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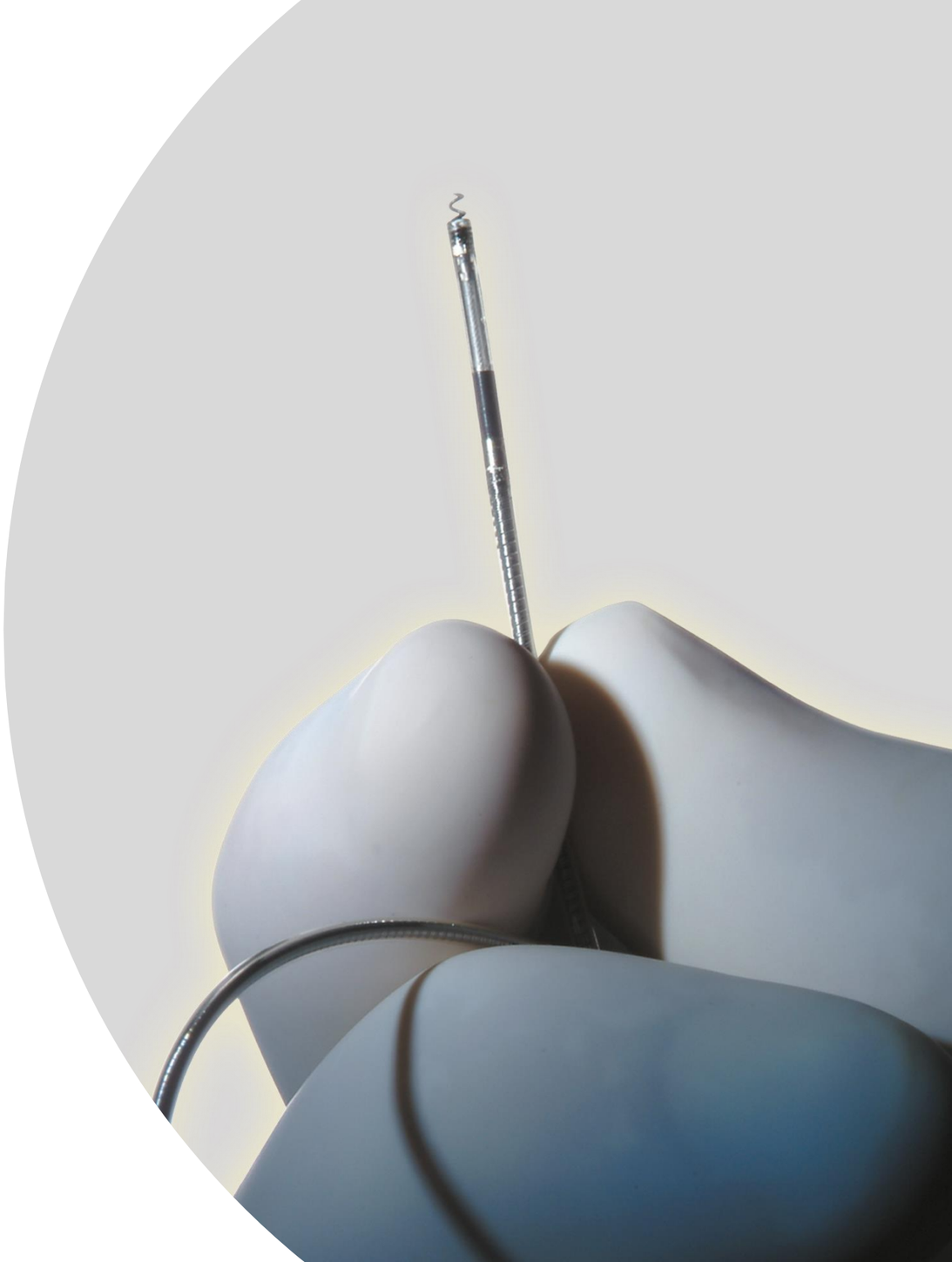
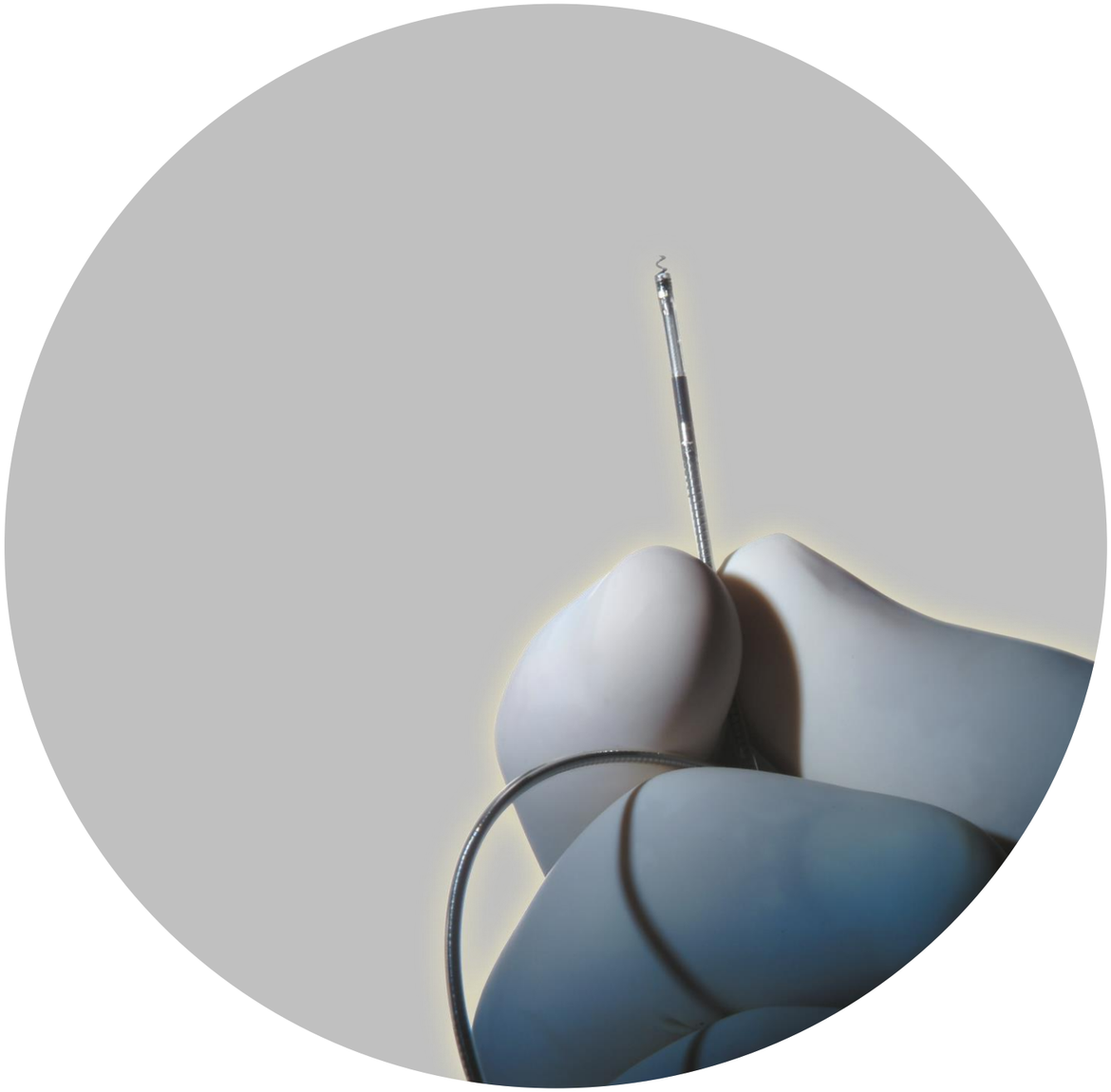
Sonde 3830 SelectSecure™



260 000+ patients

implantés au cours des **20** dernières années



1. WW sales as of 14 Jul 2021

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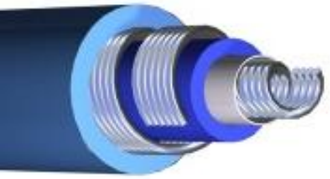
Comparaison sonde avec mandrin vs sonde sans lumière interne



Sonde avec mandrin et lumière

- Nécessité d'avoir un espace vide pour la lumière du mandrin, ce qui augmente le diamètre extérieur de 25% pour une sonde de 6 Fr

