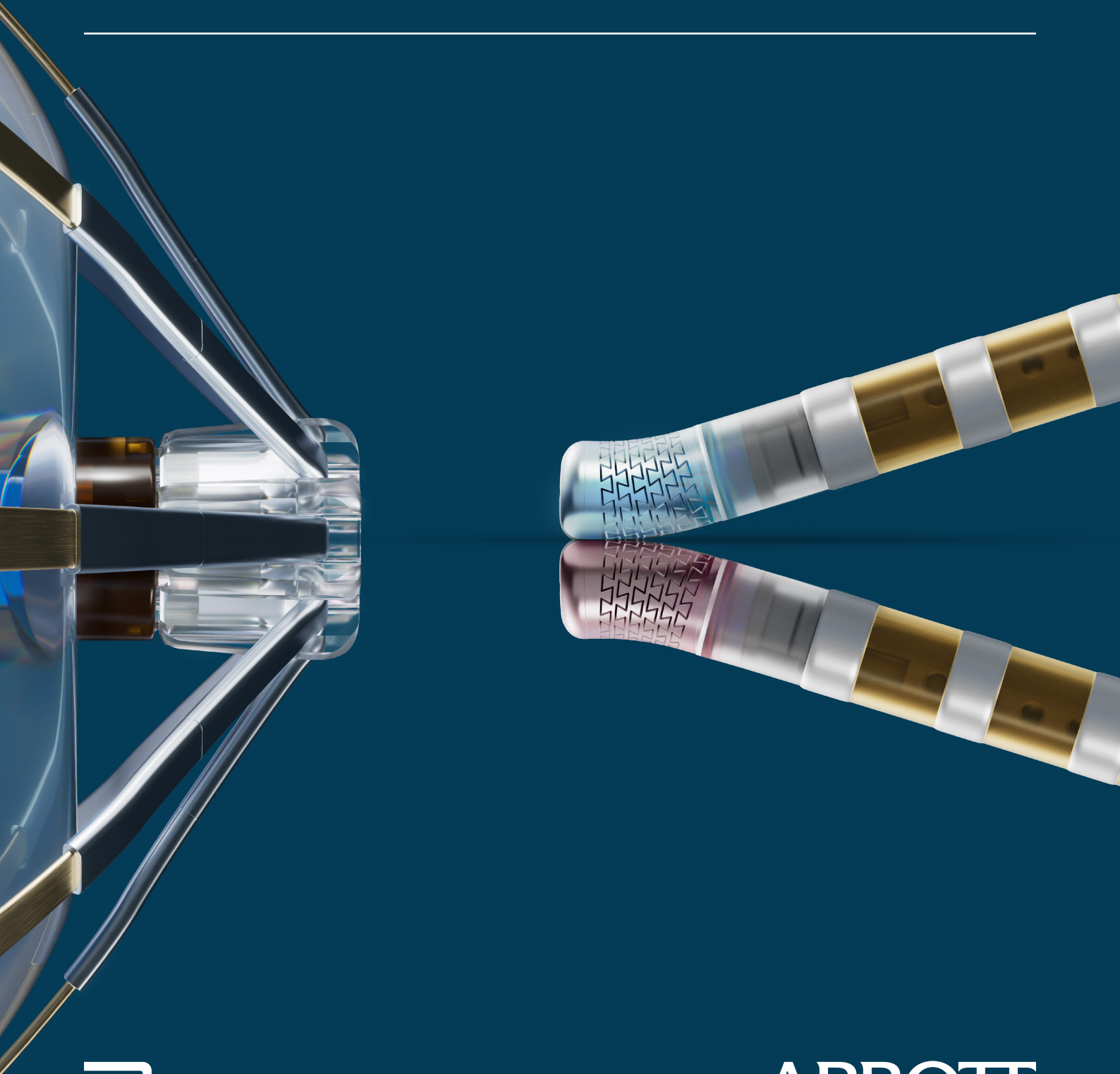


Revolt Against the Ordinary

PFA Portfolio



ABBOTT

You and your patients deserve more than ordinary.

Every tool we create is built with a comprehensive focus on pulsed field ablation (PFA) science and your clinical workflows - empowering you to tailor treatment for each patient.

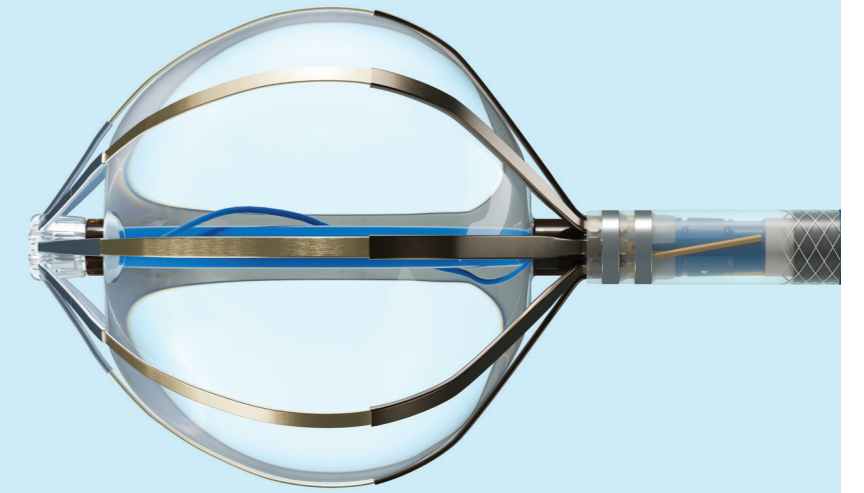
Uniquely engineered with the single goal of giving you confidence in safety, efficacy, and efficiency, our suite of PFA solutions is backed by the most comprehensive ecosystem in the industry.



Volt™ PFA System

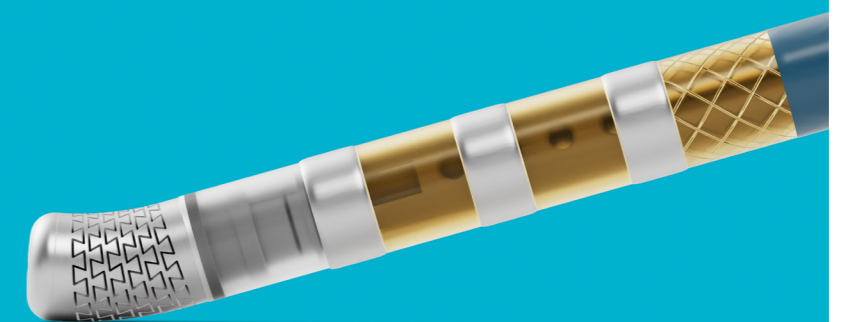
Reengineering PFA with minimal applications¹ and total control.

