

# CSP s Boston Scientific příslušenstvím

Milan Chovanec

Kardiocentrum, Nemocnice na Homolce a 1.LFUK v Praze



1. LÉKAŘSKÁ  
FAKULTA  
Univerzita Karlova



# Navigate, Fixate, and Pace

## Boston Scientific CSP Portfolio



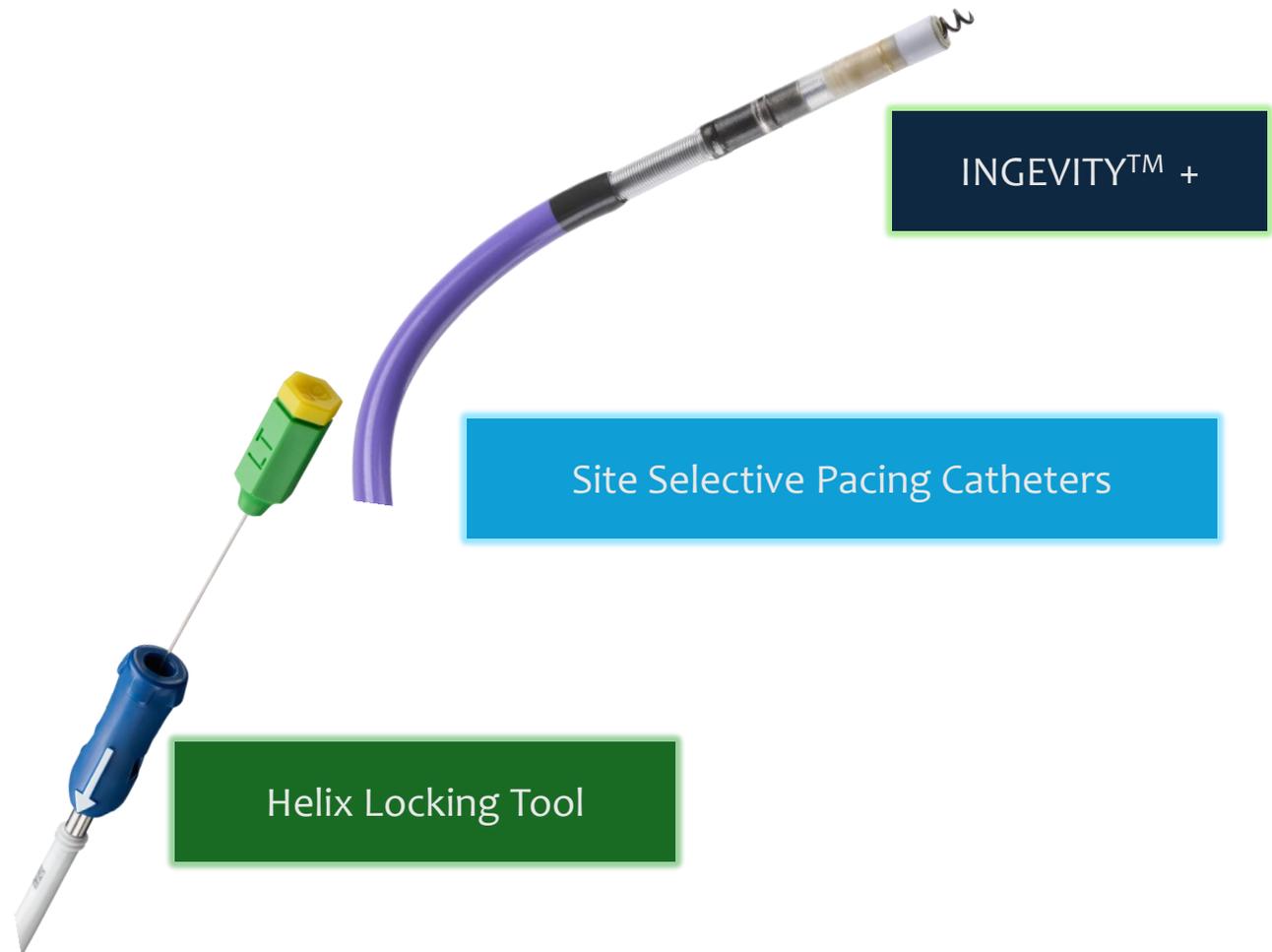
**Navigate**  
precisely



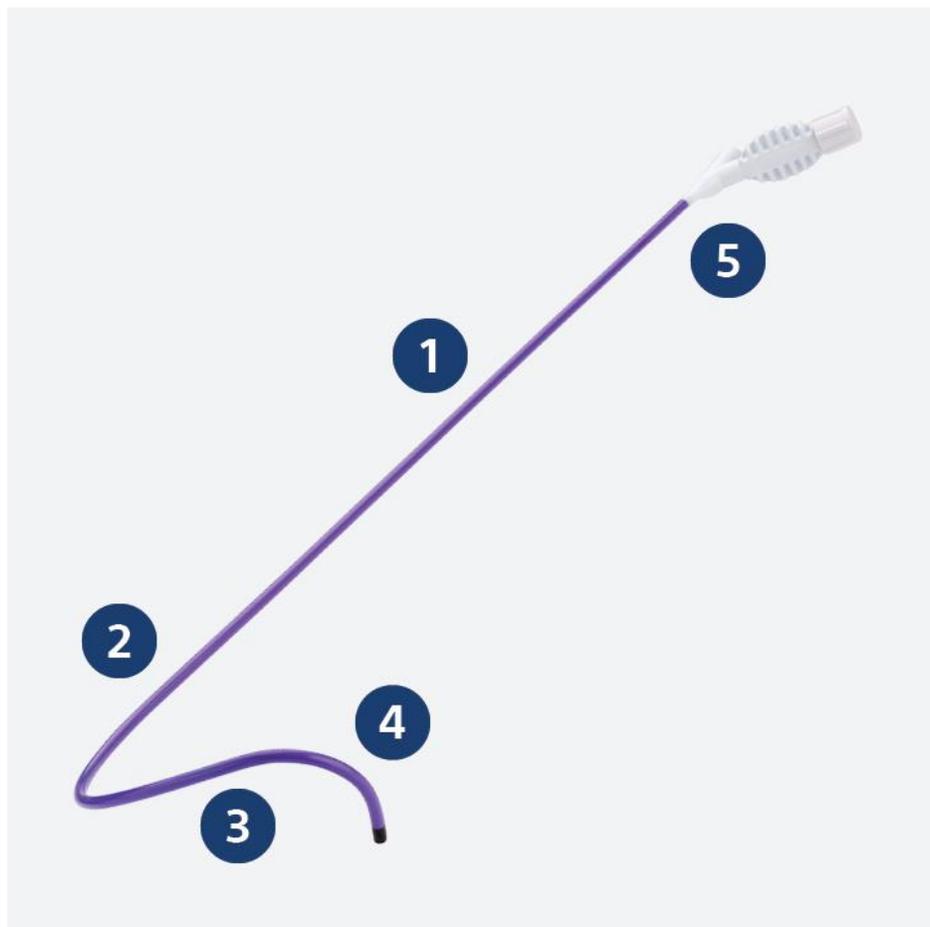
**Fixate**  
efficiently



**Pace**  
confidently

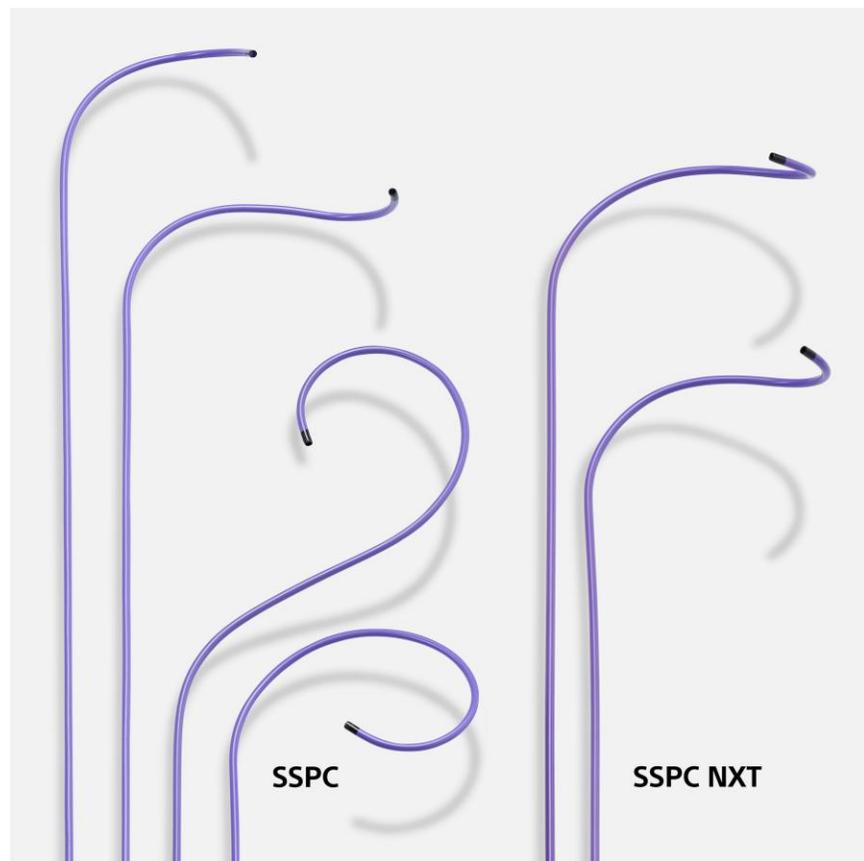


# BSC delivery system – zaváděcí sheaty



- 1.) Vylepšená opora pro větší stabilitu katétru.
- 2.) Prodloužená délka dostupná v délce 42 cm
- 3.) Nové tvary – remodelované srdeční oddíly
- 4.) jednodušší kolmé umístění na septum
- 5.) Zvětšený vnější a vnitřní průměr nabízí větší stabilitu.

# BSC delivery system – zaváděcí sheaty



OD	8 F
ID	6.5 F
Délka [cm]	42
Tuhost	++
Sekundární (septální) zakřivení	++
Chlopeň	✓
Dilatátor	✓

# Helix locking tool



Nástroj pro uzamknutí helixu na úrovni IS-1 konektoru

Uzamkne (zajistí) helix v plném vysunutí i při rotaci těla elektrody