Avantage

- Aucun changement dans la procédure d'implantation / extraction

Inconvénients

- Possible rupture du conducteur interne aux endroits avec courbures importante et contraintes élevées
- Complexité de devoir gérer le mandrin et le cathéter en parallèle lors de l'implantation

Sonde sans lumière

- Utilisation efficace de l'espace interne de la sonde
- Le câble distal occupe l'espace central

Avantages

- Pas de spirale : pas de fracture du conducteur interne
- Nécessite uniquement un cathéter pour l'implantation
- Résistance à la traction sur le corps de sonde avec le câble conducteur interne
- Extraction sans mandrin bloqueur

Différence

- Modification de la procédure d'implantation/ extraction

Sonde de stimulation cardiaque bipolaire droite la plus fine du monde

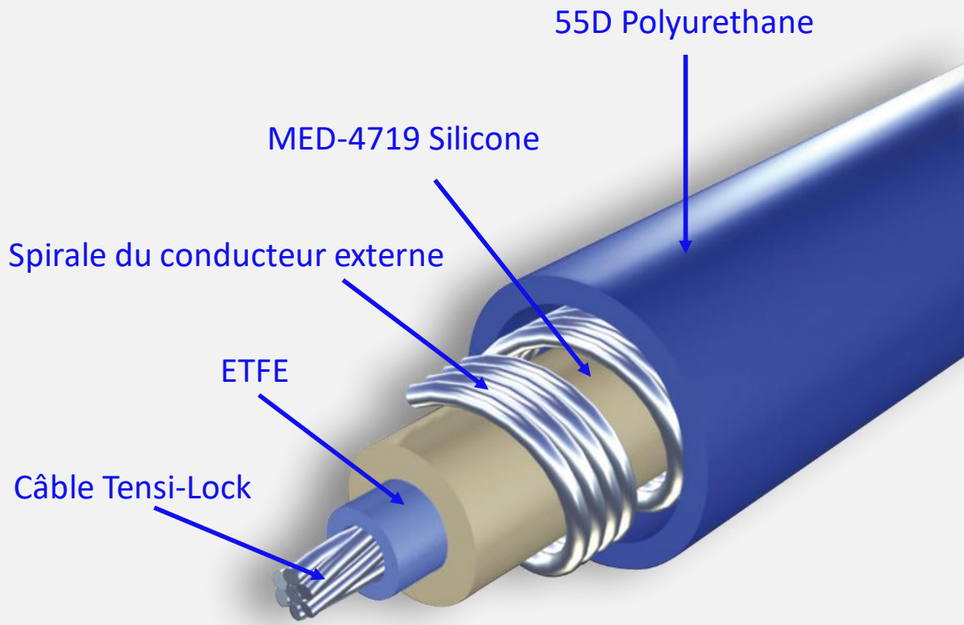
- Petite, sans lumière, et d’un diamètre de seulement 4,1 French, elle facilite l'implantation de plusieurs sondes dans le système veineux
- Bipolaire, conçue pour réduire la détection de bruit (far-field) avec un espacement court de 9 mm entre la vis et l’anneau
- Faible polarisation entre la vis et le tissu grâce à des électrodes recouvertes de nitrure de titane (TiN)
- Vis fixe électriquement active et recouverte de stéroïdes
- Compatible IRM
- Longueurs : 49, 59, 69 cm

Conçue pour une fiabilité accrue

- La redondance des isolants internes protège le câble interne pour plus de fiabilité
- L'isolation interne en silicone MED-4719 (exclusif à Medtronic) est spécialement conçue pour les sondes de stimulation afin d'assurer la stabilité du matériau et de maintenir l'intégrité à long terme de la sonde.
- Le petit corps de sonde de 4,1Fr minimise le risque d'écrasement au niveau de la pince costo-claviculaire.

Performance[2]

- Placement au niveau du His: 91,6% de survie @ 5 ans
- Placement auriculaire : 96,2% de survie @11,5 ans
- Placement ventriculaire : 97,0% de survie @10,5 ans

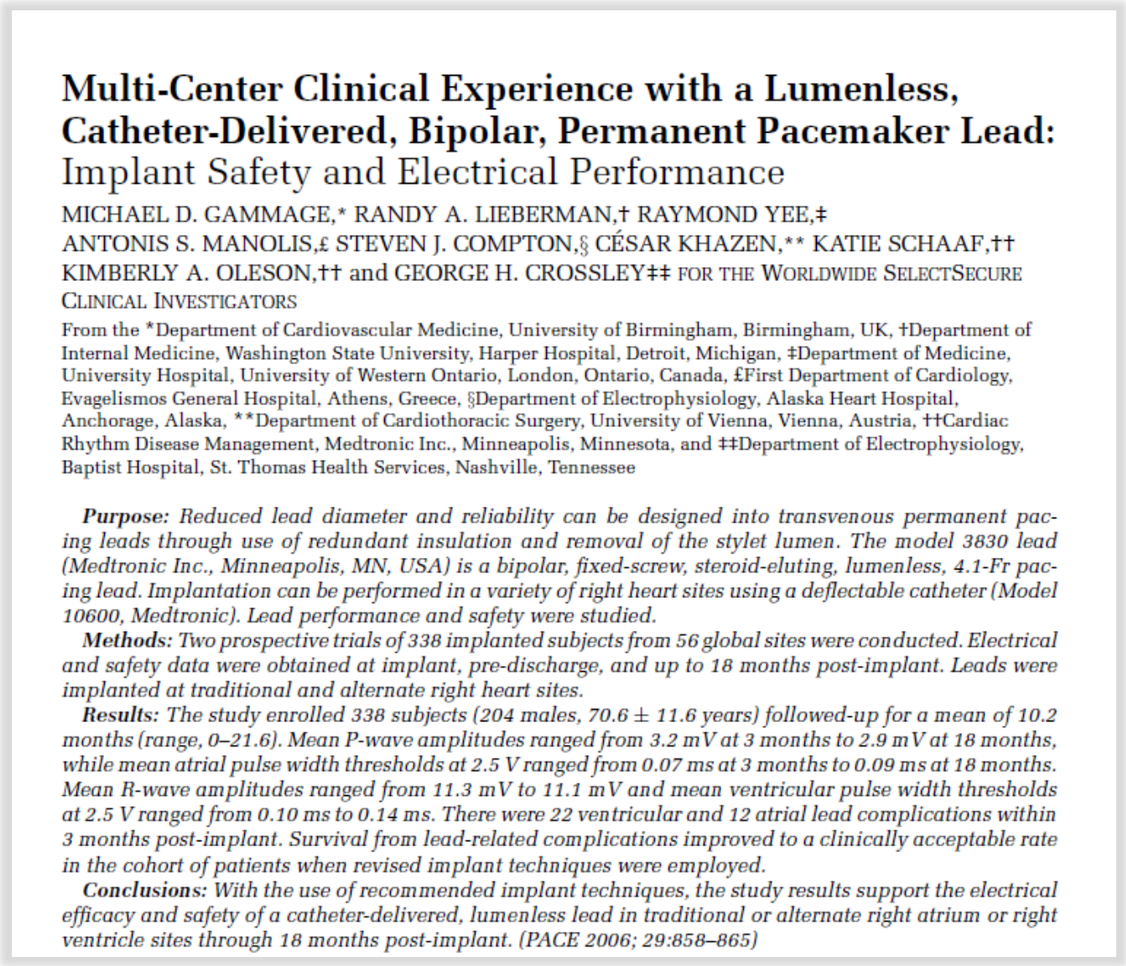


Section transversale montrant la construction du corps de la sonde

1. Compared to Medtronic stylet delivered lead Model 5076
2. Source: Product performance report Jul. 2021

Évidences cliniques

- 113 publications avec des données sur la sécurité et les performances publiés depuis 2005[1]
- Entre juin 2002 et mai 2003, étude IDE pré-commercialisation avec 338 patients avec 632 sondes[2]
- 4 909 sondes dans le registre de surveillance du produit[3]



Multi-Center Clinical Experience with a Lumenless, Catheter-Delivered, Bipolar, Permanent Pacemaker Lead: Implant Safety and Electrical Performance