Volt PFA System simplifies therapy delivery while minimizing procedural burden^{1,4,7} so you can treat more patients with ease and precision.^{1*}

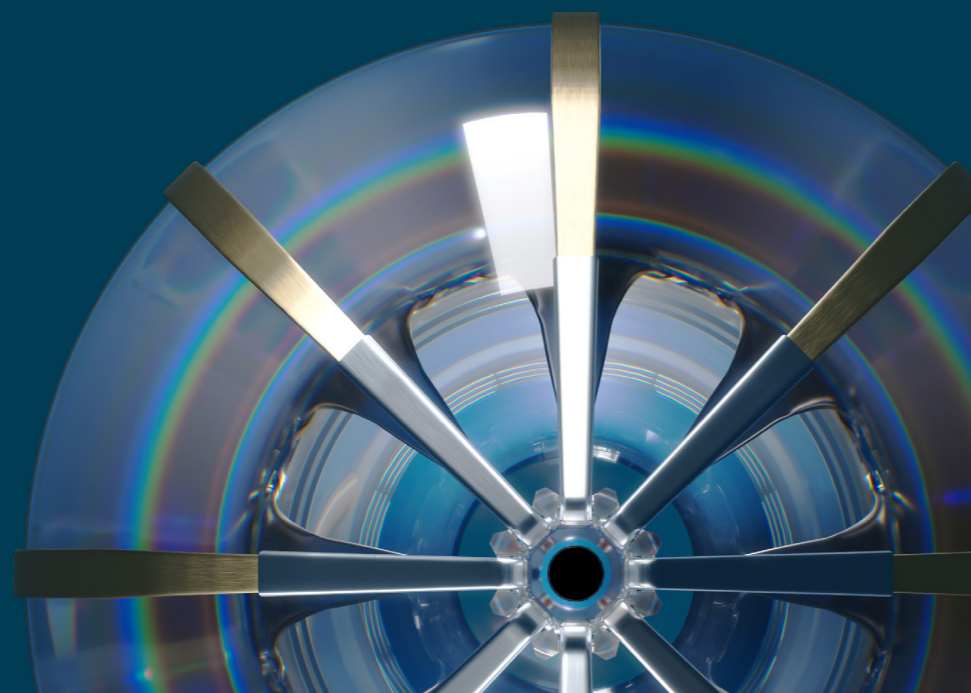


TactiFlex™ Duo Ablation Catheter, Sensor Enabled™

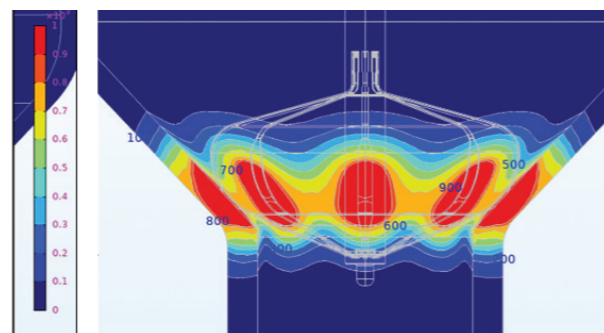
Intentionally built to provide the versatility, precision, and freedom necessary to confidently tailor therapy,²³ switch seamlessly between PF and RF energy,¹⁰ and achieve consistent, predictable lesions¹² – every time.



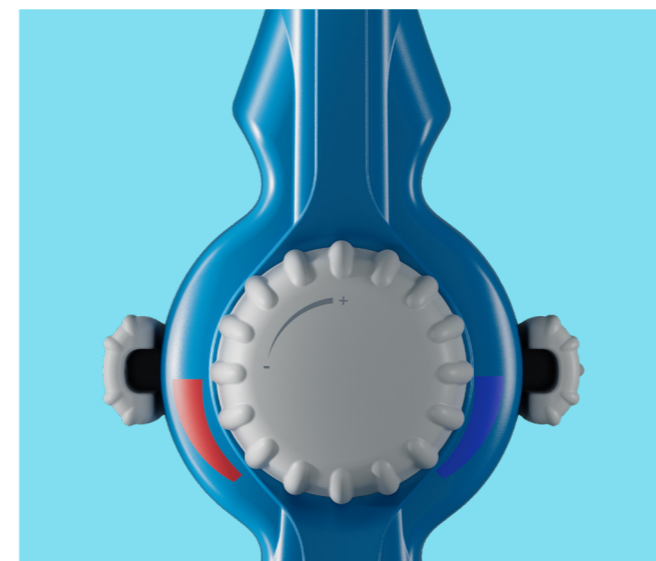
Simplicity by design



Delivers targeted lesion sets where it matters with an 8-spline balloon-in-basket design that conforms to anatomy and creates a wide-band lesion² for fewer repositions



Three handling options for optimal positioning



Bi-directional catheter handling

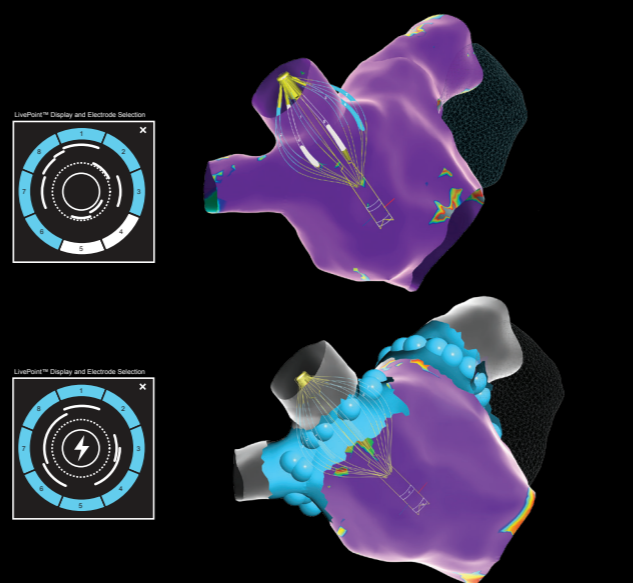


Bi-directional steering with Agilis™ NxT Steerable Introducer (13 F), the leading choice globally for precision and control



