



Medtronic

L'intérêt des sondes sans lumière pour
la stimulation de l'aire de la branche
gauche



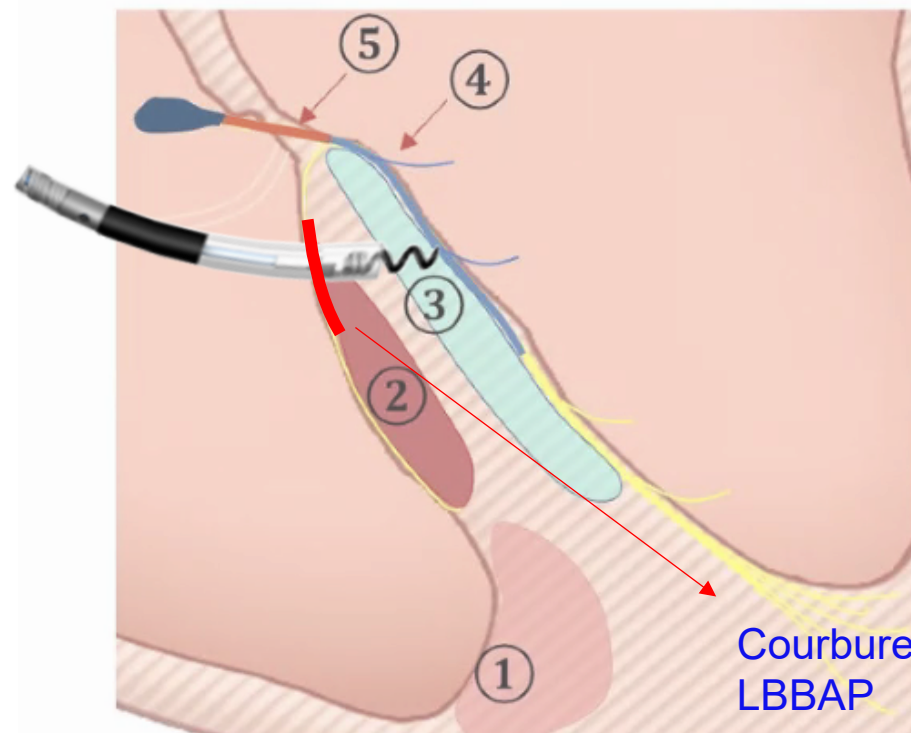
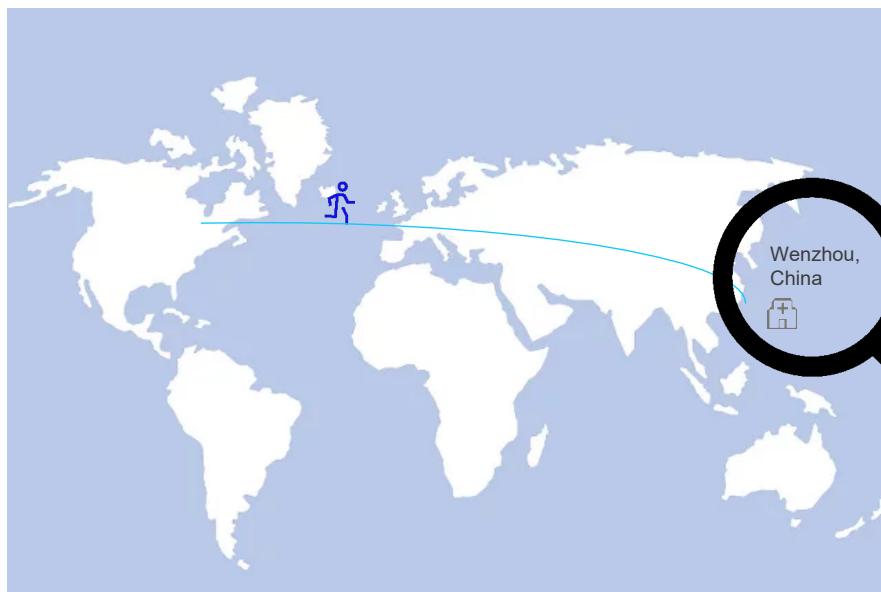
Sonde sans lumière
3830 MRI

Juliette Lardet
Cheffe de produit - Medtronic



Pourquoi Medtronic a choisi la sonde sans lumière 3830 pour la stimulation de l'aire de la branche gauche ?

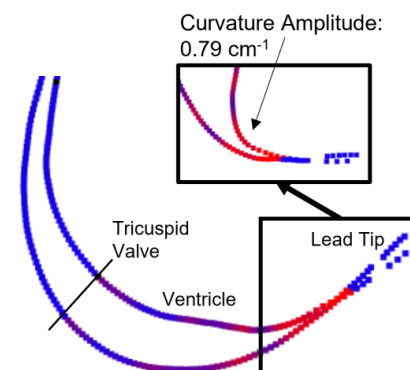
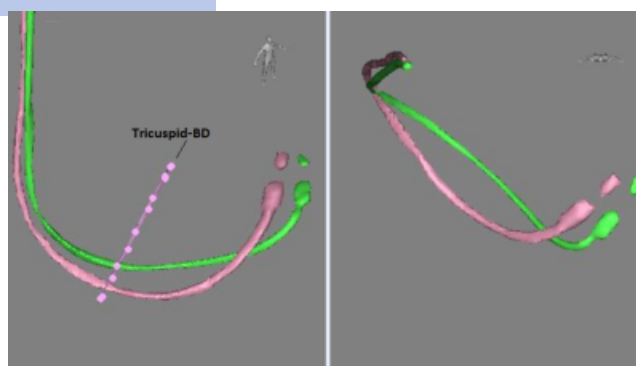
1^{ère} procédure LBBAP en Chine en 2016:
Implantation d'une sonde 3830
En présence d'un ingénieur Medtronic



Besoin d'une sonde résistante pour une implantation dans le septum

Courbure importante en LBBAP

Analyse des scans patients implantés en Branche gauche



Medtronic

Pourquoi Medtronic a choisi la sonde 3830 sans lumière pour la stimulation de l'aire de la branche gauche ?

Productions des sondes Medtronic avant l'arrivée de la stimulation de branche gauche en 2016:

Sondes Medtronic mandrinables 4076 et 5076



Production avant l'arrivée de la CSP:

≈ 1 Million d'unités / an

Sonde Medtronic sans lumière interne 3830



Production avant l'arrivée de la CSP:

≈ 20 000 unités /an

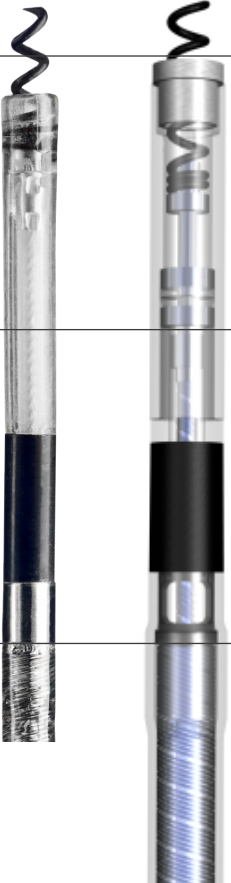
Quel a été le principal critère de choix pour la sonde à utiliser en stimulation de l'aire de la branche gauche ?

Medtronic

Le design des sondes LLL vs SDL : Un impact sur la fiabilité/résistance/performance ?

Les différences de design de sondes LLL Vs SDL:

	Sondes sans lumière interne (3830)	Sondes mandrinables
Vis	Fixe	Extensible-rétractable
Lumière	Pas de lumière interne Avec un câble central	Lumière interne Dirigée par un mandrin (pas de câble central)
	Petit diamètre (4,1 Fr)	Diamètre plus large (5.6 à 6 Fr)



L'importance du diamètre

Quels risques associés à un plus grand diamètre ?

Clinical impact and predictors of periprocedural myocardial injury among patients undergoing left bundle branch area pacing

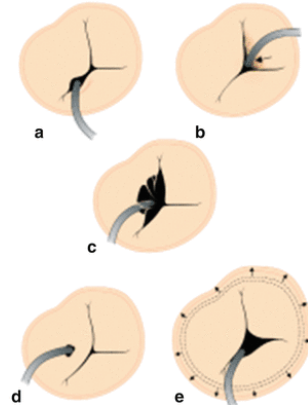
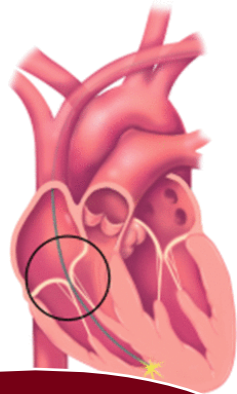
Edoardo Bressi^{1,2} · Kamil Sedláček³ · Karol Čurila⁴ · Oscar Cano^{5,6} · Justin G. L. M. Luermans⁷ · Jesse H. J. Rijks² · Roel Meiburg² · Karin C. Smits² · Uyen Chau Nguyen² · Ermenegildo De Ruvo¹ · Leonardo Calò¹ · Jordana Kron⁷ · Kenneth A. Ellenbogen⁷ · Frits Prinzen² · Kevin Vernooij² · Domenico Grieco¹

Received: 2 June 2024 / Accepted: 26 June 2024

Petit diamètre

PO-02-187 EFFECT OF PACEMAKER LEAD SIZE ON DEGREE OF TRICUSPID REGURGITATION: A FOCUS ON THE MEDTRONIC MODEL 3830 LEAD

Ashkan Ahmadian · Ingrid Hsiung · Adegbola Oluwole · ... · J. Brian DeVille · Mustafa Dohadwala · Ali Yousif... Show more



Régurgitation tricuspid²

Grand diamètre

Septum:



Lésions myocardiques¹

Dommages collatéraux



the CCO than patients with peak HsTnT \leq fourfold the URL (31% vs. 10%; $p = 0.005$), driven by more frequent hospitalizations for ACS (15% vs. 3%; $p = 0.010$). Multiple (> 2) lead repositions attempts, the use of septography and stylet-driven leads were independent predictors of higher risk of PMI with peak HsTnT $>$ fourfold the URL.