MICHAEL D. GAMMAGE,* RANDY A. LIEBERMAN,† RAYMOND YEE,‡ ANTONIS S. MANOLIS,£ STEVEN J. COMPTON,§ CÉSAR KHAZEN,** KATIE SCHAAF,†† KIMBERLY A. OLESON,†† and GEORGE H. CROSSLEY‡‡ FOR THE WORLDWIDE SELECTSECURE CLINICAL INVESTIGATORS

From the *Department of Cardiovascular Medicine, University of Birmingham, Birmingham, UK, †Department of Internal Medicine, Washington State University, Harper Hospital, Detroit, Michigan, ‡Department of Medicine, University Hospital, University of Western Ontario, London, Ontario, Canada, £First Department of Cardiology, Evagelismos General Hospital, Athens, Greece, §Department of Electrophysiology, Alaska Heart Hospital, Anchorage, Alaska, **Department of Cardiothoracic Surgery, University of Vienna, Vienna, Austria, ††Cardiac Rhythm Disease Management, Medtronic Inc., Minneapolis, Minnesota, and ‡‡Department of Electrophysiology, Baptist Hospital, St. Thomas Health Services, Nashville, Tennessee

Purpose: *Reduced lead diameter and reliability can be designed into transvenous permanent pacing leads through use of redundant insulation and removal of the stylet lumen. The model 3830 lead (Medtronic Inc., Minneapolis, MN, USA) is a bipolar, fixed-screw, steroid-eluting, lumenless, 4.1-Fr pacing lead. Implantation can be performed in a variety of right heart sites using a deflectable catheter (Model 10600, Medtronic). Lead performance and safety were studied.*

Methods: *Two prospective trials of 338 implanted subjects from 56 global sites were conducted. Electrical and safety data were obtained at implant, pre-discharge, and up to 18 months post-implant. Leads were implanted at traditional and alternate right heart sites.*

Results: *The study enrolled 338 subjects (204 males, 70.6 ± 11.6 years) followed-up for a mean of 10.2 months (range, 0–21.6). Mean P-wave amplitudes ranged from 3.2 mV at 3 months to 2.9 mV at 18 months, while mean atrial pulse width thresholds at 2.5 V ranged from 0.07 ms at 3 months to 0.09 ms at 18 months. Mean R-wave amplitudes ranged from 11.3 mV to 11.1 mV and mean ventricular pulse width thresholds at 2.5 V ranged from 0.10 ms to 0.14 ms. There were 22 ventricular and 12 atrial lead complications within 3 months post-implant. Survival from lead-related complications improved to a clinically acceptable rate in the cohort of patients when revised implant techniques were employed.*

Conclusions: *With the use of recommended implant techniques, the study results support the electrical efficacy and safety of a catheter-delivered, lumenless lead in traditional or alternate right atrium or right ventricle sites through 18 months post-implant. (PACE 2006; 29:858–865)*

Étude pré-commercialisation IDE

1. Literature review 21 Mar 2022 – Medtronic data on file
2. Gammage MD, Lieberman RA, Yee R, et al. Multi-center clinical experience with a lumenless, catheter-delivered, bipolar, permanent pacemaker lead: Implant safety and electrical performance. PACE Pacing Clin Electrophysiol. 2006;29(8):858-865.
3. Medtronic data on file

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Performances pour la stimulation hissienne

Image HBP

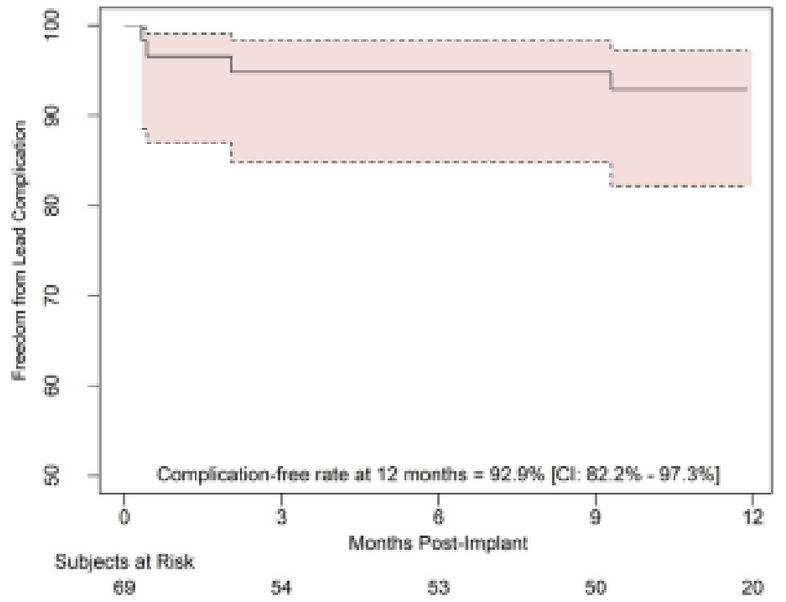
TABLE 2 Electrical Performance By Lead Location

	Atrial Side (n = 11)*	Ventricular Side (n = 40)*
Selective HBP at implantation	4 (36)	11 (28)
Nonselective HBP at implantation	7 (64)	28 (70)
PT		
HB PT at implantation, V		
Protocol-defined HBP successes, n = 43	1.4 ± 0.4	1.0 ± 0.5
Unsuccessful HBP per protocol, n = 8	3.8 ± NA	3.1 ± 0.5
Lowest PT at implantation, V†		
Protocol-defined HBP successes, n = 43	1.1 ± 0.5	0.8 ± 0.4
Unsuccessful HBP per protocol, n = 8	0.8 ± NA	1.4 ± 1.1
HB PT at 12 months, V		
Stable implantations, n = 41	1.1 ± 0.5	1.3 ± 0.6
With loss of His capture or PT >2.5 V at 12 months, n = 3	3.0 ± NA	3.0 ± NA
Lowest PT at 12 months, V†		
Stable implantations, n = 41	1.1 ± 0.5	1.2 ± 0.6
With loss of His capture or PT >2.5 V at 12 months, n = 3	2.1 ± NA	3.0 ± NA
Number with Δ HB PT >1V by 12 months	2 (20)	2 (6)
Impedance, Ω		
Implantation	511.5 ± 47.8	501.2 ± 79.3
12 months)	454.1 ± 124.3	426.9 ± 64.2
R-wave amplitude, bipolar only, mV		
Implantation	2.2 ± 0.9; n = 10	3.6 ± 1.9; n = 35‡
12 months	2.9 ± 1.3; n = 7	4.5 ± 2.4; n = 24
P/R ratio, Holter recording	0.17 ± 0.15; n = 8	0.07 ± 0.06; n = 22‡
HV interval, ms	46.4 ± 11.1	47.1 ± 10.7
QRS duration at final programmed output, ms		
Implant	121.6 ± 19.4	121.7 ± 21.0
12 months	113.0 ± 18.3	121.2 ± 21.8

Values are n (%) or mean ± SD. *Sample sizes at 12 months for the atrial side = 10 and for the ventricular side = 34. †Lowest PT is the minimum of the HB PT and either the nonselective PT for selective implantations or the RV PT for nonselective implantations. ‡$p < 0.05$.

NA = not applicable; PT = pacing thresholds; other abbreviations as in Table 1.

FIGURE 4 Kaplan-Meier Curve of Lead-Related Complication-Free Rate



Kaplan-Meier curve of lead-related complication-free rate for all patients undergoing implantation attempt is shown. The **solid line** shows the Kaplan-Meier estimate, and the **dashed line** shows the 95% confidence interval (CI).

Imaging-Based Localization of His Bundle Pacing Electrodes Results From the Prospective IMAGE-HBP Study. Vijayaraman. J Am Coll Cardiol EP 2021;7:73–84.

