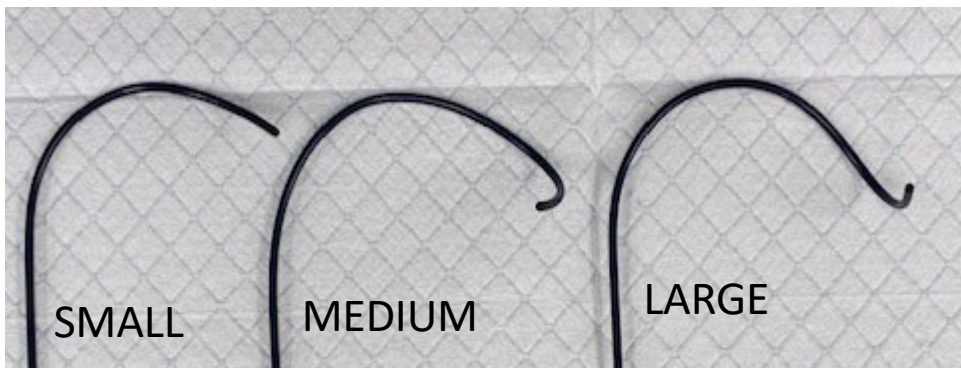
Figure 4. Panel (A). Abbott delivery and helix locking tool are shown. Panel (B): Tendril™ (Abbott) helix deployment in LAO projection. In this case, RA lead can be temporarily placed in RV septum as a backup lead during LBBPa lead positioning. Panel (C): Final position of the leads in LAO projection (left panel) and Ap view (right panel).



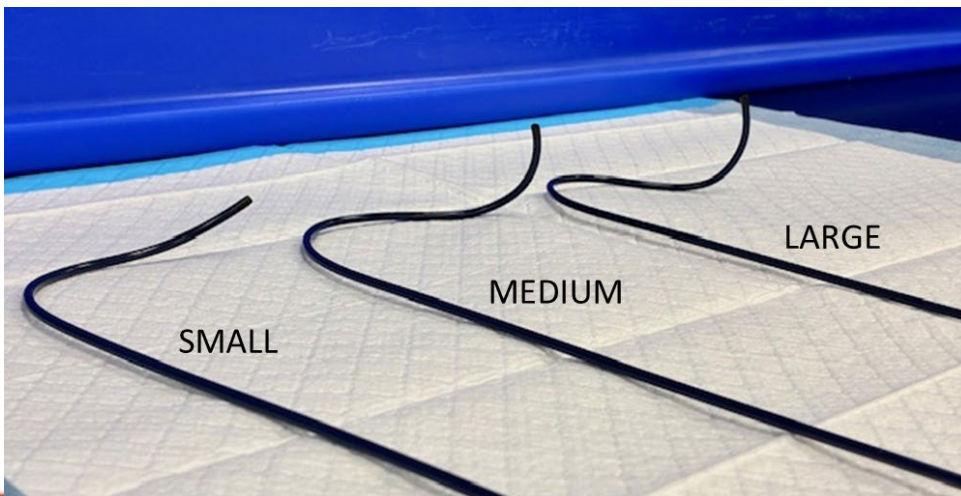
This allows torque to release and puts the inner coil in a neutral state which could prevent unexpected movement

CPS Locator 3D curves comparison

PRIMARY CURVE



SECONDARY CURVE



	Primary curve radius (mm)	Secondary curve radius (mm)
Small - DS2C100	84.68	96.30
Medium - DS2C200	94.68	55.06
Large - DS2C300	84.07	63.18

CPS Locator™ 3D

Diametro esterno	9 F (3.00 mm)
Curvature disponibili	• Small (DS2C100-42) • Medium (DS2C200-42) • Large (DS2C300-42) • Medium extra long (DS2C200-45) • Large extra long (DS2C300-45)
Materiale	• Corpo: PEBAX™ • Valvola a doppio stadio: silicone
Marker	Tungsteno nel corpo del catetere per migliorarne la visibilità

1. Pebax è un marchio di Arkema

CONTENUTO DELLA CONFEZIONE

Quantità	Contenuto
1	Catetere di rilascio CPS Locator™ 3D
1	Dilatatore

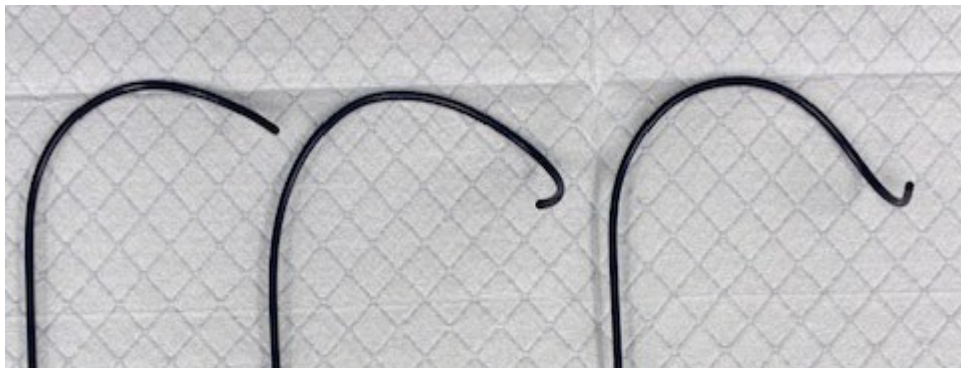
INFORMAZIONI UTILI

	Sterilizzazione, conservazione, smaltimento
Sterilizzazione	• Modalità: radiazione (R). Prodotto esclusivamente monouso • Validità di utilizzo: 24 mesi
Conservazione	Conservare a temperatura ambiente. I dati sull'invecchiamento accelerato confermano la temperatura di conservazione continua raccomandata di 23 °C. In base agli stessi dati, il prodotto può resistere a escursioni temporanee fino a 54 °C.
Confezione singola	Busta sterile contenuta in una scatola di cartone
Smaltimento	Smaltire come rifiuto sanitario in base a quanto previsto dalla normativa vigente

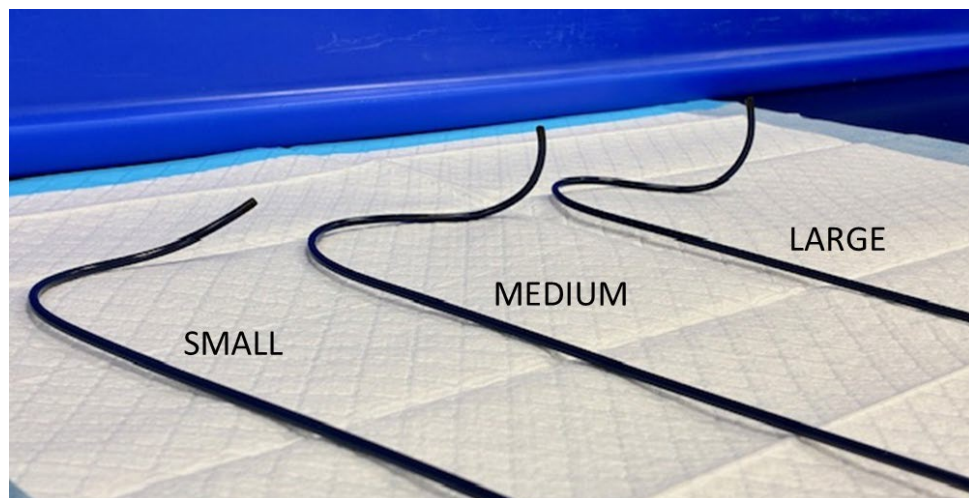
Consultare l'ultima versione del Manuale di riferimento per una lista completa e aggiornata delle specifiche, indicazioni d'uso, controindicazioni, avvertenze, precauzioni e possibili complicanze.

CPS Locator 3D curves comparison

PRIMARY CURVE

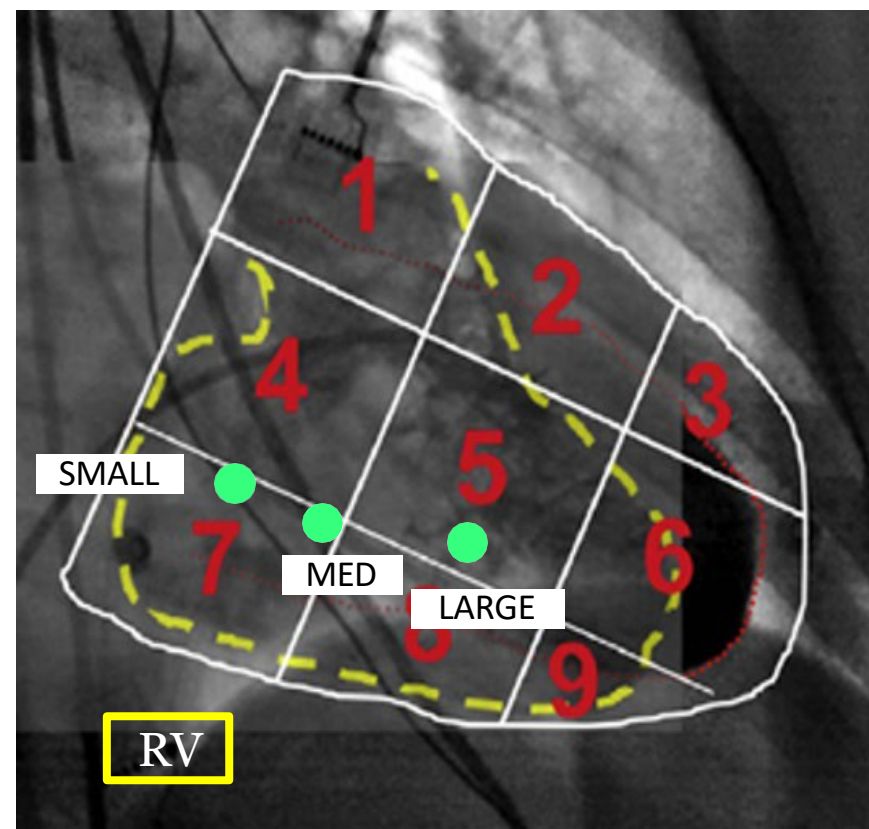


SECONDARY CURVE



Estimated RV septum landing

***dependent on RA and RV size**



UltiPace: What's New?

- Purpose-built for CSP
- Optimized for deep septal deployment
- Integrated with the Novo delivery platform
- Designed to facilitate LBBAP workflow
- Maintains the advantages of stylet-driven technology

UTILIZZO

L'elettrocattetere UltiPace™ LPA1231 è destinato al sensing e alla stimolazione permanenti nell'atrio destro, nel ventricolo destro e/o nell'area della branca sinistra, unitamente ad un generatore di impulsi compatibile. È indicato in pazienti in cui il fissaggio permanente di elettrocatteteri passivi potrebbe rivelarsi instabile. Nelle applicazioni atriali, l'impiego di un elettrocattetere con fissaggio a vite può essere indicato in presenza di un'auricola atriale anormale, modificata per via chirurgica o escissa.

CARATTERISTICHE FISICHE

Modello	LPA1231
Configurazione	Bipolare
Ancoraggio	Attivo mediante vite estraibile/retraibile, estensione 2mm
Connettore	IS-1 BI ¹
Lunghezze (cm)	46, 52, 58, 65
Diametro esterno massimo (mm)	1,9 (5,76 F)
Introduttore raccomandato	6 F (senza filo guida) ²
Superficie elettrodi (mm ²) e configurazione	Punta: 7 elicoidale Anello: 15,3 cilindrica
Superficie punta morbida (mm ²)	4,2
Distanza interelettroica (mm) punta/anello	10
Estensione della vite (numero di giri)	Guida dritta: 6-11 ³ - Guida a "J": 9-14 ³
Resistenza elettrica (Ω)	46 cm: 14-24/29-49
Punta-Pin connettore/Anello-Anello del connettore	52 cm: 16-28/33-55 58 cm: 19-31/37-61

Page 1 of 2

Elettrocattetere per stimolazione - Ultipace™ LPA1231

Documentazione ad uso esclusivo degli operatori sanitari

Cosa aggiunge UltiPace rispetto a Tendril STS?

1. Progetto nato per CSP

Tendril STS nasce come lead tradizionale da pacing.

UltiPace nasce pensando alla CSP.

2. Lunghezza dell'elica

UltiPace ha una configurazione progettata specificamente per facilitare la penetrazione nel setto interventricolare.

3. Interfaccia con il delivery system

UltiPace è stato sviluppato insieme alla piattaforma Novo.

4. Maggiore focalizzazione sulla LBBAP

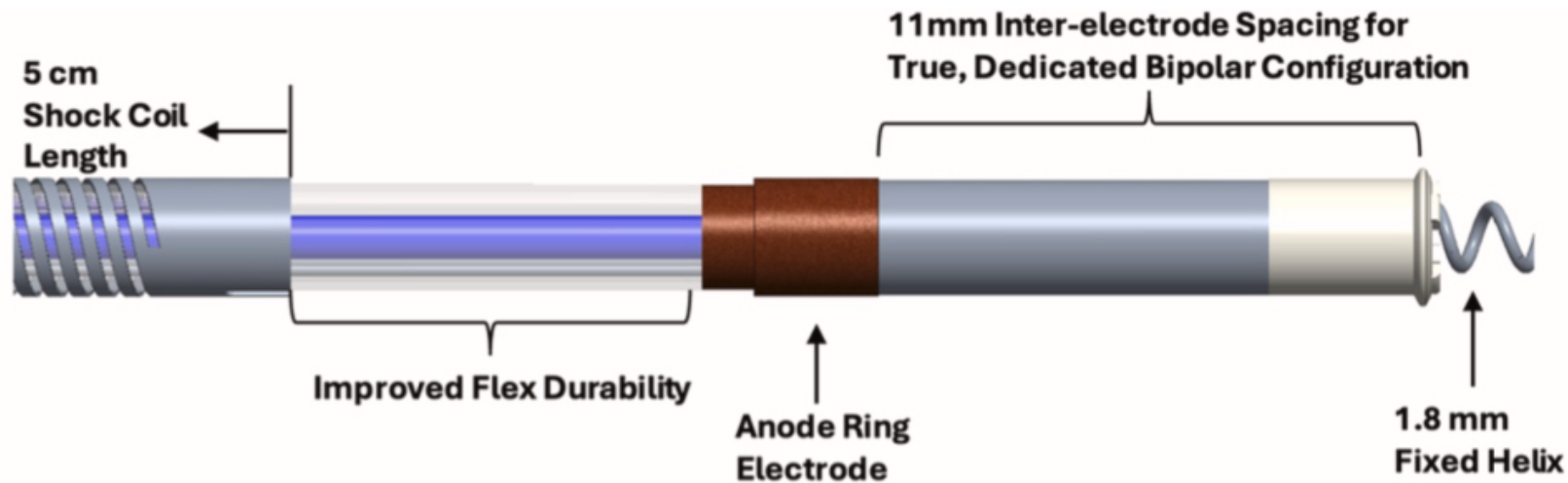
Tendril viene usato in molte sedi.

UltiPace è pensato specificamente per:

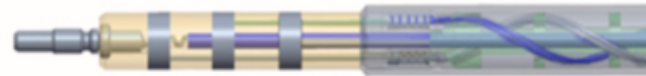
- deep septal pacing
- LBBAP
- CSP workflow

Abbott





LDA1122Q (with DF4 Connector)



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

- primo ICD lead sviluppato specificamente per LBBAP
- elica fissa da 1.8 mm
- configurazione true bipolar dedicata
- shock coil spostata più prossimalmente per aumentare la flessibilità del tratto settale
- progettato per impianto con delivery dedicato
- pensato per LOT-CRT e ICD fisiologici

Figure 1

Conduction system pacing implantable cardioverter defibrillator Model LDA1122Q Design. *Top panel:* Distal end of CSP ICD lead. *Bottom panel:* Lead design of connector end of CSP ICD lead. DF4 connector version (used for ASCEND CSP IDE Study) and DF1/IS1 connector version.

Abbott

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

ABSTRACT

BACKGROUND Use of implantable cardioverter defibrillator (ICD) leads for left bundle branch area pacing (LBBAP) has relied on adaptation of conventional leads not designed for conduction system pacing (CSP).

OBJECTIVE This study aimed to evaluate the safety and effectiveness of a purpose-built CSP ICD lead designed for implantation within the LBBA.

METHODS The ASCEND CSP Investigational Device Exemption (IDE) trial is a prospective, multicenter, global, single arm, pivotal trial evaluating the UltiSynq CSP ICD lead (Model LDA1122Q) in patients undergoing de novo ICD or cardiac resynchronization therapy defibrillator (CRT-D) implantation. The primary safety end point was freedom from lead-related serious adverse device effects through 3 months, compared with a pre-specified performance goal of 88%. The primary effectiveness end point was the 3-month composite success rate of acceptable pacing capture threshold and R-wave sensing amplitude, with a performance goal of 80%. Defibrillation testing success was assessed in a pre-specified cohort.

RESULTS Among 205 implant attempts, 202 patients (98.5%), had successful lead implantation, with LBBAP criteria met in 99.0%. Among these, LBBP or likely LBBP capture criteria were met in 86.0%. The 3-month major complication-free rate was 97.5% and the primary effectiveness end point was achieved in 94.6%, exceeding both safety and effectiveness performance goals. Defibrillation testing was successful in 100%, with 92.5% defibrillated with a single 20 J shock. Lead electrical performance remained stable through 3 months.

CONCLUSION In this pivotal IDE trial, a dedicated bipolar CSP ICD lead demonstrated high implant success, stable electrical performance, reliable defibrillation efficacy, and favorable short-term safety. Longer-term follow-up is warranted to confirm durability and sustained clinical benefit.

Table 2 Implant success rate

	Full analysis population (N = 205)
CSP ICD lead implanted	98.5% (202/205)
CSP lead implant attempted but not placed; subject received a commercially available lead	1.5% (3/205)
Deep septal placement confirmed by fluoroscopy	100.0% (202/202)
LBBAP implant success rate among subjects with CSP ICD lead implanted	99.0% (200/202)
LBBP or likely LBBP capture	86.0% (172/200)
LVSP capture	14.0% (28/200)
Implanter-reported ECG criteria for LBBAP met*	
QRS morphology transition from nonselective-LBB capture (ns-LBBP) to selective-LBB (s-LBBP)	22.0% (44/200)
or LV septal capture (LVSP) during threshold test	
Stimulation to R-wave peak time (RWPT) in lead V5 or V6 <85 ms (native narrow QRS or isolated RBBB)	46.0% (92/200)
Stimulation to R-wave peak time (RWPT) in lead V5 or V6 <100 ms (LBBB, IVCD, RBBB+fascicular block, wide escape rhythm, asystole)	29.0% (58/200)
V6-V1 interpeak interval >33 ms	55.0% (110/200)
LBB potential - V6RWPT = stim - V6RWPT (± 10ms)	6.0% (12/200)
QRS transition to s-LBBP or LVSP during programmed stimulation	6.0% (12/200)
Terminal R-wave in lead V1 during unipolar pacing	80.5% (161/200)
Final lead location (9 segments)	
1. Anterior basal septum	0.0% (0/200)
2. Mid basal septum	4.0% (8/200)
3. Posterior basal septum	1.5% (3/200)
4. Anterior mid septum	0.5% (1/200)
5. Mid septum	70.5% (141/200)
6. Posterior mid septum	12.5% (25/200)
7. Anterior apical septum	0.0% (0/200)
8. Mid apical septum	10.0% (20/200)
9. Posterior apical septum	1.0% (2/200)

*Multiple reasons or criteria could be selected.