Přidrží krouticí moment aby helix zůstal vysunutý

- Vysunutí helixu v zaváděcím katetru nebo přímo po kolmém nasměrování v septu pomocí HLT
- 5 – 7 otáček navíc



- Oboustranně broušená špička helixu – efektivní pronikání do tkáně.
- Helix penetruje endokard již od začátku rotací



Rotace těla elektrody – max 20  
Rotace helixu – max 30

# INGEVITY™<sup>?</sup>+ elektroda



Elektroda s vodičem (stylet-driven) s vysouvacím fixačním helixem

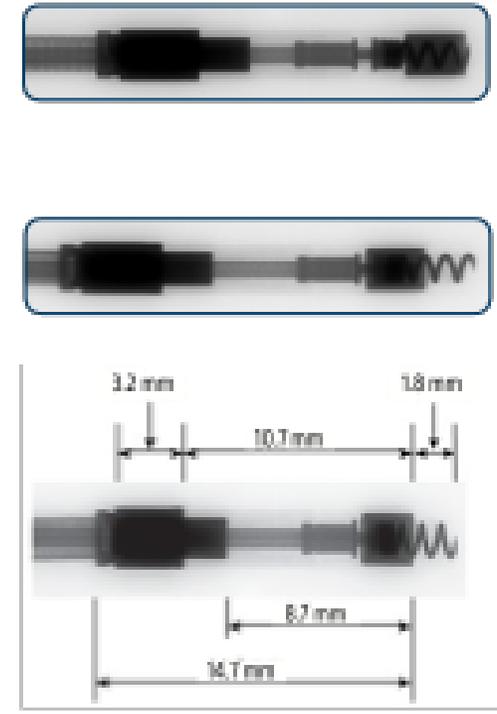
Délka [cm]	45 / 52 / 59
Typ	bipolární
Konektor	IS-1
MRI podmínky použití	1.5T & 3T
Zavaděč	6F (2 mm) / 9F (3 mm) s vodičem
Fixace typ	Aktivní / vysouvací helix
Mimimální počet otáče při fixaci	6x / 7x bez styletu
Maximální počet otáček při fixaci	60 otáček / 3 pokusy 20 otáček těla elektrody (cw/ccw)



# INGEVITY™+ elektroda

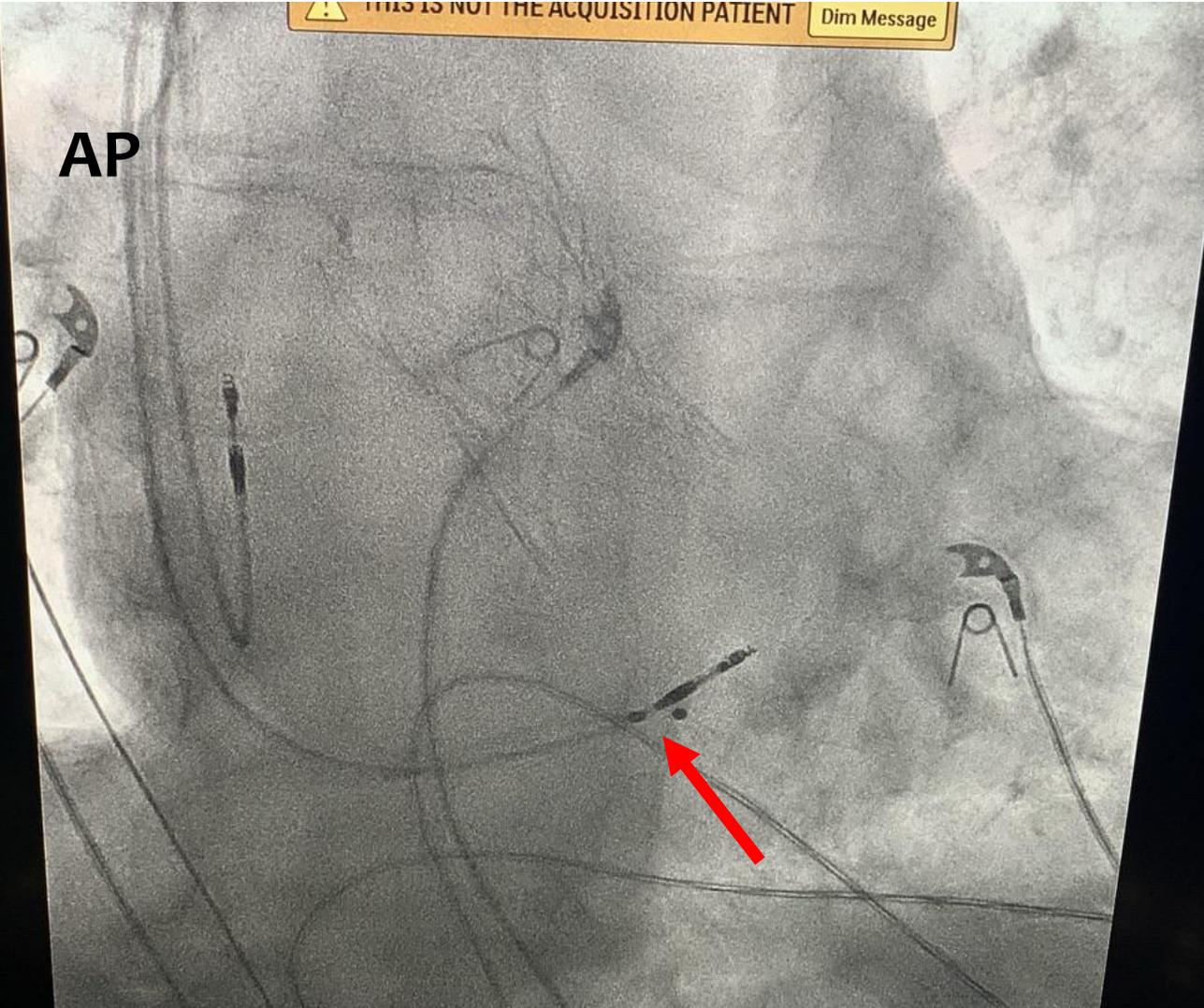


INGEVITY+	
Vzdálenost mezi elektrodami [mm]	10.7
Anoda Ø [mm] vs. plocha [mm <sup>2</sup> ]	2.0 / 20
Helix Ø [mm] vs. plocha [mm <sup>2</sup> ]	1.2 / 4.5
Steroid	dexametazon