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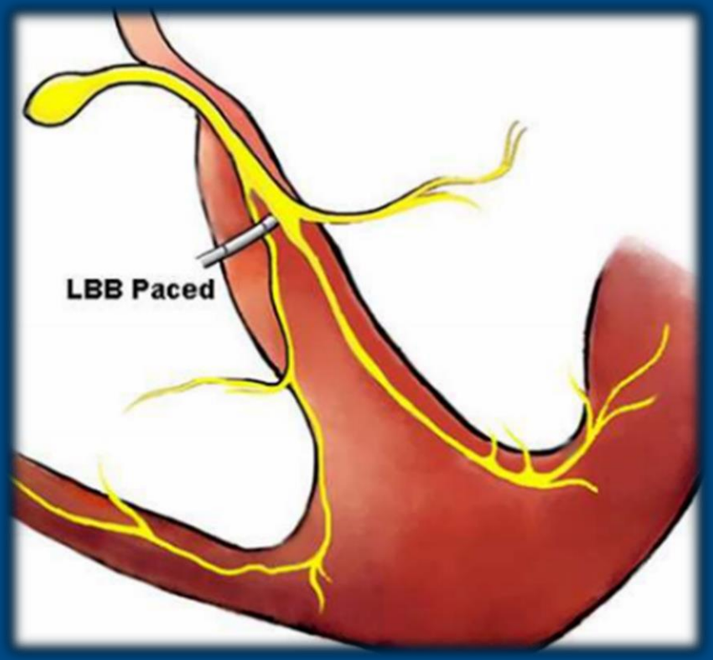
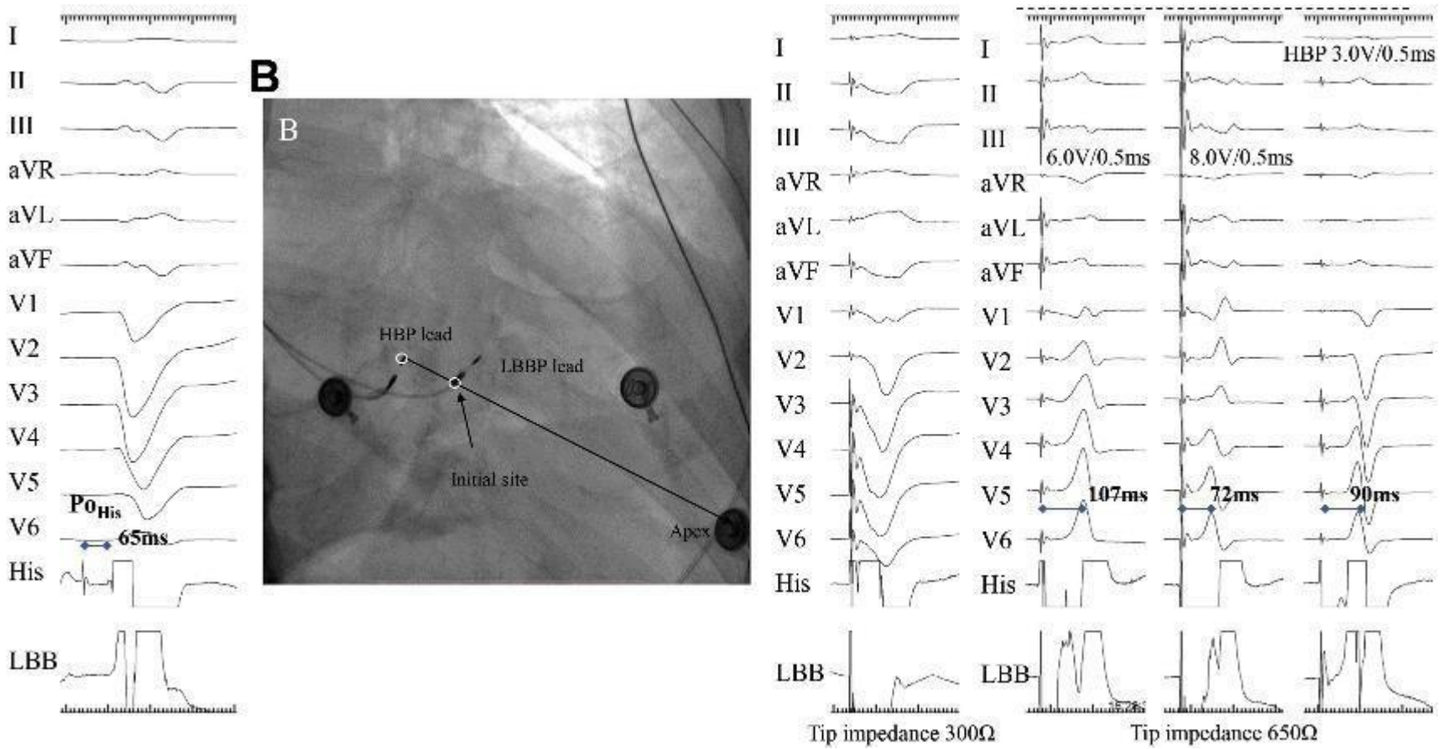
STIMULATION DE LA BRANCHE GAUCHE

PROCÉDURE D'IMPLANTATION





Performances pour la stimulation de la branche gauche

1 Patients avec indication de resynchronisation

TABLE 2 Procedural Outcomes

Procedural outcomes			
Total number of successful cases		277 (85)	
Procedure duration (min)		105 ± 54	
Fluoroscopy duration (min)		19 ± 15	
LBBP lead fluoroscopy time (n = 153) (min)		16 ± 13	
Type of device			
CRT		162 (58)	
CRT pacemaker		56 (20)	
CRT defibrillator		106 (38)	
Dual-chamber defibrillator		5 (2)	
Dual-chamber pacemaker (DDD)		87 (31)	
Single-chamber pacemaker (VVI)		23 (8)	
Pacing characteristics	Baseline	Follow-up	p value
R-wave amplitude (mV)	10.6 ± 6	12.5 ± 5.7	0.06
Impedance (Ω)	674 ± 193	530 ± 123	<0.001
LBBP threshold (V at 0.5 ms)	0.6 ± 0.3	0.7 ± 0.3	0.17
Stimulus to peak LV activation time (ms)	83 ± 16		
Complications			
Pneumothorax		3 (1)	
Pericardial effusion		0	
Device infection		2 (0.7)	
Stroke		0	
LV perforation		0	
Lead dislodgement		7 (2.5)	
Loss of left septal capture		2 (0.7)	

Values are n (%) or mean ± SD.
CRT = cardiac resynchronization therapy; LBBP = left bundle branch pacing; LV = left ventricular.

2 Patients avec indication de resynchronisation ou de stimulation cardiaque

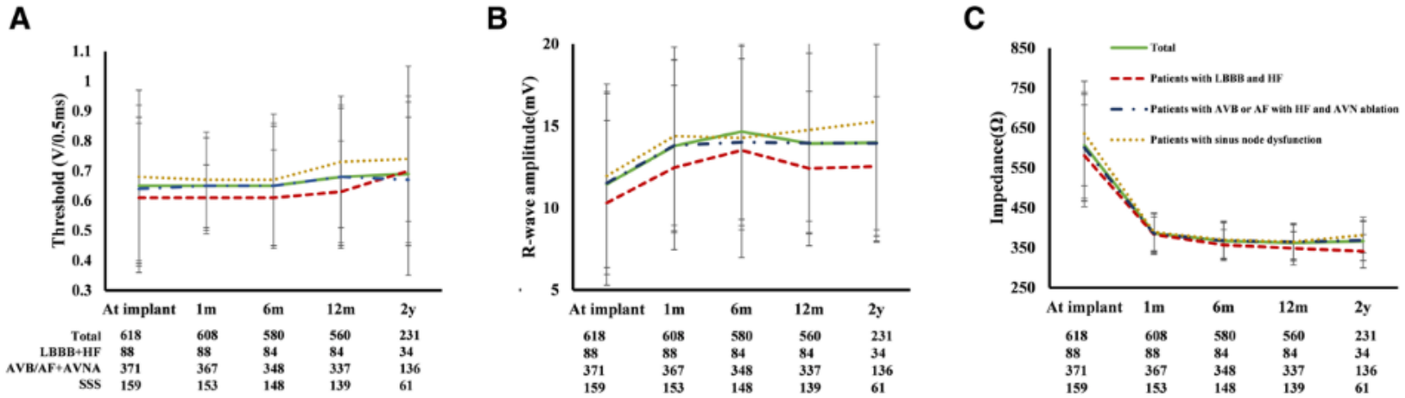


Table 3. Complications of Left Bundle Branch Pacing

Complications	Patients (n)
Complications during procedure	
Septal perforation	2
Intravenous puncture-related arterial injury	2
Coronary artery injury	0
Complications during follow-up	
Increase of capture threshold >2 V/0.5 ms	6
Loss of conduction system capture	2
Lead revision	2
Pocket infection	2
Hematoma	1
Septal perforation	1