Abbott

SelectSecure MRI SureScan 3830 Lumenless Lead + 5944RL Rotatable Connector

The first and only CE-approved pacing lead for conduction system pacing*

A single point of connection to guide implant success

Proven Reliability

Fixed helix, lumenless design for increased implant stability¹ & clinical evidence from thousands of LBBA implants to date^{2,3}

Unmatched Durability

Central cable minimize stress over time; modeling predicted a 10-year 99.98% fracture free rate⁴.

Leading Precision

Lead maneuverability enables mid-basal placement & high rates of selective LBB capture⁵
Small size minimizes risk of myocardial injury⁶ during LBBAP procedures



Designed to achieve target location

Enable physicians to achieve target clinical endpoints based on lead implant depth

Provide real-time signal monitoring

Eliminates the need to switch between signal monitoring and lead deployment

Intended to deliver procedure efficiency

Provide the benefits of a more streamlined and user-friendly procedure



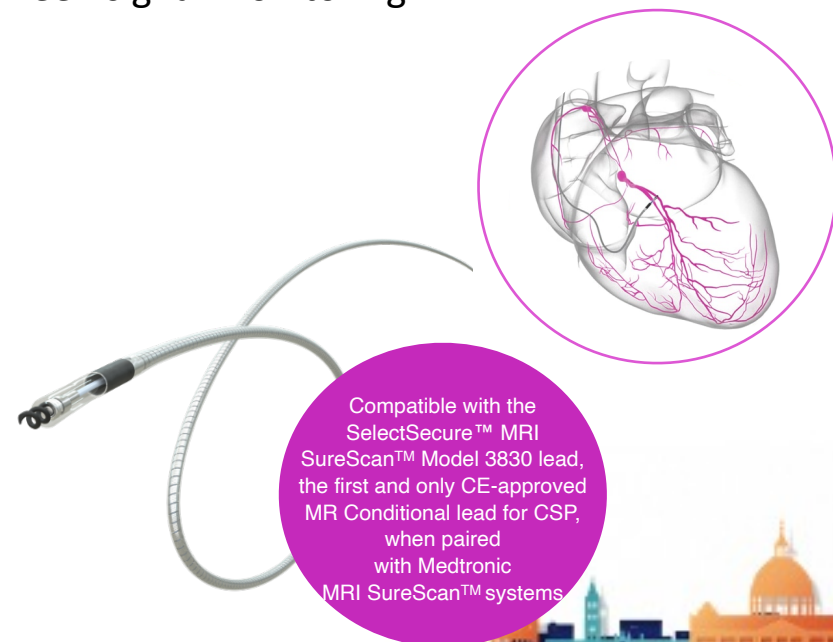
Medtronic

Intended to guide implant success and drive procedure efficiencies with a single point of connection



5944RL rotatable connector

- > Designed to help achieve target implant location through continuous visualization of ECGs, impedance and 12-lead morphology
- > Eliminates the need to switch between signal monitoring and lead deployment



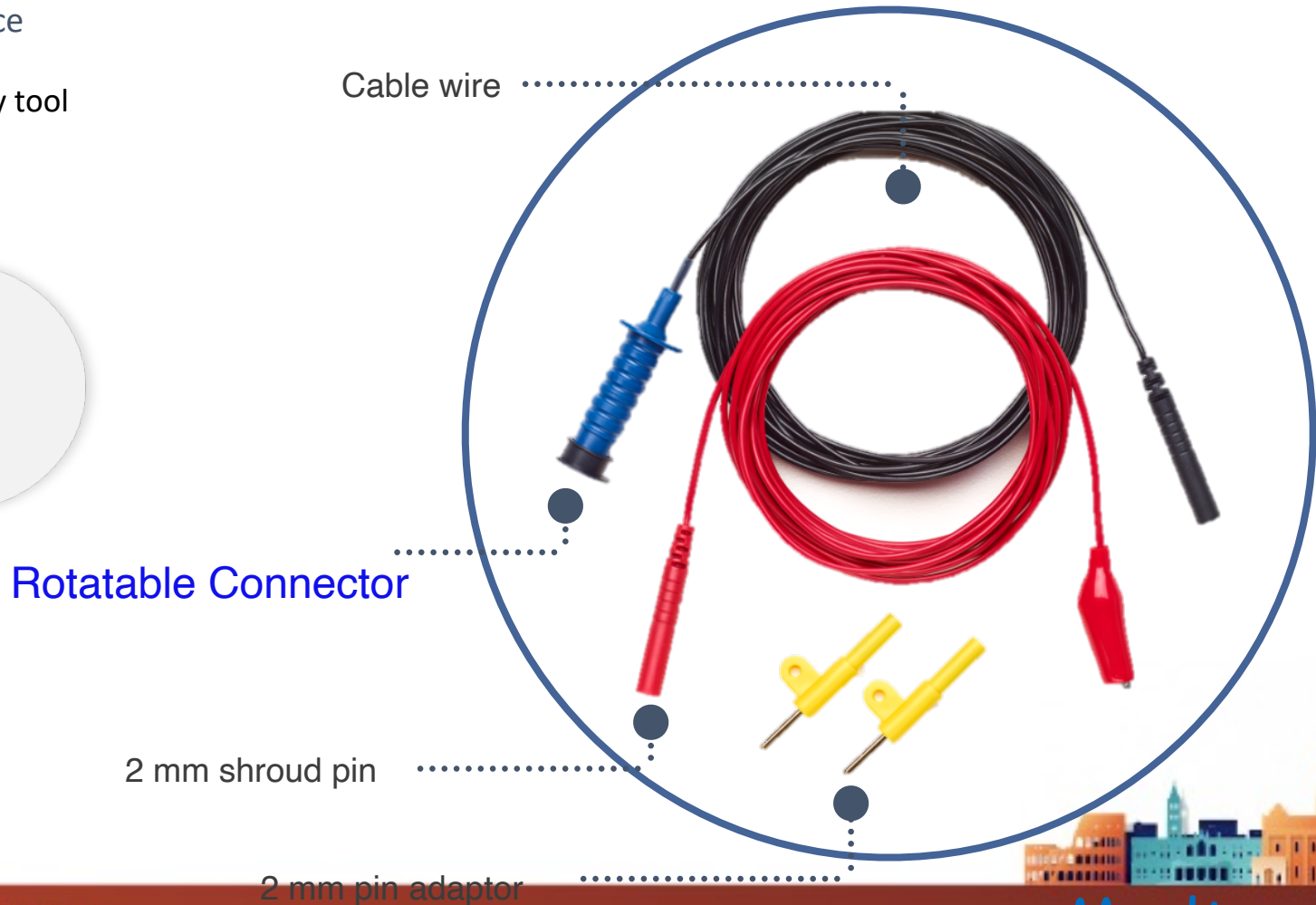
Providing continuous signal monitoring for SelectSecure™ MRI SureScan™ Model 3830 CSP procedures

Streamline the Medtronic 3830 procedure experience

The 5944RL Rotatable Connector is a single-use specialty tool designed to guide implant success and drive procedure efficiencies during Medtronic CSP procedures.

This device consists of a pair of connection cables, which includes:

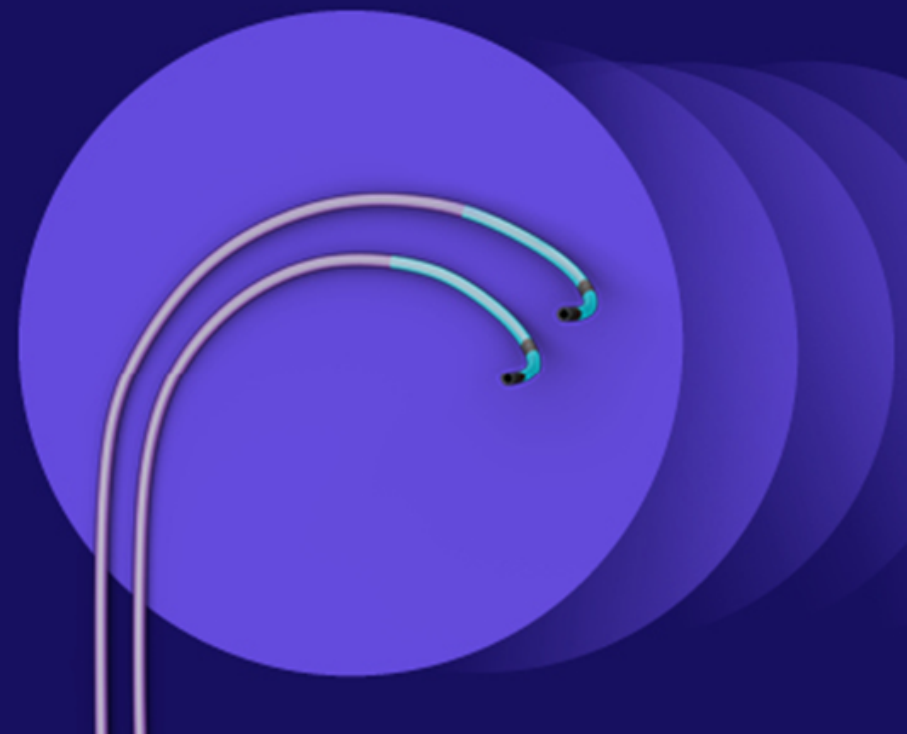
- Cathode cable (black wire)
- Anode cable (red wire)
- A pair of shrouded pin adaptors



Medtronic

C320LBB delivery system

Engineered for LBBAP, enhancing support and precision in CSP procedures

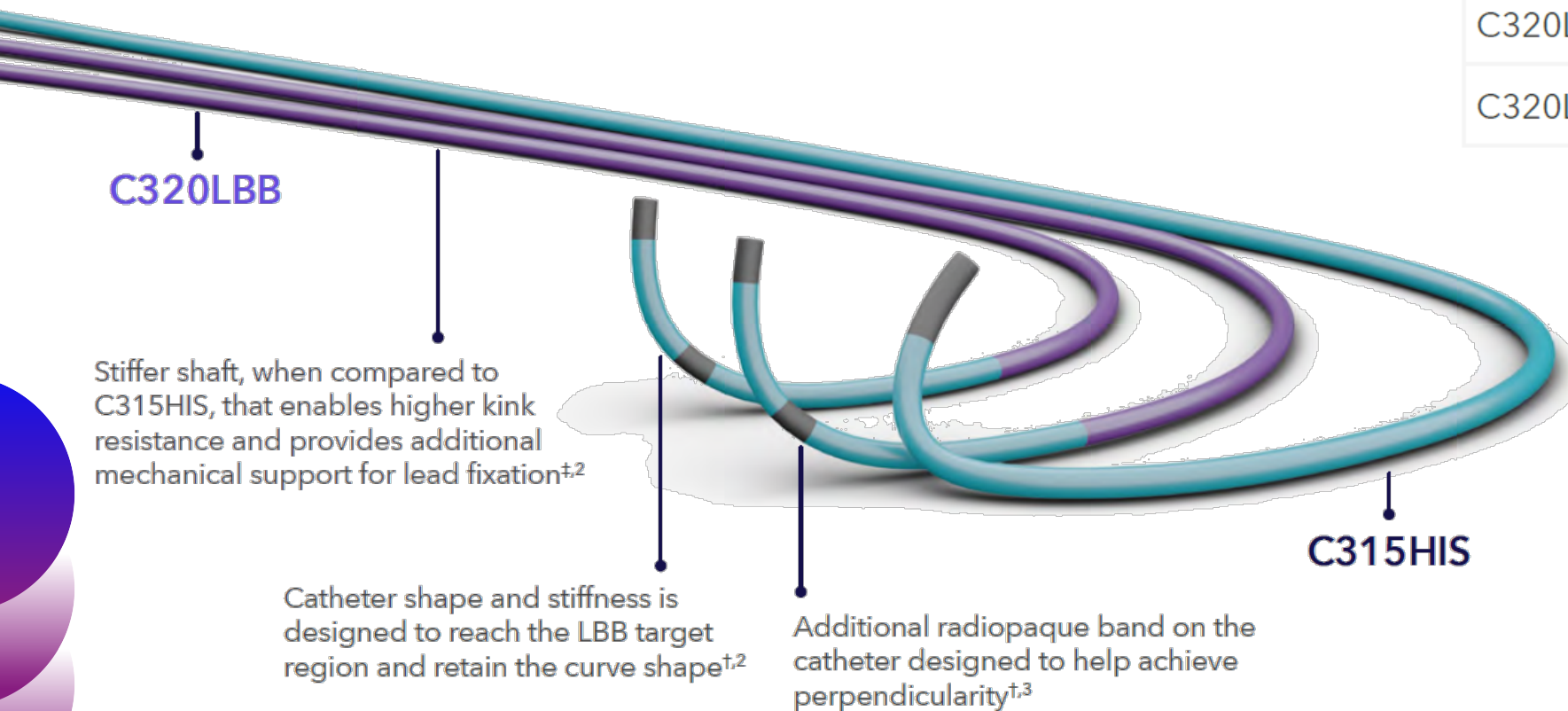


Completezza del portfolio



C320LBB delivery system

- **Maggior supporto, versatilità e precisione per le procedure di CSP**



Small curve

C320LBBS45	45 cm usable length
------------	---------------------

C320LBBS48	48 cm usable length
------------	---------------------

Large curve

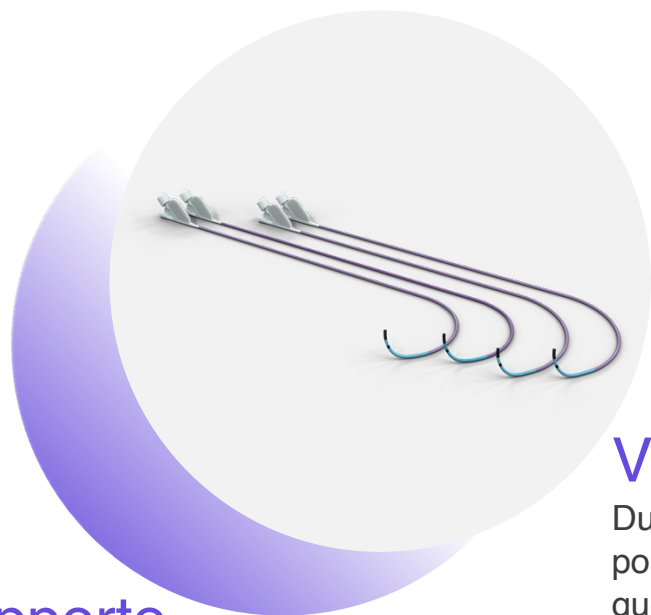
C320LBBL45	45 cm usable length
------------	---------------------

C320LBBL48	48 cm usable length
------------	---------------------



C320LBB delivery system

- **Maggior supporto, versatilità e precisione per le procedure di CSP**

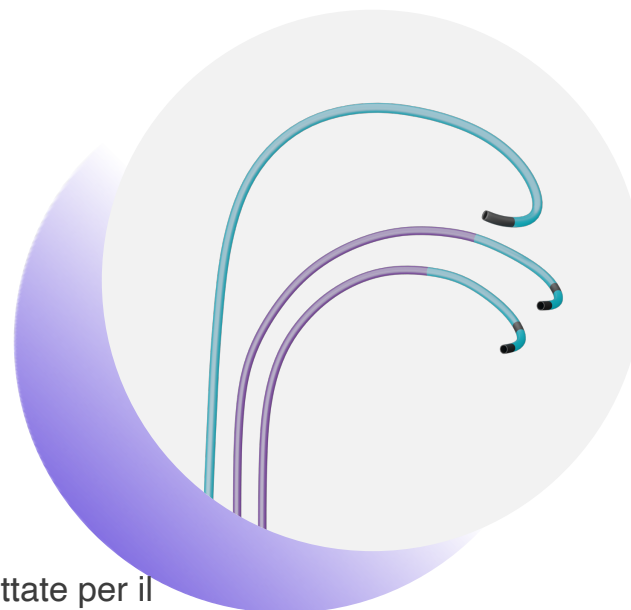


Supporto

Icorpo più rigido con
 Maggiore supporto e
 resistenza al kink

Versatilità

Due curve disponibili progettate per il
 posizionamento in LBBA, di cui
 quella larga per cuori dilatati



Precisione

Marker radiopachi
 aggiuntivi per aiutare la
 visualizzazione in
 scopia

Curva piccola

C320LBBS45	Lunghezza 45 cm
C320LBBS48	Lunghezza 48 cm

Curva larga

C320LBBL45	Lunghezza 45 cm
C320LBBL48	Lunghezza 48 cm



Supporto

Corpo più rigido con Maggiore supporto e resistenza al kink

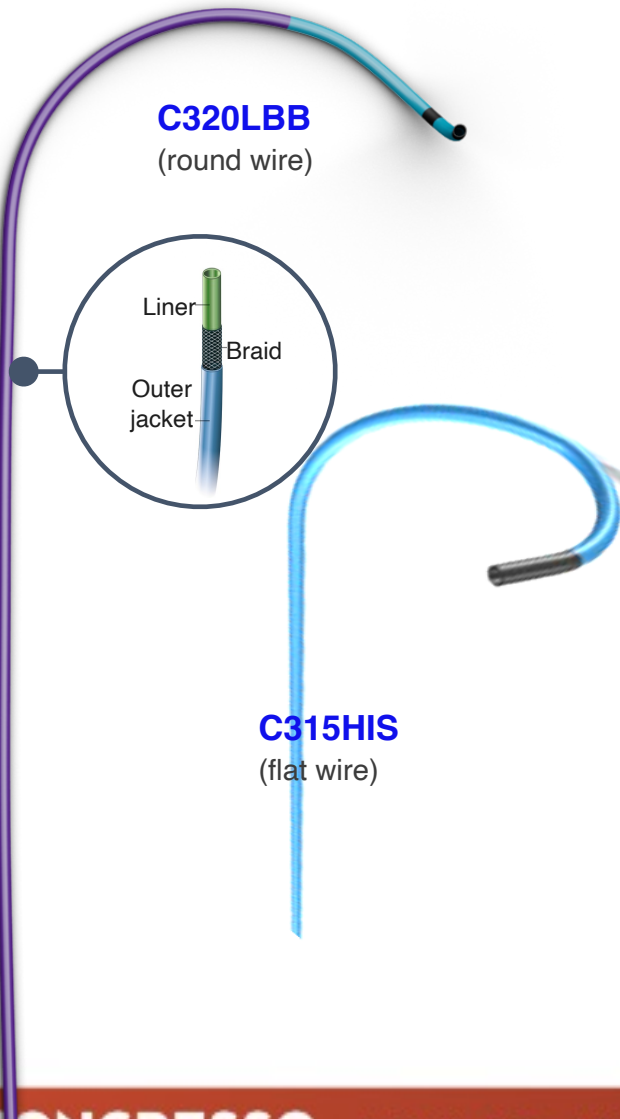
Precisione

Marker radiopachi aggiuntivi per aiutare la visualizzazione in scopia

Versatilità

Due curve disponibili progettate per il posizionamento in LBBA, di cui quella larga per cuori dilatati

