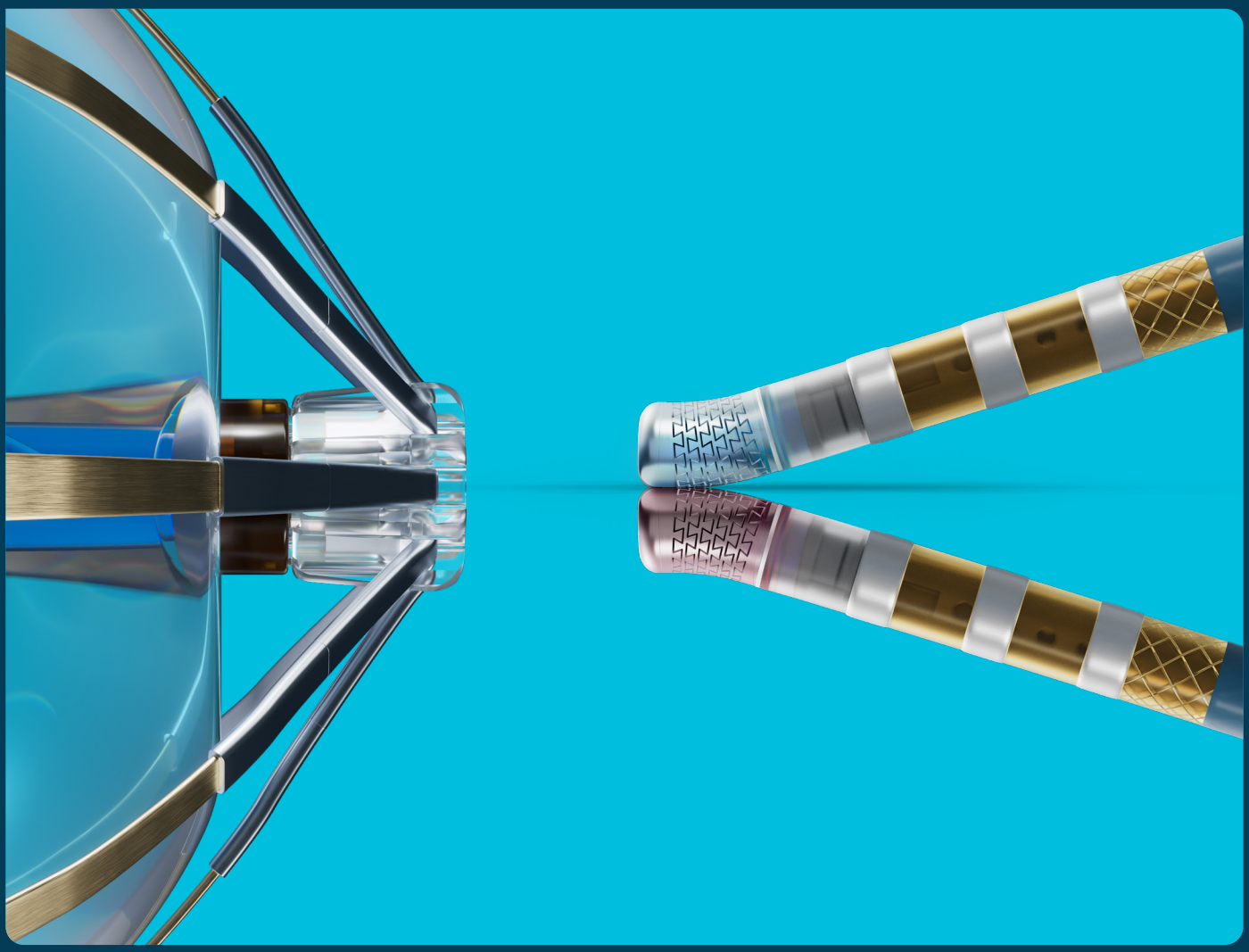
Revolt Against the Ordinary

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.