HsTnT $>$ fourfold the URL. Patients with peak HsTnT $>$ fourfold the URL exhibited a higher incidence of the CCO than patients with peak HsTnT \leq fourfold the URL (31% vs. 10%; $p = 0.005$), driven by more frequent hospitalizations for ACS (15% vs. 3%; $p = 0.010$).

moderate TR after pacer lead implant, and no patients had progression to severe TR. It is possible that a smaller lead size may be associated with less development of moderate or severe TR, but future studies are needed to confirm this theory.

1 Bressi E, et al. Clinical impact and predictors of periprocedural myocardial injury among patients undergoing left bundle branch area pacing. J Interv Card Electrophysiol. 2024.;

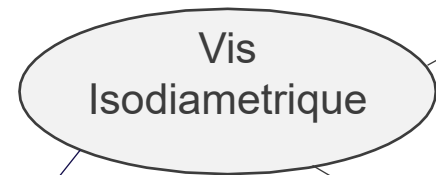
2 Ahmadian A, et al. PO-02-187 Effect of Pacemaker Lead Size on Degree of Tricuspid Regurgitation: A Focus on the Medtronic Model 3830 Lead. Heart Rhythm. 2024;21(5):S266-S267

La conception de la vis est importante

Sonde sans lumière interne



Sonde Mandrinable

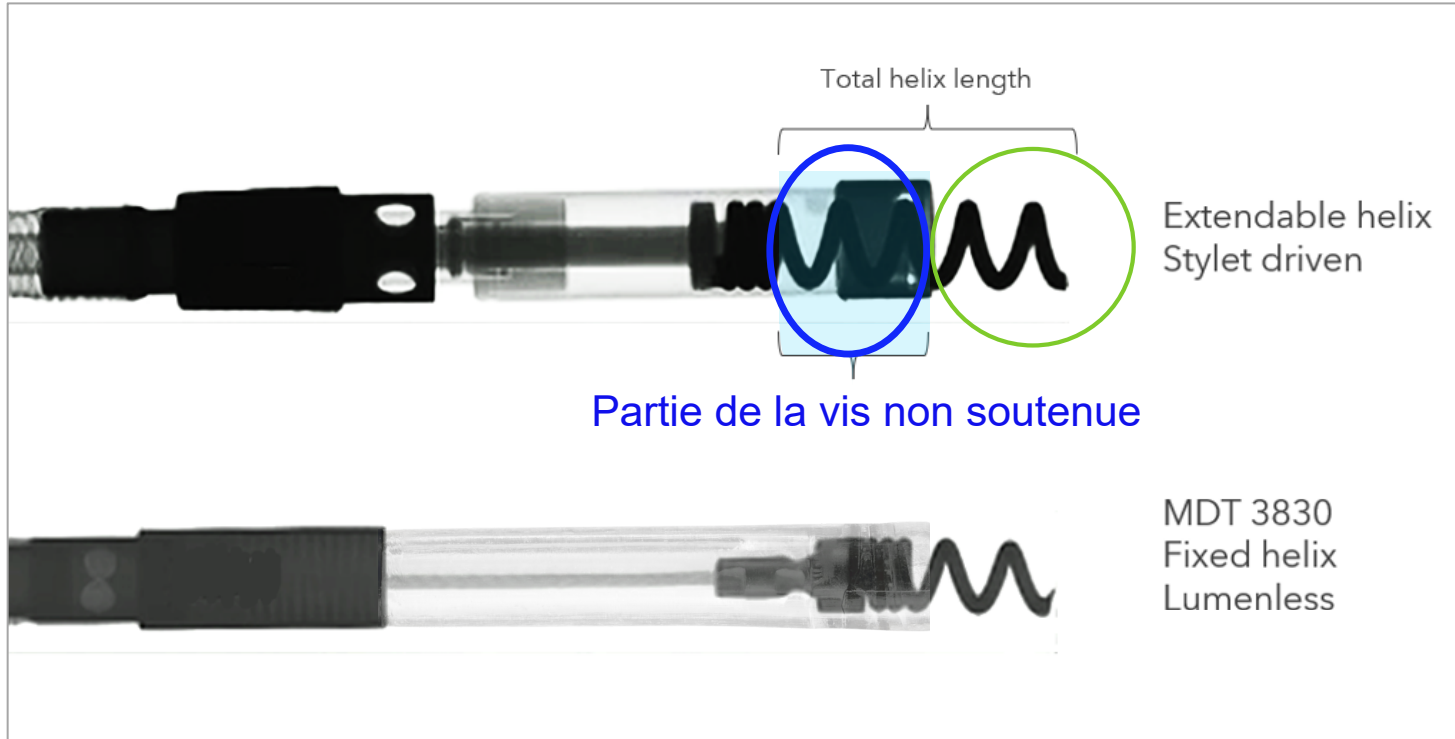


Pénétration plus douce

Limite le risque de lésions tissulaires

Moins de désalignement / risque de fracture

La « longueur non supportée » des vis est plus vulnérable à la déformation



La partie située à l'extérieur de la tubulure est soutenue par le tissu et résiste à la déformation

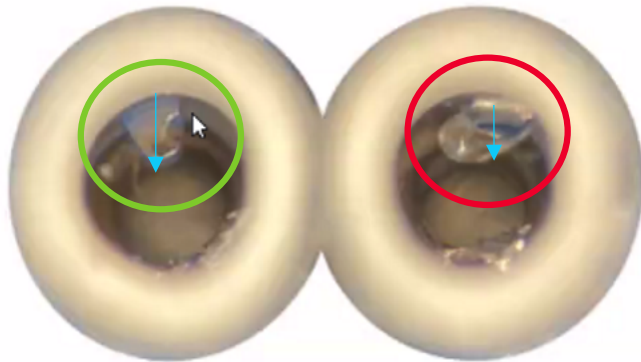
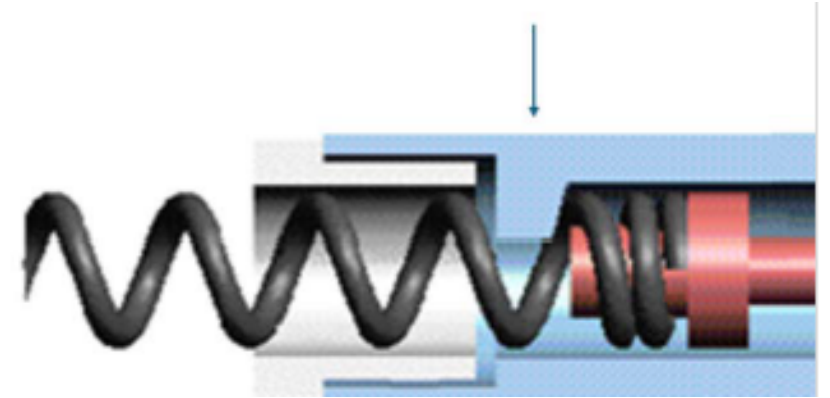
La partie de vis à l'intérieur de la tubulure correspond à la **longueur « non soutenue »**: Cette partie est **plus vulnérable** lors du repositionnement.

Les **SDL** avec des vis extensibles-rétractables ont une **plus grande partie de la vis à l'intérieur de la tubulure**, ce qui les rend **plus vulnérables à la déformation**

L'importance de la conception de la vis: Sondes mandrinables: Risque de cisaillement de la dent

Exemple de la sonde mandrinable Medtronic 4076

« Dent » : vulnérable aux dommages : serrage agressif dans des conditions d'implantation au niveau de la zone LBBA.