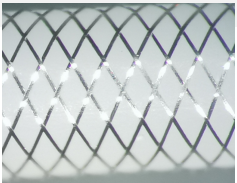
Comparazione con C315HIS



Items C315HIS Catheter

Liner Hydrophilic Liner

Braid Flat wire
0.001“*0.002”



Usable length 43cm

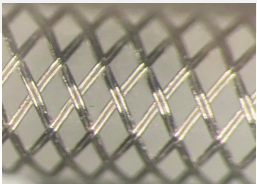
Curve His

Marker One marker

C320LBB Catheter

Hydrophilic Liner

Round wire
OD: 0.002”



45 and 48cm

S curve & L curve

Two markers

Two radio-opaque distal markers



Catheter tip not perpendicular to view

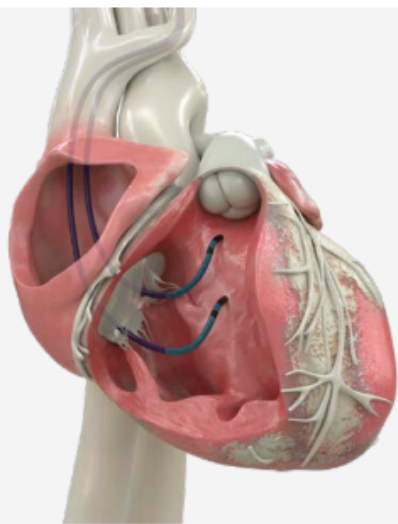
Catheter tip perpendicular to view



Large right atrium (RA) recommended curve shape example

Comparison

Small curve versus large curve
C320LBB catheter in large RA

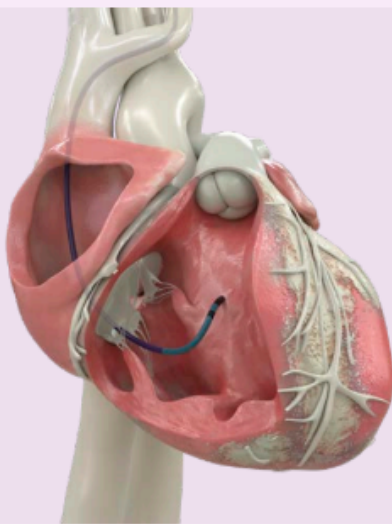


The C320LBB catheter proximal curve steers the distal tip through the tricuspid valve to the mid to high septum.

For education purposes only.

Recommended

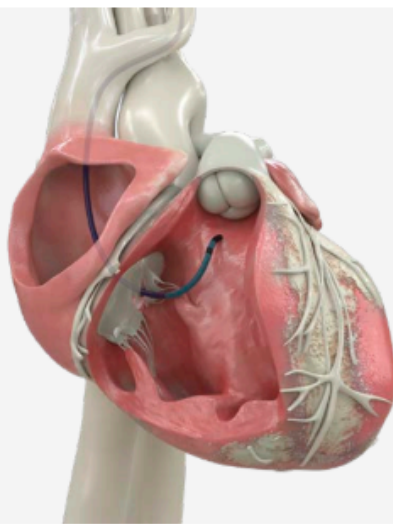
Large curve C320LBB
catheter in large RA



The large proximal curve accommodates more of the large RA dimension steering the distal tip to the appropriate LBBAP location.

Not optimal

Small curve C320LBB
catheter in large RA



The small proximal curve, when guided through the tricuspid valve, steers the distal tip higher toward the right ventricular outflow tract (RVOT).



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

OmniaSecure LEADR LBBAP Global Trial

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

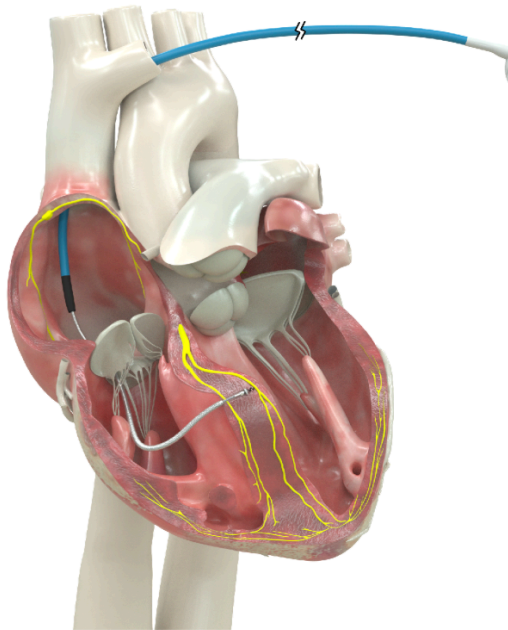
307 patients with an implant attempt; 162 patients in defibrillation cohort

100% defibrillation efficacy at implant

Primary objective passed, exceeding performance goal

97.9% freedom from OmniaSecure lead-related major complications

At 3 months



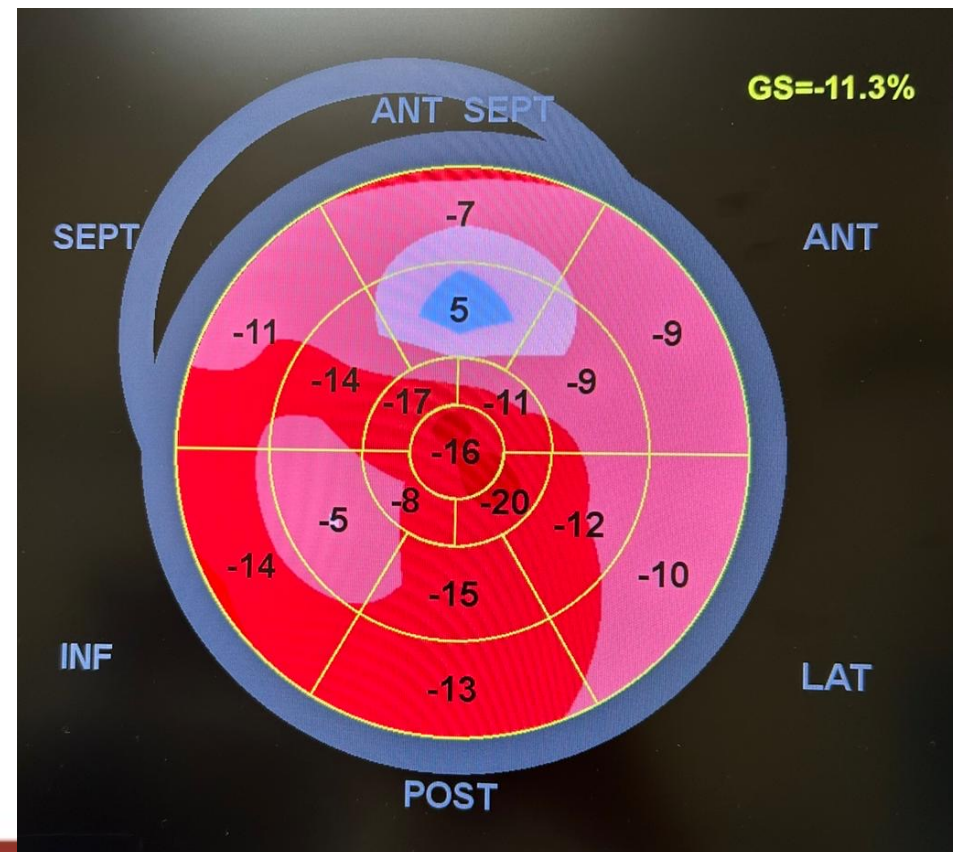
Ordering information

Item number	Type	Fixation	Connector	MR Conditional length (cm)	Diameter (Fr)
3930M64 🔗	Single coil, bipolar	Helix, active fixation	DF4	64	4.7
3930M69 🔗	Single coil, bipolar	Helix, active fixation	DF4	69	4.7
3930M74 🔗	Single coil, bipolar	Helix, active fixation	DF4	74	4.7
3930M79 🔗	Single coil, bipolar	Helix, active fixation	DF4	79	4.7
3930M84 🔗	Single coil, bipolar	Helix, active fixation	DF4	84	4.7

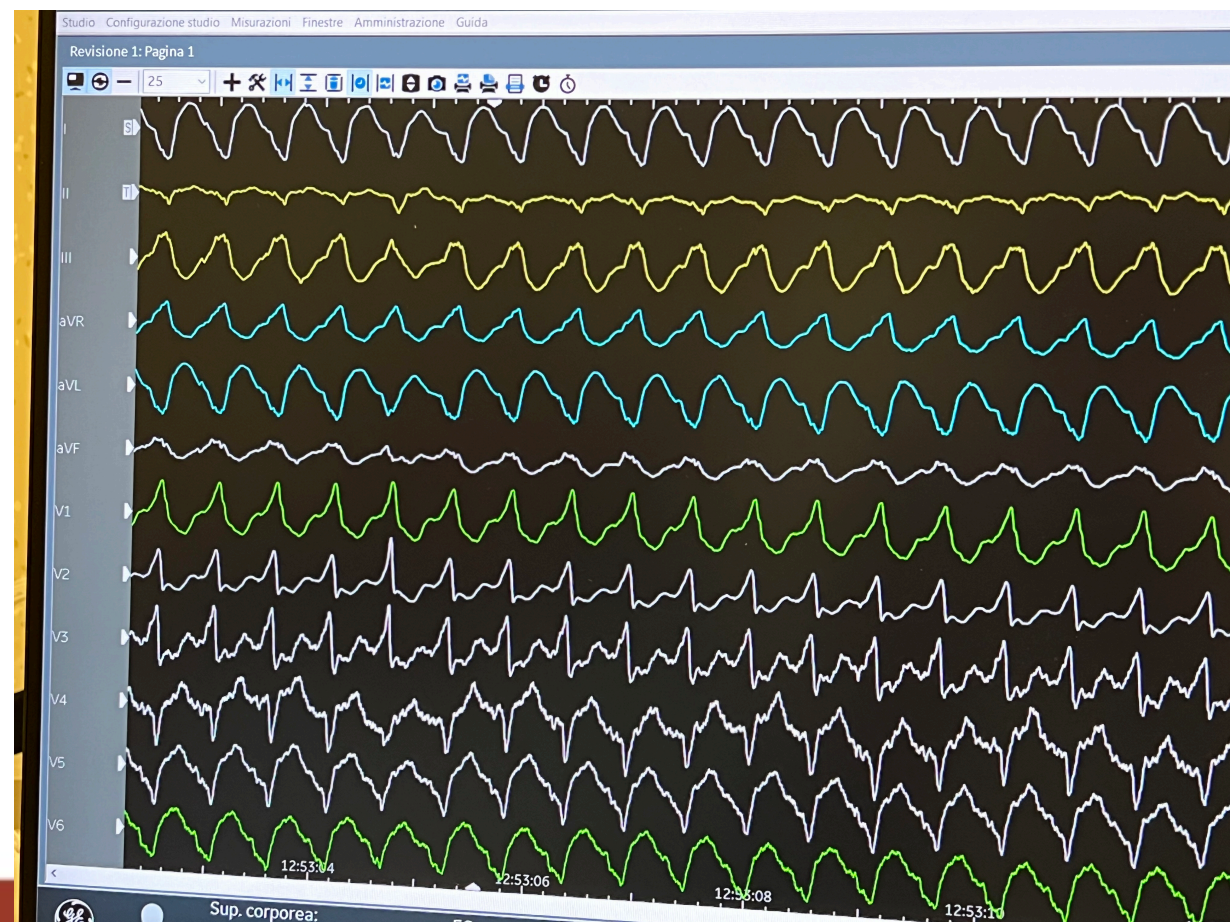
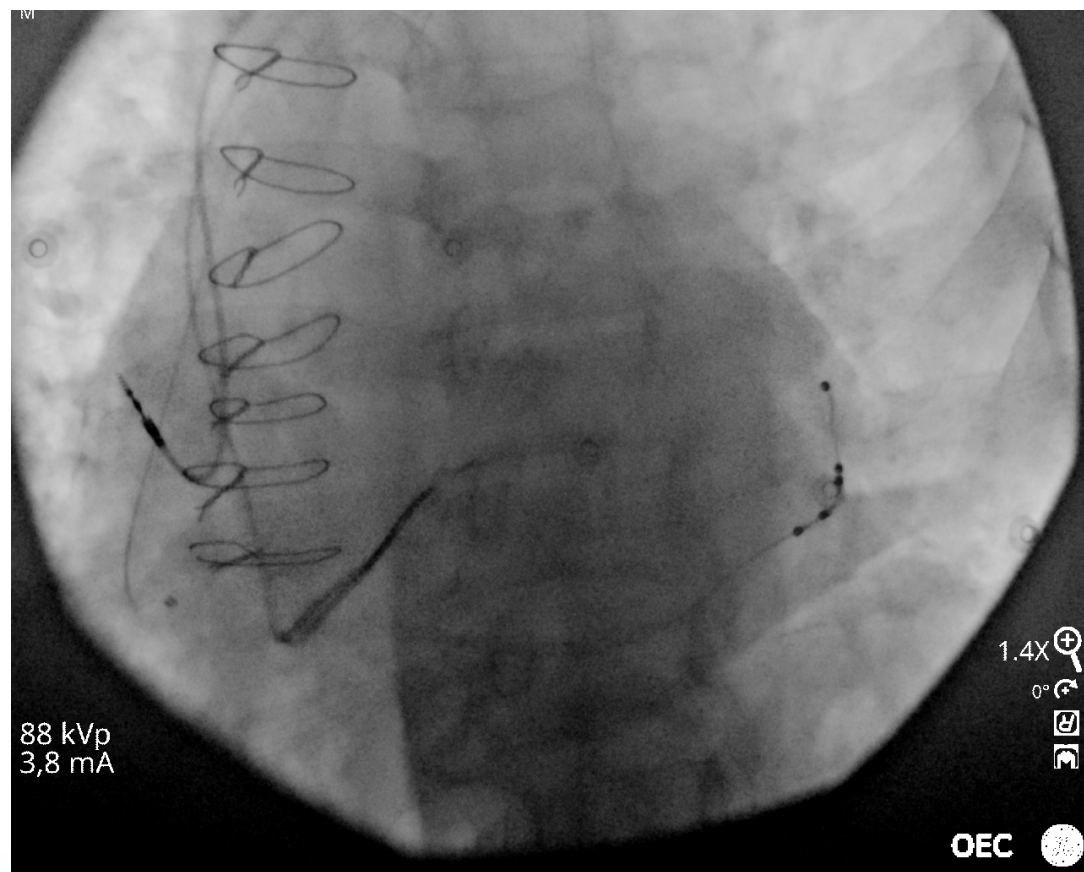
Vijayaraman, P., et al. HRS 2025 LBCT. Presented April 25, 2025.
 Vijayaraman, P., et al. ESC 2025 Oral presentation. Presented August 29, 2025.