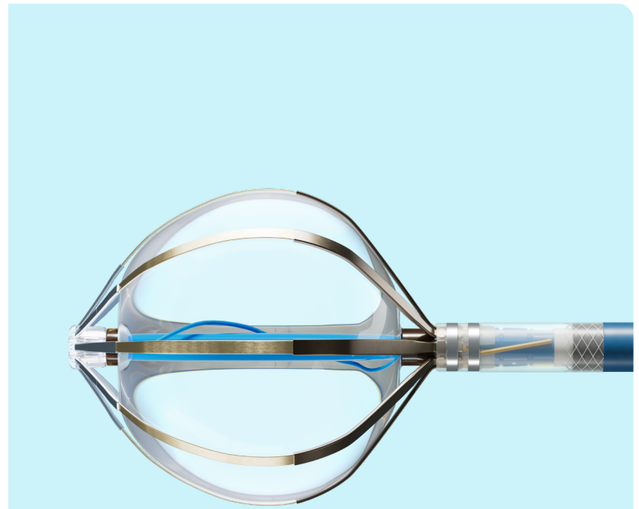
Uniquely engineered with the single goal of giving you confidence in safety, efficacy, and efficiency, our suite of PFA solutions is backed by the most comprehensive ecosystem in the industry.



Volt™ PFA System

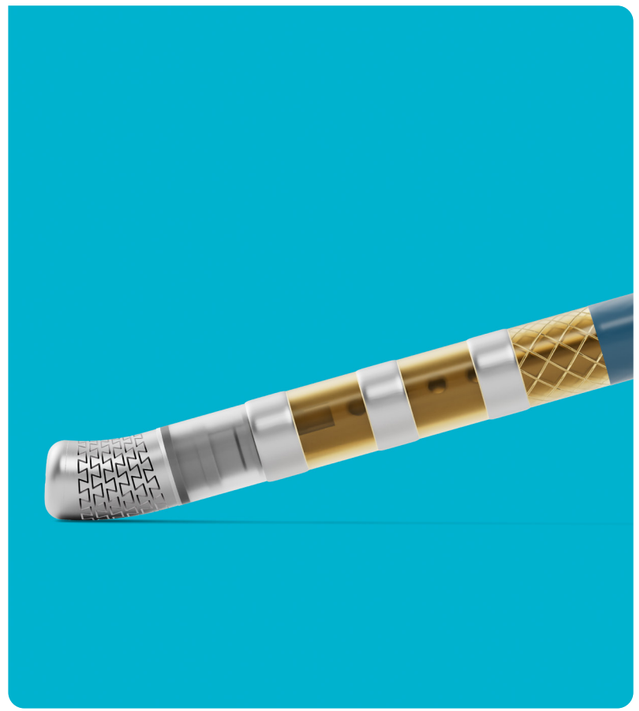
Reengineering PFA with minimal applications[1] and total control.

Volt PFA System simplifies therapy delivery while minimizing procedural burden[1-3] so you can treat more patients with ease and precision.[1*]

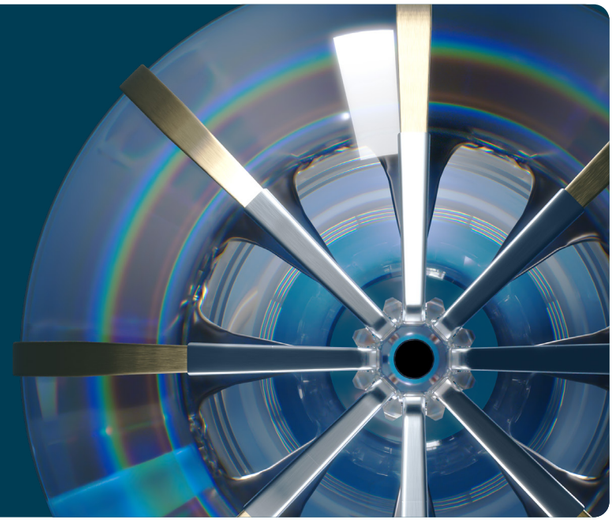


TactiFlex™ Duo Ablation Catheter, Sensor Enabled™

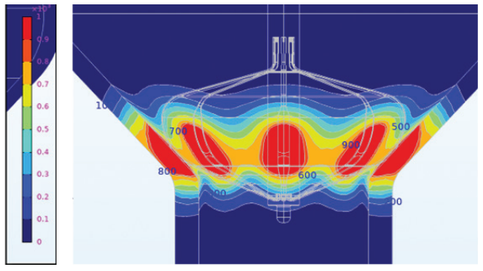
Intentionally built to provide the versatility, precision, and freedom necessary to confidently tailor therapy,[4] switch seamlessly between PF and RF energy,[5] and achieve consistent, predictable lesions[6] – every time.