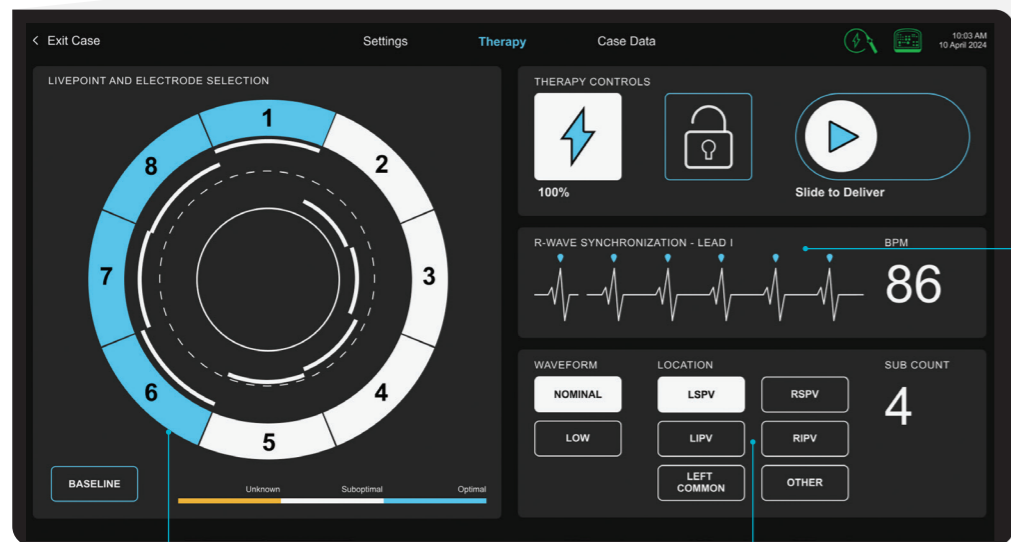
Over-the-wire

Gain real-time procedural insight with elegant impedance-based contact visualization through AutoMark and eField integration for precise lesion tracking^{3,4}



Ensures ease of use and adaptability with an intuitive generator – designed for now and the future

Control at your fingertips



Make contact informed therapy applications with LivePoint™ Display
Customize therapy by tapping on/off electrodes to select those for delivery

Monitor applications by location, even in standalone mode

Prevent ventricular arrhythmia induction with ECG gated delivery

Current™ PFA Generator is designed to minimize microbubbles⁵ and patient movement for stability during energy delivery²



The only standalone generator with an integrated tissue contact display – empowering contact-guided energy applications, with or without a mapping system⁴

Volt™ PFA Catheter, Sensor Enabled™ features distal and proximal magnetic sensors for seamless EnSite™ X EP System integration – designed for now and the future



Eliminates the need for general anesthesia through light sedation compatibility,^{6,14} allowing for use with or without propofol¹⁴

VOLT-AF IDE and VOLT CE Mark studies

Subjects under conscious sedation (CS) and deep sedation (DS) workflows experienced **acute effectiveness with no significant difference in safety** when compared to general anesthesia (GA) procedures.^{6,14}

