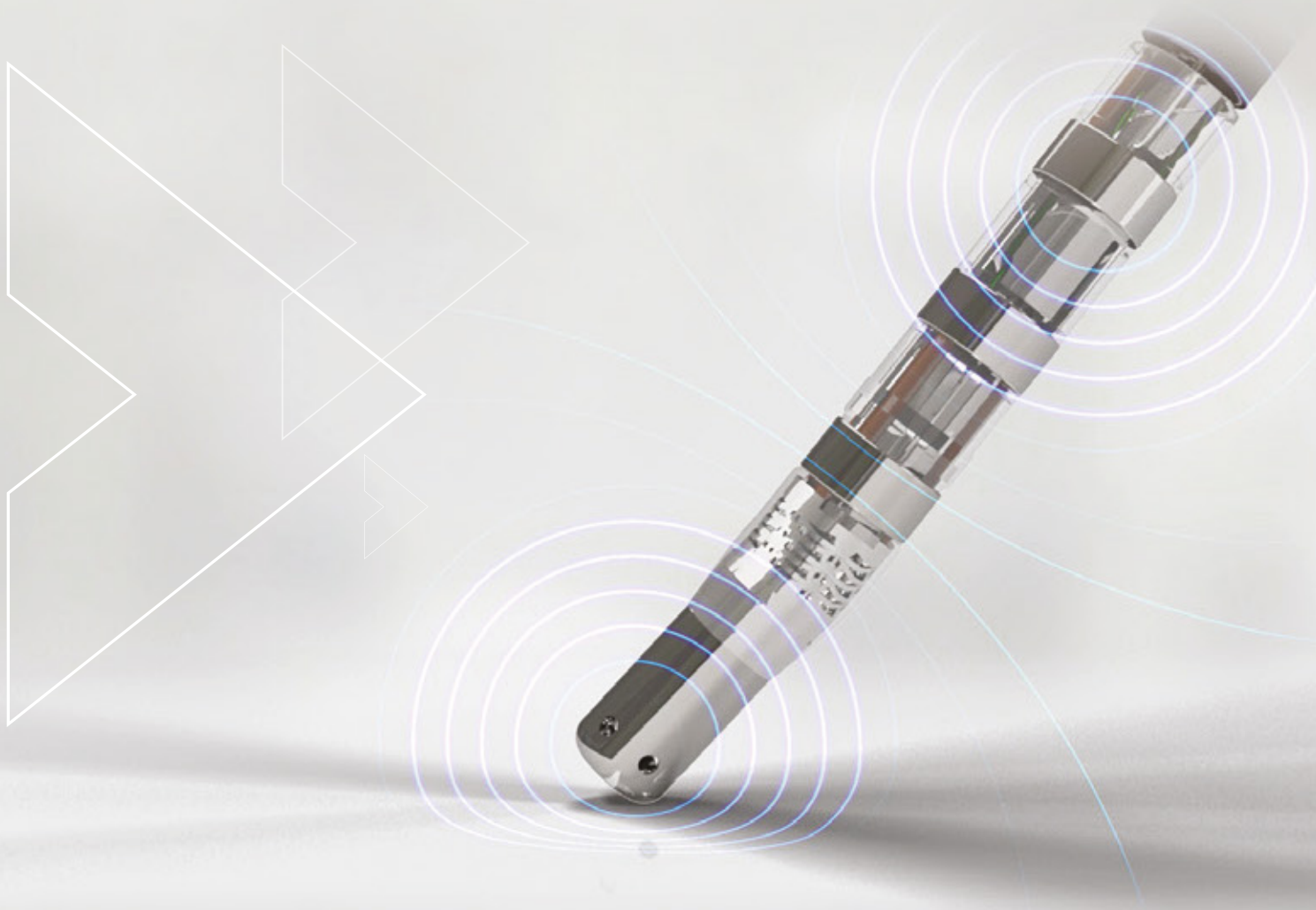


**INTELLANAV STABLEPOINT™**  
Ablation Catheter  
Clinical Compendium



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# PUBLICATION LIST BY TOPIC

## Lesion Characterization (PVI)

- Fukaya, et al., [Optimal Local Impedance Parameters for Successful Pulmonary Vein Isolation in Patients with Atrial Fibrillation](#)
- Ikenouchi, et al., [Requirement of Larger Local Impedance Reduction for Successful Lesion Formation at Carinal Area during Pulmonary Vein Isolation](#)
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## Lesion Characterization (CTI)

- Sasaki, et al., [Local Impedance Measurements during Contact Force-Guided Cavotricuspid Isthmus Ablation for Predicting an Effective Radiofrequency Ablation](#)

## Local Impedance & Contact Force Relationship

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## High-Power Ablation

- Solimene, et al., [Prospective Evaluation of Local Impedance Drop to Guide Left Atrial Posterior Wall Ablation with High Power](#)

## Pre-Clinical

- Gutbrod, et al., [Improved Ablation Efficiency in PVI Guided by Contact Force and Local Impedance: Chronic Canine Model](#)
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## Editorial

- Chu, et al., [Local Impedance for the Optimization of Radiofrequency Lesion Delivery: A Review of Bench and Clinical Data](#)

## 2022 CLINICAL PUBLICATIONS

### **Optimal Local Impedance Parameters for Successful Pulmonary Vein Isolation in Patients with Atrial Fibrillation**

Fukaya H, Mori H, Oikawa J, et al.