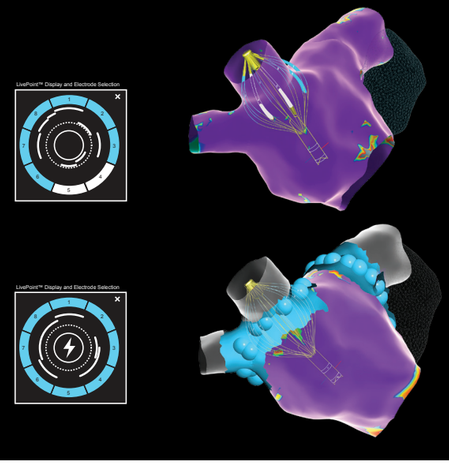
Simplicity by design



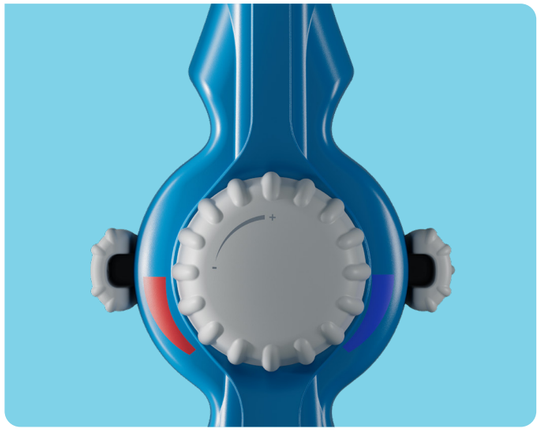
Delivers targeted lesion sets where it matters with an 8-spline balloon-in-basket design that conforms to anatomy and creates a wide-band lesion[7] for fewer repositions



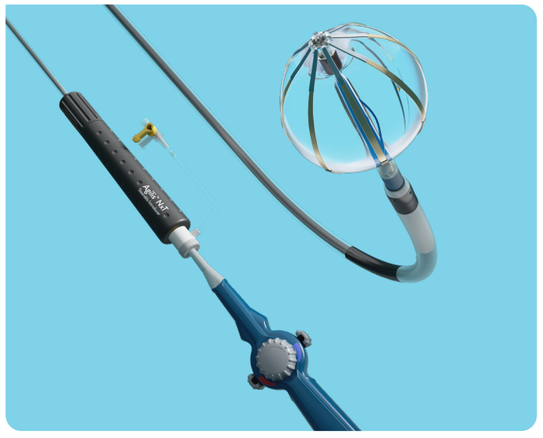
Gain real-time procedural insight with elegant impedance-based contact visualization through AutoMark and eFields integration for precise lesion tracking[8,9]



Three handling options for optimal positioning



Bi-directional catheter handling



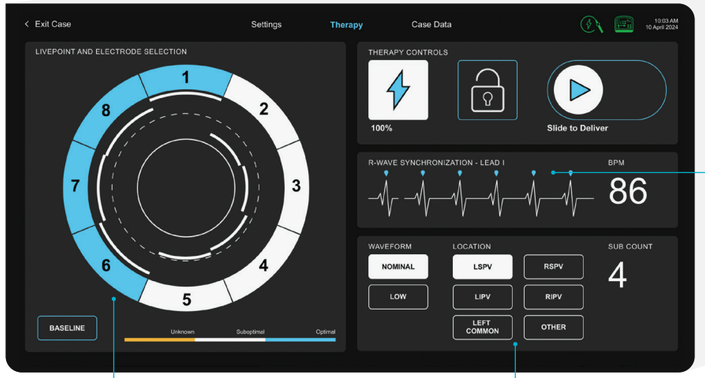
Bi-directional steering with Agilis™ NxT Steerable Introducer (13 F), the leading choice globally for precision and control