BASALE

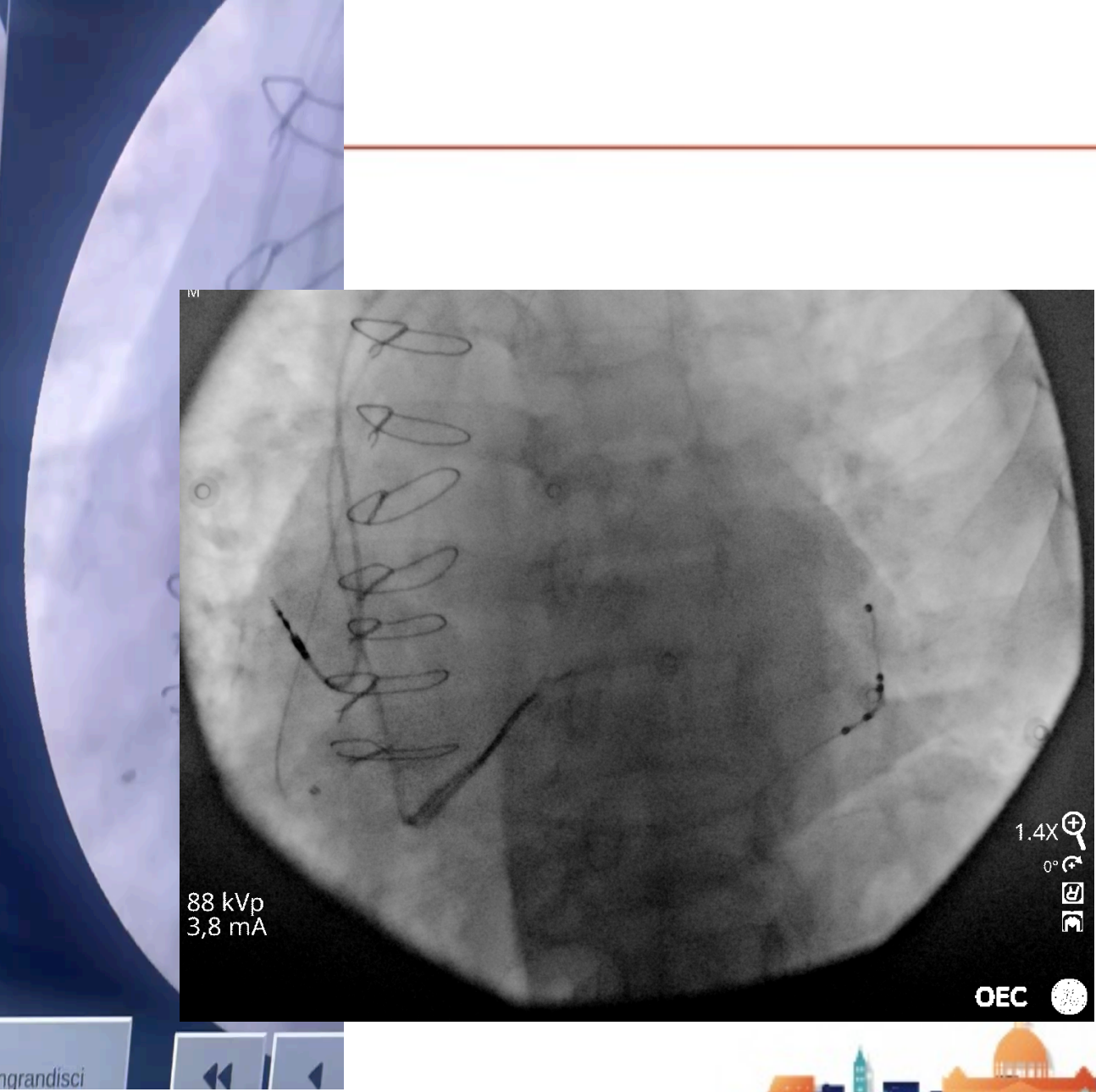
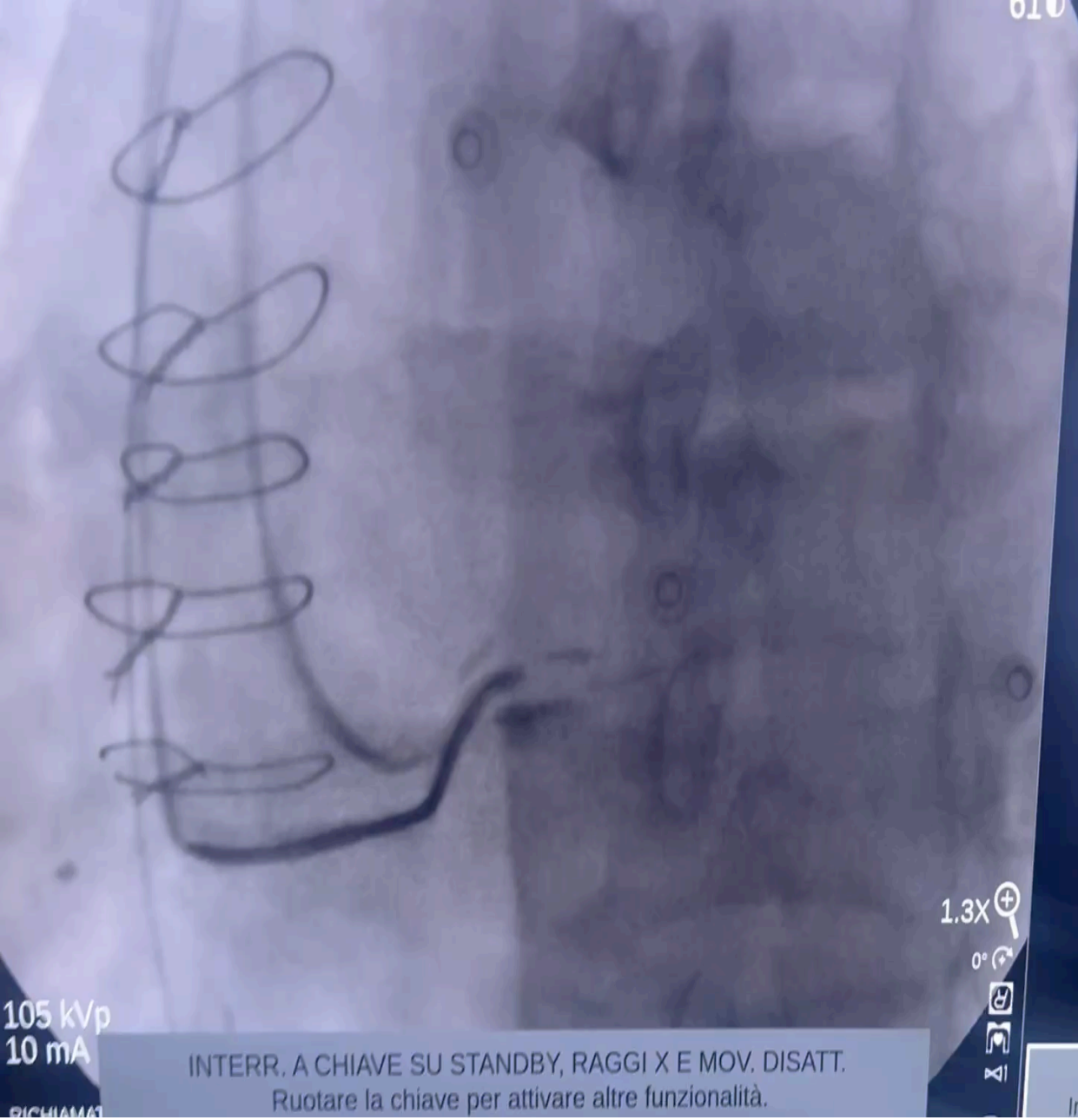


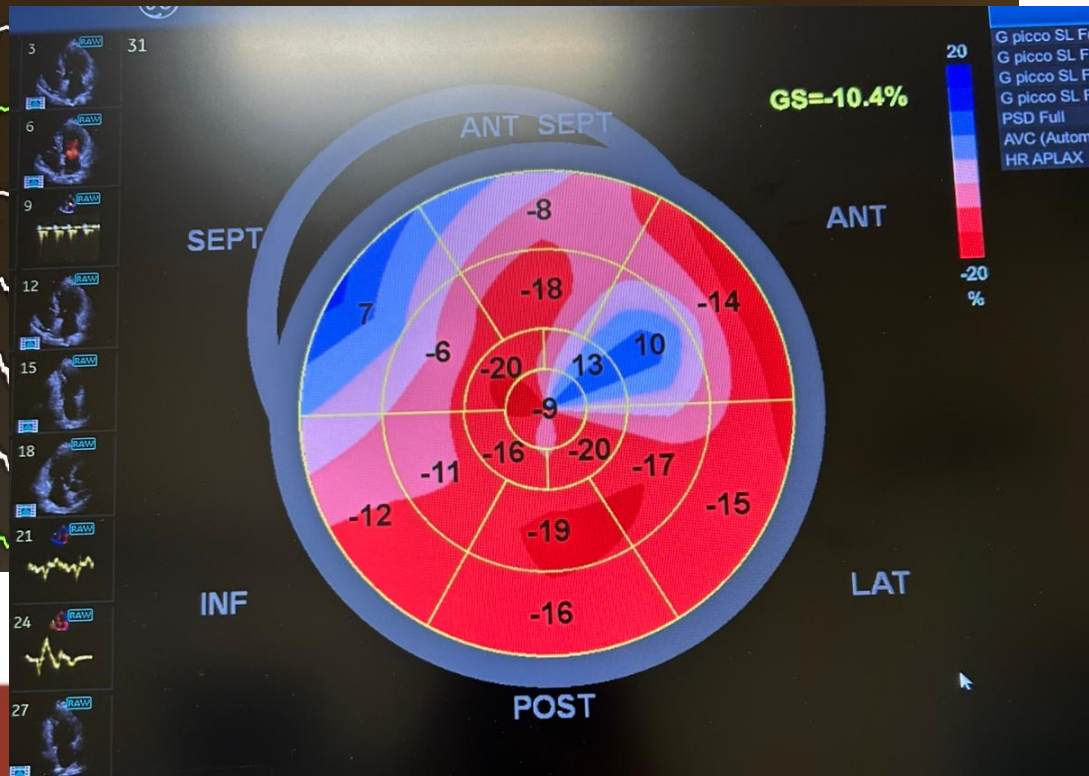
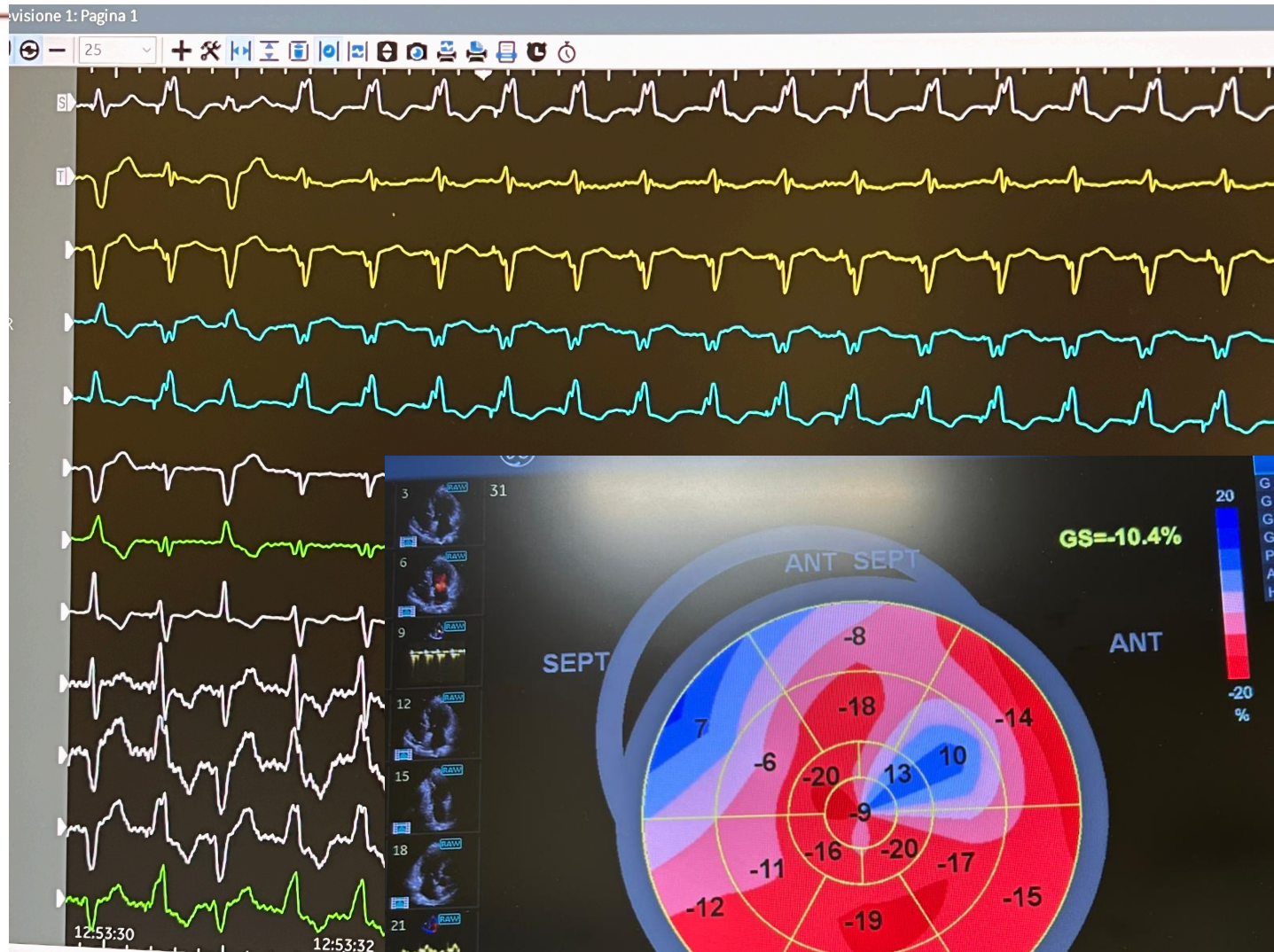
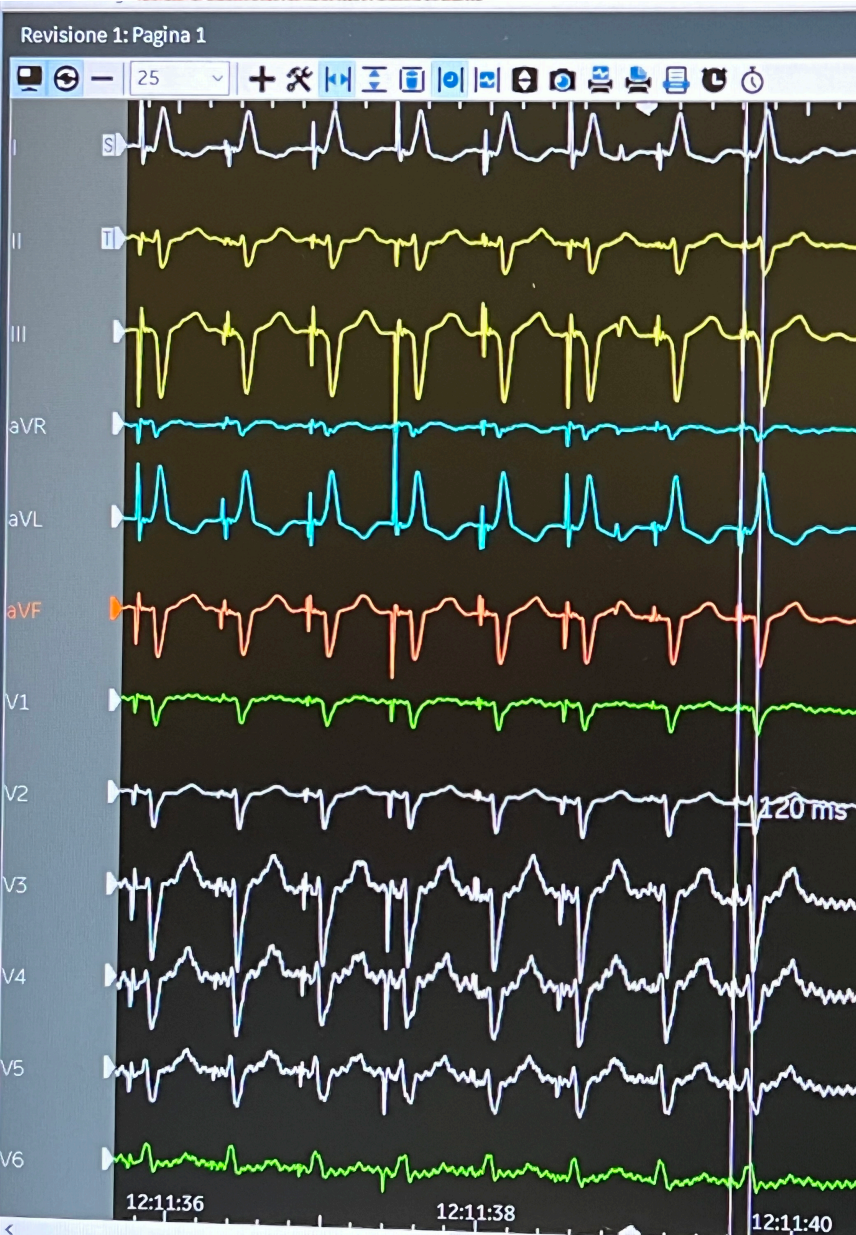
CS vena postero-laterale