CS/DS workflows, compared to GA showed

↓ 18%

less time in the lab (31.9 min)¹⁴

↓ 14%

lower procedure time (16 min)¹⁴

↓ 33%

less time in the LA (15.8 min)¹⁴

Acute effectiveness

98.5%

GA subjects (255/259)¹⁴

100%

CS/DS subjects (56/56) (p = 1.000)¹⁴

Safety

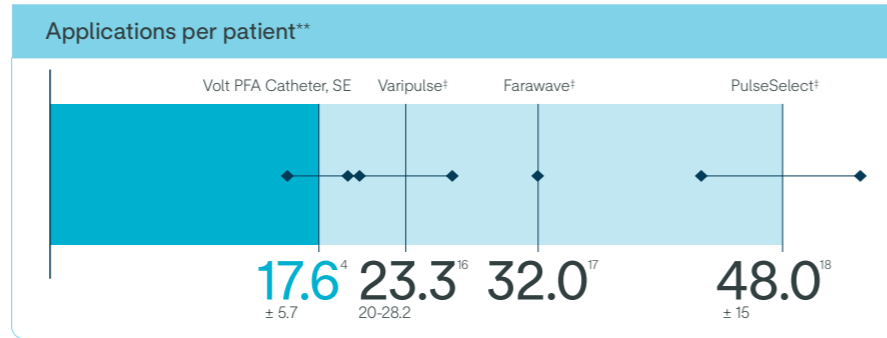
0%

primary safety events observed in subjects without propofol^{6,14}

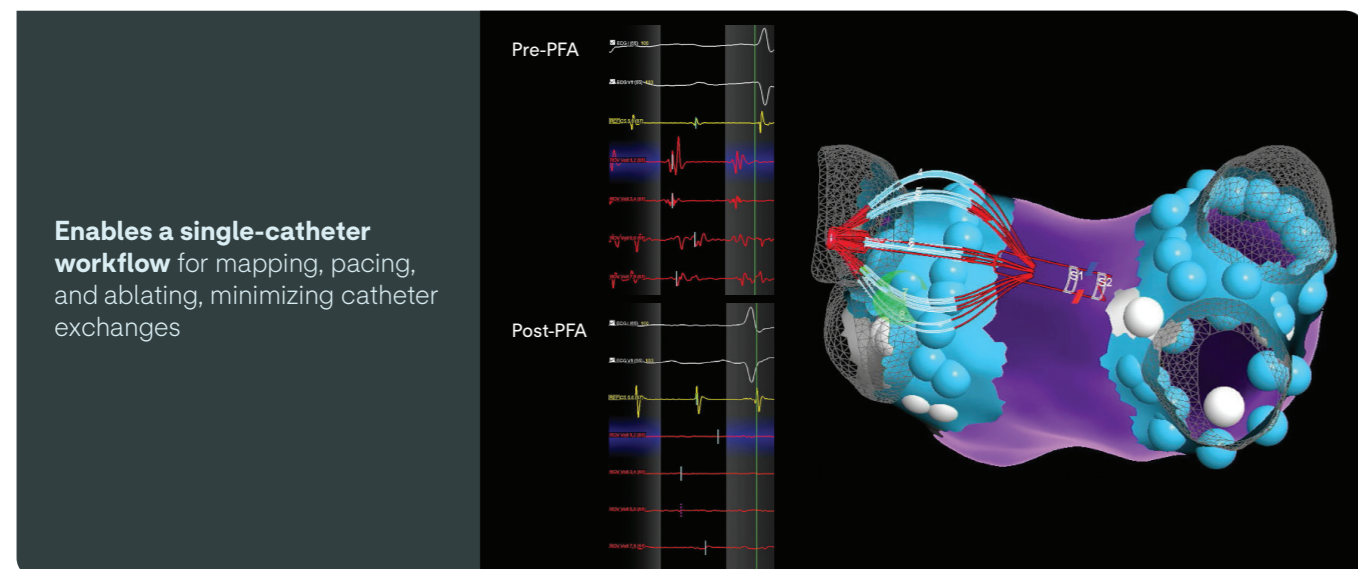
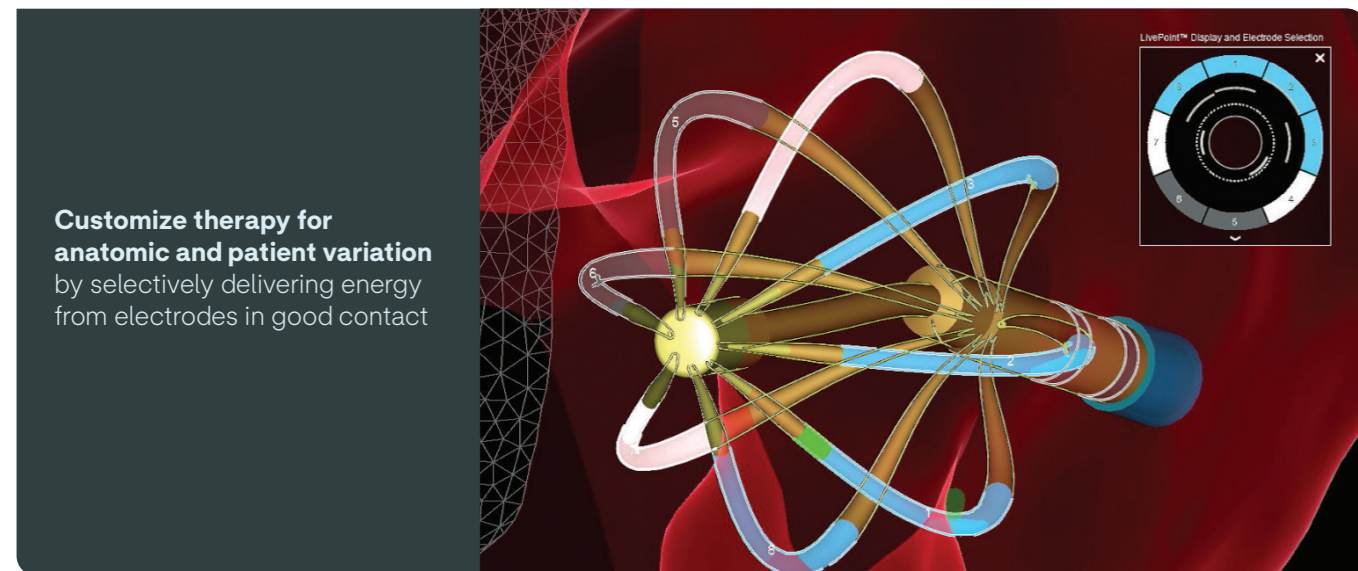
Unmatched performance with minimal applications

Fewer applications:¹ minimizing catheter repositions and increasing procedural efficiency¹

2 Create PVI with as few as two applications per vein¹



Based on published data from multicenter experience and separate studies, which may involve different patient populations and other variables. Not a head-to-head comparison. Data presented for informational purposes only.



Treat more patients safely

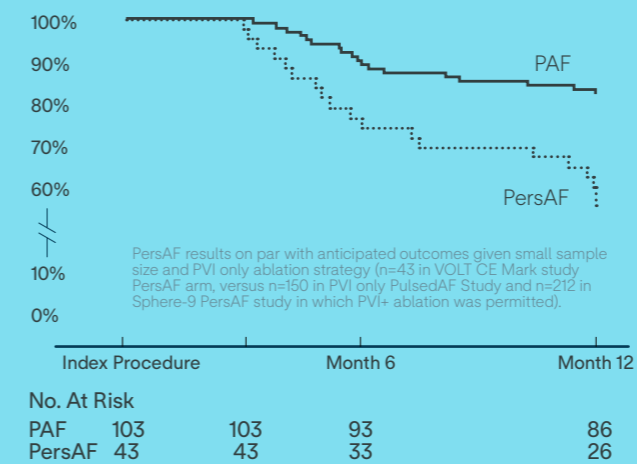
CE Mark 12-month results¹⁹

Protocol required PVI only left atrial ablation with the Volt™ PFA System

Effectiveness

83.5% of PAF (n=103) subjects free from documented AF/AFL/AT recurrence at 12-months

12-month effectiveness



PersAF results on par with anticipated outcomes given small sample size and PVI only ablation strategy (n=43 in VOLT CE Mark study PersAF arm, versus n=150 in PVI only PulsedAF Study and n=212 in Sphere-9 PersAF study in which PVI+ ablation was permitted).