632 patients – succès 97,8%

1. Left Bundle Branch Area Pacing for Cardiac Resynchronization Therapy: Results From the International LBBAP Collaborative Study Group. Vijayaraman et al. JACC Clin Electrophysiol 2021 Feb;7(2):135-147
2. Long-Term Safety and Feasibility of Left Bundle Branch Pacing in a Large Single-Center Study. Su et al. Circ Arrhythm Electrophysiol. 2021;14:e009261. DOI: 10.1161/CIRCEP.120.009261

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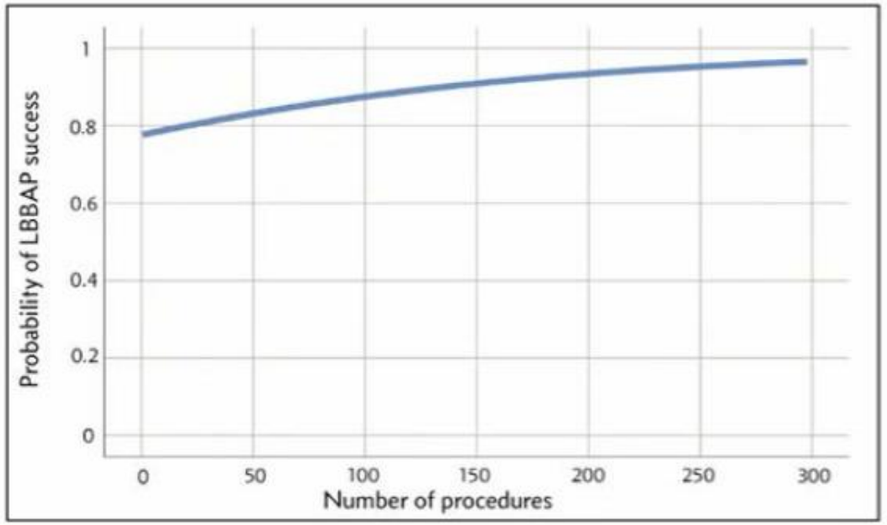
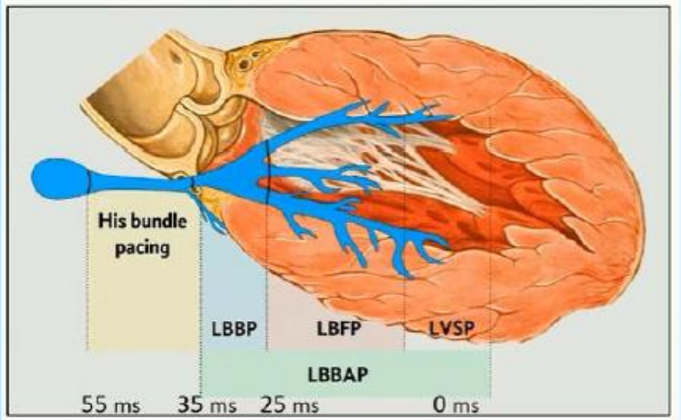
MELOS

- 2,533 pts. included, 31 implanters; Pt. age 74y, 58% female, 27.5% HF, 22.4% LBBB
- Threshold 0.77V, sensing 10.6mV
- Success rate: Brady 91.6%, heart failure 76.8%
- Predictors of failure: Broad baseline QRS, depressed EF, heart failure

Feasibility, Success Rate, Learning Curves



Fascicular pacing is the dominant type



LBBAP capture types:

LBFP (69.5%), **LVSP** (25.1%) and **LBBP** (9%).

Complications

Intraprocedural IVS perforation - 3.7%
Delayed IVS perforation - 0.08%
Acute chest pain - 1%
ST elevation in multiple leads - 0.24%
Acute coronary syndrome - 0.43%
Coronary artery fistula - 0.28%
LBBAP lead dislodgement - 1.5%
Threshold > 2 V - 0.67%
LBBAP lead non-screwable - 0.43%
Stroke - 0%

TOTAL LBBAP lead related: 8.2%

Presented by M. Jastrzebski as a late-breaking clinical trial at the EHRA congress 2022

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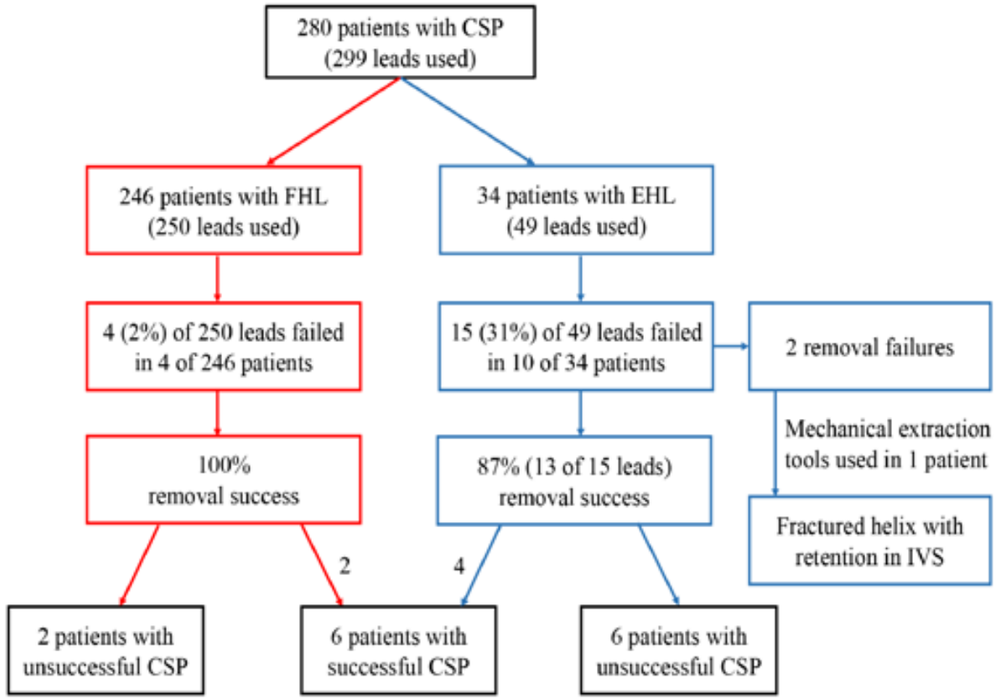
Vis fixe vs. Vis rétractable pour la stimulation du système de conduction

Figure 1. Distribution of lead design and failure



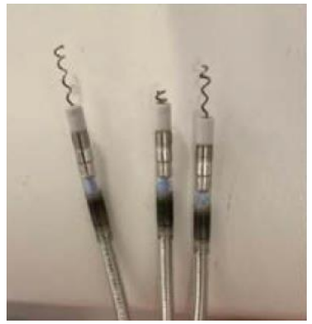
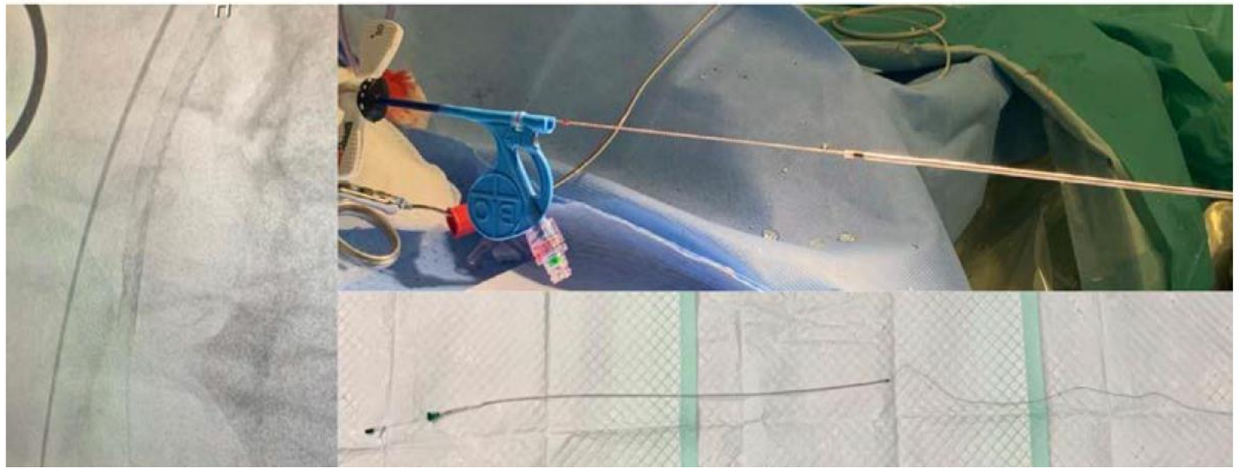


Figure 3. Complete unraveling of lead body and separation of lead helix



Use of extendable helix leads for conduction system pacing: differences in lead handling and performance. J Cardiovasc Electrophysiol 2022 May 6. doi: 10.1111/jce.15528.