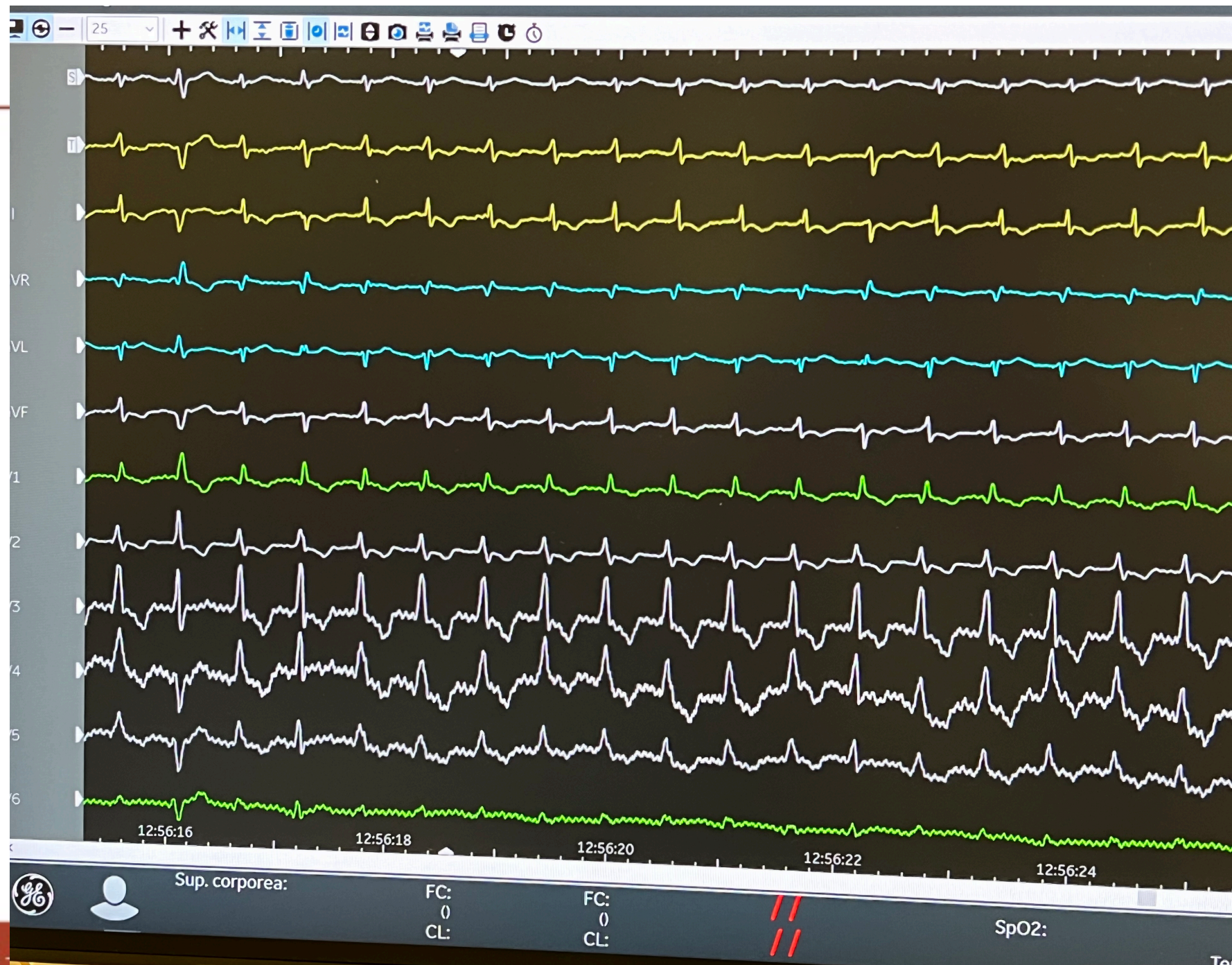
Da W a CSP



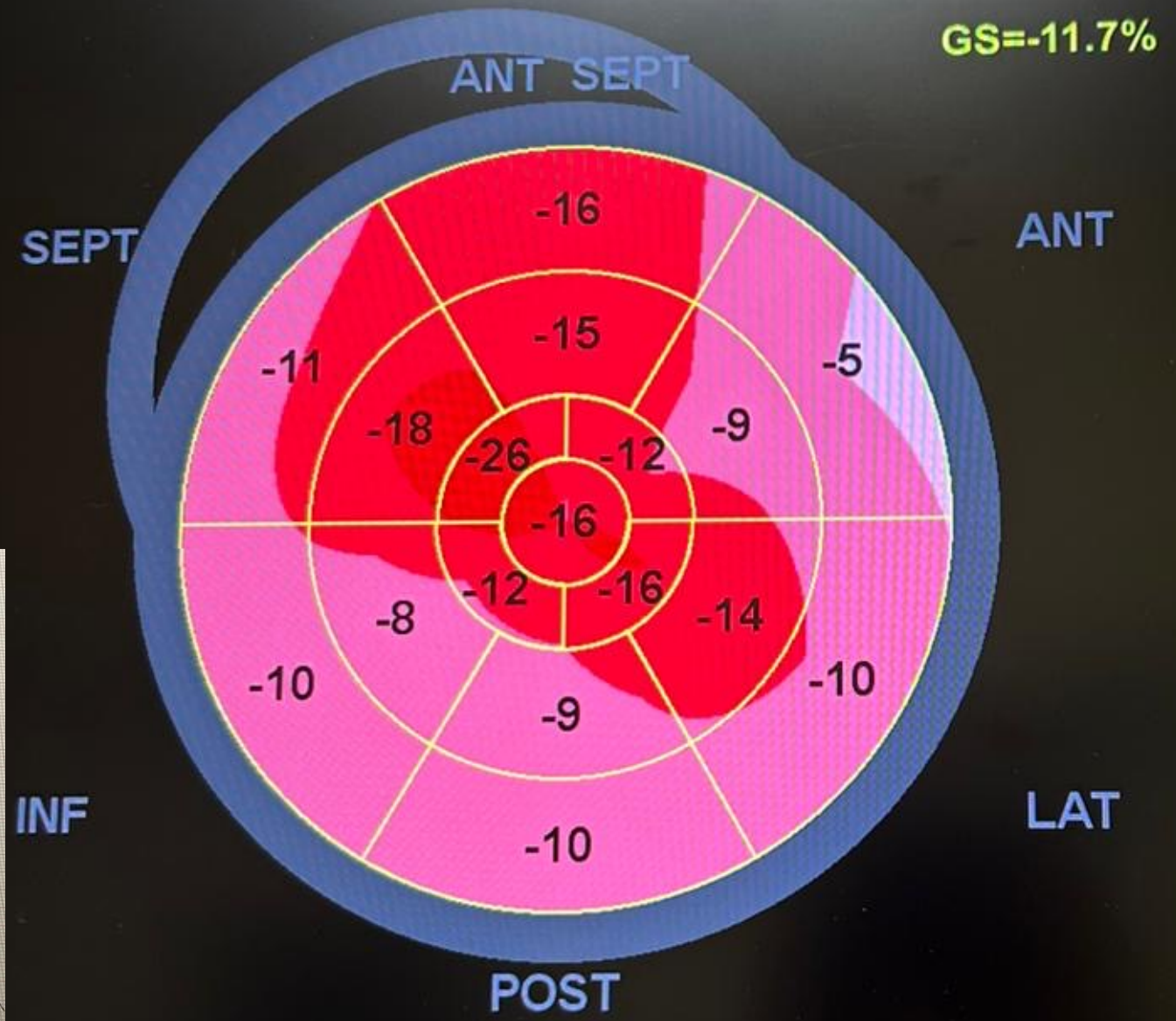
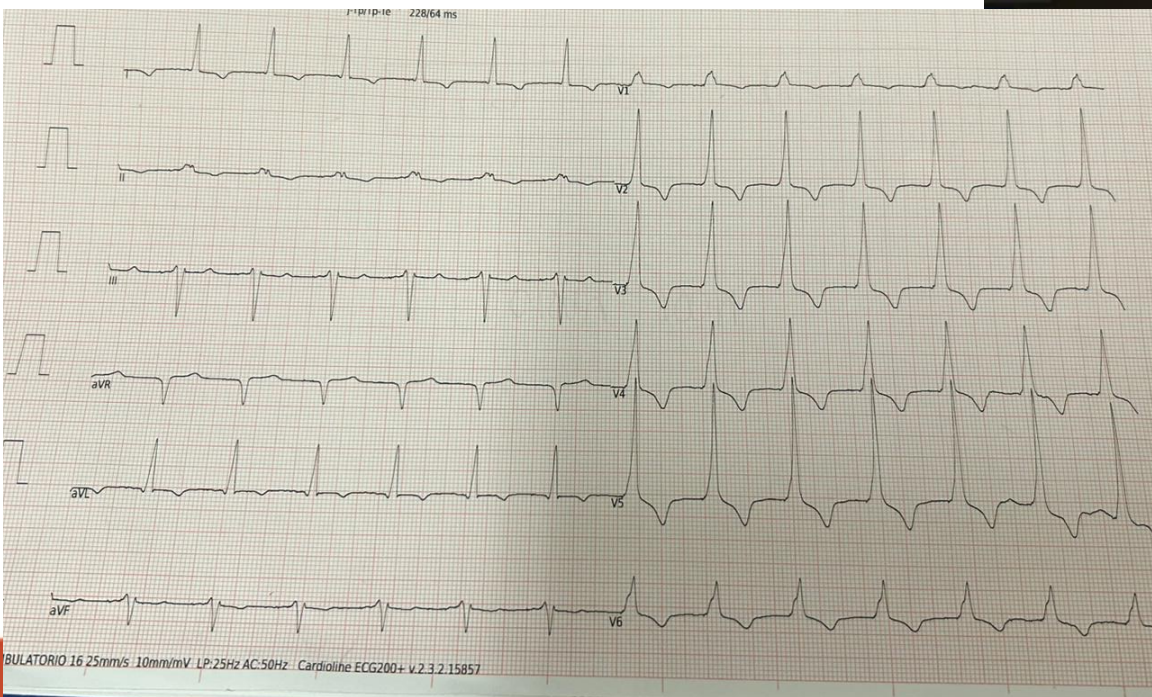




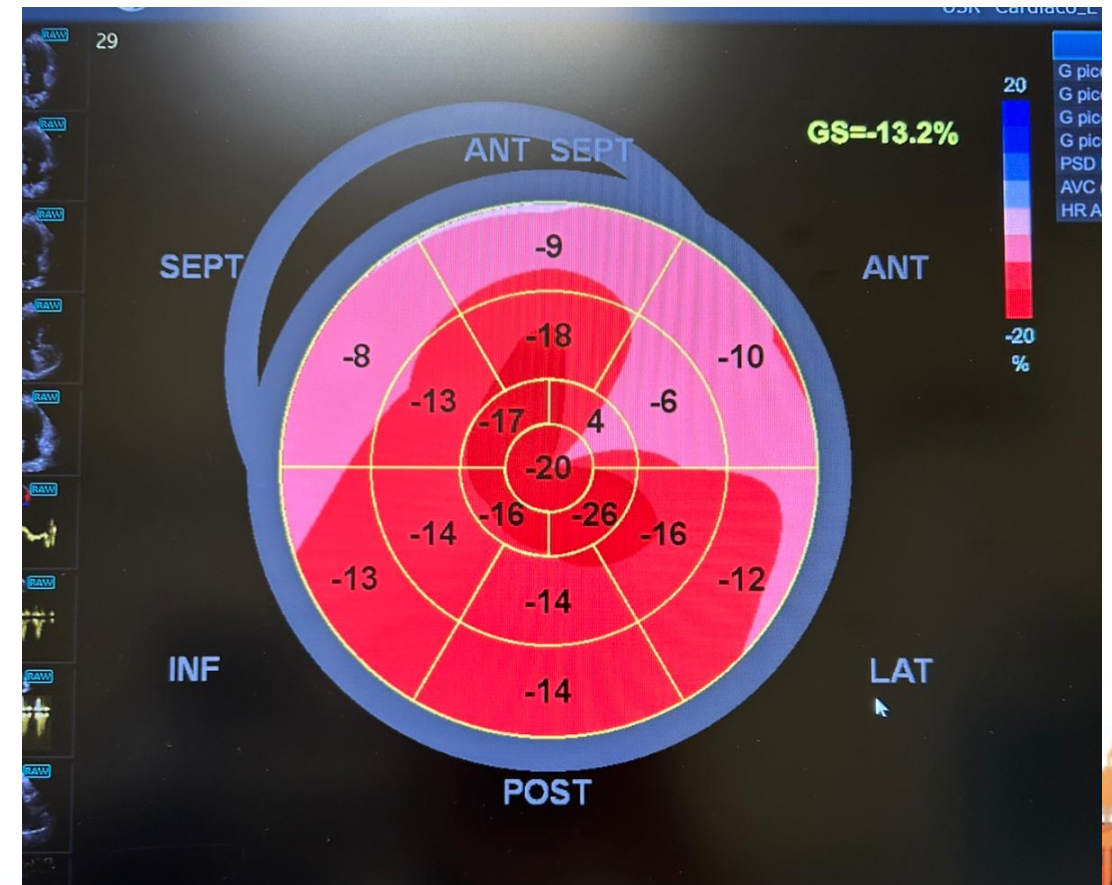
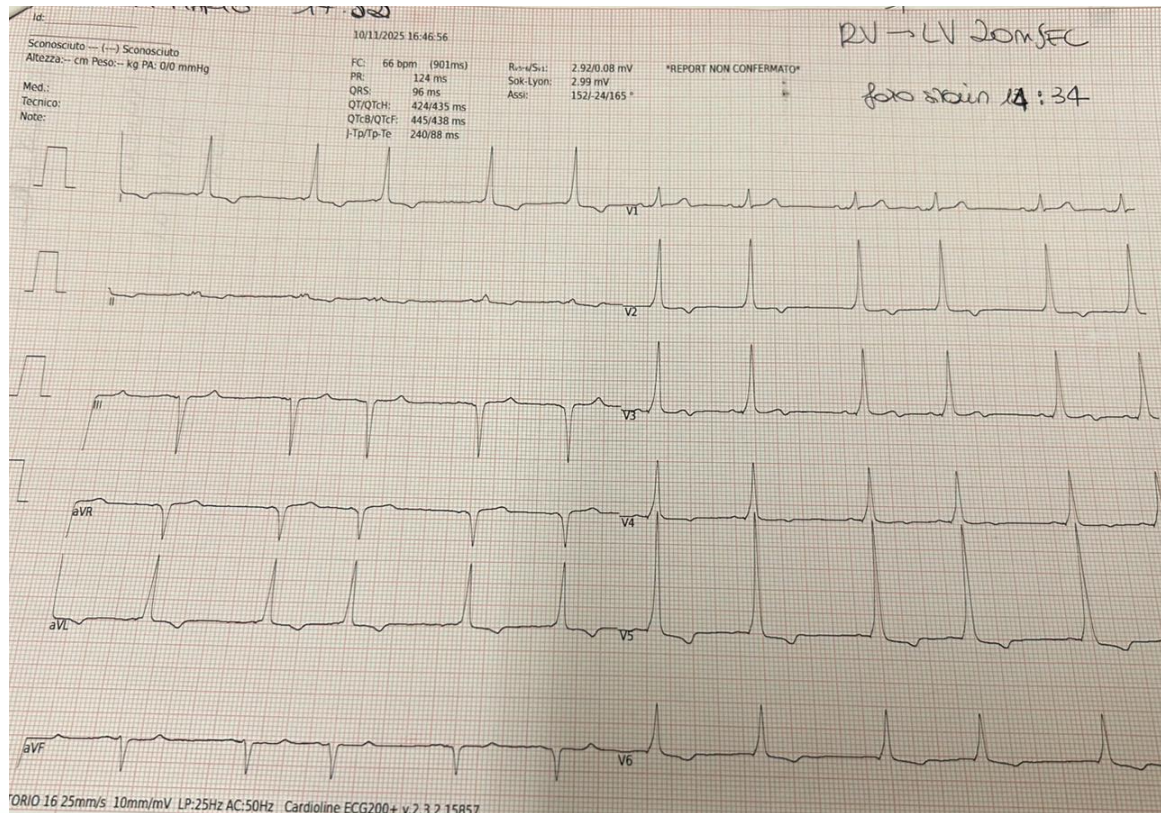
LOT. CRT/D



LV -RV 20 ms



RV-LV 20 ms



Performance of an active fixation stylet-driven lead in left bundle branch area pacing: Results from INSIGHT-LBBA

Daniel J. Friedman, MD,¹ Ilya Shadrin, MD, PhD,¹ Seth Goldberg, MD, FHRS,² Kevin M. Trulock, MD,³ Apoor Patel, MD, FHRS,⁴ Zak Loring, MD, MHS,¹ Sara A. Coles, MD,¹ Gaurang Gandhi, MD, FHRS,⁵ Gaurav A. Upadhyay, MD, FHRS,⁶ Nicholas Wold, MS,⁷ Paul W. Jones, MS,⁷ Stephen B. Ruble, PhD,⁷ Jonathan Weinstock, MD, FHRS,⁷ Christopher A. Latanich, MD⁸

ABSTRACT

BACKGROUND Left bundle branch area pacing (LBBAP) has been rapidly adopted despite a lack of leads with approved indications for LBBAP.

OBJECTIVE This study aims to analyze the performance of a 6Fr active fixation, stylet-driven lead in LBBAP.

METHODS The multicenter INSIGHT-LBBA registry analyzed consecutive LBBAP implant attempts with INGEVITY+ leads. Data were retrospectively collected with standardized entry via REDCap. Prespecified safety (lead-related complication [LRC]-free rate with performance goal >90% at 3 months) and effectiveness (pacing capture threshold [PCT] ≤2 V@0.4 ms and R-waves ≥5 mV; 3-month performance goal = 80%) endpoints were analyzed. External validation of lead effectiveness was performed on a separate cohort of LBBAP patients from the LATITUDE remote monitoring database.

RESULTS The study enrolled 1122 single- or dual-chamber pacemaker patients from 8 US sites (mean age 76 ±10 years, 43% female, 48% atrioventricular [AV] block, 40% sinus node dysfunction). Those successfully implanted had a median follow-up of 302 days. Left bundle or left septal capture was achieved in 95.6% of patients (1073 of 1122) and 89.6% of leads (1073 of 1197, 1.07 leads per patient). The 3-month LRC-free rate was 97.7% (lower confidence limit [LCL] 96.6%) with an LRC-free rate of 97.2% at 24 months. At 3 months, 98.8% (LCL 97.7%) of PCTs were ≤2 V, and 94.8% (LCL 92.7%) of sensed amplitudes were ≥5 mV. Results were stable through 24 months; 864 LBBAP implants were analyzed in the external validation cohort, and lead effectiveness was clinically indistinguishable across datasets.

CONCLUSION In this study of an active fixation, stylet-driven lead, all prespecified performance goals for pacing, sensing, and LRC rates were met when used for LBBAP. External validation demonstrated concordant results.

CLINICAL TRIAL REGISTRATION NCT06014866

KEYWORDS Complications; Conduction system pacing; Electrical performance; Left bundle branch area pacing; Stylet-driven lead

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Introduction

Left bundle branch area pacing (LBBAP) has demonstrated rapid growth because of its ability to achieve physiological activation of the left ventricle with more stable thresholds and reduced procedural time compared with His bundle pacing.¹ For years, the majority of clinical data supporting this growth

have come from a 4.1Fr lumenless lead with a fixed extended electrically active helix.² Compared with stylet-driven leads, this lumenless lead is less stiff, with lower torqueability, and its smaller diameter delivery sheath may be more prone to kinking, potentially providing less support during challenging LBBAP implants.³ Recent publications have supported the

From the ¹Duke University Hospital, Durham, North Carolina USA, ²New York Presbyterian Queens, Flushing, New York, USA, ³Community Heart and Vascular Hospital, Indianapolis, Indiana, USA, ⁴Houston Methodist Hospital, Houston, Texas, USA, ⁵TriHealth, Cincinnati, Ohio, USA, ⁶University of Chicago Medicine, Chicago, Illinois, USA, ⁷Boston Scientific, St Paul, Minnesota USA, and ⁸Essentia Health, Duluth, Minnesota, USA.

<https://doi.org/10.1016/j.hrthm.2025.01.041>

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INSIGHT-LBBAP – Key Points



Study population:

- 1122 patients, multicenter
- (8 US sites)
- LBBAP using Ingevity +
- (6Fr, stylet-driven lead)
- Real-world retrospective registry



Electrical performance

- Pacing threshold ≤2V: **98.8% at 3 months**
- R-wave ≥5 mV: **94.8%**
- Parameters stable up to 24 months



Safety (Lead reliability)

- LRC-free rate:
 - **97.7% at 3 months**
 - **97.2% at 24 months**
- Overall complications: **2.8%**



Procedural success

- LBBAP success: **95.6%**
- First-attempt success: **90.6%**
- Lead-level success: **89.6%**



Lead fracture (key point)

- **0 distal conductor fractures observed**
- 1 proximal (clavicular) fracture
- Follow-up up to ~24 months



Main complications

- Lead dislodgement: **2.3% (most common)**
- Elevated threshold/loss of capture: **0.4%**
- Oversensing: **0.1%**
- Perforation: **0.1%**



ORIGINAL ARTICLE

Implantation Success, Electrical Performance, and Safety of an Active Fixation Stylet-Driven Lead for LBBAP in Clinical Practice: A Multicenter Experience

Amato Santoro¹ | Matteo Ziacchi² | Raimondo Calvanese³ | Antonio Rapacciuolo⁴ | Mario Volpicelli⁵ | Luca Poggio⁶ | Pasquale Nocerino⁷ | Davide Castagno⁸ | Valter Bianchi⁹ | Paolo Liberato Maggiano¹⁰ | Gabriele Dell'Era¹¹ | Cosimo Mandurino¹² | Gianluca Mirizzi¹³ | Gianluca Savarese¹⁴ | Leonardo Marinaccio¹⁵ | Carmelo La Greca¹⁶ | Gregorio Covino¹⁷ | Gianluca Zingarini¹⁸ | Marco Varalda¹⁹ | Francesco Vitali²⁰ | Claudia Baiocchi¹ | Monica Campari²¹ | Sergio Valsecchi²¹ | Matteo Bertini²⁰

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Correspondence: Amato Santoro (amato.santoro@gmail.com)
Received: 23 July 2025 | Revised: 15 November 2025 | Accepted: 20 December 2025
Keywords: conduction system pacing | left bundle branch area pacing | pacemaker implantation | stylet-driven lead

ABSTRACT

Background: Left bundle branch area pacing (LBBAP) has emerged as a promising physiological pacing strategy. However, its feasibility and safety using conventional stylet-driven leads (SDL) such as INGEVITY+ remain under investigation. **Objective:** To evaluate the clinical performance, safety, and follow-up outcomes of LBBAP using the INGEVITY+ lead in a real-world electrophysiology setting. **Methods:** From 2021 to 2024, 207 consecutive patients underwent LBBAP implant attempts using the INGEVITY+ lead across 19 centers. Of these, 146 had bradycardia indications, and 61 had heart failure indications. A control group of 200 patients received standard right ventricular (RV) pacing with the same lead. Procedural outcomes, electrical parameters, complications, and mid-term lead performance were assessed. **Results:** LBBAP was successfully achieved in 201 (97%) cases. Procedural and fluoroscopy times were slightly longer for LBBAP than for RV pacing. Acute complications included one helix fracture, one atrioventricular block, and one septal perforation. During a median follow-up of 9 months, no lead fractures were reported; lead dislodgment occurred in three cases. Kaplan–Meier analysis showed no significant difference in time to first lead-related complication between the LBBAP and RV pacing groups (hazard ratio: 4.69, 95%CI: 0.63–34.90, *p* = 0.139). Electrical performance remained stable, with 98% of retained leads maintaining capture thresholds ≤ 2 V and 92% with sensed amplitudes ≥ 5 mV. **Conclusions:** LBBAP using the INGEVITY + SDL is feasible and safe in clinical practice, with excellent implant success and stable mid-term electrical performance. These findings support its use as a viable conduction system pacing strategy.