Repeat ablation and durably isolated PVs

94.5% freedom from repeat ablation (5.5%, n=138/146)

90.0% of veins were durably isolated in repeat ablations after the blanking period

Primary safety endpoint¹⁹

0% of subjects reporting hemolysis, acute kidney injury, phrenic nerve injury

2.7% of subjects experienced a primary safety endpoint event

58.1% of PersAF (n=43) subjects free from documented AF/AFL/AT recurrence at 12-months

In multiple analyses, **no clinically relevant hemolysis** was observed, and biomarkers did not exhibit statistically significant change^{8,9,20}

Volt PFA System directly targets tissue, avoiding the blood pool, and removes the need for additional fluid⁸

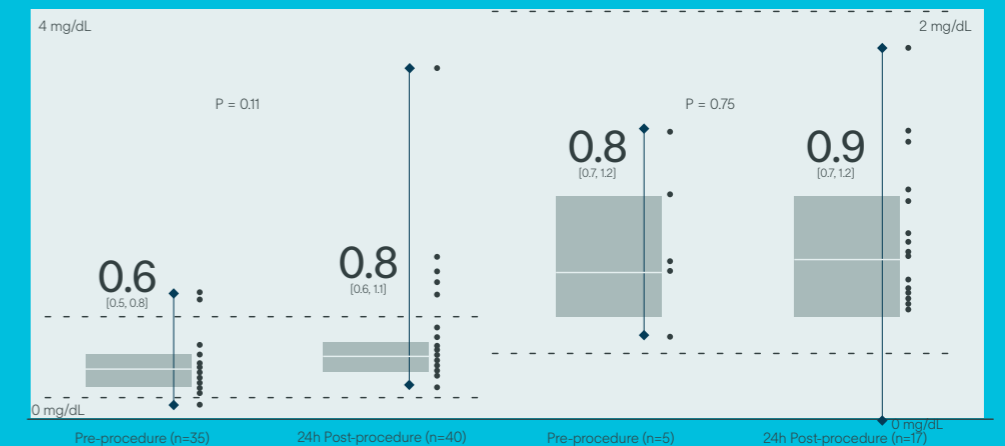
VOLT-AF IDE analysis

Total Bilirubin (mg/dL)²⁰

Haptoglobin (g/dL)²⁰

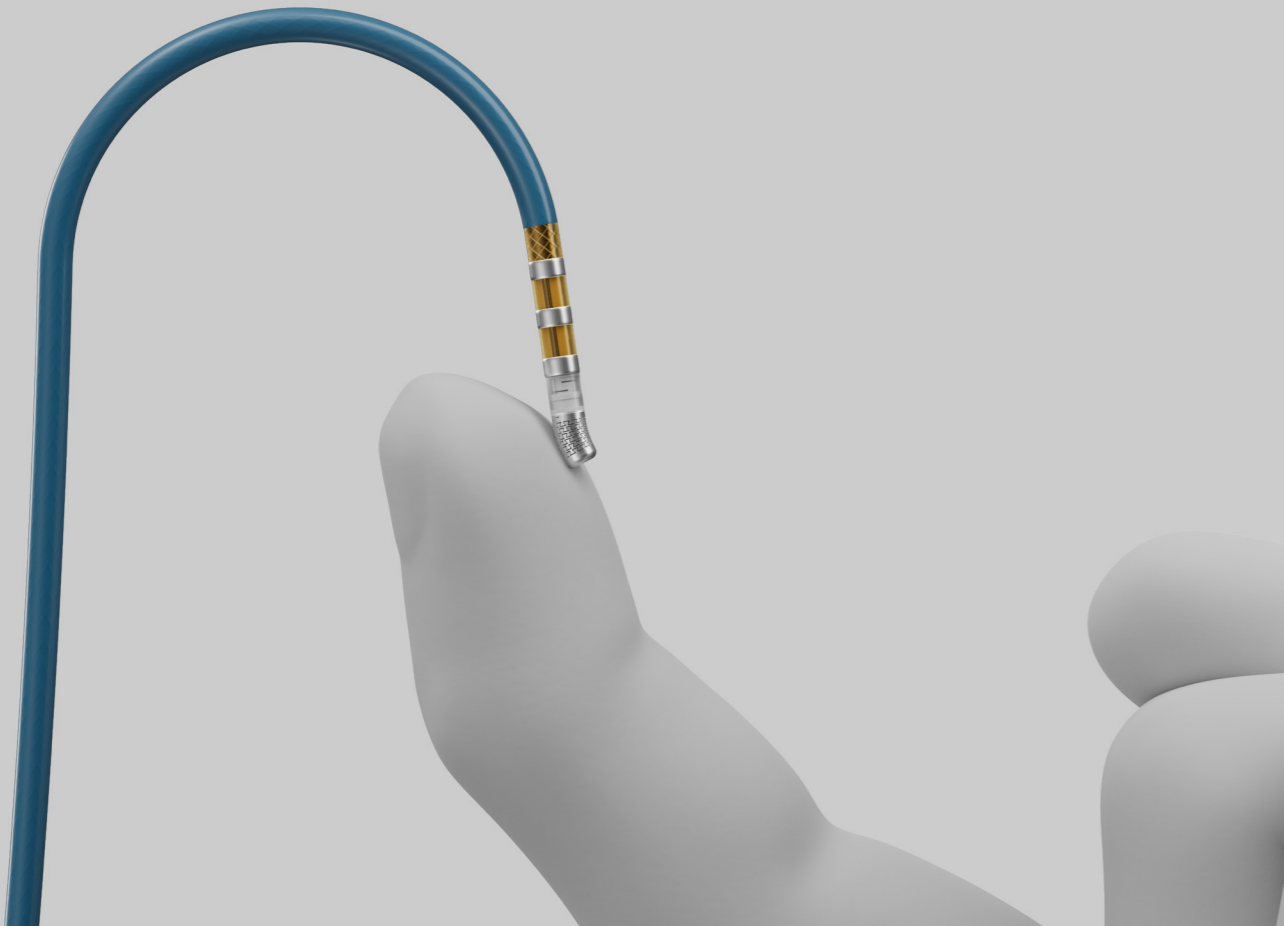
0%

Hemolysis or kidney injury reported in either VOLT-AF IDE or VOLT CE Mark studies^{1,20}



No periprocedural hydration protocol performed
Applications per patient: 17.7 ± 3.8 PFA applications/subject
Non-significant changes in hemolysis biomarkers and renal function in 157 subjects across 27 sites²⁰

TactiFlex™ Duo Ablation Catheter, Sensor Enabled™



Predictability drives confidence

Achieve reproducible outcomes with **consistent lesion quality** that redefines safety

1.4%

primary safety event rate¹¹

0

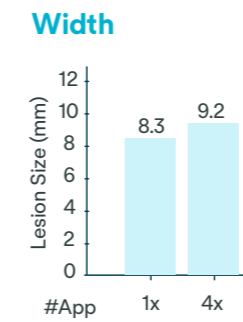
phrenic injury or pulmonary vein stenosis¹¹