*Journal of Cardiovascular Electrophysiology* (November 2022), available at:

<https://onlinelibrary.wiley.com/doi/10.1111/jce.15748>

- STABLEPOINT™ local impedance (LI) parameters for successful pulmonary vein isolation (PVI) were evaluated for 102 patients (5257 ablations).
- LI drops were higher for successful vs unsuccessful ablations.
- The optimal LI drop was 20.0  $\Omega$  and the LI % cutoff value was 11.6%.

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### **Requirement of Larger Local Impedance Reduction for Successful Lesion Formation at Carinal Area during Pulmonary Vein Isolation**

Ikenouchi T, Takigawa M, Goya M, et al.

*Journal of Interventional Cardiac Electrophysiology* (July 2022), available at:

<https://doi.org/10.1007/s10840-022-01282-1>

- Evaluated the local impedance (LI) drop and % LI drop for predication in acute lesion durability during PVI with STABLEPOINT.
- 23 patients underwent PVI with the operators blinded to LI.
- Generator impedance drop, LI drop and % LI drop were associated with successful lesions.
- The carina was significantly associated with gaps.
- LI drop and % LI drop were equally predictive of acute lesion durability.
- Optimal LI drops were  $\geq 24\Omega$  with  $\geq 15\%$  LI drop at the carina,  $\geq 21\Omega$  with  $\geq 14\%$  at non-carinal sites significantly predicted acute successful lesions with a negative predictive value of 93-99%.

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### **Prospective Evaluation of Local Impedance Drop to Guide Left Atrial Posterior Wall Ablation with High Power**

Solimene F, Schillaci V, Stabile G, et al.

\*Ablation of persistent AF patients is outside the use of labeled indication of the STABLEPOINT Catheter

*Journal of Interventional Cardiac Electrophysiology* (July 2022), available at:

<https://doi.org/10.1007/s10840-022-01317-7>

- Evaluated the safety and efficacy of posterior wall isolation (PWI) using high power (50 W) ablation.
- 30 persistent AF patients received PWI with STABLEPOINT.
- First-pass floor line block was achieved in 26 (87%) and first-pass roof line block in 17 (57%).
- After touch-up ablations, PWI was achieved in 28 patients (93%) with endocardial ablation only.
- Local impedance (LI) drop was the most important predictor of acute conduction block.
- The optimal LI drops were 19  $\Omega$  roof line and 18  $\Omega$  for the floor line.
- Catheter orientation angle, CR and baseline LI were not significant predictors of acute block.

## 2022 CLINICAL PUBLICATIONS

### **When Local Impedance Meets Contact Force: Preliminary Experience from the CHARISMA Registry**

Solimene F, De Sanctis V, Maggio R, et al.

*Journal of Interventional Cardiac Electrophysiology* (March 2022), available at:

<https://doi.org/10.1007/s10840-022-01163-7>

- Investigated the impact of contact force (CF) on local impedance (LI) during pulmonary vein isolation (PVI).
- 45 de novo PVI patients were treated with STABLEPOINT with a total number of 2895 point-by-point ablations.
- The total procedure time was  $118 \pm 34$  min with a total fluoroscopy time of  $13 \pm 8$  min.
- For each 10 g of CF, LI drop increased from  $22.4 \pm 7\Omega$  to  $24.0 \pm 8\Omega$  at 2 to 25 g CF intervals with little change beyond 25g.
- CF significantly affected LI drop with higher contact ( $> 25$  g) appearing to have less impact on LI drop.

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### **The Correlation Between Local Impedance Drop and Catheter Contact in Clinical Pulmonary Vein Isolation Use**

Yasumoto K, Egami Y, Kawanami S, et al.

*PACE* (August 2022) available at: <https://doi.org/10.1111/pace.14500>

- Studied the correlation between LI drop and catheter contact parameters.
- Contact angle showed good correlation with LI drop and multivariate analysis showed that CA was an independent predictor for LI drop among the parameters tested.
- The LI drop in the blocked segments ( $27.3 \pm 9.8 \Omega$ ) was significantly higher than in the segments with conduction gaps ( $19.6 \pm 6.4 \Omega$ ).

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### **Local Impedance Measurements during Contact Force-Guided Cavotricuspid Isthmus Ablation for Predicting an Effective Radiofrequency Ablation**

Sasaki T, Nakamura K, Minami K.