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Conçue pour sa simplicité d’extraction chronique

- La construction isodiamétrique du corps de la sonde facilite le retrait de la sonde.
- Élimine la nécessité d’un mandrin bloqueur.
- Le câble Tensi-Lock™ est conçu pour préserver l'intégrité de la sonde en minimisant l'étirement du corps de la sonde pendant l'extraction.

"Taux élevé de succès d'extraction avec un faible taux de complication "[2]

"Moins de risques d’extraction partielle par rapport aux sondes conventionnelles "[3]

Comparais… …après le test d'étire…

1. Medtronic data on file
2. Vijayaraman et al. Extraction of the permanent His bundle pacing lead: Safety outcomes and feasibility of reimplantation. Heart Rhythm 2019
3. Sheperd et al. Extraction of SelectSecure leads compared to conventional pacing leads in patients with CHD and congenital AV block. Heart Rhythm 2015

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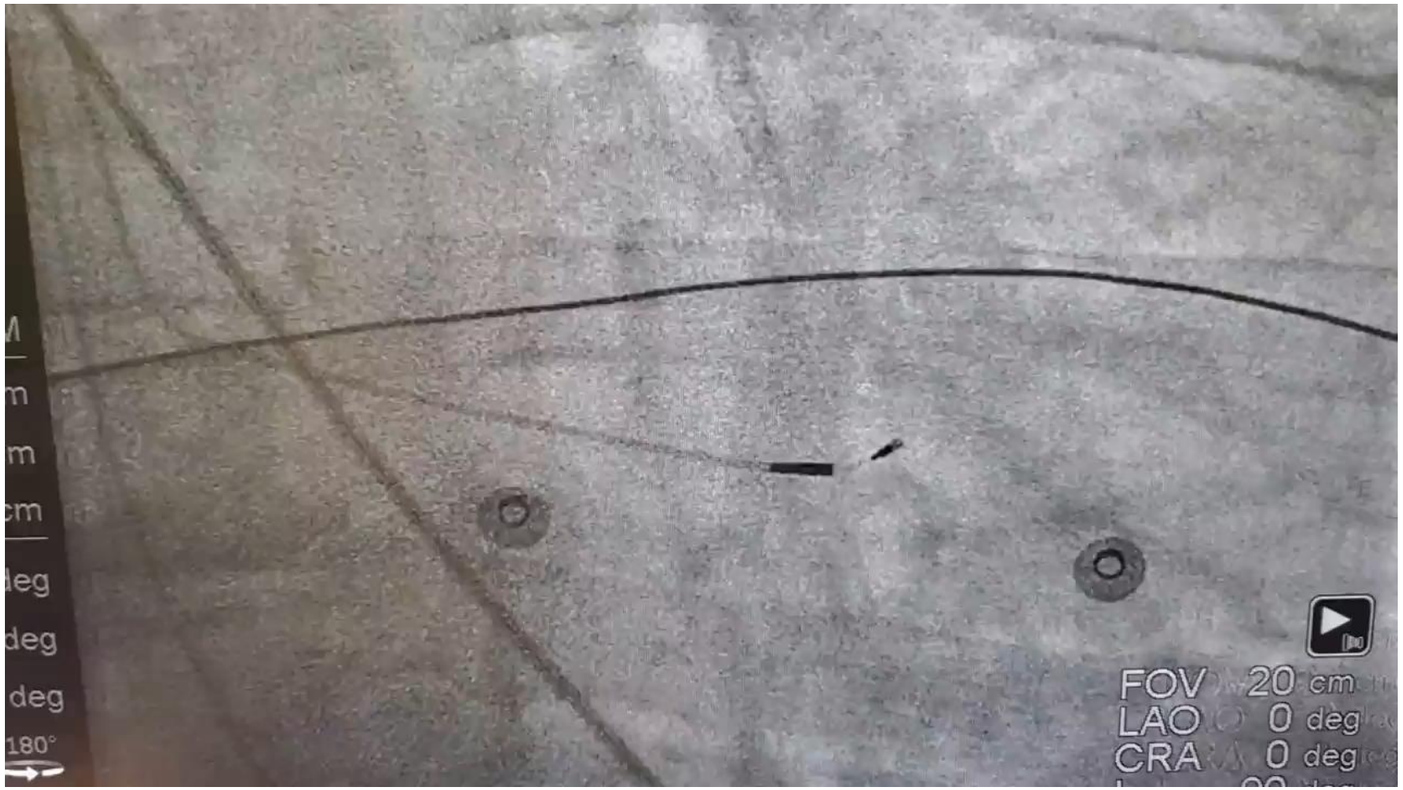
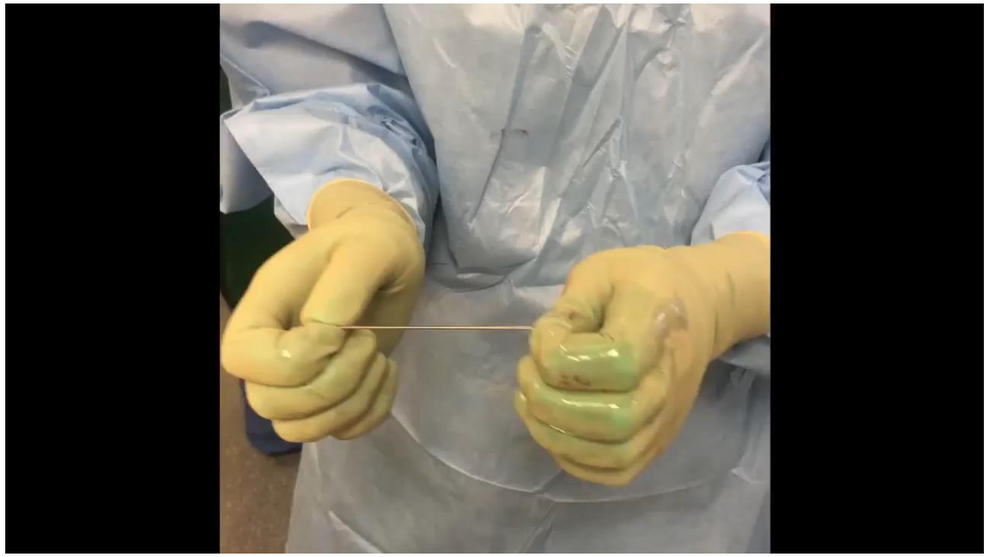
Exemple d’extraction





Extraction of Left Bundle Branch Pacing Lead. Vijayaraman et al. J Am Coll Cardiol EP. 2020 Jul, 6 (7) 903–904
Late dislodgement of left bundle branch pacing lead and successful extraction. Ponnusamy et al. J Cardiovasc Electrophysiol. 2021;32:2346–2349

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Le design de la 3830 va être repris pour une sonde de défibrillation

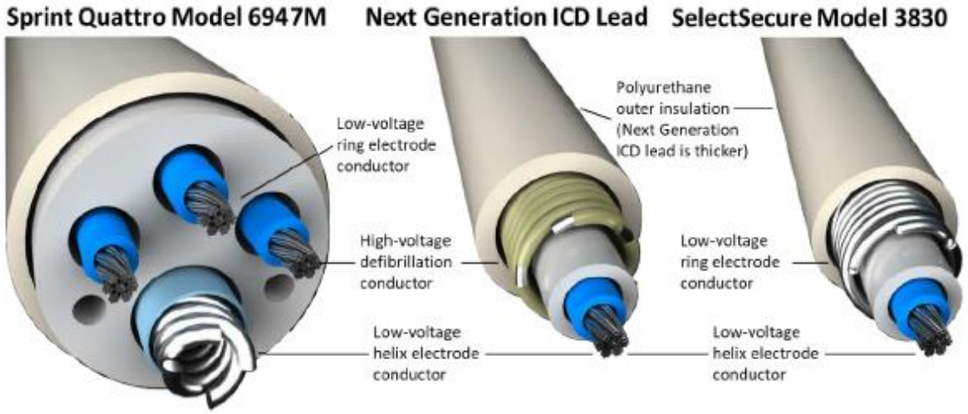

Figure 1: Cross-sectional Comparison of Sprint Quattro Model 6947M, Next Generation ICD and SelectSecure Model 3830 leads