Study population

- 207 patients (LBBAP group)
- 200 control (RV pacing)
- Multicenter (19 Italian centers)
- LBBAP using Ingevity+
- 6Fr, stylet-driven lead
- Real-world retrospective study



Safety (Lead reliability)

- No lead fractures during follow-up (~9 months)
- Lead dislodgement: ~1.5% (3 cases)
- Overall low complication rate
- Similar safety vs RV pacing



Electrical performance

- Pacing threshold ≤2V: 98% at follow-up
- R-wave ≥5 mV: 92%
- Parameters stable over time
- Comparable to RV pacing



Procedural success

- LBBAP success: 97%
- LBB capture: 78%
- LV septal pacing: 22%
- Longer procedure and fluoroscopy time vs RV pacing



Main complications

- Lead dislodgement: 3 cases
- Helix fracture (acute): 1 case
- AV block: 1 case
- Septal perforation: 1 case



No long-term adverse sequelae



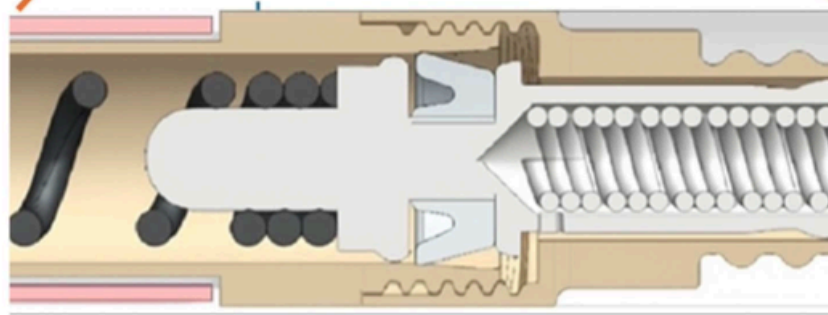
Lead fracture (key point)

- 0 lead fractures at follow-up
- Despite:
 - deep septal implantation
 - multiple screw attempts
- Preserved lead integrity

A long, thin, flexible cable with a white connector at one end and a small, cylindrical component at the other. The cable is coiled in a large loop. The white connector has a label with some text, including "SMA". The cylindrical component is also labeled with "SMA".



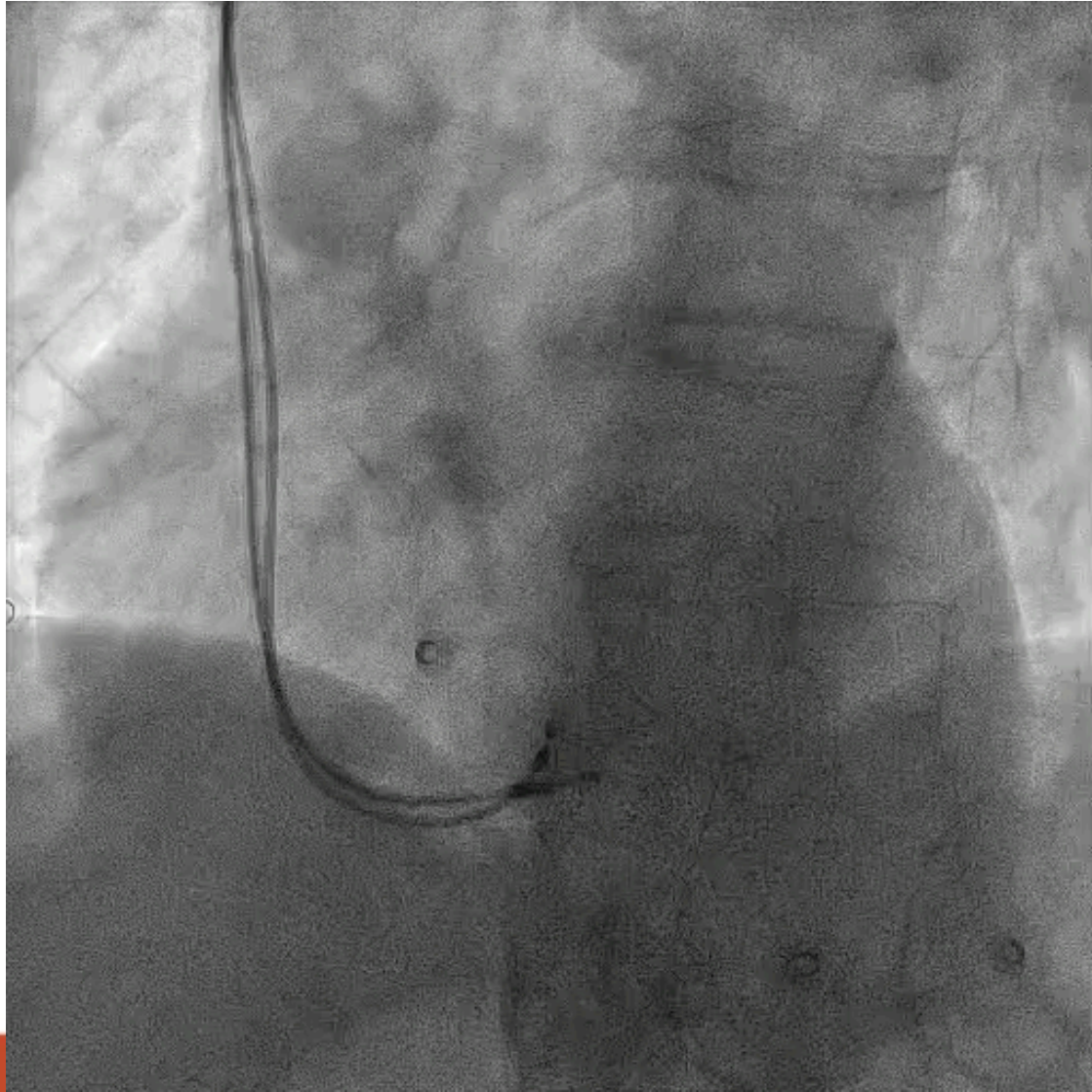
A close-up photograph of a cable assembly. On the left, a black spring is attached to a black plastic component. An orange line points from the text 'Spring' to this component. To the right, another black plastic component is connected to a braided metal shielded cable. An orange line points from the text 'Shielded cable' to this component.



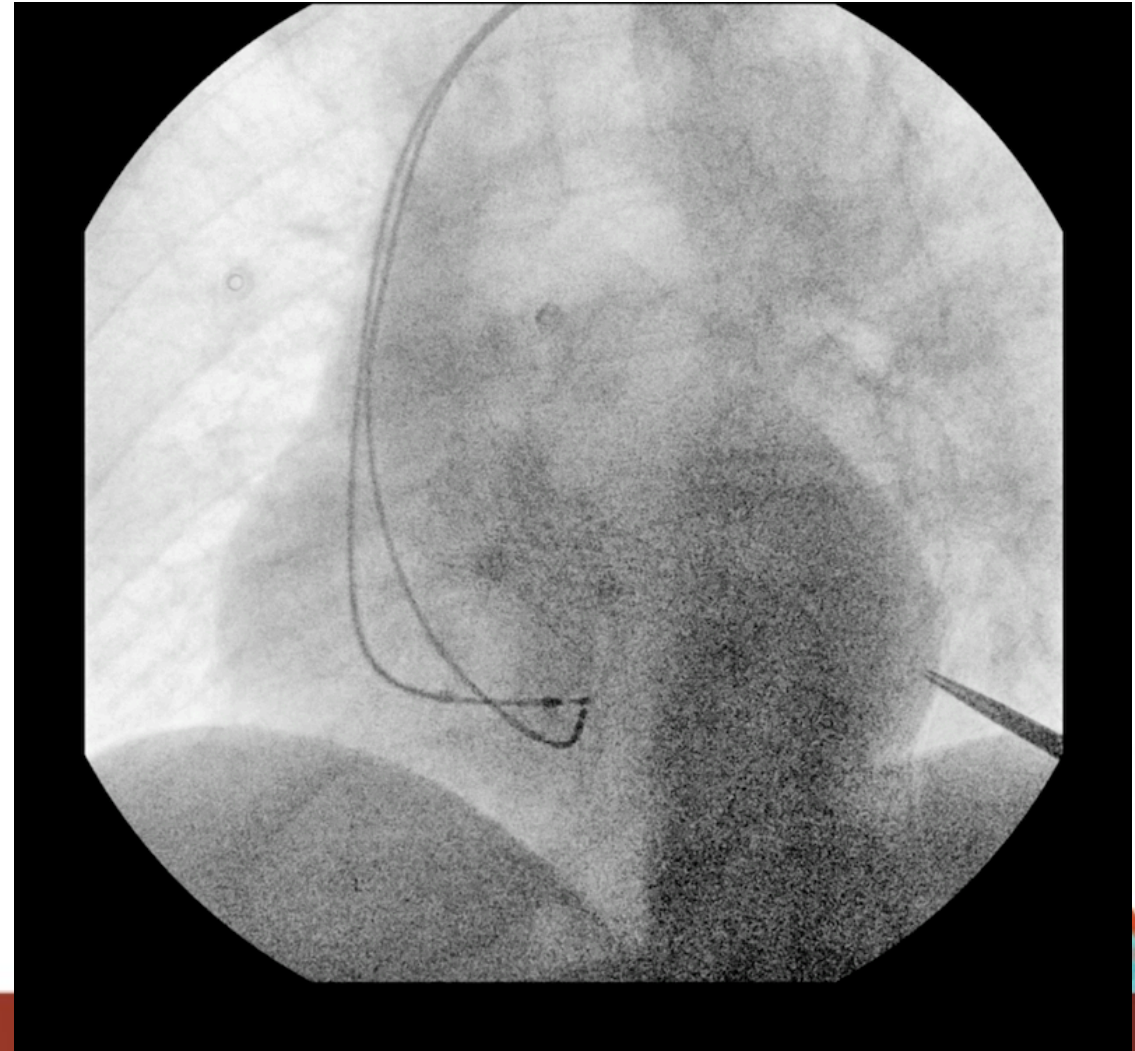
This study demonstrates that LBBAP using the INGEVITY+ SDL—a lead originally designed for conventional pacing—is feasible, safe, and effective in routine clinical practice. Implant success rates were high and complication rates remained low. Electrical performance and lead stability were comparable to standard RV pacing, with excellent mid-term follow-up outcomes. These findings support the use of INGEVITY+ as a viable option for LBBAP.

FIGURE 1 | (A) The INGEVITY+ pacing lead is a 6Fr steroid-eluting, endocardial pace/sense lead designed for permanent implantation for either atrial or ventricular applications including Left Bundle Branch Area pacing as an alternative to right ventricular pacing. (B) The site-selective pacing catheter sheaths family includes four fixed curve sheaths. (C) Distal tip fluoroscopic view and coupler joint design.

SPCC 2 perpendicolarità atrio normale



SPCC 2 ricerca della perpendicolarità

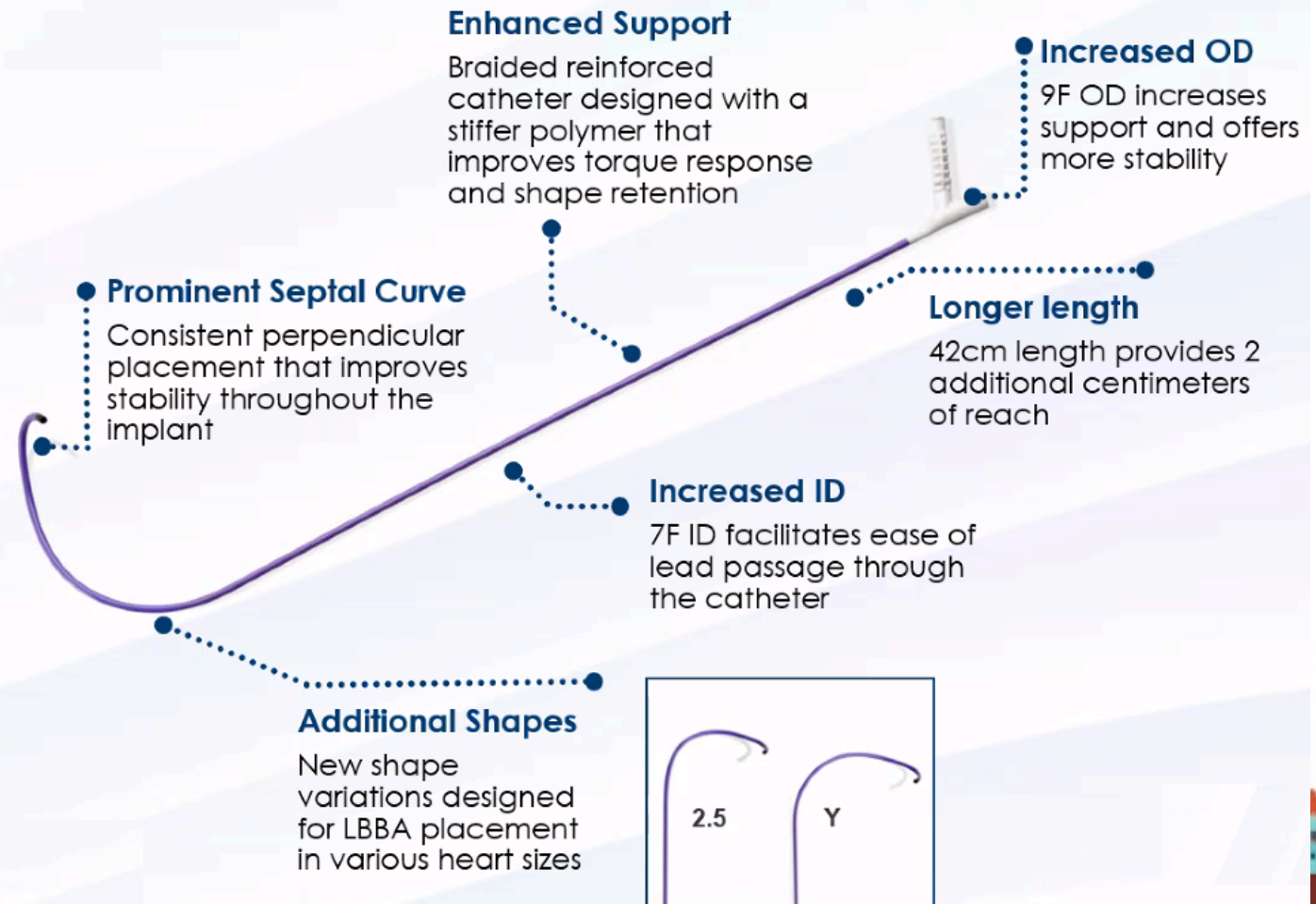




Specifications

Product Feature	SSPC	SSPC NXT
Outer Diameter	8Fr	9 Fr
Inner Diameter	6.5 Fr	7 Fr
Working Length	40 cm	42 cm
Hydrophilic Inner Coating	+	++
Support	++	+++
Septal Curve	++	+++
Hub	Purple	White
Hemostatic Valve	✓	✓
Dilator in Packaging	✓	✓

Features of SSPC NXT





Site Selective Pacing Catheter Portfolio

SSPC & SSPC NXT

Boston
Scientific

SSPC



SSPC 1

SSPC 2

SSPC 3

SSPC 4

Model	Name	Length
9181	SSPC 1	40cm
9182	SSPC 2	40cm
9183	SSPC 3	40cm
9184	SSPC 4	40cm



SSPC NXT



SSPC NXT 2.5

SSPC NXT Y

Model	Name	Length
9286	SSPC NXT 2.5	42cm
9287	SSPC NXT Y	42cm





Optimal Zones for LBBP

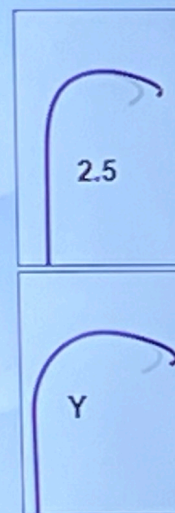
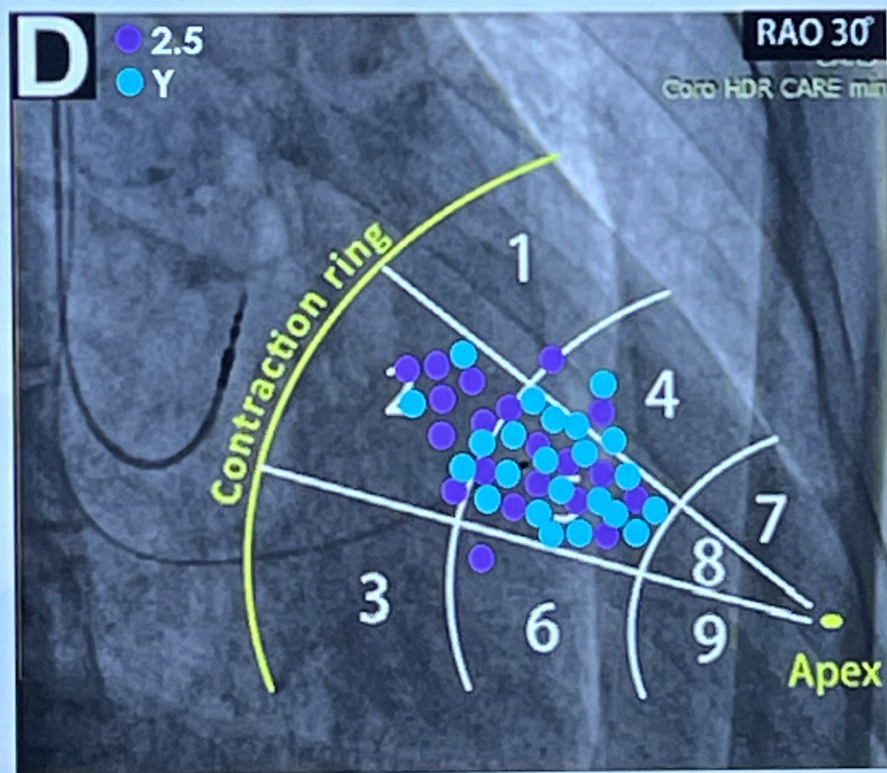
Results from 9 Partition and LME