Over-the-wire

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

Control at your fingertips



ECG gated delivery

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

Current™ PFA Generator is designed to minimize microbubbles[10] **and patient movement** for stability during energy delivery[7]

The only standalone generator with an integrated tissue contact display—empowering contact-guided energy applications, with or without a mapping system[9]

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,[2,3] allowing for use with or without propofol[3]

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.[2,3]

CS/DS workflows, compared to GA showed

↘18%

less time in the lab (31.9 min)[14]

↘14%

lower procedure time (16 min)[3]

↘33%

less time in the LA (15.8 min)[3]

Acute effectiveness

98.5%

GA subjects (255/259)[3]

100%

CS/DS subjects (56/56) (p = 1.000)[3]

Safety

0%

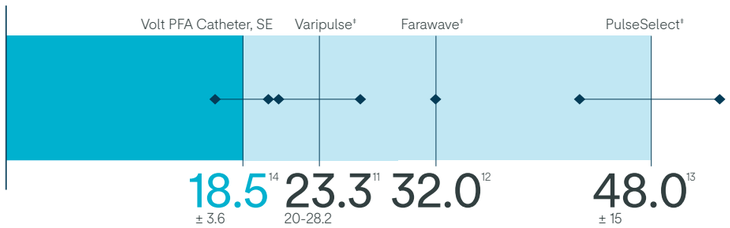
primary safety events observed in subjects without propofol[2,3]

Unmatched performance with minimal applications

Minimal applications:[1] minimizing catheter repositions and increasing procedural efficiency[1]

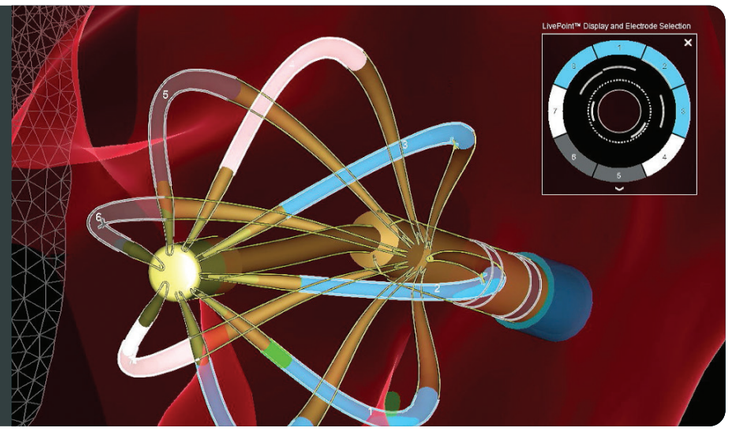
2 **Create PVI with as few as two applications per vein**[1]

Applications per patient**

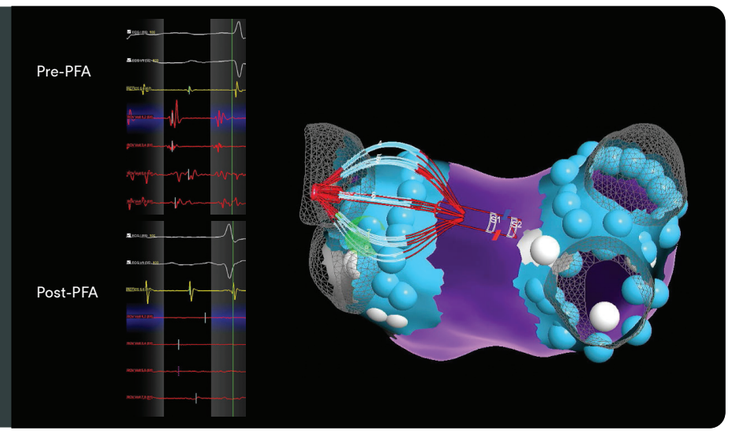


Based on published data from multicenter experience and separate studies, which may involve different patient populations and other variables. Not a head-to-head comparison. Data presented for informational purposes only.