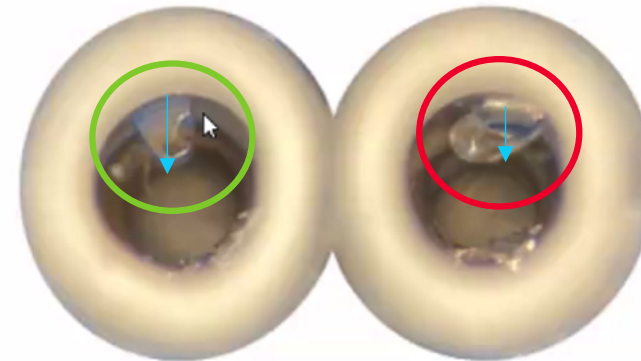
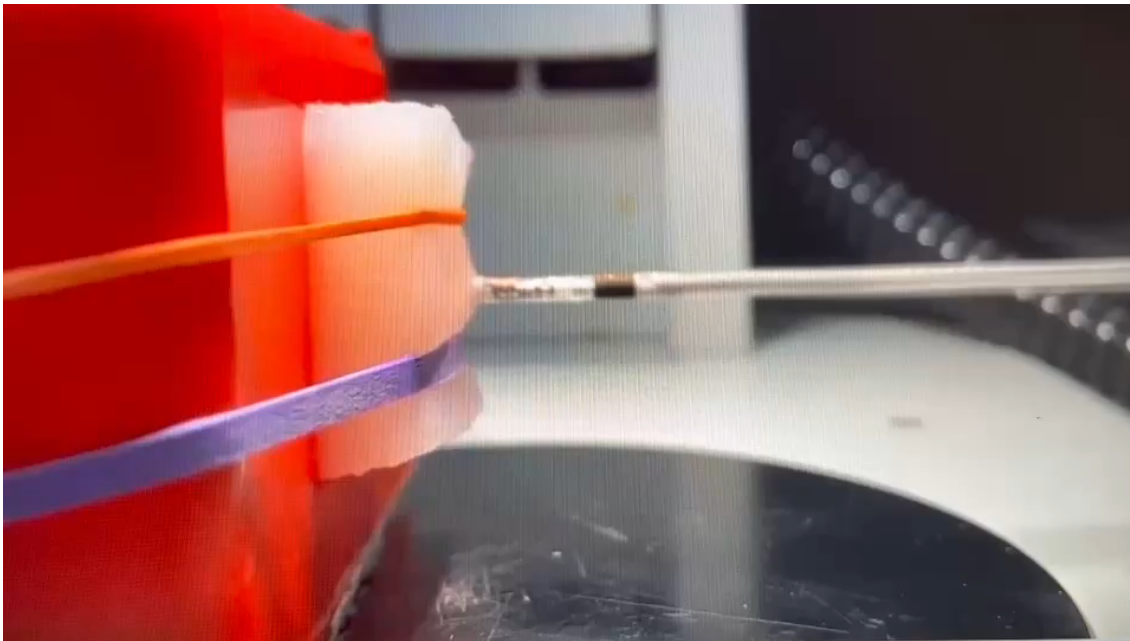
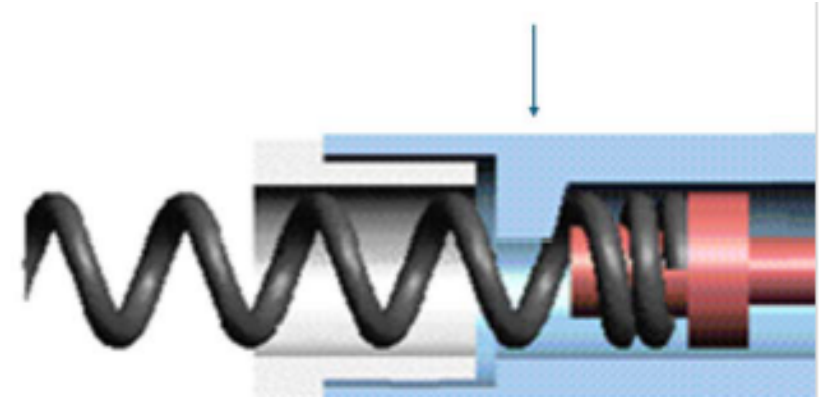


Dent cisillée :
La vis n'est plus maintenue
Pénétration dans le septum impossible

L'importance de la conception de la vis: Sondes mandrinables: Risque de cisaillement de la dent

Exemple de la sonde mandrinable Medtronic 4076

« Dent » : vulnérable aux dommages : serrage agressif dans des conditions d'implantation au niveau de la zone LBBA.



Dent cisailée :
La vis n'est plus maintenue
Pénétration dans le septum
impossible

La vis fixe limite les possibilités de désalignement des composants (**absence de pièces mobiles**)

Espace inter-électrode

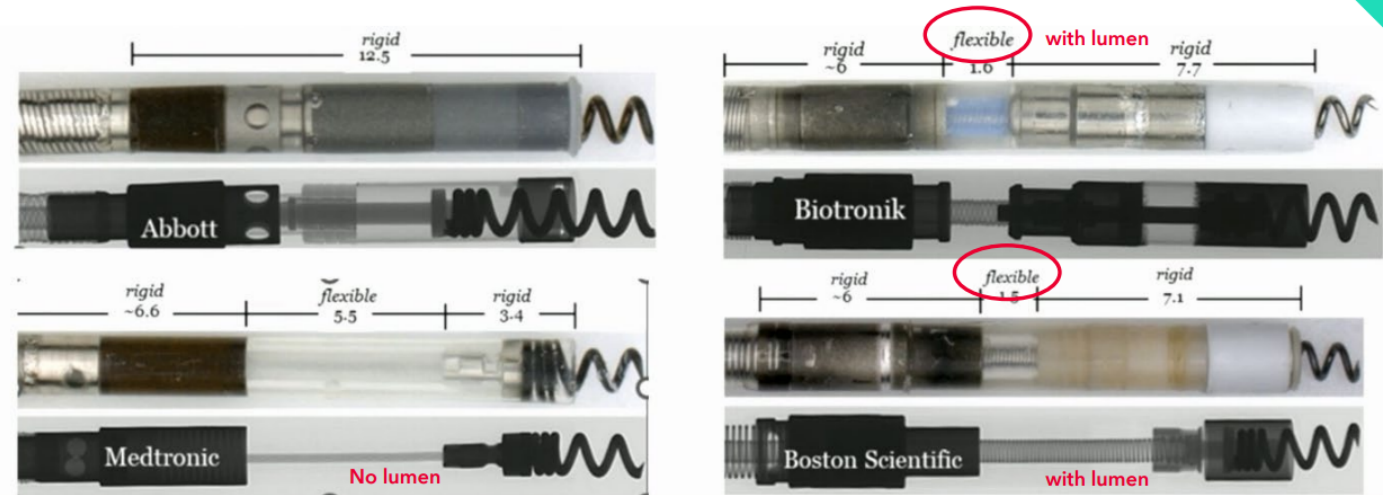
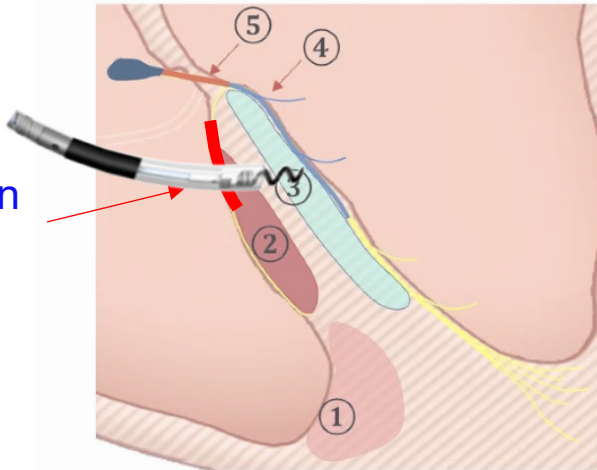
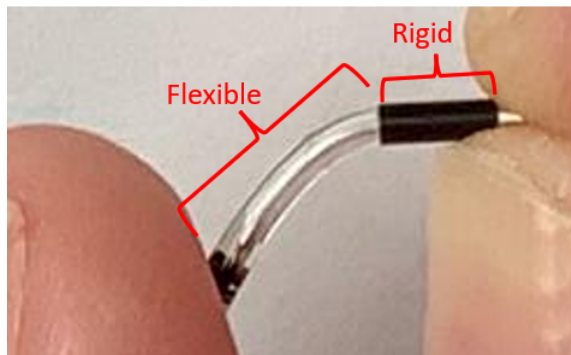
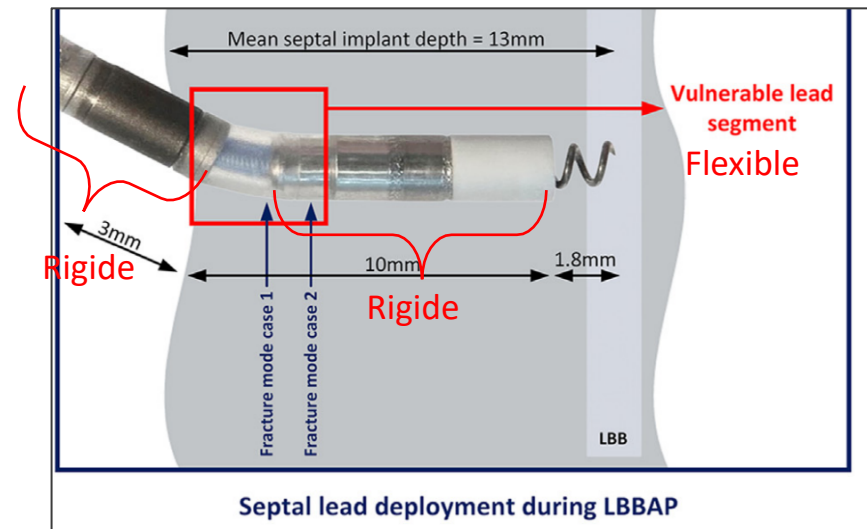


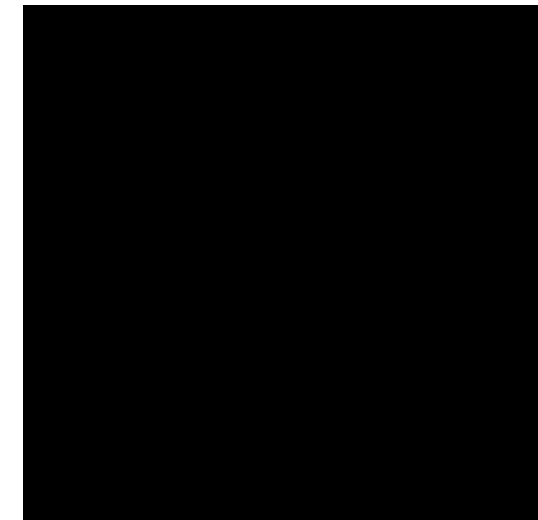
Image Présentée par le Prof. Harran Burri- ESC 2024



Medtronic SelectSecure 3830



Sonde mandrinable



1 Özpak E, De Pooter J, et al. Lead performance of stylet-driven leads in left bundle branch area pacing: results from a large single-center cohort and insights from in-vitro bench testing. Heart Rhythm 2024

LIFE-LBBAP

Objectif: évaluer en vie réelle le taux de défaillance des sondes LLL et SDL en LBBAP dans une large cohorte de patients