Boston
Scientific

9 Partition Method Results



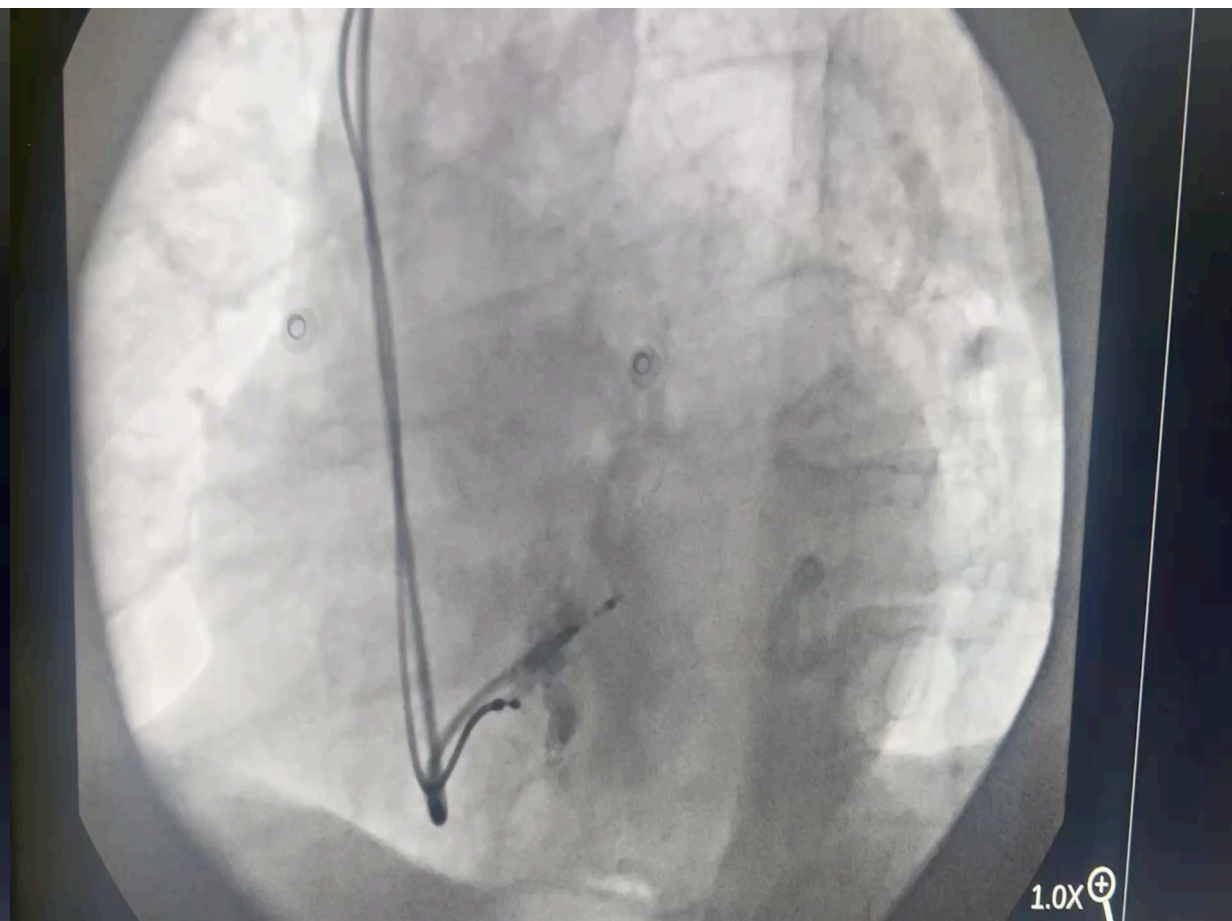
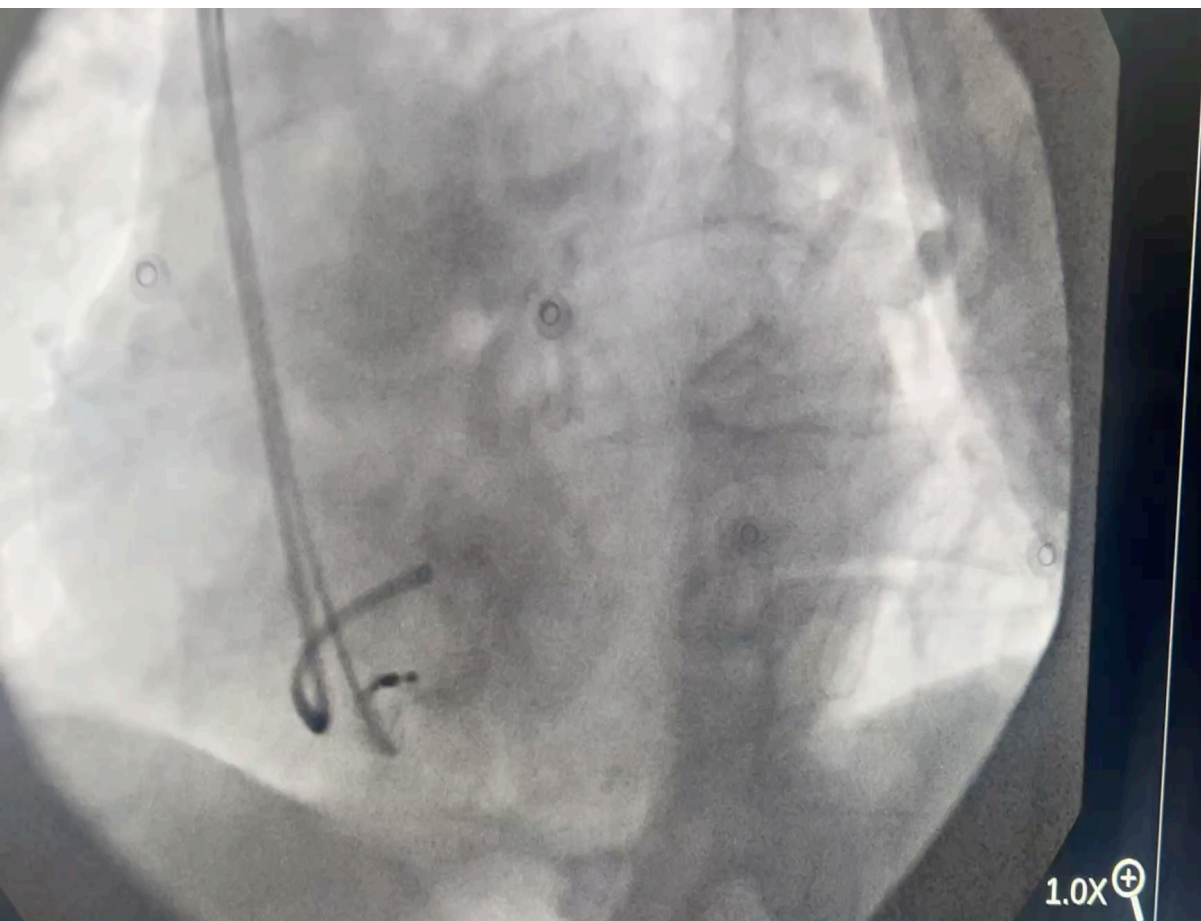
SSPC NXT LME Results

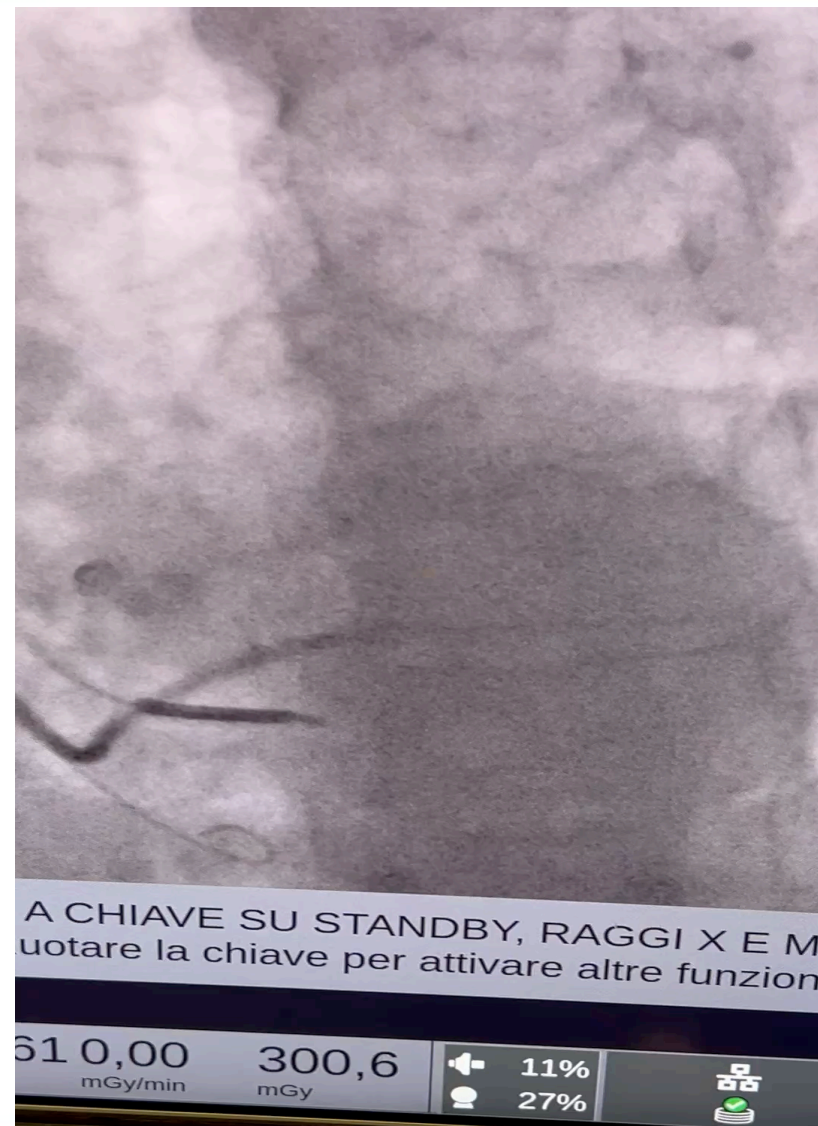
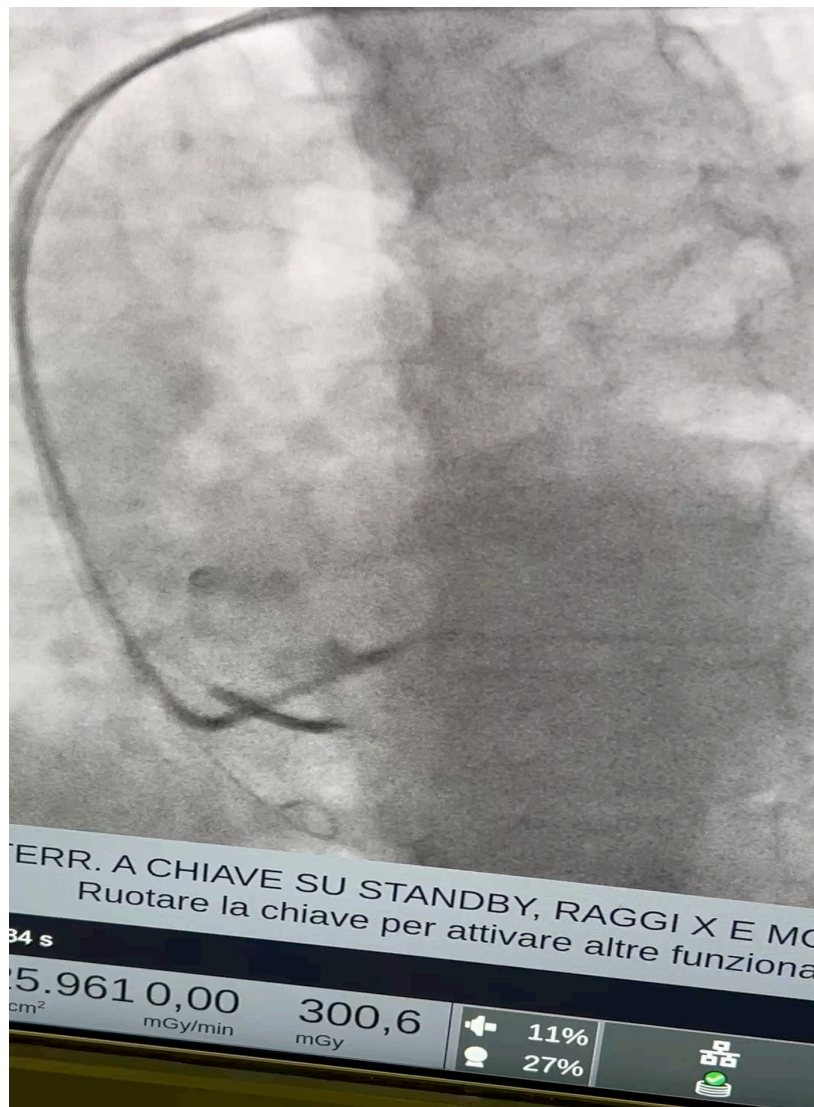


Location of distal catheter tip is not reflective of where the lead was placed in that zone

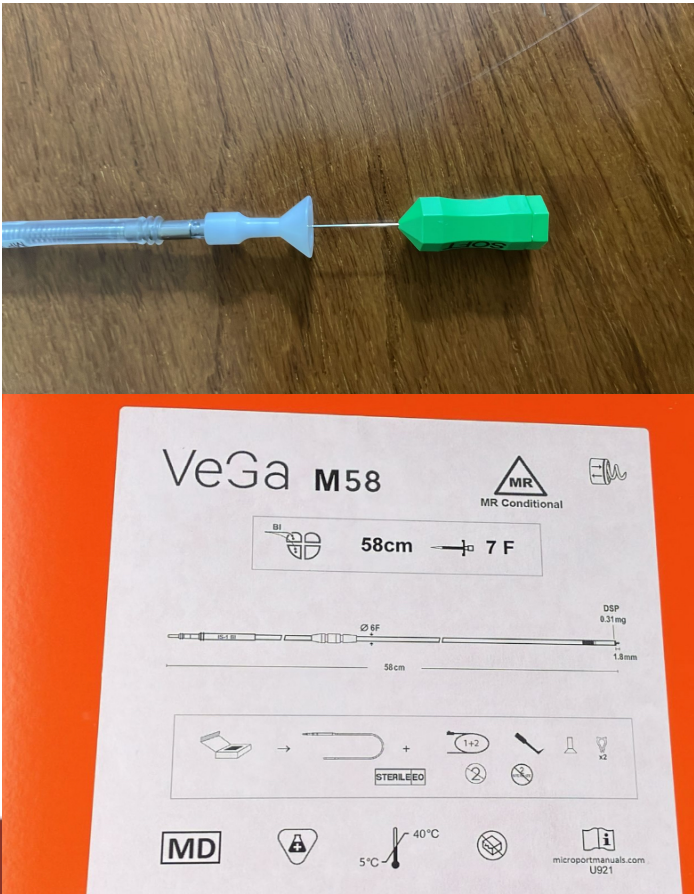


NXT





Microport



Microport

VEGA R58

- Lunghezza 58 cm
- Vite retraibile da **1,5 mm**
- Superficie di stimolazione **4 mm²**

VEGA M58

- Lunghezza 58 cm
- Vite retraibile da **1,8 mm**
- Superficie di stimolazione **5,85 mm²**

Quindi la **M58** non è semplicemente un'altra lunghezza:

Cosa cambia realmente?



Elica più lunga

- 1,8 mm vs 1,5 mm
- Maggiore penetrazione nel tessuto



Elettrodo distale più grande

- 5,85 mm² vs 4 mm²
- Maggiore superficie di contatto



Sistema di blocco della vite

- Nella confezione del modello M58 è presente un imbuto dedicato che

Clinical Performance and Lead Reliability of the VegaM Lead in Conduction System Pacing Compared With the Vega Lead in Right Ventricular Pacing: A Multicenter Observational Study: in progress.....

Study Objective

To evaluate the clinical performance, electrical stability, and lead reliability of the **VegaM lead in conduction system pacing (CSP)** compared with the **Vega lead in conventional right ventricular pacing (RVP)**.

Study Population

CSP Group

- VegaM lead
- LBBAP or left ventricular septal pacing

Control Group

- Vega lead
- Right ventricular pacing

Inclusion Criteria

- Ventricular implantation
- Available device interrogation
- At least one follow-up evaluation

Exclusion Criteria

- No follow-up
- Non-ventricular lead position

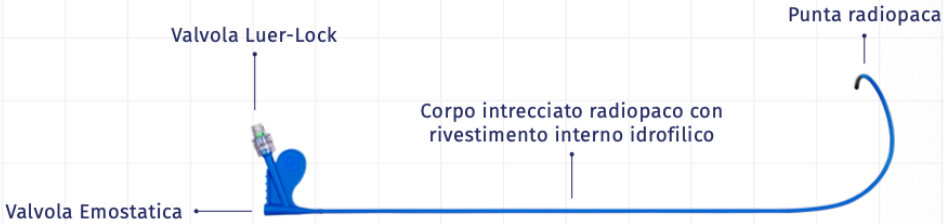
Procedural Data Collection

- Type of pacing strategy
- Type of CSP
- Procedure duration
- Fluoroscopy time
- Venous access and generator side
- Number of lead attempts
- Number of leads used
- Number of lead repositionings
- Number of screw attempts
- Implant depth (when available)
- Procedural success and bailout strategy

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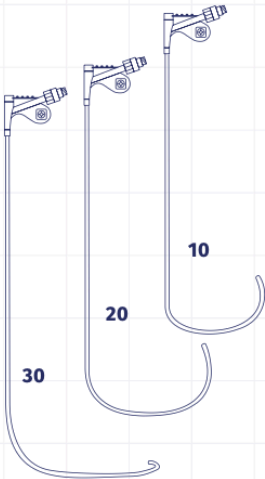


Microport



Ampia gamma 3D

3 Forme

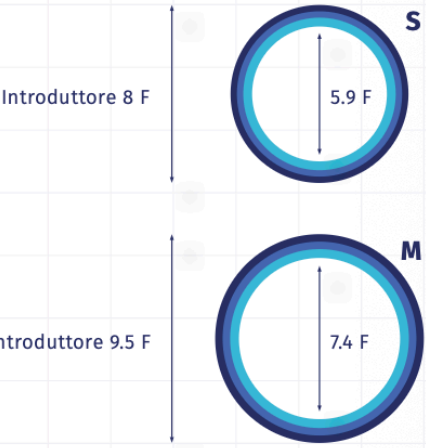


Forma 10
Progettato per cuori piccoli

Forma 20
Progettato per cuori normali

Forma 30
Progettato per cuori grandi o dilatati

2 Diametri



¹ 99% DEI MEDICI HA ESPRESSO SODDISFAZIONE PER LA RISPOSTA ALLA TORSIONE DEL CATETERE DURANTE LA VALUTAZIONE CLINICA (STUDIO POLARIS).
² 99% DEI MEDICI HA ESPRESSO SODDISFAZIONE PER L'ADEGUATEZZA DELLA FORMA DEL CATETERE DURANTE LA VALUTAZIONE CLINICA (STUDIO POLARIS).
³ 100% DEI MEDICI HA ESPRESSO SODDISFAZIONE PER LA RESISTENZA AL KINCKING DEL CATETERE DURANTE LA VALUTAZIONE CLINICA (STUDIO POLARIS)

Una nuova gamma per l'impianto LBBAP

- ✓ **Semplice** – Navigazione senza sforzo grazie al catetere guida flessibile e supportivo, per un posizionamento preciso dell'elettrocattetere.^{1,2}
- ✓ **Mirato** – Progettato per garantire un'accuratezza anatomica e un accesso LBBAP personalizzato per il paziente.²
- ✓ **Supportivo** – Intreccio rinforzato in materiale termoplastico per una resistenza superiore al kincking.³

Specifiche

Catetere guida

				FLEXIGO 3D S				FLEXIGO 3D M			
MODELLO				S10-40	S20-40	S30-40	S10-45	S20-45	S30-45	M20-41	M30-41
LUNGHEZZA DEL CATETERE				40 cm			45 cm			41 cm	
LUNGHEZZA DEL DILATATORE				45 cm			50 cm			46 cm	
DIAMETRO INTERNO				5.9 F (1.98 mm)						7.4 F (2.49 mm)	
INTRODUTTORE MINIMO RICHIESTO				8 F						9.5 F	
FILO GUIDA				Compatibile con guida da 0,035" (non inclusa)							
MATERIALE				PEBAX® con rivestimento interno idrofilico							
PUNTA RADIOPACA				Si							
PUNTA ATRAUMATICA				Si							
TAGLIERINA COMPATIBILE				Taglierina FLEXIGO S						Taglierina FLEXIGO M	

NELLA CONFEZIONE DEL CATETERE GUIDA FLEXIGO 3D È CONTENUTO 1 CATETERE, 1 DILATATORE E 2 STRUMENTI TVI (TRANS VALVULAR INSERTION TOOL - STRUMENTO DI INSERIMENTO TRANS-VALVOLARE).