Customize therapy for anatomic and patient variation by selectively delivering energy from electrodes in good contact



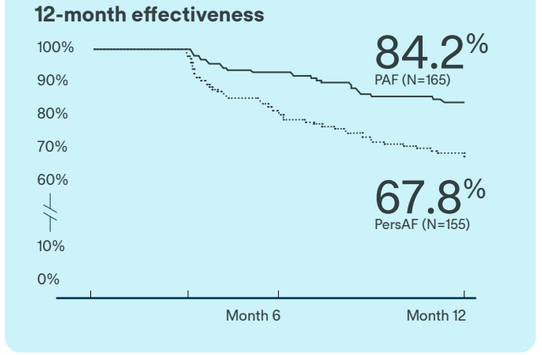
Enables a single-catheter workflow for mapping, pacing, and ablating, minimizing catheter exchanges



Treat more patients safely

VOLT-AF IDE 12-Month Results[14]

Freedom from documented AF/AT/AFL recurrence
Protocol required PVI only left atrial ablation with the Volt™ PFA System



94.1%
Freedom from repeat ablation

5.9% repeat ablation (19/320 patients)

1.9%
Primary safety event rate

Primary safety endpoint[14]

0% Of subjects experienced clinically apparent hemolysis, acute kidney injury, esophageal injury phrenic palsy, symptomatic PV stenosis

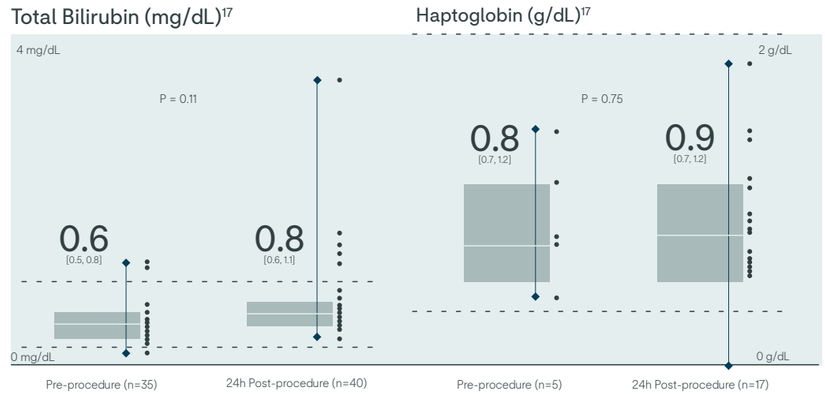
In multiple analyses, **no clinically relevant hemolysis** was observed, and biomarkers did not exhibit statistically significant change[15-17]

Volt PFA System directly targets tissue, avoiding the blood pool, and removes the need for additional fluid[15]

0%

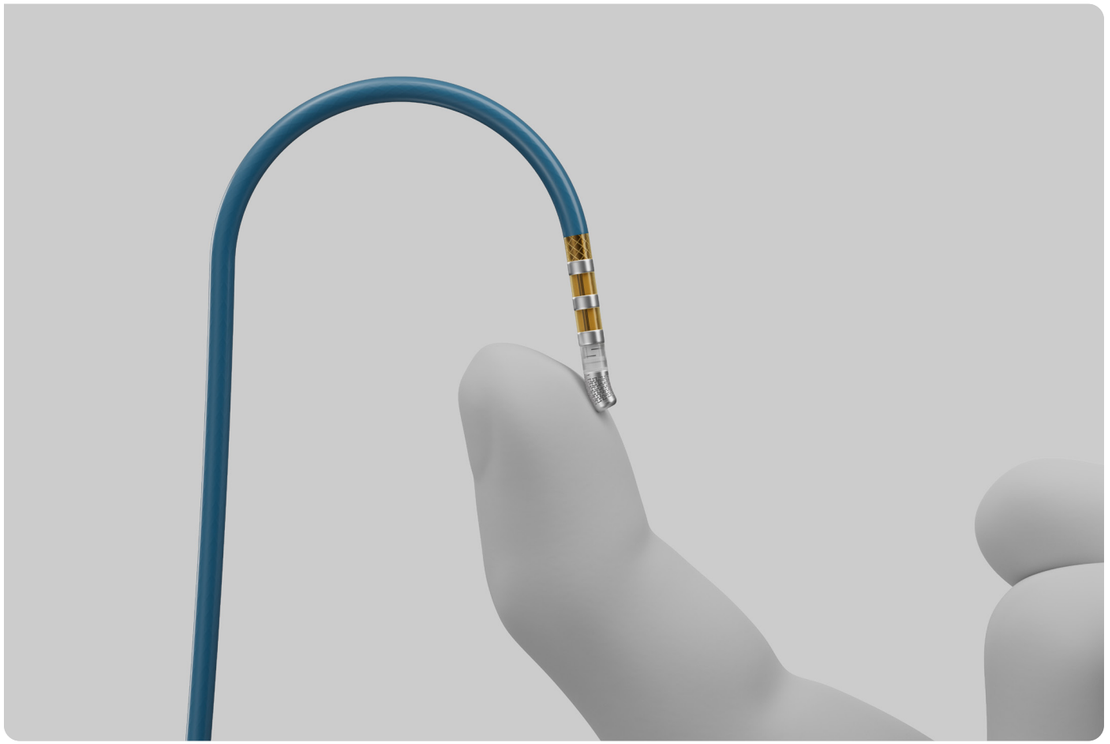
Hemolysis or kidney injury reported in either VOLT-AF IDE or VOLT CE Mark studies[16,17]