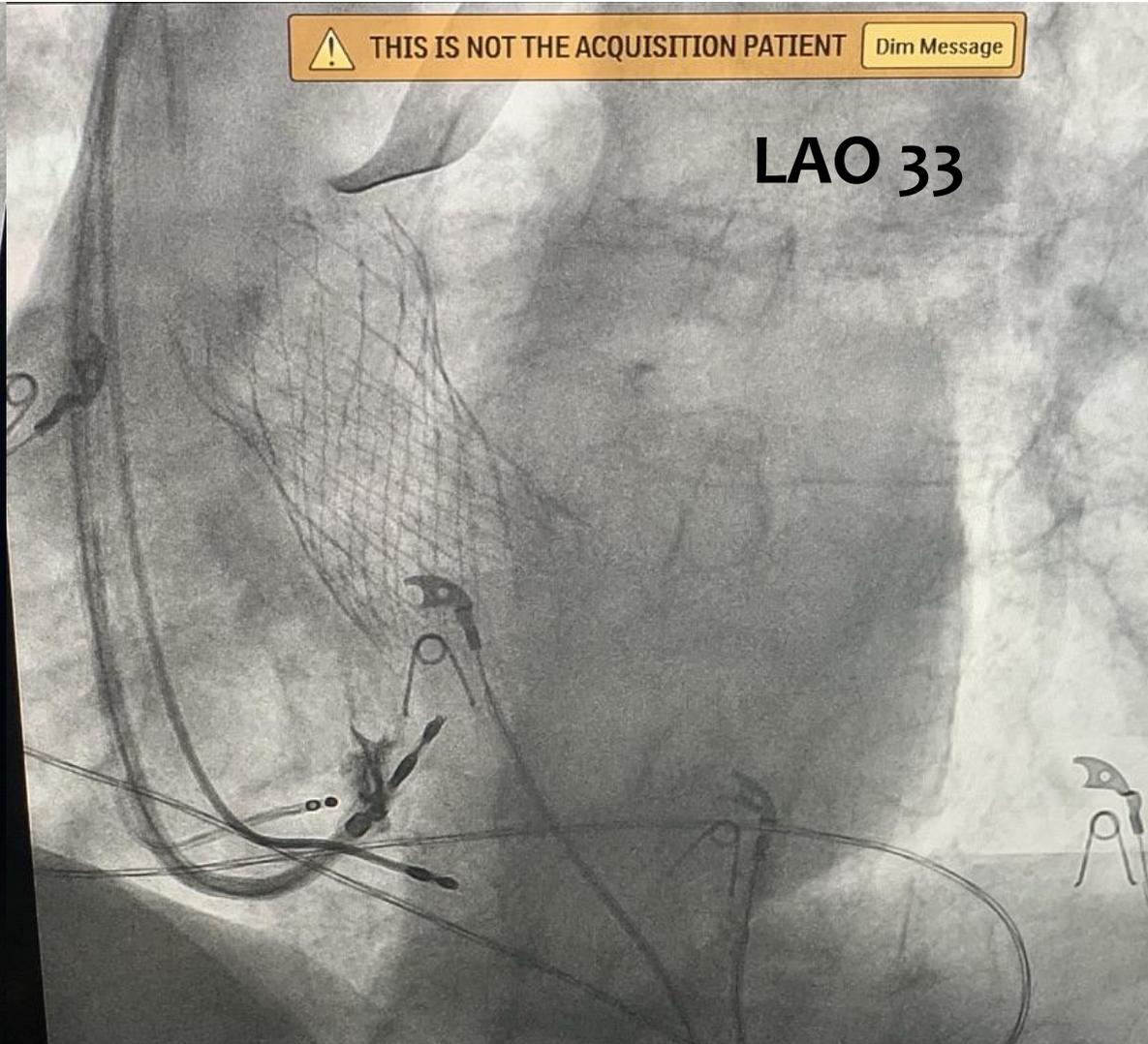
⚠ THIS IS NOT THE ACQUISITION PATIENT Dim Message

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⚠ THIS IS NOT THE ACQUISITION PATIENT Dim Message

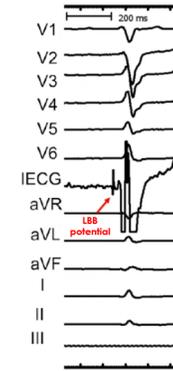
LAO 33



# INGEVITY™+ elektroda

## Stylet design:

- Otáčení těla elektrody je nezávislé na styletu
- Elektrická měření lze provádět přímo na styletu v průběhu fixace: COI, impedance, EKG ...
- Zvyšuje tuhost a penetrabilitu
- Lumen poskytuje možnost extrakčního nářadí (locking stylet)



## Distal tip designed for:

- Precise positioning with electrically active helix
- Allows for mapping with helix retracted
- Clear visual confirmation of helix extension/retraction under fluoro



# Akutní repozice elektrody – INGEVITY™<sub>+</sub>

Screwdriver / Drill / Entanglement

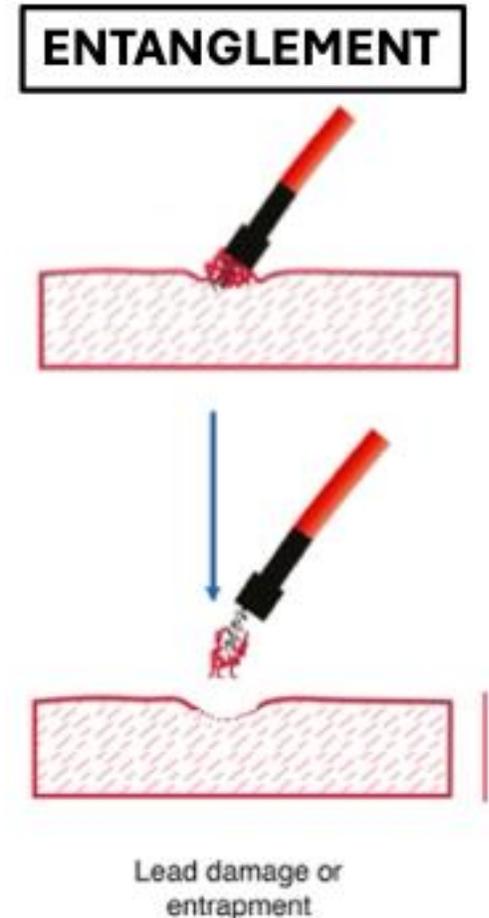
**Doporučené strategie repozice v případě namotání helixu elektrody (entanglement) při LBBAP implantaci:**

**1.) Axiální tah s rotací těla elektrody**

- sheat do místa inzerce tipu elektrody
- Tah na tělo elektrody
- Rotace těla elektrody s pokračujícím tahem

**2.) Axiální tah bez rotace**

- Stáhnout sheat
- Tah na tělo elektrody
- *Zvážit použít locking-stylet*



# Akutní repozice elektrody – INGEVITY™<sub>+</sub>

- Zaváděcí sheat v místě inserce elektrody
- Otáčet tělem elektrody s vysunutým helixem
- Otáčení tělem elektrody s vysunutým helixem snižuje jeho poškození v průběhu repozice
- Pokud to není jednoduše možné zvážit extrakci elektrody (locking stylet, ...)