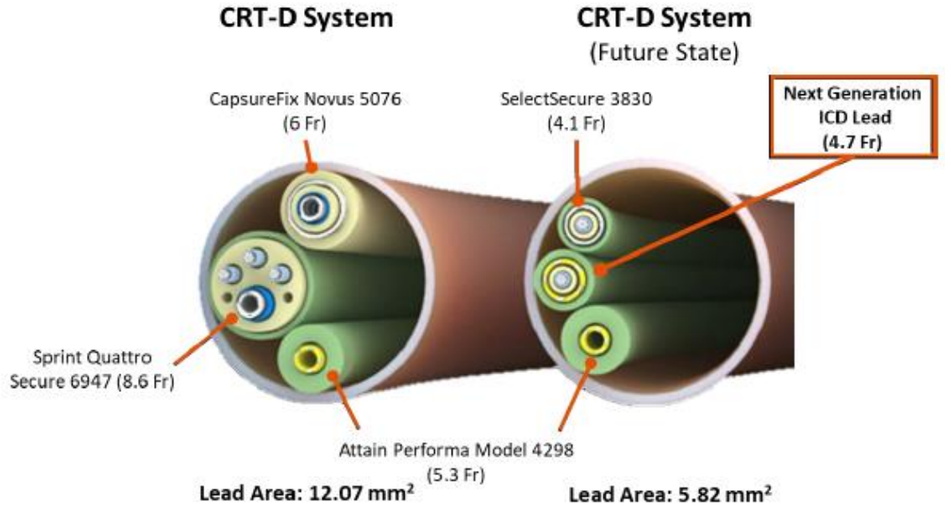

Figure 3: Illustration of the Next Generation ICD Lead in a Future State CRT-D system

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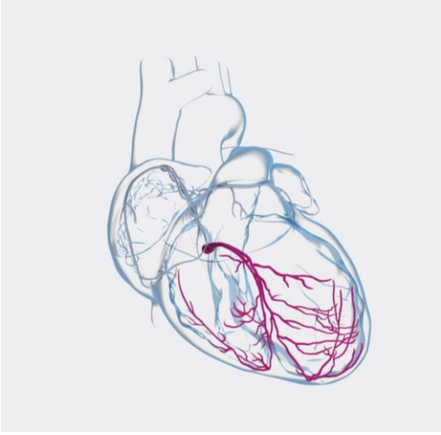
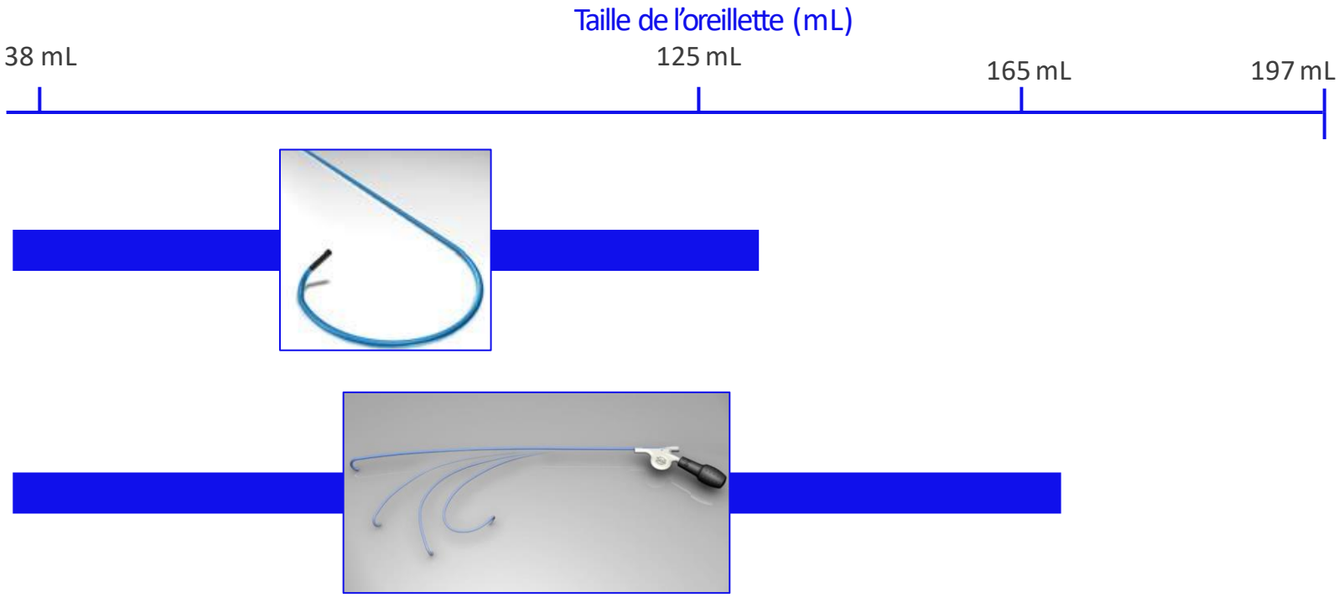
Sélection du cathéter[1]





C315HIS

- Courbe fixe, forme HIS, 7 Fr
- Courbe hors plan conçue pour atteindre la région hissienne ou para hissienne

C304-HIS

- Déflectable et préformé, forme HIS, 9 Fr
- Courbe hors plan conçue pour atteindre le faisceau de His
- Marqueurs radio-opaques pour faciliter l'orientation

C304-L69

- Déflectable, 9 Fr
- Son design n'inclut pas de courbe hors plan pour atteindre le faisceau de His
- Utilisé uniquement pour de oreillettes larges si le C315HIS ou C304-HIS ne permettent pas d'atteindre le faisceau de His

1. Using modeling study of 20 different patient anatomies, selected to include patients with atria ranging from 38-197 mL RA volumes. Based on literature, RA volume of healthy subjects ranges from 61-139 mL.