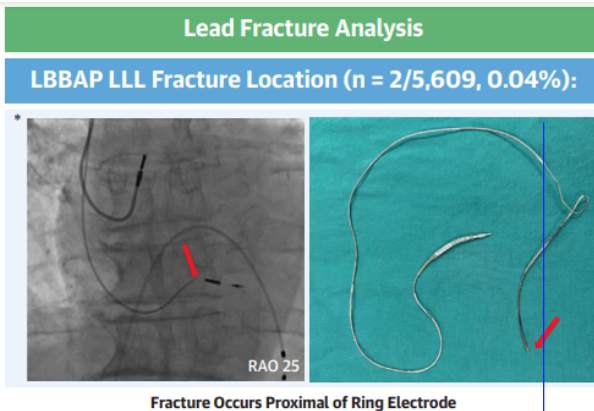
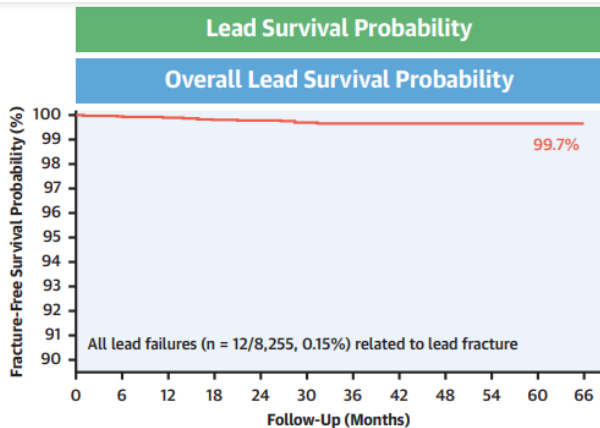
Design de l'étude:

A l'initiative d'un groupe de médecins de 17 centres, multicentrique, observationnelle (Europe, Asie, US)

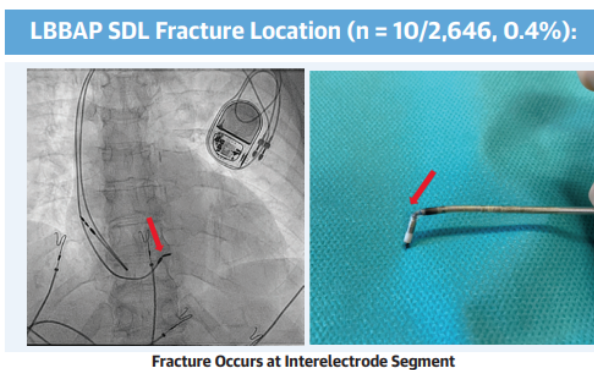
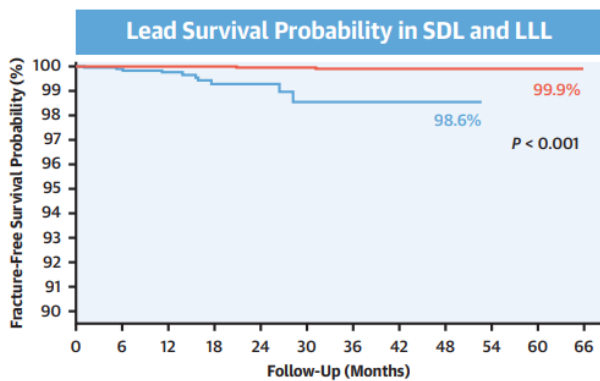
N=8,255 patients

LLL: sondes 3830 Medtronic (68%)

SDL : Solia Biotronik; Tendril Abbott ; Ingevity Boston Scientific, Vega MicroPort (32%)



Taux de fracture x10



Temps de suivi x2

SDL : 0,4% de fracture en BG à 10,3 mois (N=10/2646)

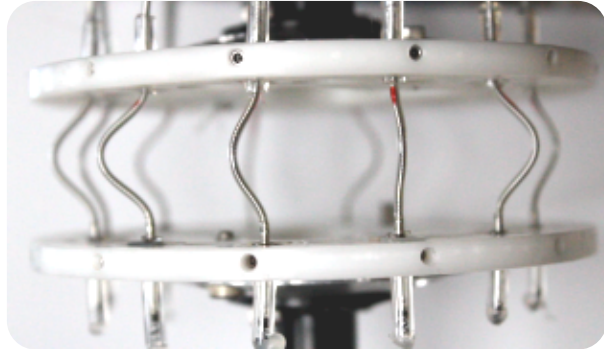
LLL : 0,04% de fracture en BG à 19,5 mois (N=2/5604)

Les fractures du conducteur pour les SDL sont apparues au niveau de l'espacement inter-électrode.

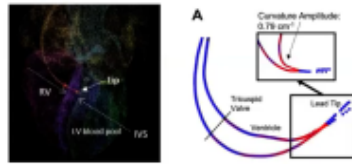
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Les données de fiabilité et de performance de la sonde 3830 en LBBAP

Résistance à 10 ans en LBBAP équivalente à la stim. VD⁵

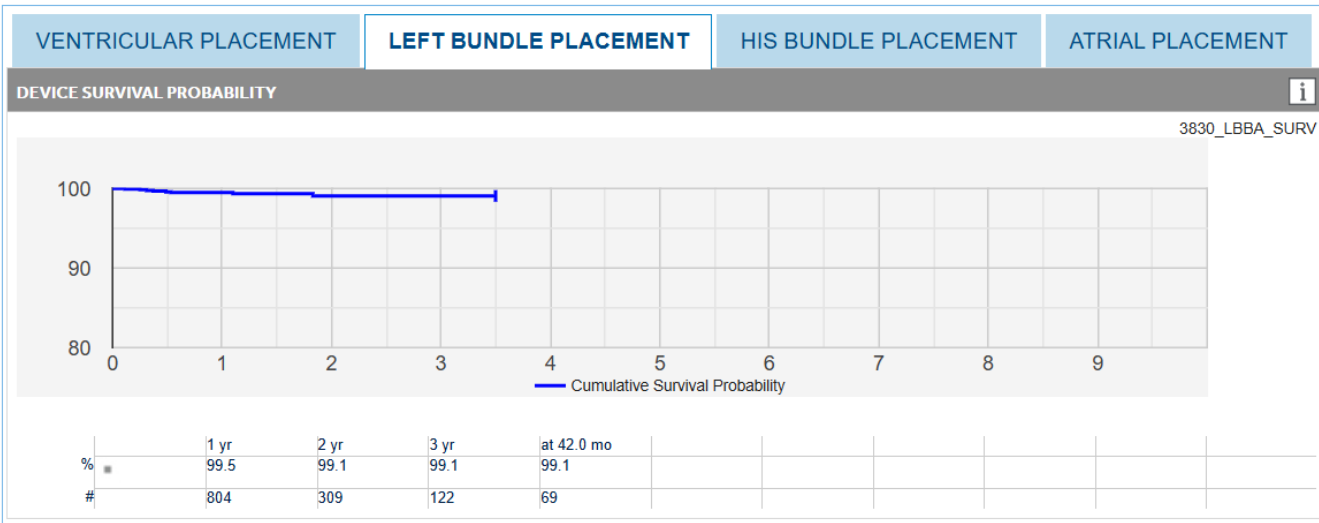


- Tests en banc d'essais >400 000 millions cycles/10 ans
- Taux de fracture estimé à 10 en BG: 0 à 0,02%



Registre PSR de suivi Actif

3830 SelectSecure



Données en vie réelle- >20 000 patients



Implant success rate, procedure adverse events from 53 original research manuscripts

Retrospective analysis of electrical performance and lead complications

Retrospective analysis of electrical performance

- 97% des patients libres de toutes complications à 6 mois
- Seuils de stimulation bas et stables : <1V après 18 mois de suivi

1. Ellenbogen KA, Left bundle branch area pacing using the Model 3830 lead: A systematic literature review and meta-analysis, Presented at APHRS 2022. 19 November 2022. Singapore.
 2. Vijayarajan P, Model 3830 Lead Performance for Left Bundle Branch Area Pacing: Results from a Multi-Center Registry, Presented at APHRS 2022. 19 November 2022. Singapore.
 3. Kron J, Performance of Model 3830 Left Bundle Branch Area Pacing: Results from CareLink and Registration Data, Presented at APHRS 2022. 18 November 2022. Singapore.
 4. SelectSecure 3830 Left Bundle Branch Area Pacing Safety and Efficacy Utilizing RWE. Medtronic data on file.
 5. Zou et al. Clinical use conditions of lead deployment and simulated lead fracture rate in left bundle branch area pacing. J Cardiovasc Electrophysiol. 2023 Mar;34(3):718-725

PRODUCT SURVEILLANCE REGISTRY RESULTS		QUALIFYING COMPLICATIONS	
Number of Leads Enrolled in Study	2154	Failure to Capture	3
Cumulative Months of Follow-Up	21713	Impedance Out of Range	1
Number of Leads Active in Study	1926	Lead Dislodgement	4

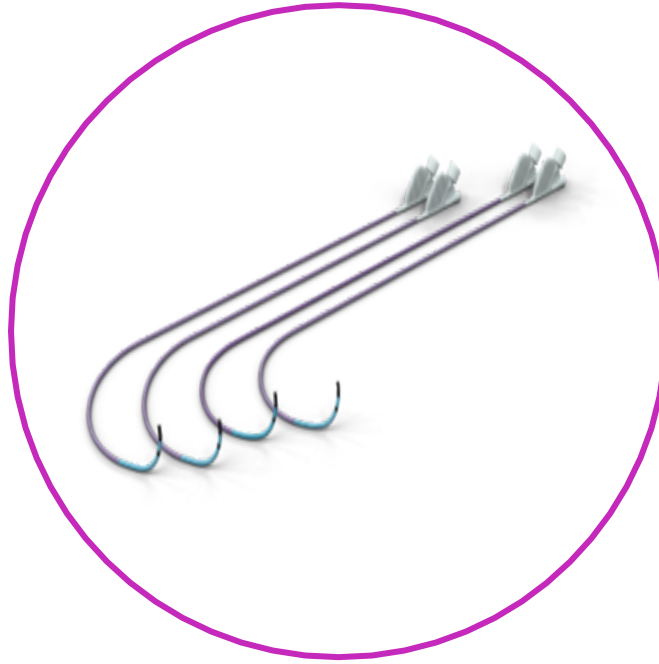
Les futures innovations Medtronic en CSP