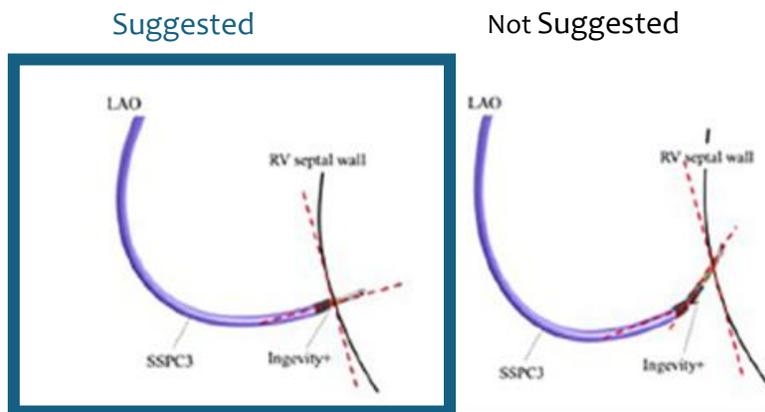


Figure 1: Lead Catheter Orientation

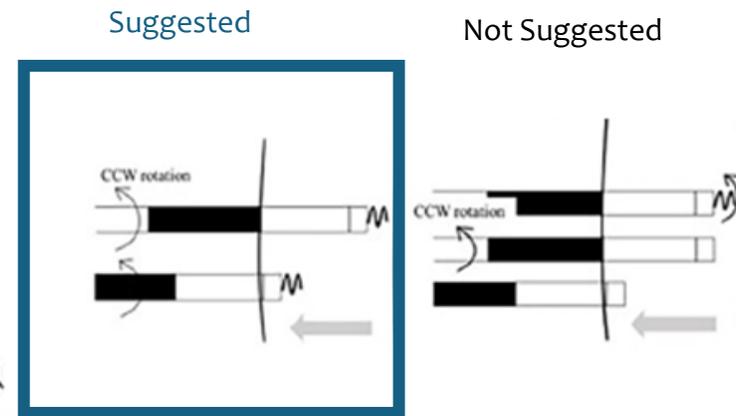


Figure 2: Helix Position Prior to Lead Body Rotation

NNH: 1. 1. – 3. 11. 2025	Boston	Abbott	Medtronic
Σ	56	95	343
♂♀	35 (62.5%)	64 (67.4%)	234 (68.2%)
Ø Věk [r]	75 ± 11	76 ± 8	75 ± 9
Čas výkonu [min]	35,9 ± 13.0	36.0 ± 15.0	40.9 ± 20.4
Fluoro time [min]	4.2 ± 3.4	3.9 ± 2.9	5.0 ± 5.1
ZPRAVA	3 (5.4%)	4 (4.2%)	18 (5.2%)
KS / CRT-D	35 (62.5%) / 21 (37.5%)	83 (87.3%) / 12 (12,6%)	229 (66.7%) / 114 (33.3%)
Stim parametry Ø:	0.9/0.4 ... 698 ... 12.2	1.2/0.4 ... 670 ... 10.6	1.1/0.4 ... 685 ... 9.7
QRS před/po [ms]	CRT-D 168± 32 / 129± 14	162± 23 / 129± 14	157± 28 / 124± 15
	KS 115± 27 / 111± 10	111± 25 / 109± 12	120± 28 / 111± 13
CRT-D V6RWPT	93± 13	86± 11	83± 10
KS V6RWPT	72± 13	74± 10	74± 10

# Shrnutí

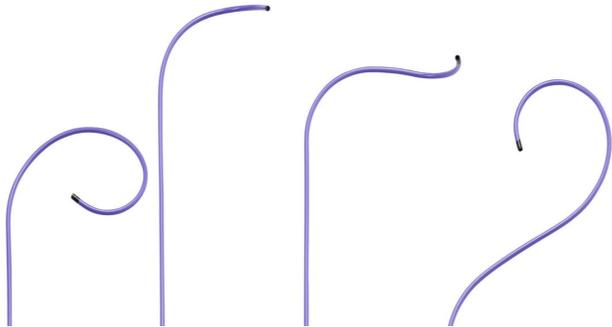
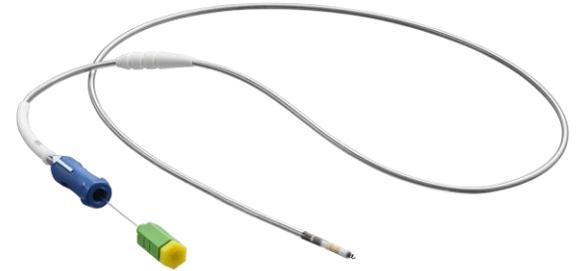
- BSC nabízí systém pro efektivní a stabilní dosažení stimulace převodního systému (CSP)
- Úspěšnost a dosažení CSP je srovnatelná s konkurenčními systémy
- Zaváděcí sheaty s různými křivkami zahnutí umožňují precizní zacílení LBBAP i u dilatovaných nebo remodelovaných srdečních oddílů
- Stylet-driven: lepší tuhost a možnost extrakce (locking-stylet)
- HLT: spolehlivé uzamčení vysunutého helixu





- Elektroda, obrázky, vlastnosti, rozměry
- Zavaděče ...
- Celý zaváděcí systém – Helix locking systém
- Naše výsledky
- Závěr

NNH: 1. 1. – 3. 11. 2025	Boston	Abbott	Medtronic
$\Sigma$	56	95	343
	35 (62.5%)	64 (67.4%)	234 (68.2%)
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Stim parametry Ø:	0.9/0.4 ... 698 ... 12.2	1.2/0.4 ... 670 ... 10.6	1.1/0.4 ... 685 ... 9.7
Jiná LBB elektroda	15 (26.8%)	7 (7.4%)	-----
KS / CRT-D	35 (62.5%) / 21 (37.5%)	83 (87.3%) / 12 (12,6%)	229 (66.7%) / 114 (33.3%)
QRS před/po [ms]	CRT-D 168± 32 / 129± 14	162± 23 / 129± 14	157± 28 / 124± 15
	KS 115± 27 / 111± 10	111± 25 / 109± 12	120± 28 / 111± 13
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## What is the Helix Locking Tool?

- The Helix Locking Tool (HLT) is a standalone accessory designed to provide control over the terminal pin.
  - Extend and retract the helix
    - Clockwise rotation extends the helix
    - Counterclockwise rotation retracts the helix
  - Holds torque on the terminal pin to keep the helix extended
- **Do not exceed maximum turn counts outlined in the pacing lead's IFU**
  - Example: INGEVITY+ maximum turn count for terminal pin rotation is 30 turns.



# Fixate into the LBBA

## The CSP Portfolio designed to optimize workflow



Radiopaque markers indicate **clear helix extension/retraction** and **facilitate lead placement**.

### After navigating to the precise location:

1. Pre-extend the helix in the catheter or extend directly in the septum with the Helix Locking Tool<sup>1</sup>
2. Pre-torque the inner coil with up to 5-7 additional turns<sup>1</sup>



Helix Fully Extended



Helix Fully Retracted



Tip features a two-faceted grind helix tip for **efficient tissue penetration**. The helix can penetrate the tissue at the start of helix extension



Lock helix into full extension with the Helix Locking Tool<sup>2</sup>

Maximum lead body turns positioning: 20  
Maximum terminal pin rotations: 30

<sup>1</sup> INGEVITY+ IFU <https://www.bostonscientific.com/elabeling/us/en/home.html>  
<sup>2</sup> Boston Scientific data on file: 97178577



# Fixate into the LBBA

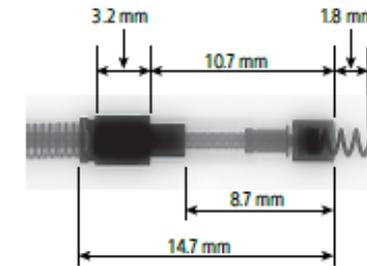
## Lead Body Rotations

Progress safely into the septum with continuous pacing from the stylet<sup>1</sup> to the electrically active helix and more responsive lead body with the INGEVITY+ pacing lead<sup>2</sup>

Extensive fatigue testing to ensure the lead body **can withstand lead body turns** including outer insulation wrinkling<sup>3</sup>



Lead body **design easier to grip** compared to lumenless leads<sup>4</sup>



**Clear fluoroscopic markers** to determine lead depth

Uninterrupted feedback from the stylet to **monitor impedance, injury, and ECG** while rotating the lead body<sup>1,4</sup>

<sup>1</sup> Boston Scientific data on file: 184951-460

<sup>2</sup> Chapman, D, Morgan, F, Tiver, K. et al. Assessing Torque Transfer in Conduction System Pacing: Development and Evaluation of an Ex Vivo Model. J Am Coll Cardiol EP. 2024 Feb, 10 (2) 306–315.