0

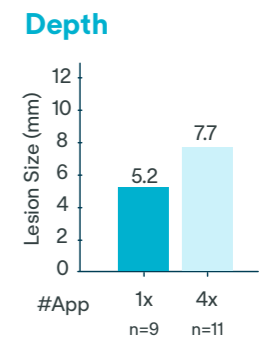
deaths or esophageal injury¹¹

Reproducible durable lesion formation¹¹ supports the efficiency you need

Transcend limitations in challenging anatomies** with **precise depth and width achieved with PFA controlled lesion stacking¹⁰**



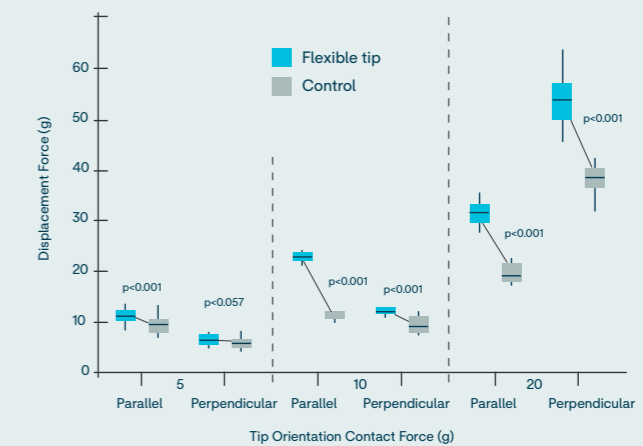
Achieve fast, transmural lesions, in a **single application** with **reliable depth > 5 mm¹⁰**



Applications in porcine ventricular tissue; confirmed via TTC stain. (n=6 animals)

2x more stable^{2,13}**

Displacement force of catheter on LV tissue



Enhanced PFA Index (PI) workflow uses real-time tissue response to guide lesion formation and incorporates PI workflow consistency, providing actionable insights to inform ablation procedures based on lesion formation factors¹²

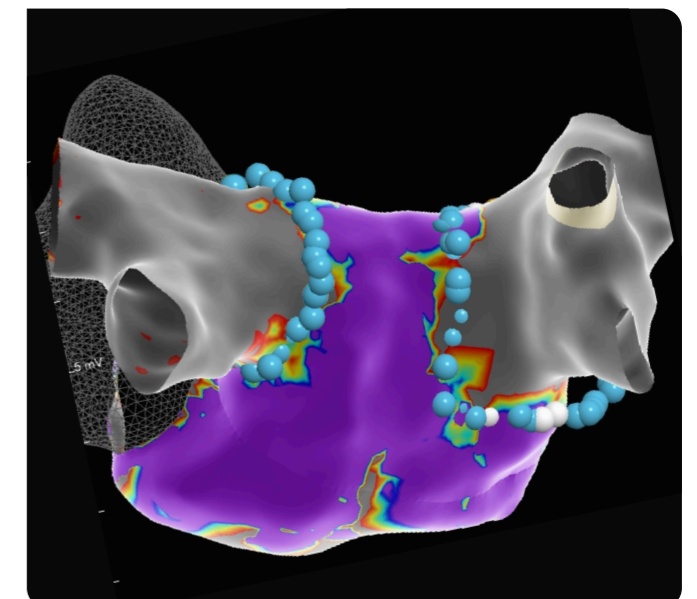
Predictive accuracy¹²

89%

For clinically relevant lesions

≥5 mm

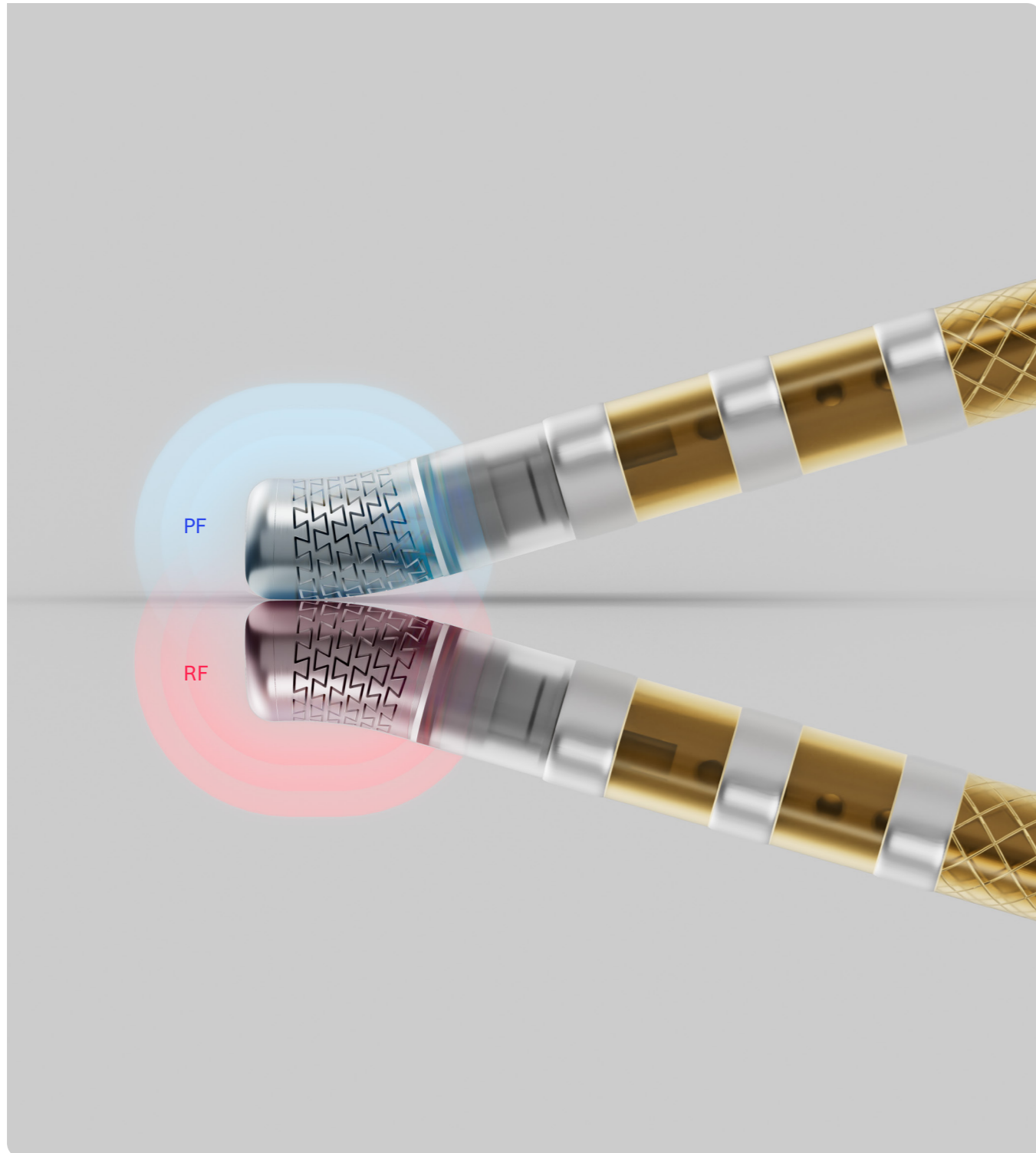
Depth and width consistently produced when PI ≥ 51*