Connecteur rotatif 5944RL
Prévu pour 2025



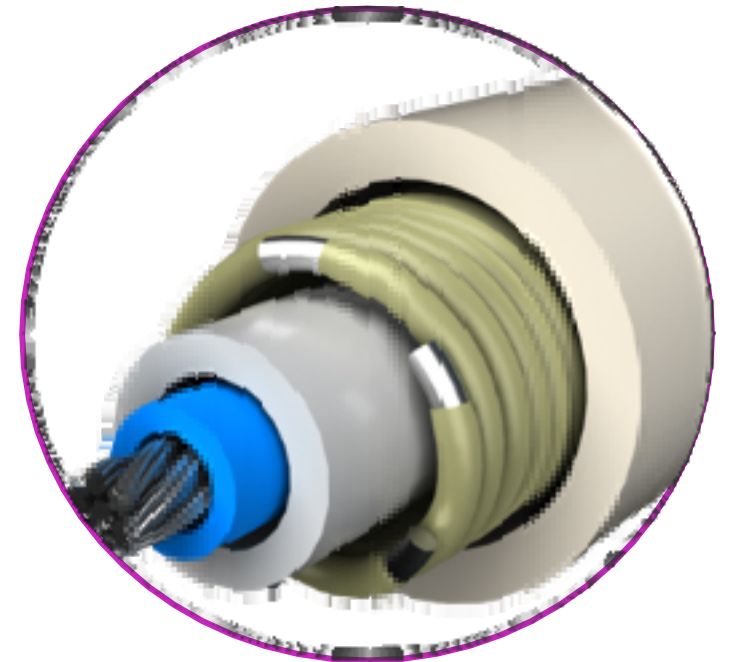
Surveillance continue du signal pendant l'implantation de la sonde

Nouvelles gaines plus longues
prévues pour le printemps 2026



2 tailles: 45 et 48 cm

Sonde de défibrillation
Omnia Secure 2026-2027

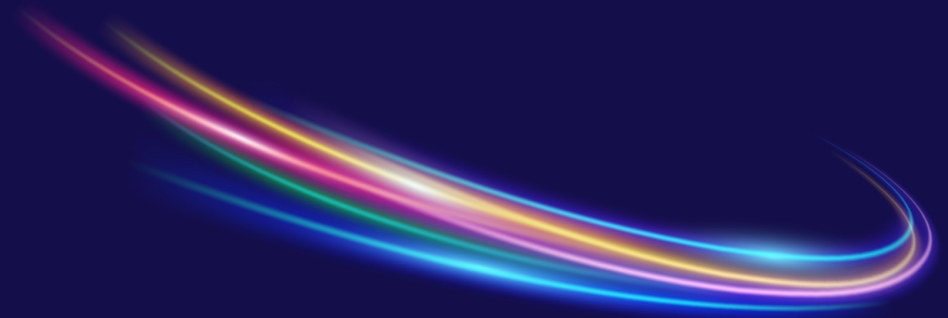
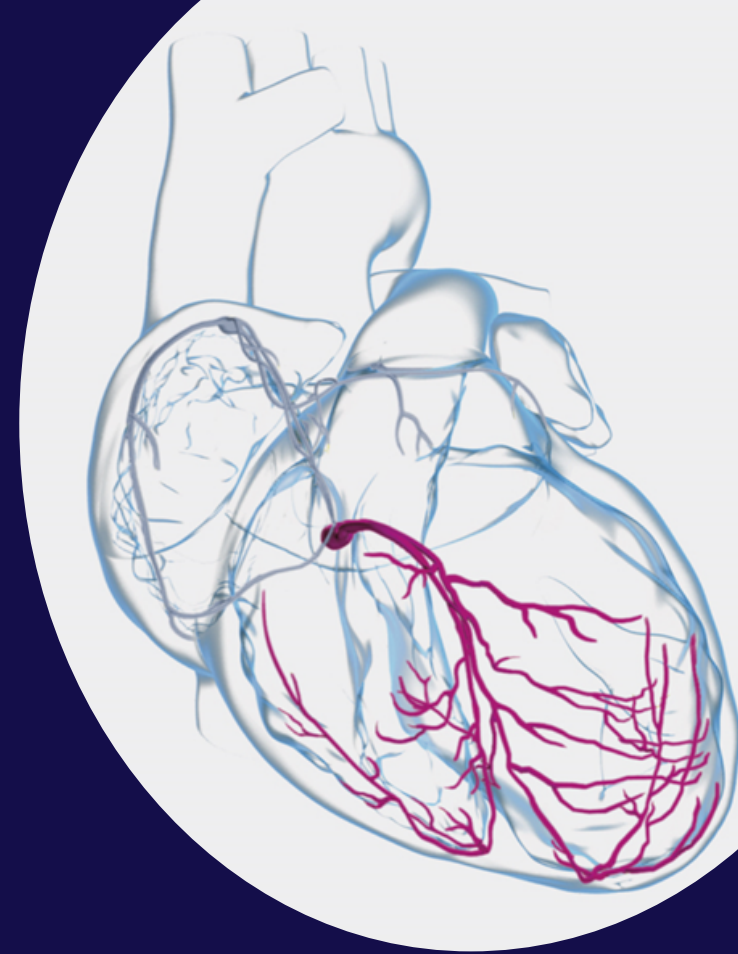


- Sur le même design que la sonde 3830
- Corps de sonde 4.7 Fr
- Positionnement via un cathéter porteur



Medtronic

Merci pour votre attention



Etudes clinique – Fractures de vis de sondes SDL

Left bundle branch area pacing with stylet-driven leads (SDL) as compared to lumenless leads (LLL)

- Prospective single-centre study on left bundle branch area pacing
- 153 patients with initial LLL (3830 lead)
153 patients with initial SDL (Solia, Tendril, Vega, Ingevity leads)
- 4 crossovers in each group after initial failure (and successful implantation in half of the patients with the other lead type)
- No differences in electrical parameters at implantation and follow-up of 7.7±5.8 months

	Stylet-driven (SDL)	Lumenless (LLL)	P
<i>Peri-operative complications</i>			
	N=164	N=157	
Perforation	19 (11.6%)	16 (10.2%)	0.59
Micro/macro dislodgements	10 (6.1%)	7 (4.5%)	0.62
Helix damage	10 (6.1%)	0 (0%)	0.007
<i>Post-operative complications</i>			
	N=147	N=132	
Macro dislodgement	8 (5.4%)	4 (3.0%)	0.39
Loss CS capture	9 (6.1%)	4 (3.0%)	0.26

- 306 patients
- Toutes les sondes: Medtronic, Biotronik, Abbott, Boston et Microport
- Même taux de succès
- Plus de déplacements et de pertes de capture de la BG avec les SDL (non significatif)
- **6.1% de casses de vis sondes SDL - 0 sur la 3830**
- Les auteurs privilégient la 3830 pour les jeunes patients en raison de son « excellente longévité »

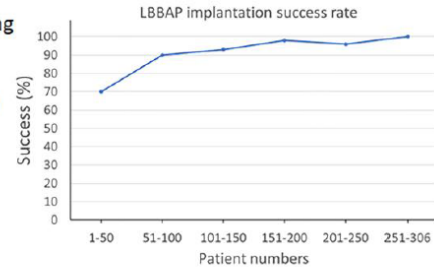
We favoured the 3830 lead in young patients (which explains the difference in age between the groups) because of its excellent longevity

Repositionnement des sondes

Le ratio de succès d'implantation dans le septum suite au changement de sonde est le même dans les deux sens

Left bundle branch area pacing with stylet-driven leads (SDL) as compared to lumenless leads (LLL)