Taglierina

		FLEXIGO Slitter S						FLEXIGO Slitter M	
MATERIALE	IMPUGNATURA	Policarbonato							
	LAMA	Acciaio inox							
CATETERE FLEXIGO 3D COMPATIBILE		S10-40	S20-40	S30-40	S10-45	S20-45	S30-45	M20 – 41	M30 - 41
DIAMETRO DELL'ELETTROCATETERE DA STIMOLAZIONE COMPATIBILE		4.1 - 4.8 F						5.6 - 6 F	

LA TAGLIERINA FLEXIGO È FORNITA IN UNA CONFEZIONE SEPARATA

LBBOT clinical trial

Left Bundle Branch Area Pacing (LBBAP) Monitoring Assistant: Evaluation of Portable ECG Solution (LBBOT)
ClinicalTrials.gov ID NCT07254013 **Sponsor** MicroPort CRM

Study Overview

Brief Summary

To evaluate the capability to monitor LBB success criteria with the use of a Smart ECG system (ECG monitor, 12 leads ECG cable, ECG viewer software) during a cardiac device implantation involving the placement of a pacing lead in interventricular septum area

Detailed Description

The clinical investigation aims to support physicians with a portable and easy to use solution to display ECG and to provide automatic calculation of key ECG indicators (Left Ventricular Activation time (LVAT) and V6-V1 interval) for LBB implantation procedure. This allows physicians to concentrate on lead placement with the benefice from immediate ECG measurements thanks to the automatic software.

The Smart ECG system is class IIA device and it is composed of:

1. CE-marked Smart ECG, Class Ila medical device (rule 10 Annex VIII of MDR)
2. ECG viewer Software (HookUp SmarV2) (providing 12 lead ECG display + automatic interval measurements + shadow plot for QRS visualization) Class Ila medical device (rule 11 Annex VIII of MDR).
3. CE -marked 12 leads ECG cables radiotransparent and defibrillation proof (Class I device)
4. Commercial PC used in combination with the devices under evaluation

The study is a pre-market, non-pivotal study: HookUp Smart V2 software is a non-implantable Class IIA device, with no interaction with the human body and the demonstration of conformity with general safety and performance requirements is based on the results of non-clinical testing methods alone (as article 61(10) from MDR.

Inclusion criteria:

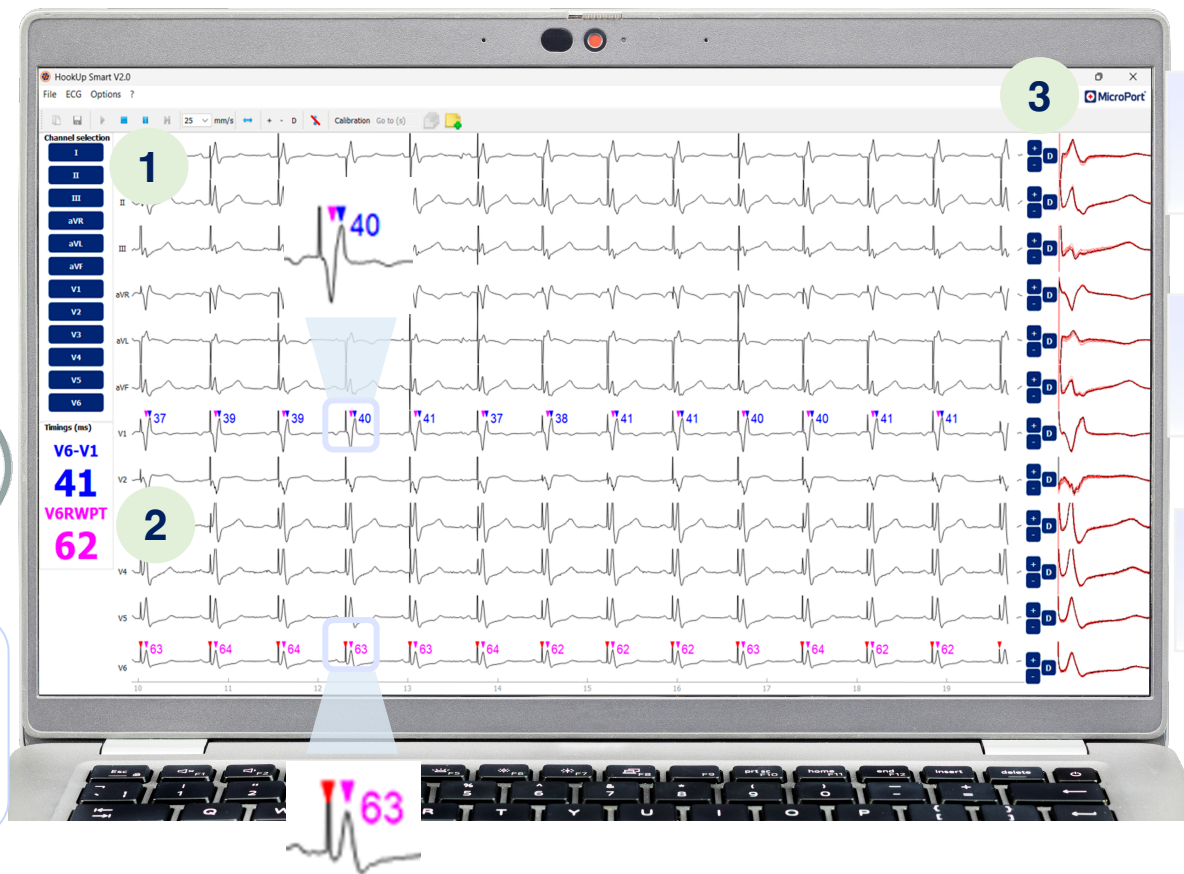
Subject with indication for LBBAP using an Electrophysiology ECG monitoring system (EP System) as part of pacemaker or CRT-P or CRT-D implant procedure (de novo implant, device revision or upgrade including LOT-CRT)



Microport

A white rectangular device labeled "SMART ECG" and "phySO HUB" is connected to a bundle of white cables. The cables are coiled and end in black clips with colored bands (green, yellow, red, black). A Bluetooth symbol and signal waves are shown to the right of the cables.

- ## Cavo ECG radiotrasparente



3. Shadow Plot offre una visione della morfologia del complesso QRS, battito-battito

Microport

Pairing SmartECG-laptop

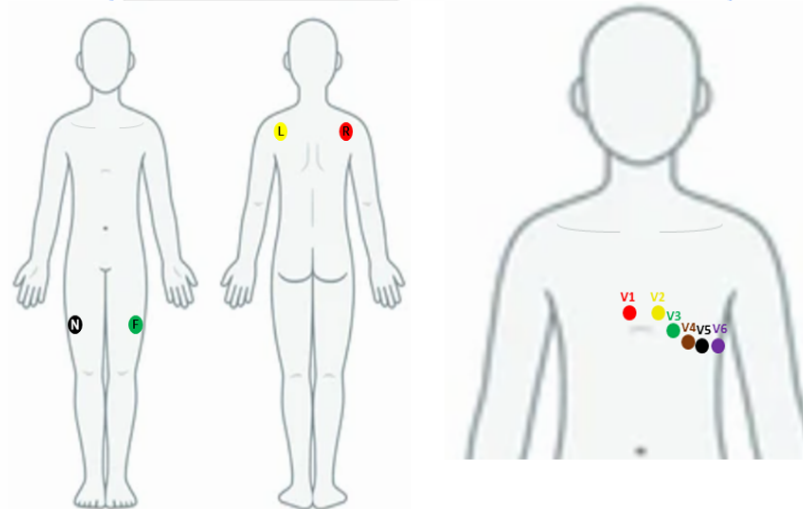
Attivare l'accoppiamento
BlueTooth tra SmartECG e
laptop



Smart ECG deve essere
posizionato entro un raggio di 3
metri dal PC

Preparazione del paziente

Attivare l'accoppiamento
BlueTooth tra SmartECG e
laptop



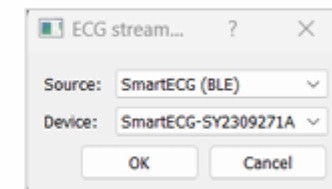
Posizionamento standard
degli elettrodi a 12
derivazioni

Start del software HookUp Smart

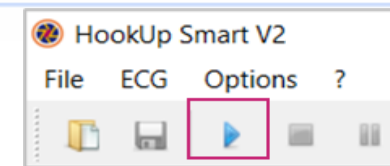
Avvio del SW
HookUp Smart



Controllare il dispositivo
SmartECG accoppiato



Avviare la visualizzazione



Dettagli sulle funzionalità del sw HookUp Smart di LBBOT

1. Barra strumenti

Comandi riproduzione (Avvia, Pausa, Interrompi, Tempo reale)

Velocità di scorrimento (25-200 mm/s) e regolazione della scala

Calibri e strumenti di misurazione

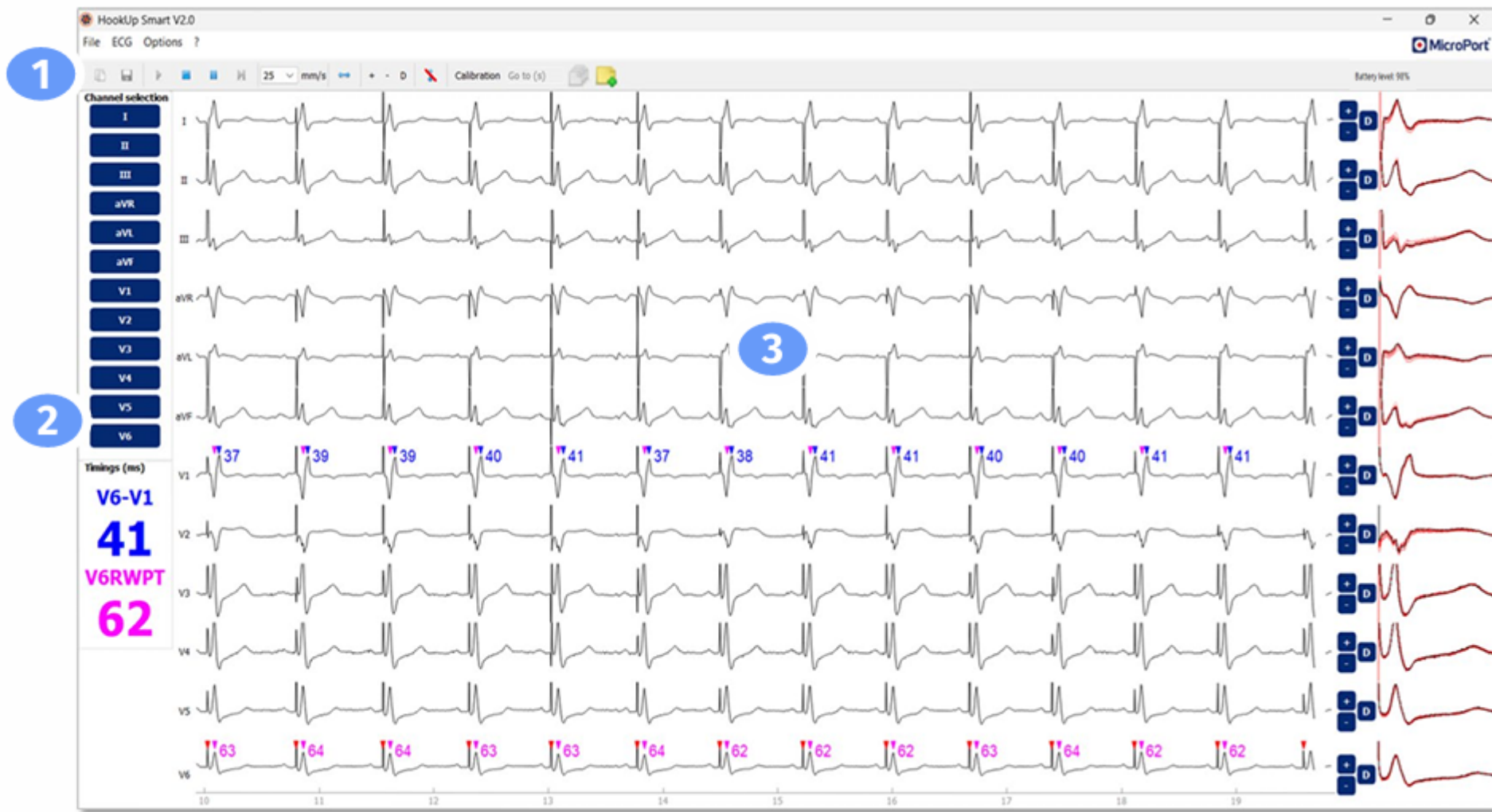
2. Selezione e layout delle derivazioni ECG

Selezione e sequenza delle derivazioni

Personalizzazione display

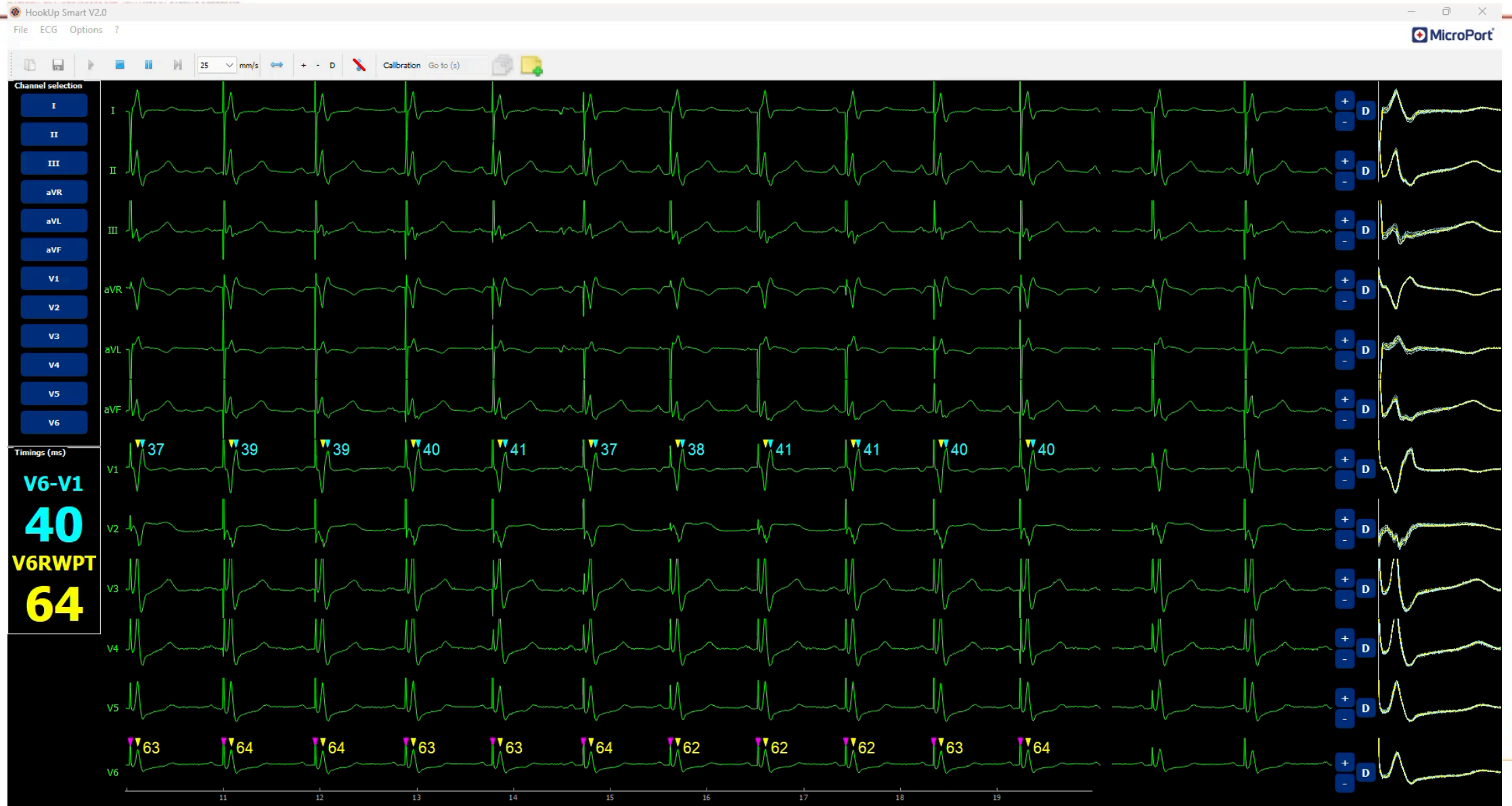
3. ECG real-time

Visualizzazione continua dell'ECG a 12 derivazioni



Microport

LBOT: visualizzazione in real-time



Take Home Message

«We shape our tools, and thereafter our tools shape us» Marshall

McLuhan.....

The next challenge is not simply implanting CSP...It 'is understanding when and how to perform it correctly