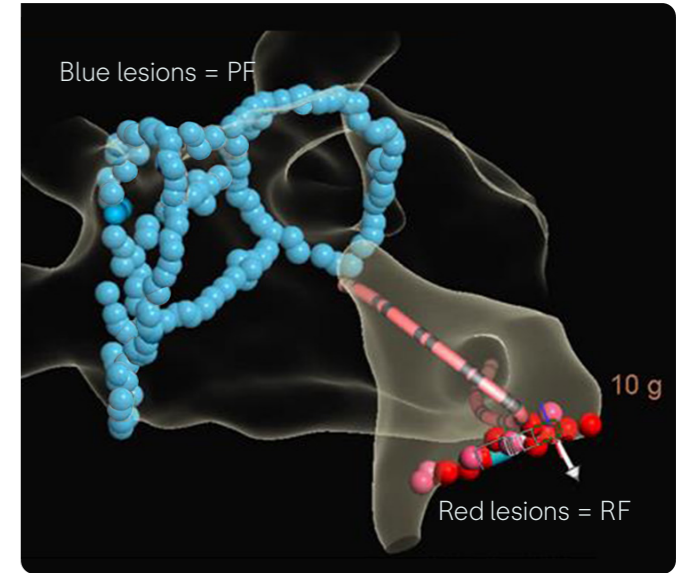
*Positive predictive value of 80% in healthy porcine ventricular tissue

Built to switch

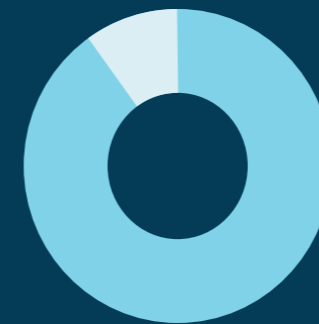
Break free from one-size-fits-all solutions to tailored energy delivery that **adapts to every patient, every procedure, every anatomy**^{2,10}



Feel the freedom of choosing the right energy for the right tissue with **the ability to seamlessly switch between PF and RF**²



When given a choice:



91%
PFA only

9%
PF+RF or RF only¹⁰

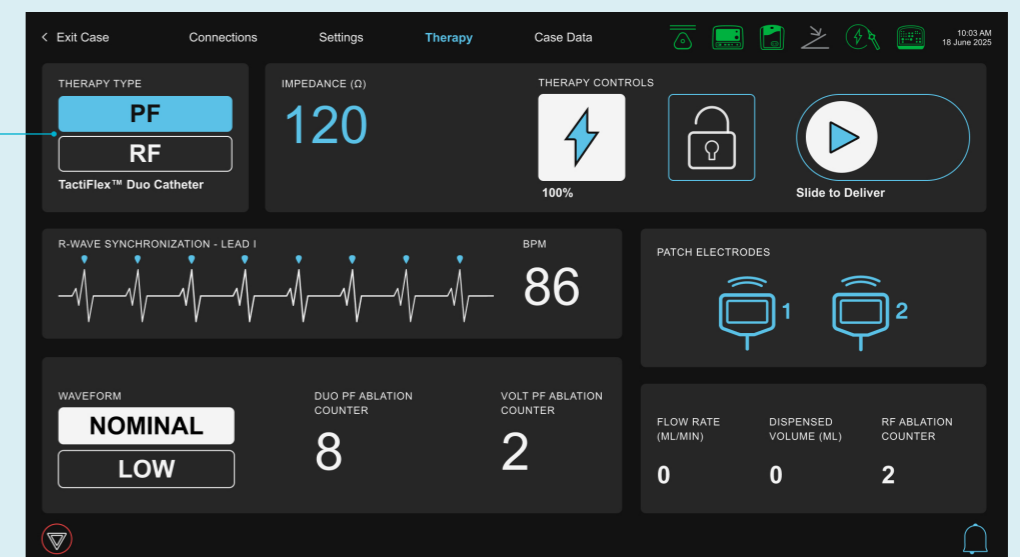
Optimize patient safety and clinical workflow through sedation-flexible waveforms, astutely engineered to minimize nerve and muscle stimulation - **with or without general anesthesia**¹⁰

35.4%

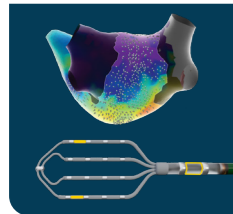
used conscious sedation or deep sedation vs. general anesthesia¹⁰

144 patients in 21 centers in Australia and Europe

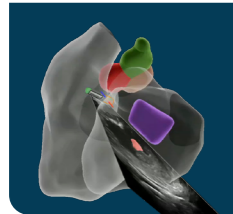
Switch between PF and RF



Liberated from limits



Superior high-density ablation and mapping tools including the novel Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™, configured for high-density mapping to empower confident, data-driven decisions



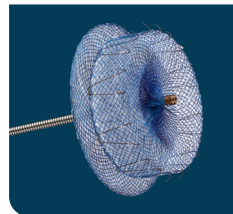
ICE driven intelligence with AI-assisted contouring on ViewFlex™ Xtra ICE Catheter, Sensor Enabled™ - designed to streamline workflows



Unrestricted access with various curve sizes, and 8.5 and 13 French sizes - with Agilis™ NxT Steerable Introducer liberates you to navigate with confidence



Promote primary healing and eliminate re-access restrictions²¹ by delivering secure, non-masking percutaneous sutures to the access site of every procedure with Perclose ProGlide™ Suture-Medication (SMC) System



Confidently reduce risk of stroke and dependence on oral anticoagulants²² with the Amplatzer™ Amulet™ LAAO designed for complete closure of the left atrial appendage

Access a purpose-built ecosystem featuring the most advanced tools to support every AFib case – from active closure to left atrial appendage occlusion (LAAO). Designed to complement your clinical expertise, this suite empowers you to deliver more personalized, comprehensive care – expanding what's possible for your patients.