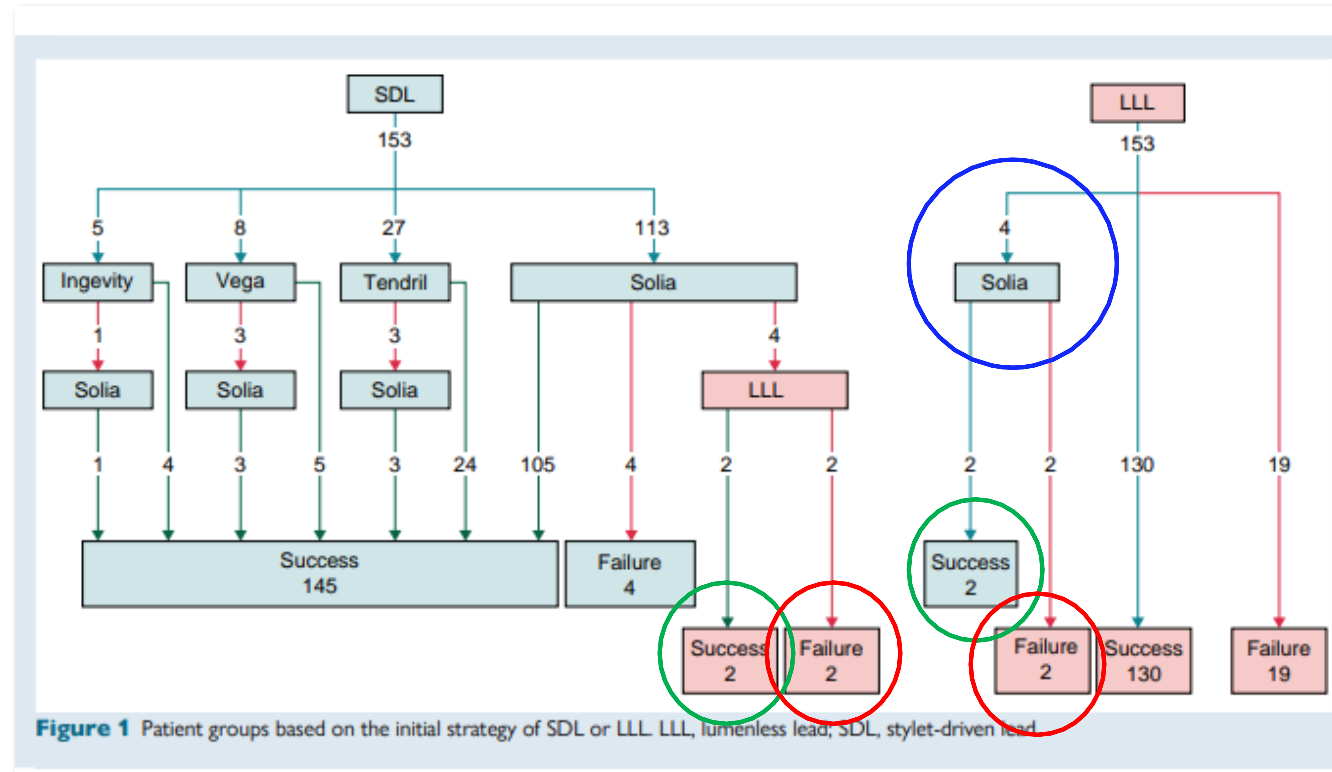
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- 4 crossovers in each group after initial failure (and successful implantation in half of the patients with the other lead type)
- No differences in electrical parameters at implantation and follow-up of 7.7±5.8 months



Success rate according to lead type (after learning curve of 50 patients)



	SDL	LLL	P
<i>Per-operative complications</i>			
Perforation	11.6%	10.2%	0.59
Micro/macro dislodgements	6.1%	4.5%	0.62
Helix damage	6.1%	0%	0.007
<i>Post-operative complications</i>			
Macro dislodgement	5.4%	3.0%	0.39
Loss conduction system capture	6.1%	3.0%	0.26



Sritharan A, Kozhuharov N, Masson N, Bakelants E, Valiton V, Burri H. Procedural outcome and follow-up of stylet-driven leads compared with lumenless leads for left bundle branch area pacing. Europace. 2023

Etude sur les extractions de sondes 3830

TECSPAM study

CSP Lead Extraction

CSP lead extraction in 341 pts. from 10 centers, dwell time 22 ± 26 m

- HBP - 224 leads (**223 LLL**, 1 SDL (BIO))
- LBBAP - 117 leads (**98 LLL**, 19 SDL (17 BIO, 1 ABT, 1 BSX))

Lead fracture: 3 MDT (20, 38 and 55m), 2 BIO (6 and 18m)

Clinical success 100%, complete procedural success 99%, no major complications

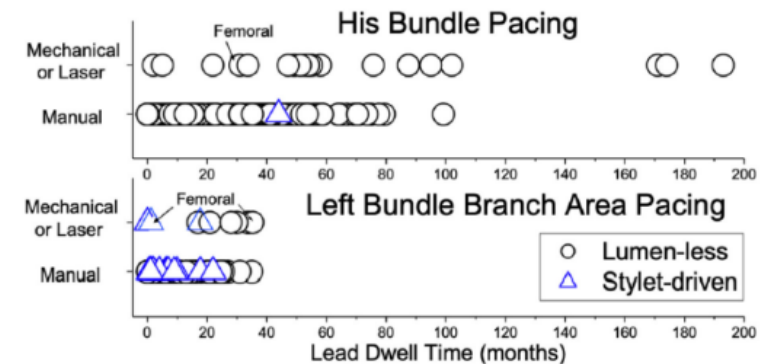
- Manual traction in 91%,
- Mechanical tools in 9%

95% successful CSP reimplant

Vijayarajan P. et al. TECSPAM study. Heart Rhythm 2024

30 Internal use only

TIME-COURSE of CSP LEAD EXTRACTION



Mechanics of lumenless pacing lead strength during extraction procedures based on laboratory bench testing



Pierce J. Vatterott, MD, FACC,* Blandine Mondésert, MD, FACC,† Mark Marshall, MSci,‡ Thomas Lulic, MSME,‡ Bruce L. Wilkoff, MD, FHRS, FACC, CCDS§

From the *Minneapolis Heart Institute East, Arrhythmia Science Center, Minneapolis, Minnesota, †Department of Medicine, Montreal Heart Institute, Montreal, Canada, ‡Medtronic, Inc., Cardiac Rhythm Management, Minneapolis, Minnesota, and §Cleveland Clinic, Robert and Suzanne Tomsich Department of Cardiovascular Medicine, Cleveland, Ohio.

BACKGROUND With the advent of conduction system pacing, use of the Medtronic SelectSecure Model 3830 lead has increased substantially. However, with this increased use, the potential need for lead extraction also will increase. Lumenless lead construction requires an understanding of both applicable tensile forces as well as lead preparation techniques that can influence consistent extraction.

OBJECTIVE The purpose of this study was to use bench testing methodologies to characterize the physical properties of lumenless leads and to describe related lead preparation methods that support known extraction techniques.

METHODS Multiple 3830 lead preparation techniques, commonly used in extraction practices, were compared on the bench to assess rail strength (RS) in simple traction and use conditions with simulated scar. Retention of the IS1 connector vs severing the lead body preparation techniques were compared. Distal snare and rotational extraction tools were evaluated.

RESULTS The retained connector method provided higher RS compared to the modified cut lead method: mean 11.42 lbf (9.85–12.73 lbf) vs 8.51 lbf (1.66–14.32 lbf), respectively. Snare use distally did not significantly affect RS: mean 11.05 lbf (8.58–13.95 lbf). Lead damage occurred with the TightRail extraction tool at angles $\geq 90^\circ$, which could occur with right-sided implants.

CONCLUSIONS When extracting SelectSecure leads, the retained connector method to maintain cable engagement benefits preservation of the extraction RS. Limiting traction force to < 10 lbf (4.5 kgf) and avoiding poor lead preparation methods are critical to consistent extraction. Femoral snaring does not change RS when needed and offers a method to regain lead rail in cases of distal cable fracture.

KEYWORDS Cardiac function; Catheters; Conductor failure; Lead extraction; Left bundle branch area placement; Pacemaker leads

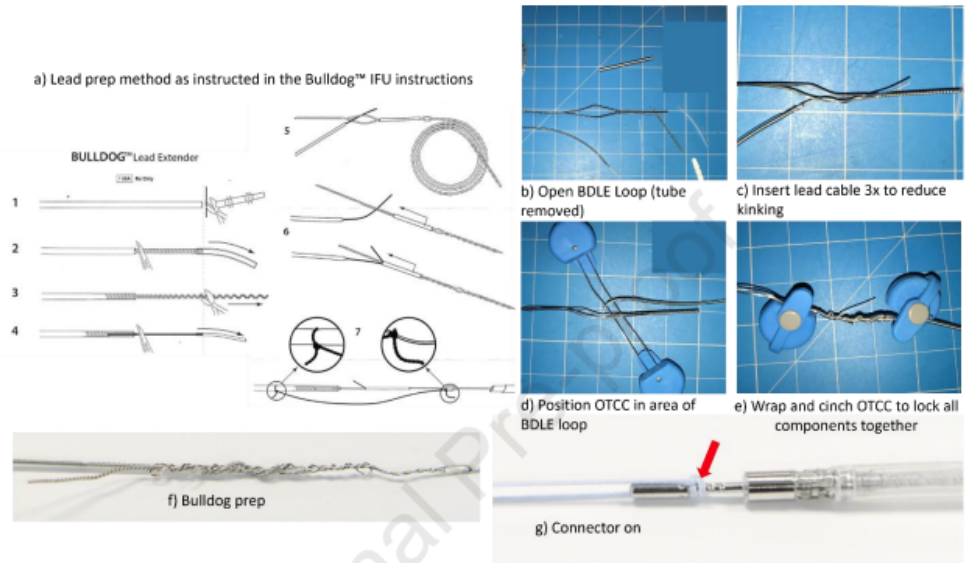
(Heart Rhythm 2023;20:902–909) © 2023 Heart Rhythm Society. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

Introduction

Medtronic SelectSecure Model 3830 lumenless leads (Medtronic, Inc., Minneapolis, MN) were released in Europe in January 2003 and in the United States in August 2005.¹ These leads were developed to reduce the diameter of pacing leads, improve reliability, and allow precise catheter delivery. Smaller-diameter cardiac leads may provide benefits such as reduced incidence of lead subclavian crush, reduced venous stenosis, reduced tricuspid valve involvement, and improved ease of extraction.^{2–5} Initially embraced by the pediatric world, the adoption of the conduction system pacing system has led to a rapid growth in implants of the 3830 lead.^{2,3,5}

The 3830 pacing lead has a unique lumenless lead design. Due to elimination of the central lumen, which contributes about 40% of the diameter of a standard 7F pacemaker lead, the 3830 lead is only 4.1F diameter.⁴ Traditional coaxial, multilumen, and co-radial lead designs use a coiled inner conductor with a central lumen, which allows for insertion of a shapeable stylet to facilitate steering and placement (Figure 1). This inner coiled conductor and lumen has 3 adverse effects. (1) It requires space, necessitating a larger lead diameter. (2) It can be susceptible to tight bending conditions, allowing for conductor kinking with flexion. This kinking can lead to a point of repetitive localized stress

Funding Sources: This work was funded by Medtronic. Disclosures: Dr Vatterott reports being a consultant for Medtronic, Boston Scientific, and Cook Medical. Dr Mondésert reports a research grant from Boston Scientific; being a consultant for Medtronic, Biotronik, and Milestone Pharma; speaker honoraria from Boston Scientific, Abbott, Pfizer, Bayer, and Servier; and proctor for Philips (lead extraction division). Dr Wilkoff reports being a consultant for Medtronic, Ab-



82

Vatterott PJ, Mondésert B, Marshall M, Lulic T, Wilkoff BL. Mechanics of lumenless pacing lead strength during extraction procedures based on laboratory bench testing. Heart Rhythm. 2023 Jun;20(6):902-909. doi: 10.1016/j.hrthm.2023.02.025. Epub 2023 Mar 1. PMID: 36868544.