*Journal of Arrhythmia* (April 2022), available at: <https://doi.org/10.1002/joa3.12680>

- The relationship between contact force (CF) and local impedance (LI) were evaluated for cavotricuspid isthmus (CTI) ablation.
- A total of 50 patients and 602 lesions were analyzed.
- Starting LI, absolute and % LI drops were greater in effective vs ineffective ablation sites.
- Initial and mean CF did not differ at effective and ineffective ablation sites.
- Results of this study found that LI drops of  $21\Omega$  and 10.8% drop change may be appropriate ablation targets for CTI ablation.

## 2021 CLINICAL PUBLICATION

### **The Role of Local Impedance Drop in the Acute Lesion Efficacy during Pulmonary Vein Isolation Performed with a New Contact Force Sensing Catheter—A Pilot Study**

Szegedi N, Sallo Z, Perge P, et al.

*PLOS ONE* (September 2021), available at: <https://doi.org/10.1371/journal.pone.0257050>

- Pilot study that evaluated the local impedance (LI) cut-off value that predicts successful pulmonary vein isolation (PVI) lesion formation.
- There was a total of 645 RF applications, 561 were successful and 84 were unsuccessful.
- Successful applications were shorter and had a larger LI drop.
- There was no difference in successful and unsuccessful lesions for mean CF, FTI, or CF range.
- The optimal LI drop was 21.8  $\Omega$  on the anterior wall and 18.3  $\Omega$  on the posterior wall.

## 2022 PRECLINICAL PUBLICATION

### **Improved Ablation Efficiency in PVI Guided by Contact Force and Local Impedance: Chronic Canine Model**

Gutbrod S, Shuros A, Koya V, et al.

*Frontiers in Physiology* (January 2022), available at:

<https://www.frontiersin.org/articles/10.3389/fphys.2021.808541/full>

- Assessed the effects of local impedance (LI) on ablation workflow when combined with contact force (CF).
- The LI during RF ranged from 23.0 – 34.0  $\Omega$  at both 30W and 50W workflows.
- There was an inverse relationship between LI prior to RF delivery and the RF duration required for an effective lesion.
- After 5 g of force, there was no correlation between force and LI drop.
- The 50W power strategy was the most efficient. LI + CF allows for customization of the ablation strategy based on local tissue variation rather than a uniform approach that could potentially lead to overtreatment.

## 2020 PRECLINICAL PUBLICATION

### **Combined Local Impedance and Contact Force for Radiofrequency Ablation Assessment**

Garrott K, Laughner J, Gutbrod S, et al.

*Heart Rhythm* (August 2020), available at: <https://doi.org/10.1016/j.hrthm.2020.03.016>

- Evaluated the utility of local impedance (LI) with contact force (CF) in assessing RF ablation efficacy in vivo.
- In vivo, STABLEPOINT LI was different between when the catheter was in contact with blood pool vs myocardium.
- LI drop correlated with lesion depth both in vitro and in vivo informing sufficient lesion creation (LI > 20 $\Omega$ ) and excessive heating with LI drops > 65 $\Omega$ .
- Total RF time was significantly reduced when using LI guidance compared to 30 second workflow.

## 2022 IN-VITRO PUBLICATIONS

### **Time Dependency in the Radiofrequency Lesion Formation for a Local Impedance Guided Catheter in an Ex Vivo Experimental Model**

Kawano D, Mori H, Tsutsui K, et al.

*Journal of Arrhythmia* (December 2022), available at:

<https://onlinelibrary.wiley.com/doi/10.1002/joa3.12789>

- In an ex vivo experimental model, the relationships between local impedance (LI), RF delivery time and lesion formation were tested.
- The correlation between LI drop and ablation time was non-linear.
- The time to a 90% decay in the LI drop differed depending on the power setting, with the 50W setting being shorter than the 40W setting.
- Deeper and wider lesion were predominately created within the time to 90% decay of the LI drop.

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### **Comparison of Two Catheters Measuring Local Impedance: Local Impedance Variation vs Lesion Characteristics and Steam Pops**

Amemiya M, Takigawa M, Goya M, et al.

*Journal of Interventional Cardiac Electrophysiology* (April 2022), available at:

<https://doi.org/10.1007/s10840-022-01214-z>

- Investigated the difference in local impedance (LI) on the MIFI OI and STABLEPOINT catheters in-vitro.
- The absolute LI drop was significantly larger for the STABLEPOINT catheter but the % LI drops were similar.
- The lesions produced by the STABLEPOINT catheter were generally larger.
- In both catheters, %LI drop was superior to LI drop in correlation to lesion size and in predicting steam pops and normalizing the difference between catheters.

## 2021 EDITORIAL

### **Local Impedance for the Optimization of Radiofrequency Lesion Delivery: A Review of Bench and Clinical Data**

Chu G, Peter Calvert P, Futyma P, et al.

*Journal of Cardiovascular Electrophysiology* (December 2021), available at:

<https://onlinelibrary.wiley.com/doi/10.1111/jce.15335>

- RF catheter ablation has been evolving for over three decades.
- The role of impedance in determining lesion creation is an important piece of this process.
- Local impedance (LI) is a novel tool which has the potential to understand substrate and tailor ablation in a way not possible with other ablation metrics and tools.



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