Empower yourself to set new standards in patient outcomes – your way – using the highest standard of tools in mapping, ablation, and navigation. When it comes to your patients, ordinary is not an option.



Revolt Against the Ordinary with the PFA ecosystem engineered for extraordinary performance. Talk to your Abbott representative today.



* Faster procedures allow us to treat more patients.
 ** Compared to standard solid-tip ablation catheters.

1. Tiltz, R.R. (2025, January 17) Acute results demonstrate safety and effectiveness of balloon-based pulsed field ablation system for de novo PVI in PAF and PersAF [Late Breaking Presentation]. AF Symposium 2025, Boston MA, USA.
2. Data on file 91060208.
3. Silberbauer J, et al. (2025, April 26) Initial Clinical Experience with the TactiFlex DUO System: Safety and Acute Results of the FOCALFLEX Study [Oral presentation]. Presented by Daniel Scherr. Heart Rhythm Society 2025, San Diego, CA.
4. Lo M, et al. (2025, April 26) Acute Results of the FlexPulse IDE Trial [Poster presentation]. Heart Rhythm Society 2025, San Diego, CA.
3. Data on file 90985059.
4. Data on file 91057904.
5. Data on file 91104530.
6. Data on file 90985036.
7. Acute safety and procedural characteristics of conscious and deep sedation to general anesthesia workflows with novel balloon-based PFA system (Oral presentation and abstract by Roland Tiltz, EHRA 2025)
8. Marcon L, Della Rocca DG, Vetta G, et al. Hemolysis Biomarkers After Pulmonary Vein Isolation via a Balloon-In-Basket PFA Catheter. *Circulation*. Online Version of Record before inclusion in an issue. doi:10.1161/CIRCULATIONAHA.124.070333.
9. Overmann JA, Marques M, Lafean C, Pipenhagen C, Moon BL, Verma A. Hemolysis Profile of a Novel Balloon-Filled Basket Pulsed Field Ablation Catheter. Poster presented at: AF Symposium 2025; 2025 Jan 15-17; Boston, MA.
10. Data on file 91062308.
11. Koruth J, et al. Acute and chronic pulmonary vein isolation durability and safety assessments of a focal dual-energy, flexible 4mm contact-sensing tip [Poster presentation]. Heart Rhythm Society 2025, San Diego, CA.
12. Friedman, et al. (2025 September) Development of a PFA index to guide energy delivery with a force sensing flexible, irrigated tip catheter [Oral presentation]. ESC 2025, Madrid, Spain.
13. Ambrosius N, et al. Flexible, Kerfed Ablation Catheter Tip Provides Superior Stability in a Bench Model APHRS 2018: Abstract Book; 2018, October 17-18; Taipei, Taiwan. Abstract nr 1170.
14. Abbott reports 90486839 and 90773365.
15. Lo M, et al. (2025, April 26). Procedural efficiency, safety and acute effectiveness of conscious and deep sedation workflows with novel balloon-based PFA system [Poster presentation.] Heart Rhythm Society 2025, San Diego, CA.
16. Reddy VY, Calkins H, Mansour M, et al. Pulsed Field Ablation to Treat Paroxysmal Atrial Fibrillation: Safety and Effectiveness in the AdmIRE Pivotal Trial. *Circulation*. 2024;151(0). doi:10.1161/CIRCULATIONAHA.124.070333.
17. Reddy VY, Gerstenfeld EP, Natale A, et al. Pulsed Field Ablation to Treat Paroxysmal Atrial Fibrillation: Safety and Effectiveness in the AdmIRE Pivotal Trial. *Circulation*. 2024;151(0). doi:10.1161/CIRCULATIONAHA.124.070333.
18. Verma A, Haines DE, Boersma LV, et al. Pulsed Field Ablation for the Treatment of Atrial Fibrillation: PULSED AF Pivotal Trial. *Circulation*. 2023;151(14):1433-1445. doi:10.1161/CIRCULATIONAHA.123.063988.
19. Tiltz R, et al. (2025, April 26.) Long-Term Safety and Effectiveness of balloon-based PFA system for de novo PVI to treat PAF and PersAF: Results from the VOLT CE Mark Study [Oral presentation]. Presented by Prash Sanders. Heart Rhythm Society 2025, San Diego, CA.
20. Woods C, et al. (2025, April 26). Procedural efficiency, safety and acute effectiveness of conscious and deep sedation workflows with novel balloon-based PFA system [Poster presentation]. Heart Rhythm Society 2025, San Diego, CA.
21. Salcido, R. (2017) Primary intention healing occurs where vessel wall edges are brought together, adjacent to each other. This can be achieved with sutures and other methods. *Advances in Skin & Wound Care: Healing by intention*.
22. Lakkireddy D, Thaler D, Ellis CR, et al. 2021. Amplatzer Amulet left atrial appendage occlude versus Watchman device for stroke prophylaxis (Amulet IDE): A randomized, controlled trial. *Circulation*, 144(19), 1543-1552
23. Sanders, P. et al. (2025, November 13). Beyond Pulmonary Veins: Ablation Trends and Targets with a Novel Flexible-Tip Dual-Energy PF/RF Ablation Catheter [Oral presentation]. Presented by Prash Sanders. Asia Pacific Heart Rhythm Society (APHRS) 2025, Yokohama, Japan.

Abbott

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 cardiovascular.abbott

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

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MAT-2513388 v1.0 | Item approved for EMEA use, with the exception of Finland.



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