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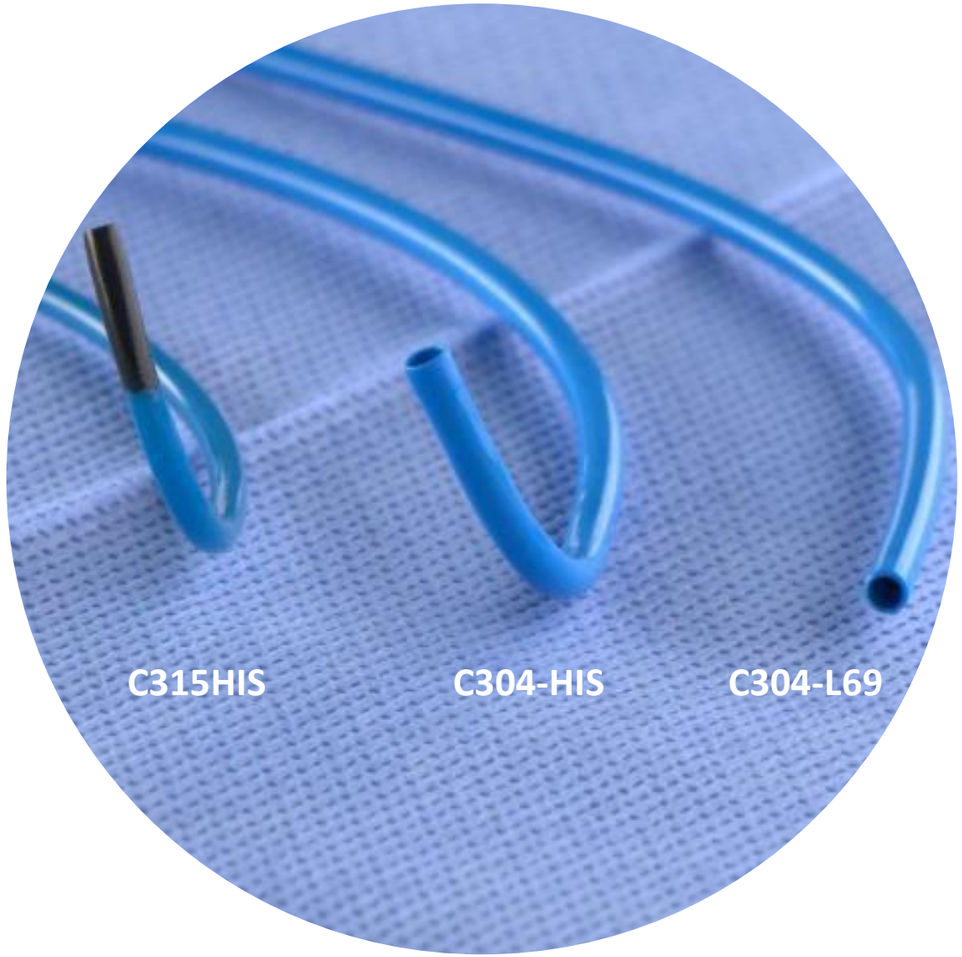
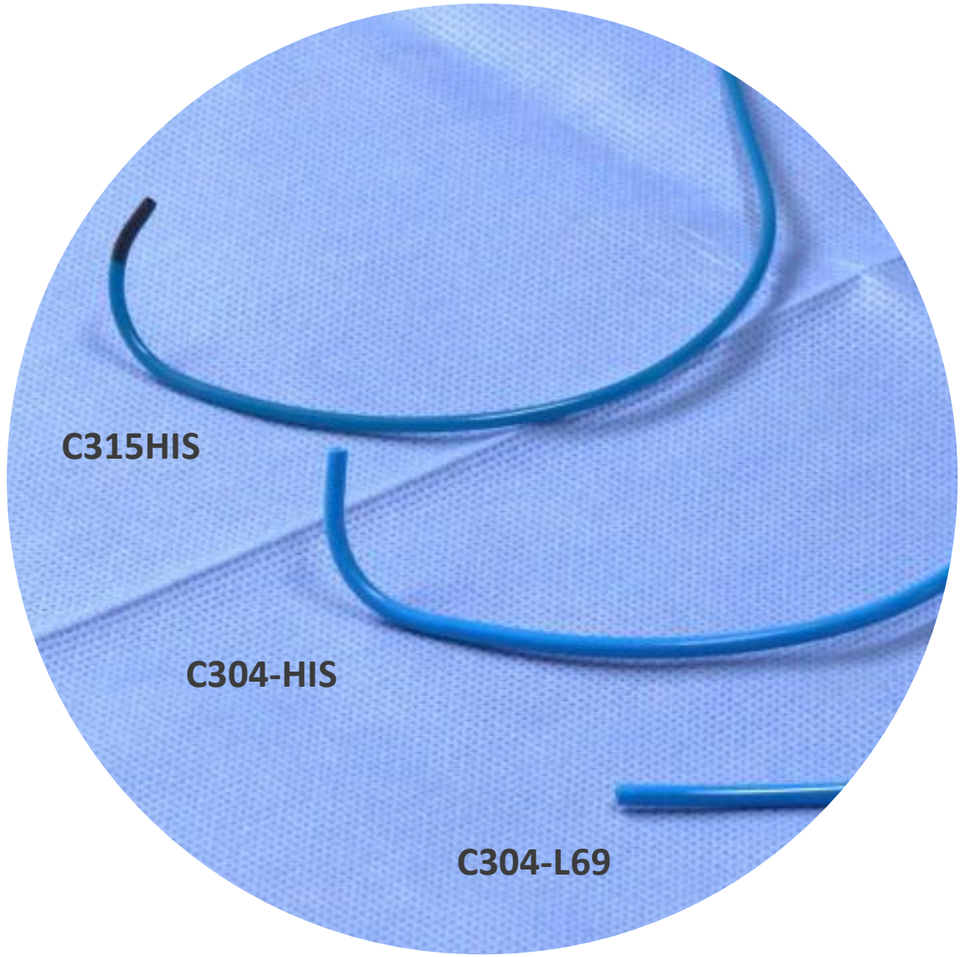
Comparaison des cathéters



Extrémité distale – Vue de face



Extrémité distale – Vue de côté

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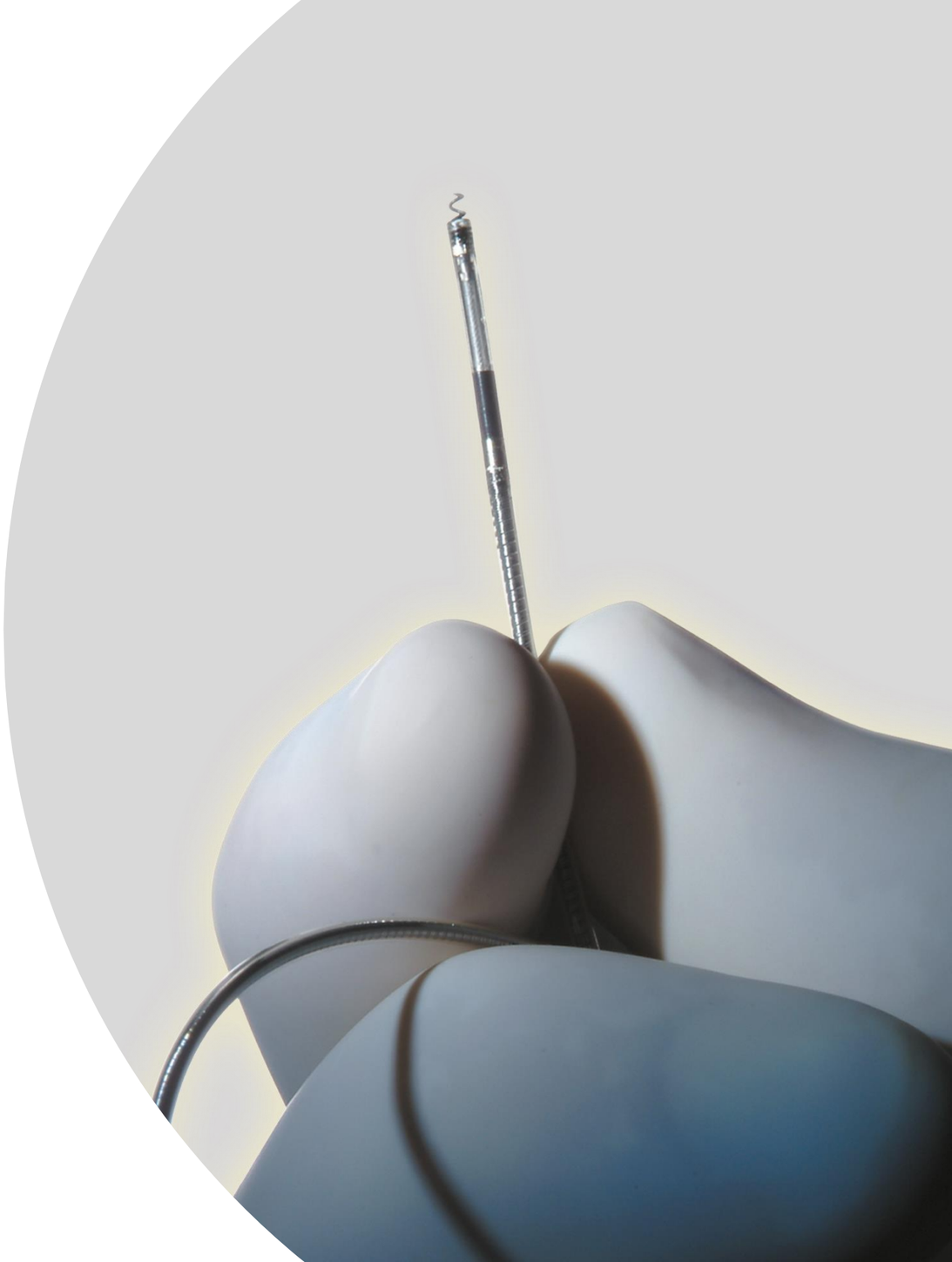
Merci de votre attention



Brief statement

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan™ device, see the MRI SureScan™ technical manual before performing an MRI. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

For applicable products, consult instructions for use on www.medtronic.com/manuals. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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