<https://doi.org/10.1016/j.jacep.2023.10.035>

<sup>3</sup> Boston Scientific data on file: ELN 12481298, 12941008

<sup>4</sup> Burri H, Jastrzebski M, Cano Ó, et al. EHRA clinical consensus statement on conduction system pacing implantation: executive summary. Endorsed by the Asia-Pacific Heart Rhythm Society (APHRS), Canadian Heart Rhythm Society (CHRS) and Latin-American Heart Rhythm Society (LAHRS). Europace. 2023;25(4):1237-1248. doi:10.1093/europace/euado44



# Need to Reposition?

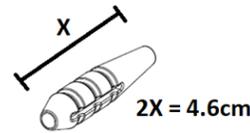
## Acute Removal Techniques

Removal techniques specifically for INGEVITY+ developed to successfully remove the lead in the infrequent event of helix entrapment<sup>1,2</sup>

Two acute removal strategies were identified for successful INGEVITY+ removal when the helix is substantially entangled during an LBBAP implant<sup>2</sup>:

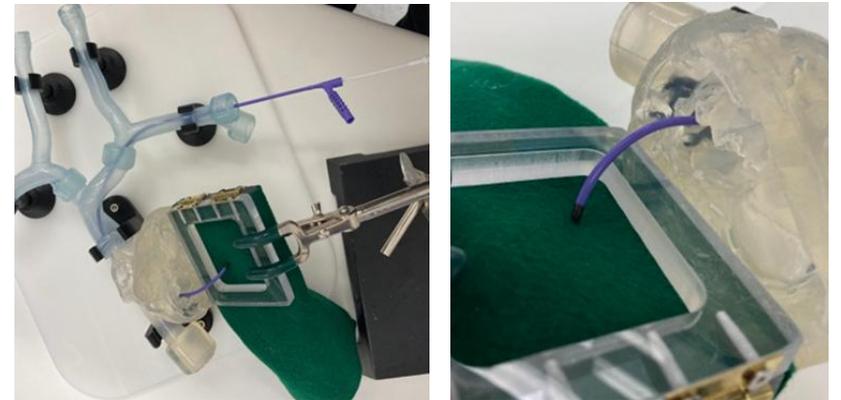
### Strategy 1: Axial Tension with Lead Body Rotation

- Recreate the implant pathway with the catheter.
- Apply tension to the lead body (achieve  $\sim 4.6\text{cm}$  of lead stretch).
- Sustain that tension while rotating the lead body counterclockwise



### Strategy 2: Axial Tension Only

- Remove the catheter from the implant pathway.
- Apply traction along the lead body.
- A locking stylet and other typical extraction tools may be used to aid this process.



<sup>1</sup> Jastrzębski et al. Left bundle branch area pacing outcomes: the multicentre European MELOS study, *European Heart Journal*, Volume 43, Issue 40, 21 October 2022, Pages 4161–4173, <https://doi.org/10.1093/eurheartj/ehac445>  
<sup>2</sup> Boston Scientific data on file 184951-460