La prochaine génération de sonde de défibrillation

OBJECTIFS POURSUIVIS

Fiabilité

- Design basé sur celui sans lumière de la 3830 qui a de bonnes données de fiabilité en vie réelle
- Résistance à la fatigue accrue (testée sur banc test) par rapport à la Sprint Quattro qui présente aussi une bonne fiabilité en vie réelle

Facilité d'extraction

- Etude animale sur le long terme en cours

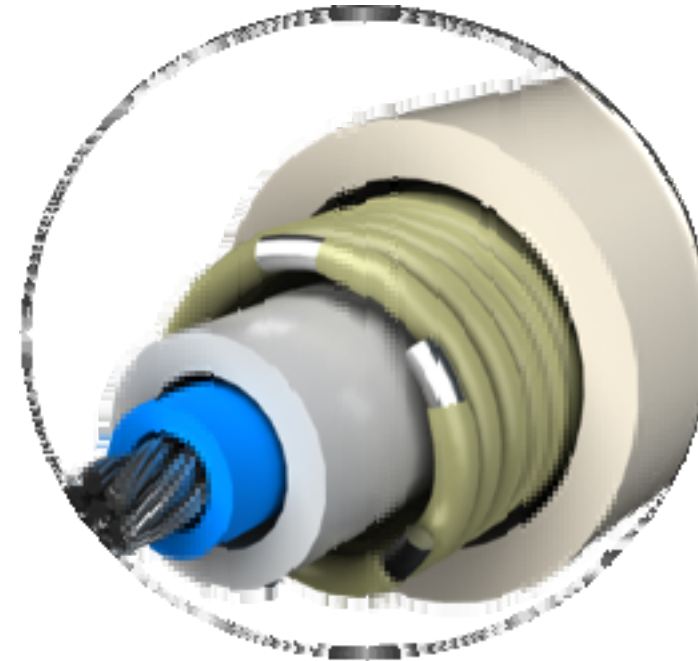
Reduction de l'obstruction veineuse

Facilité de positionnement

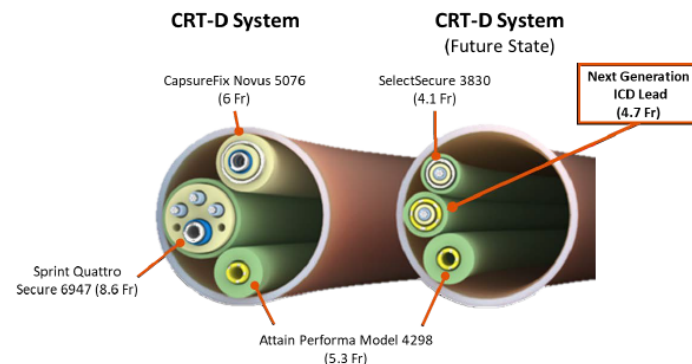
- Positionnement avec les cathéters C315 et C304 utilisés pour la 3830



Sprint Quattro ICD Lead



Sonde de stimulation 3830 Select Secure



Prochaine génération de sonde

- Corps de sonde 4.7 Fr
- Positionnement via un cathéter porteur

Résistance de la sonde 3830 démontrée pour des conditions de repositionnement et de rotation extrêmes

Results: The number of attempts to place the 3830 lead for LBBAP was 2.1 ± 1.3 (range: 1–7) with 13 ± 6 lead rotations at the final attempt. Extreme implant conditions were simulated in bench testing with 5 applications of 20 turns followed by up to 400 million bending cycles. Reliability modeling predicted a 10-year fracture rate of 0.02%.

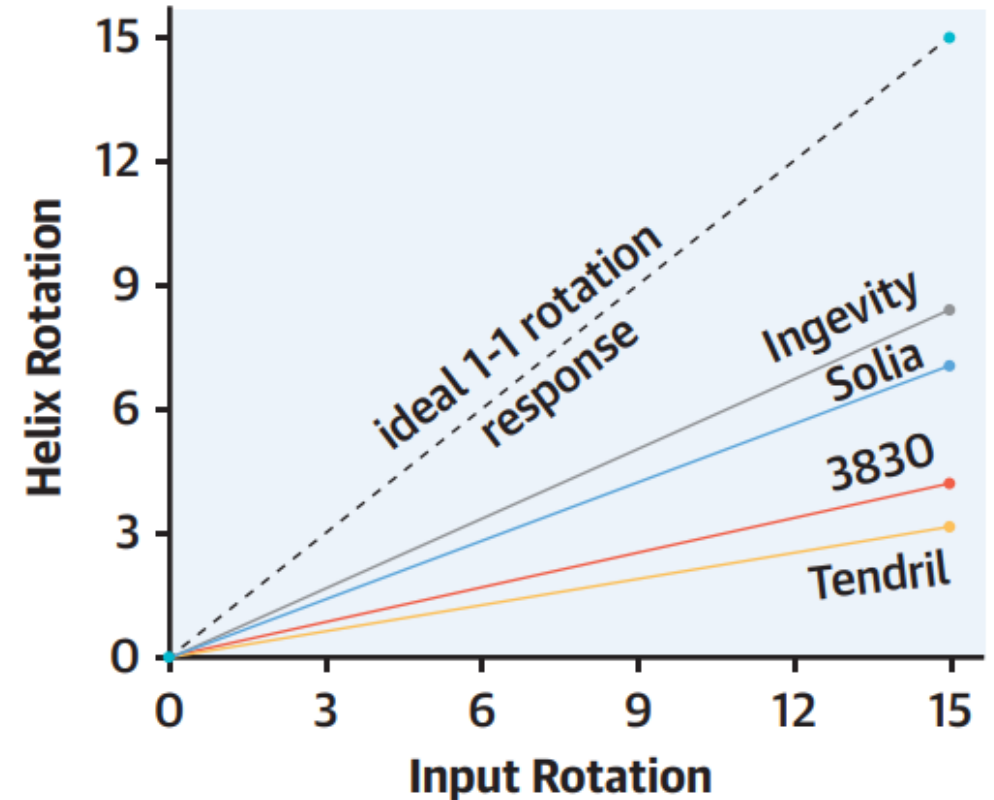
The proximal end of the lead was rotated by hand for a minimum of 20 continuous turns, then released. The process was repeated at least 5 times. This exposure represents an extreme scenario where a physician attempts to implant the lead at 5 different locations, each time applying 20 continuous rotations with no release of built-up torque. Preconditioning is illustrated in Figure 2A.

4 | DISCUSSION

The mechanical use conditions associated with LBBAP include the potential for a higher number of turns and more severe bending conditions compared to standard endocardial pacing. We found that there was no impact on fatigue performance after multiple applications of 20 turns, and that the level of bending curvature observed in the clinical portion of the study did not result in expected higher rates of long-term fractures for the 3830 lead. Bending stress is proportional to curvature, so we used curvature rather than angle as our measure of in-vivo stress.¹⁵ The result of our model for intracardiac fracture rate (0.02% at 10 years) is within the confidence

Recommandations du nombre de tours différent pour chaque sonde

EACH LEAD HAS A UNIQUE TRANSFER FUNCTION FOR ROTATIONAL RESPONSE. A salient observation from this work is the variance in the ability of different leads to transmit rotation to the helix. Given the differences observed in the rotation response curves across the leads evaluated in this study, it appears that although leads are similar in design and appearance, each lead possesses a unique transfer function that characterizes its behavior during deployment for CSP. Understanding these differences is potentially of significant clinical importance to tailoring the deployment technique to the specific lead being used, which could enhance the accuracy and safety of CSP lead implantation. Of note is that



Nouvelles données présentées à l'APHRS : Sous analyse de l'étude LEADR

Poster 1

Recommandations de programmation pour une nouvelle sonde de défibrillation bipolaire intégrée : Analyse de l'essai LEADR (VD)