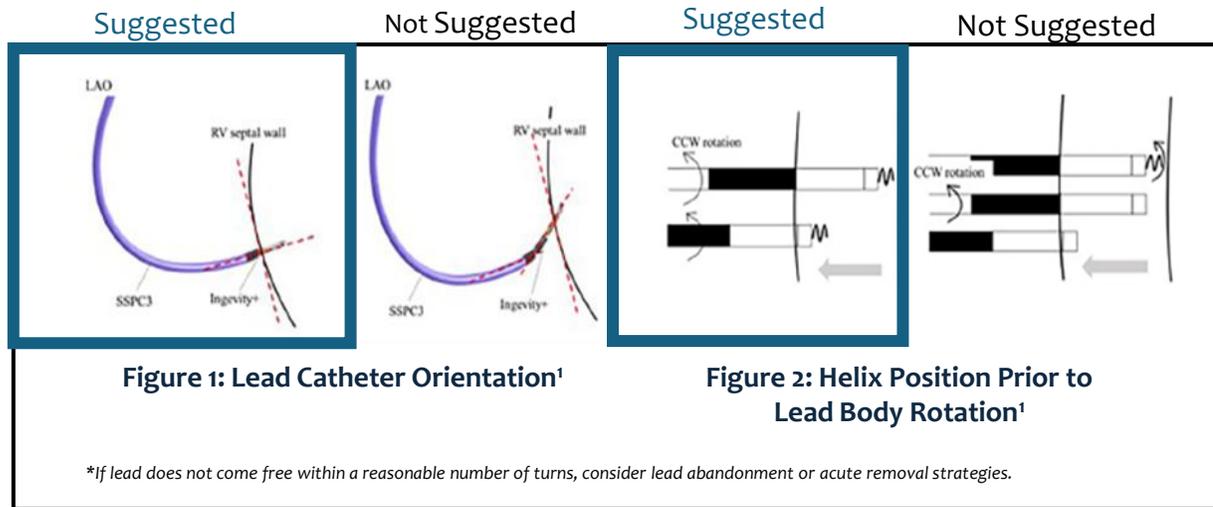


# Need to Reposition?

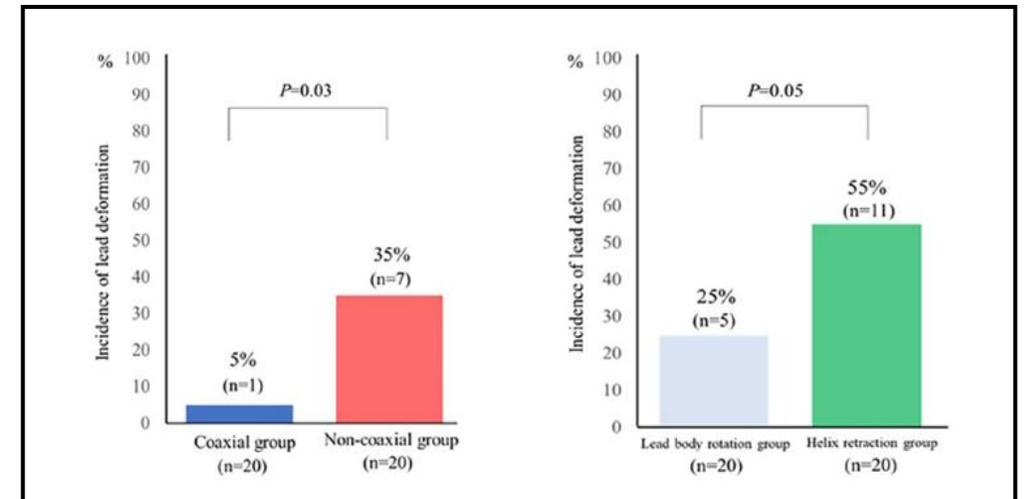
## Acute Repositioning Techniques

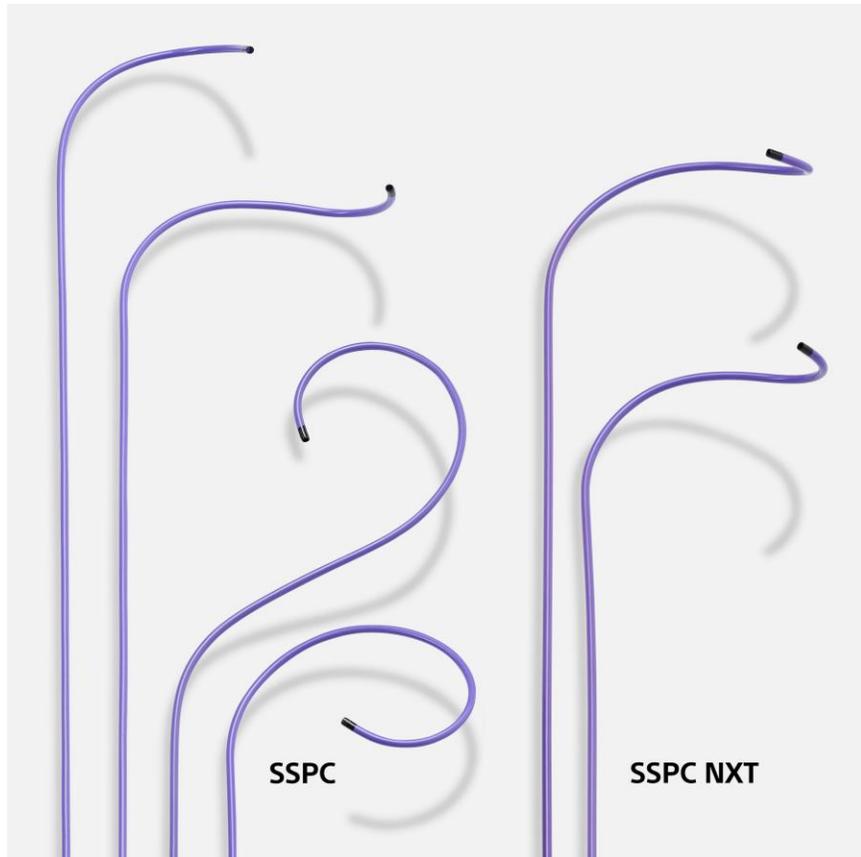
### Simplified techniques with LBBAP repositioning needs in mind

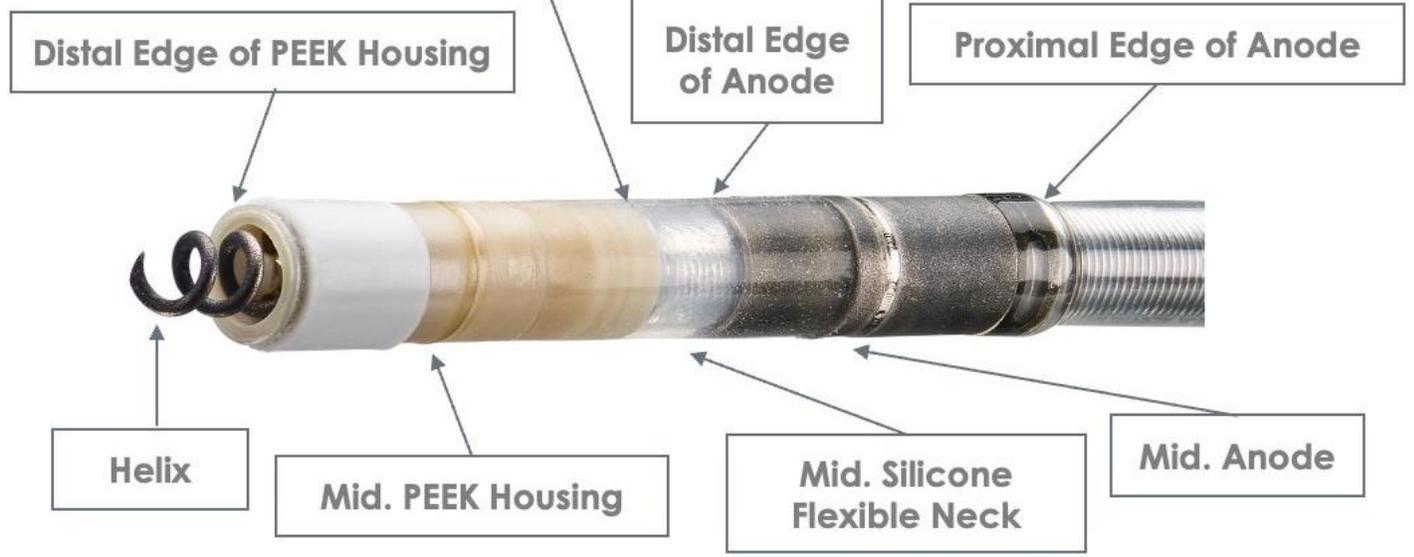
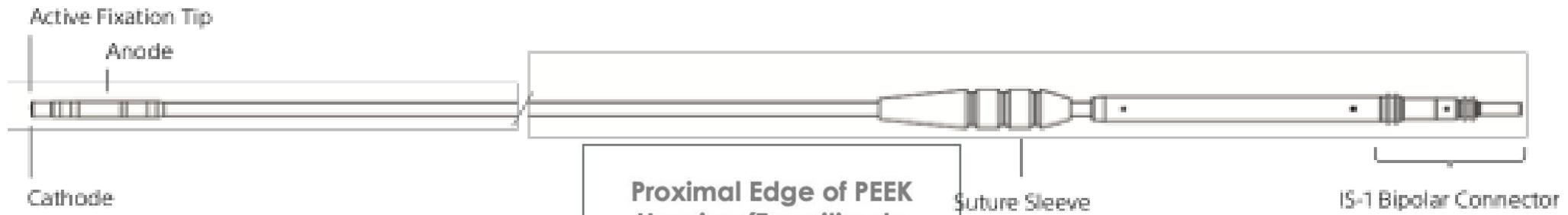
1. Recreate implant pathway with catheter tip
2. Keeping helix extended, with Helix Locking Tool removed, counter-clock lead body with caution to disengage from tissue



The simplified technique of lead body turns with an extended helix decreased helix damage during repositioning.<sup>1</sup>









# INGEVITY™+ for LBBAP

Proven Longevity. Predictable Performance.

## Capture the LBBA with our 6 Fr stylet-driven, extendable-retractable, bipolar pacing lead

The INGEVITY+ pacing leads achieved **zero conductor fractures** and a **95.6% success rate** in LBBA procedures from the INSIGHT-LBBA data set and rigorous R&D testing. INGEVITY+ pacing leads are proven for longevity in this new application.<sup>1,2,3,4</sup>

Precisely navigate and continuously pace with Boston Scientific's CSP portfolio anchored by the INGEVITY+



1 Boston Scientific data on file: 184951-436  
2 Boston Scientific data on file: ELN 12481339  
3 Boston Scientific data on file: 184951-434  
4. Friedman DJ, Shadrin I, Goldberg S, et al. Performance of an active fixation stylet-driven lead in left bundle branch area pacing: Results from INSIGHT-LBBA. Heart Rhythm. Published February 4, 2025. <https://doi.org/10.1016/j.hrthm.2025.01.04>



# INGEVITY+ for LBBAP

## Designed for Precision in a new application

### Tri-filar inner coil

- Enhanced design from INGEVITY classic to INGEVITY+
- Bare inner coil allows for stylet pacing as the cathode<sup>1</sup>
- Predictable performance with low and consistent turn counts



6Fr lead design is easier to grip compared to lumenless leads<sup>2</sup>

### Stylet Design

- Lead body rotates independently from stylet allowing for continuous impedance, injury and ECG monitoring during fixation<sup>2</sup>
- Open-lumen for conventional extraction tools<sup>3,4</sup>
- Extends beyond the anode for greater tip control during fixation<sup>5</sup>



### Distal tip designed for:

- Precise positioning with electrically active helix
- Allows for mapping with helix retracted
- Clear visual confirmation of helix extension/retraction under fluoro

<sup>1</sup> Boston Scientific data on file: 184951-460  
<sup>2</sup> Burri H, Jastrzebski M, Cano Ó, et al. EHRA clinical consensus statement on conduction system pacing implantation: executive summary. Endorsed by the Asia-Pacific Heart Rhythm Society (APHRs), Canadian Heart Rhythm Society (CHRS) and Latin-American Heart Rhythm Society (LAHRS). *Europace*. 2023;25(4):1237-1248. doi:10.1093/europace/euad044

<sup>3</sup> Vatterott, Pierce, et al. "Strategies to Increase the INGEVITY Lead Strength during Lead Extraction Procedures Based on Laboratory Bench Testing." *Pacing and Clinical Electrophysiology*, vol. 44, no. 8, 21 July 2021, pp. 1320-1330, <https://doi.org/10.1111/pace.14303>.

<sup>4</sup> Vatterott, Pierce, et al. "Strategies to Maximize Lead Tensile Strength during Extraction in Three Families of Pacing Leads." *HeartRhythm*, vol. 21, no. 6, 10 Jan. 2024, pp. 929-938, [www.heartrhythmjournal.com/article/S1547-5271\(24\)00016-X/fulltext](http://www.heartrhythmjournal.com/article/S1547-5271(24)00016-X/fulltext), doi: 10.1016/j.hrthm.2024.01.005.

<sup>5</sup> Boston Scientific data file: 042010-959

# INGEVITY+ Fatigue Testing



## Fatigue testing completed to demonstrate suitability for LBBAP:

- Distal Tip<sup>1,2</sup>:
  - 400 million cycle fatigue
  - Stress accelerated fatigue
- Intracardiac<sup>3</sup>
- Subcutaneous w/ outer insulation wrinkling<sup>4</sup>
- Bellmouth w/ outer insulation wrinkling<sup>5</sup>

## Conclusions:

1. **Zero Conductor Fractures!** Under simulated use conditions, INGEVITY+ leads demonstrated a minimum **10-year survivability** in the LBBA<sup>2,4,5</sup>
2. **23 years!** Stress accelerated fatigue of the distal tip demonstrated at **2.3X the 10-year life survivability** with zero conductor fractures.<sup>2</sup>
3. **Durable lead body!** The INGEVITY+ lead body is **durable** even when exposed to rough simulated LBBAP use, including outer insulation wrinkling.<sup>4,5</sup>

<sup>1</sup> Boston Scientific data on file: 184951-436

<sup>2</sup> Boston Scientific data on file: ELN 12481339

<sup>3</sup> Boston Scientific data on file: 184951-434

<sup>4</sup> Boston Scientific data on file: ELN 12481298

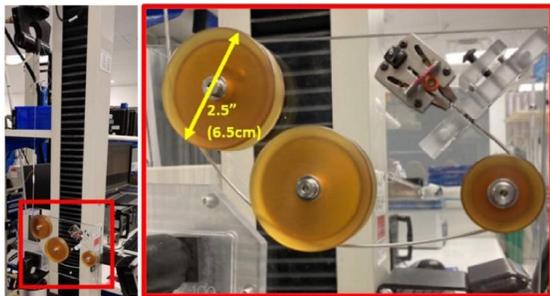
<sup>5</sup> Boston Scientific data on file: ELN 12941008

Bench Test results may not necessarily be indicative of clinical performance.

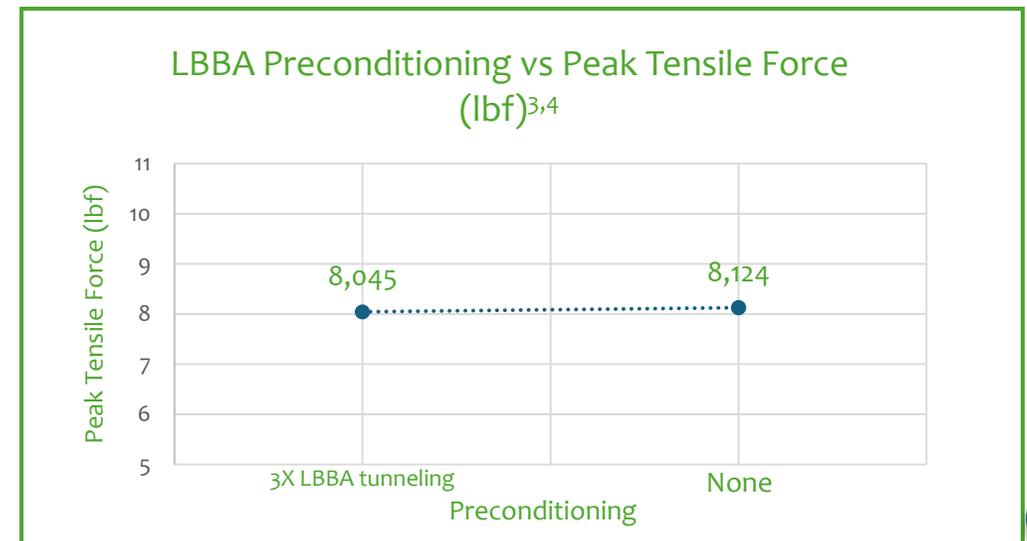
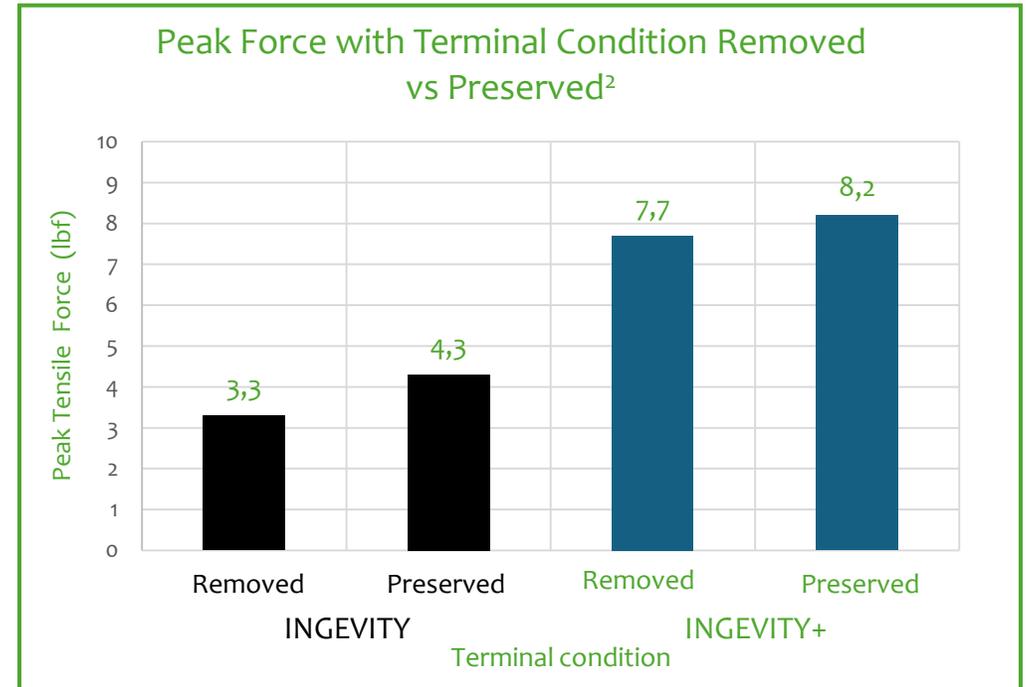
# Extraction

Design enhancement to the tri-filar coil and joint construction from INGEVITY to INGEVITY+ translates to greater extraction strength by **200%**.<sup>1,2</sup>

INGEVITY+ extraction strength is **not impacted** by the new handling conditions of LBBAP.<sup>3,4</sup>



Pulley system simulating critical bending along the extraction pathway of a typical RA appendage implant.