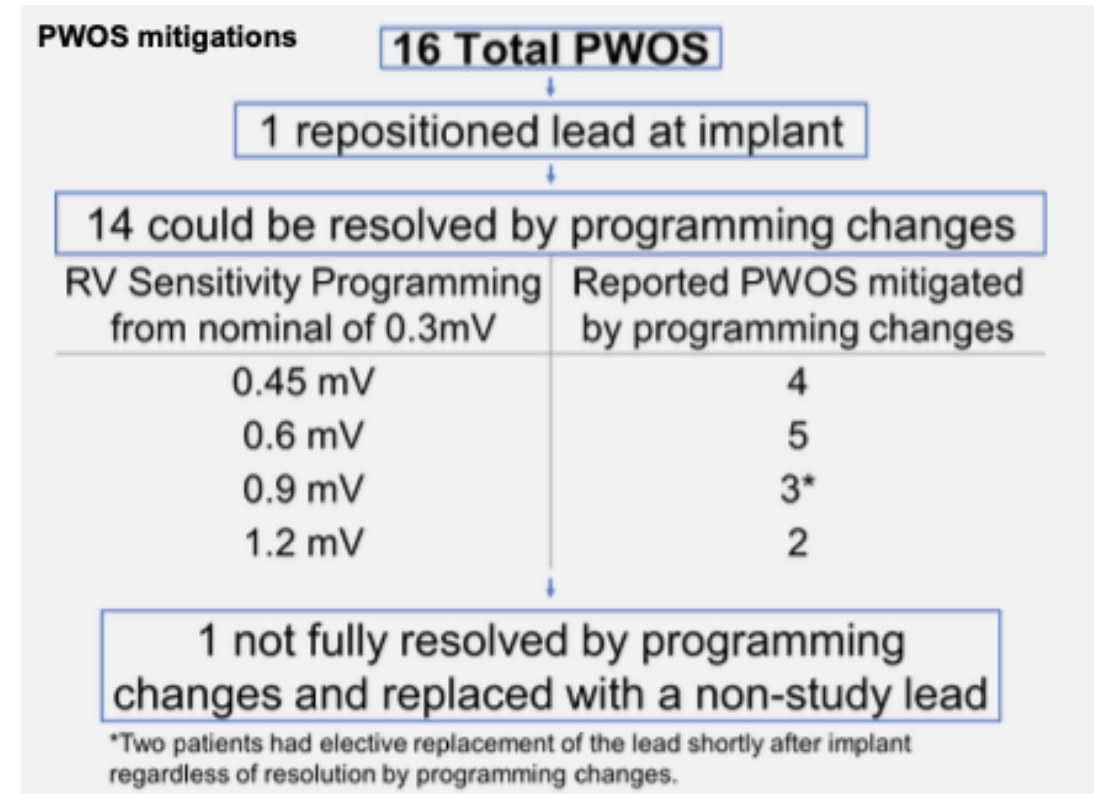
657 patients, 45 centres, 17 pays

Rapport sur les **PWOS** (surdétection de l'onde P) dans l'essai LEADR qui a évalué l'innocuité et l'efficacité de OmniaSecure.

CONCLUSIONS

- L'essai clinique LEADR a montré une **grande efficacité de la défibrillation : 97.5%** (test à l'implantation)
- **Faible taux de complications liées à la sonde VD : 97.1% free**
- **0 fracture** au cours du suivi ($12,7 \pm 4,8$ mois).
- **Faible occurrence de PWOS** et **absence de chocs inappropriés** dus à des PWOS

- PWOS doit être pris en compte lors de l'évaluation de l'implant et peut être atténué en programmant un réglage moins sensible.
- La détection TV/VF n'est pas affectée lorsqu'elle est programmée sur des paramètres moins sensibles.

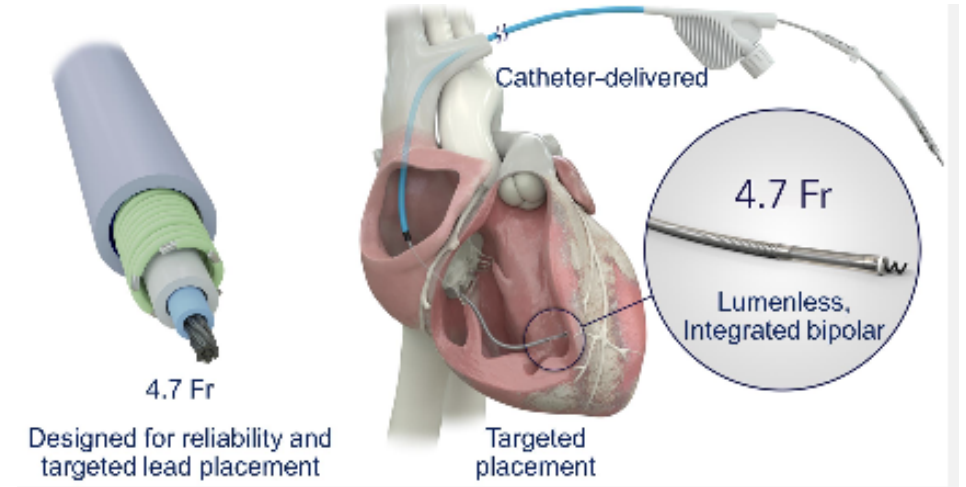


Nouvelles données présentées à l'APHRS

Poster 2

Efficacy and Safety Results of a Novel Small-Diameter Defibrillation Lead by Body Habitus: Analyse de l'essai LEADR

Ce poster se concentre sur l'analyse de l'habitus corporel (BMI, Poids, taille, classe NYHA)



CONCLUSIONS

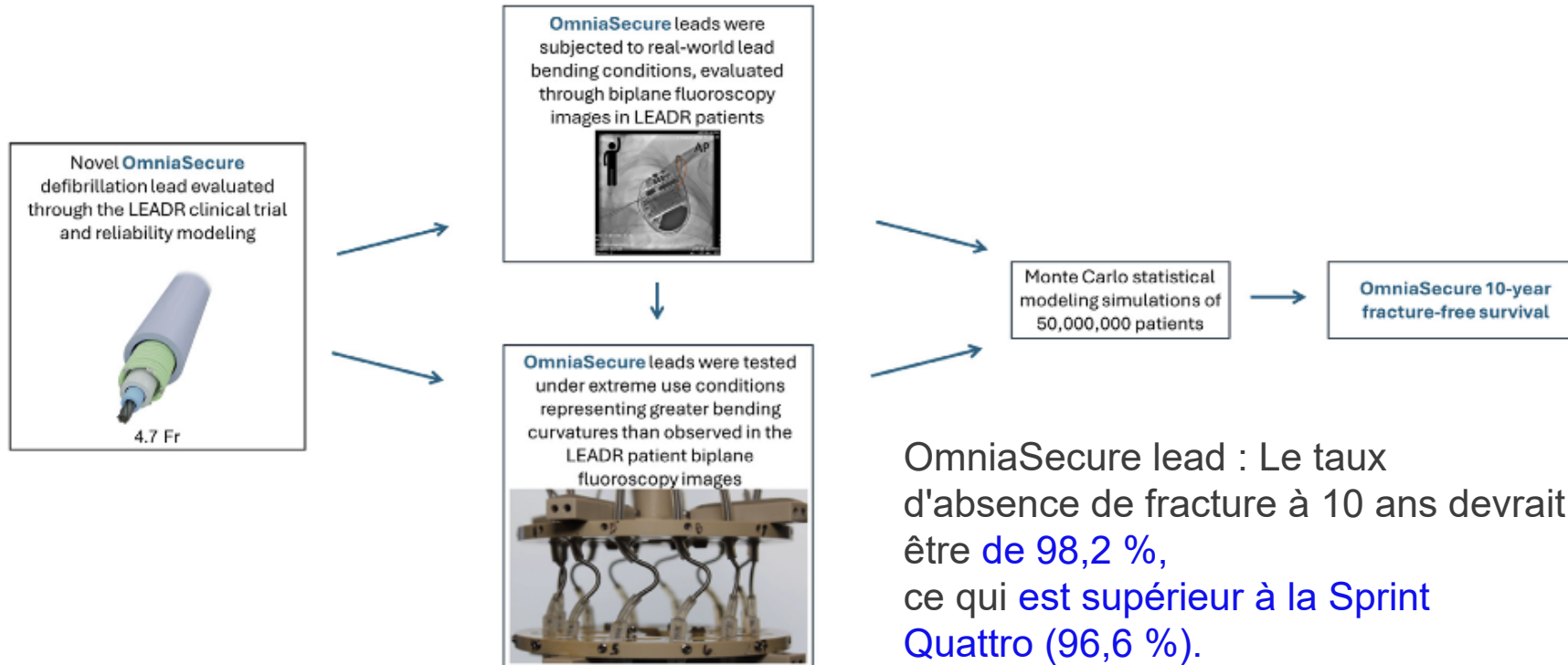
- **Aucune fracture** de la sonde OmniaSecure
- **Paramètres électriques** (seuil de capture, impédance, Onde R...) sont restées chroniquement **stables pendant $12,7 \pm 4,8$ mois.**
- L'efficacité de la défibrillation au moment de l'implantation était élevée et ne différait pas en fonction des caractéristiques du patient (**poids, taille, BMI, classe NYHA**) : **97.5% (test à l'implantation)**
- Le **taux de complications majeures** liées à la sonde VD **faible** et ne **diffère pas en fonction des caractéristiques des patients (poids, taille, BMI, classe NYHA)** : **97.1% libre de complications à 6 et 12 mois**
- Le suivi de l'essai LEADR est en cours et un essai évaluant l'OmniaSecure implantée au niveau de la branche gauche est en cours.

Omnia Secure Reliability Data

Publiée récemment dans Hearth Rhythm

Durabilité élevée prévue pour la nouvelle sonde de défibrillation de petit diamètre OmniaSecure

Objectif : Prévoir la survie sans fracture à 10 ans de la sonde de défibrillation OmniaSecure à l'aide d'une modélisation de la fiabilité.



Conclusion

Conformément à l'expérience des premiers essais cliniques, dans lesquels aucune fracture n'a été observée après 12,7 +/- 4,8 mois, la modélisation prévoit une **performance sans fracture très durable à 10 ans de la sonde OmniaSecure pour une utilisation standard au niveau du VD.**

Ce modèle a prédit avec précision les performances d'autres sondes commercialisées et prévoit que la sonde OmniaSecure **dépassera le taux de survie sans fracture établi par la sonde fiable Sprint Quattro.**