<sup>1</sup> Vatterott, Pierce, et al. "Strategies to Increase the INGEVITY Lead Strength during Lead Extraction Procedures Based on Laboratory Bench Testing." Pacing and Clinical Electrophysiology, vol. 44, no. 8, 21 July 2021, pp. 1320-1330, <https://doi.org/10.1111/pace.14303>.  
<sup>2</sup> Vatterott, Pierce, et al. "Strategies to Maximize Lead Tensile Strength during Extraction in Three Families of Pacing Leads." HeartRhythm, vol. 21, no. 6, 10 Jan. 2024, pp. 929-938, [www.heartrhythmjournal.com/article/S1547-5271\(24\)00016-X/fulltext](http://www.heartrhythmjournal.com/article/S1547-5271(24)00016-X/fulltext), <https://doi.org/10.1016/j.hrthm.2024.01.005>.  
<sup>3</sup> Boston Scientific data on file: 184951-434  
<sup>4</sup> Boston Scientific data on file: ELN 12724521  
 Bench Test results may not necessarily be indicative of clinical performance.



# Navigate to the septum

## Site Selective Pacing Catheters

Physician-designed catheters,  
precision-engineered to reach further

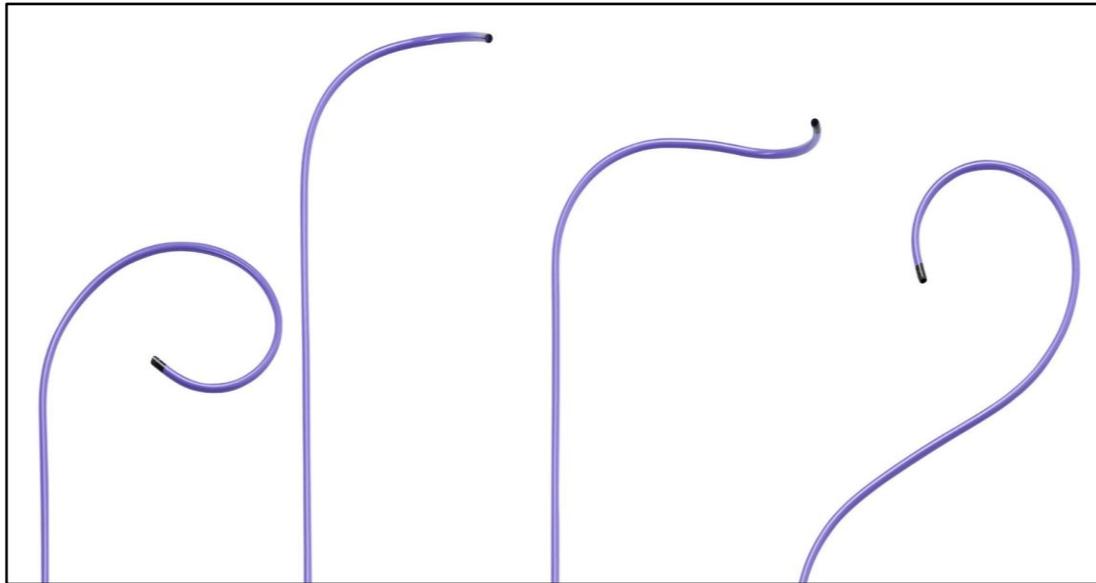
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**SSPC 1**  
C-Shape

**SSPC 2**  
Multipurpose

**SSPC 3**  
Extended Hook

**SSPC 4**  
Right-Sided



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	✓	✓

“Use of the **BSC delivery system** was associated with **significantly shorter fluoroscopy times** ( $9.8 \pm 7.4$  mins vs.  $15.5 \pm 8.1$  mins;  $p = 0.02$ ) and a trend towards reduced procedure times.”<sup>1</sup>

\*compared to the existing Medtronic system

<sup>1</sup> Braunstein et. al. (2021, August) Early Experience with a Novel Fixed Curve Delivery system with Style-Driven Leads for Permanent Left Bundle Branch Pacing, Heart Rhythm 2021, DOI: <https://doi.org/10.1016/j.hrthm.2021.06.965>



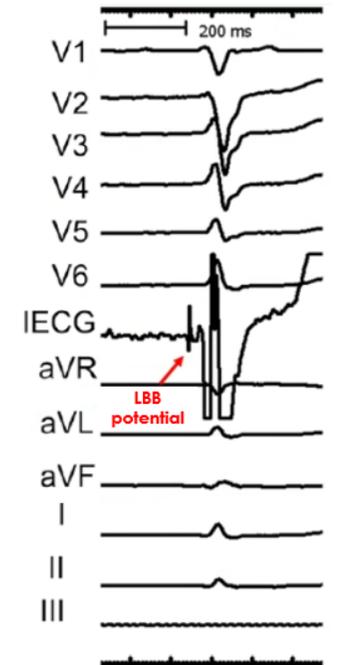
# Navigate to the septum

## INGEVITY+

Map with the helix retracted to  
**avoid snagging tissue<sup>1</sup>**

Electrically active helix for  
**precise location<sup>1</sup>**

**Stylet driven** allows familiar handling for  
directionality and support during lead  
positioning



<sup>1</sup> Burri H, Jastrzebski M, Cano Ó, et al. EHRA clinical consensus statement on conduction system pacing implantation: executive summary. Endorsed by the Asia-Pacific Heart Rhythm Society (APHRS), Canadian Heart Rhythm Society (CHRS) and Latin-American Heart Rhythm Society (LAHRS). *Europace*. 2023;25(4):1237-1248. doi:10.1093/europace/euad044  
<sup>2</sup> Huan et al. Left bundle branch potential - *BMC Cardiovascular Disorders* (2022) 22:376

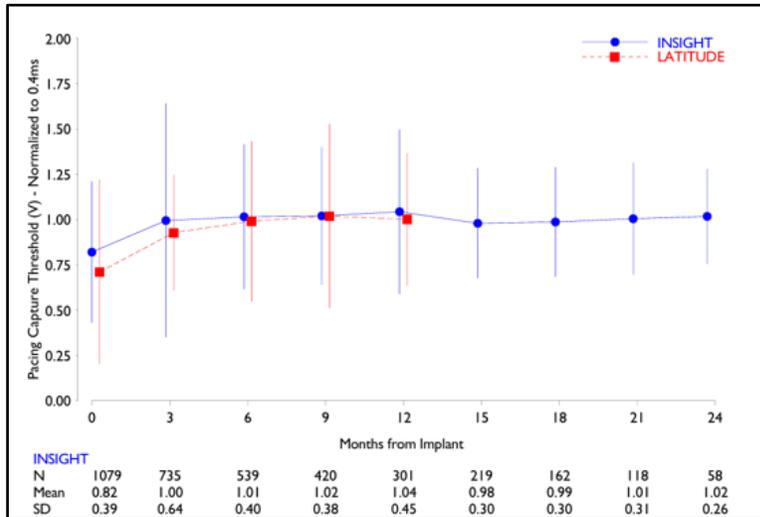


# Pace confidently

## Evaluate Lead Position

Based on the INSIGHT-LBBA data set which evaluated 1122 leads, INGEVITY+ demonstrated low and consistent thresholds<sup>1</sup>

Pacing Capture Thresholds @ 0.4 Pulse Width Throughout Follow-up<sup>1</sup>



Thresholds remained less than 2V at 0.4ms at 3 months<sup>1</sup>

Mean thresholds at 3 months were

**1.0 V**  
**@ 0.4ms**

Total Projected Longevity with **100%** RV paced<sup>2</sup>  
Boston Scientific ACCOLADE™ MRI DR EL Pacemaker **1.6 Amp Hr**

**12.1 YEARS**

<sup>1</sup> Friedman DJ, Shadrin I, Goldberg S, et al. Performance of an active fixation stylet-driven lead in left bundle branch area pacing: Results from INSIGHT-LBBA. Heart Rhythm. Published February 4, 2025. <https://doi.org/10.1016/j.hrthm.2025.01.04>  
<sup>2</sup> Longevity Calculator, Nominal RA settings, RV: 2.5V at 0.4ms, 650 ohms, 100% RV Paced, <https://www.bostonscientific.com/en-EU/medical-specialties/electrophysiology/device-longevity/longevity-calculator.html>