VOLT-AF IDE analysis



No periprocedural hydration protocol performed
Applications per patient: 17.6 ± 3.8 PFA applications/subject
Non-significant changes in hemolysis biomarkers and renal function in 157 subjects across 27 sites[17]

TactiFlex™ Duo Ablation Catheter, Sensor Enabled™



Predictability drives confidence

FlexPulse 12-month results[21]

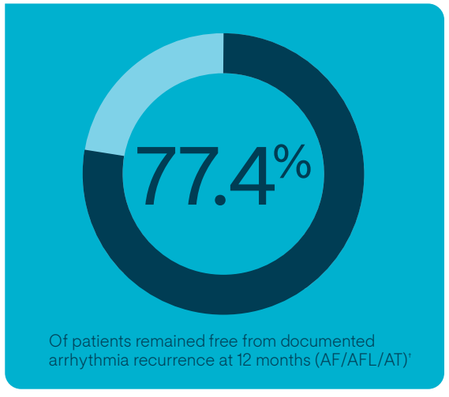
1.7%

Primary safety event rate

91.7%

Freedom from repeat ablation (n=165/180)[‡]

No stroke/TIA, esophageal lesions, phrenic injury, pulmonary vein stenosis, or device and/or procedure related deaths reported



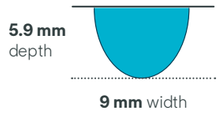
Of patients remained free from documented arrhythmia recurrence at 12 months (AF/AFL/AT)[†]

†Freedom from documented AF/AFL/AT recurrence detected by protocol-specific TTMs, 12-lead ECGs, and Holter monitors
‡After blanking period through 12 months

Reproducible durable lesion formation[6,18] supports the efficiency you need

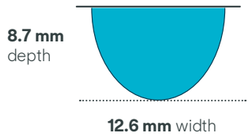
Achieve fast, transmural lesions, in a **single application** with **reliable depth > 5 mm**[6,22]

1x applications



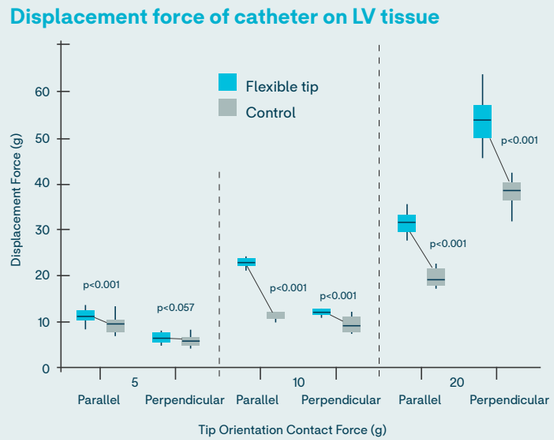
Transcend limitations in challenging anatomies** with **precise depth and width achieved with PFA controlled lesion stacking**[5,22]

4x applications



Applications in porcine ventricular tissue; confirmed via TTC stain. (n=2 animals for PF 1 x Application; n=3 animals for PF 4 x Application)

2x more stable[19,20**]



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 factors[6]

PFA Index retrospective analysis[21†]

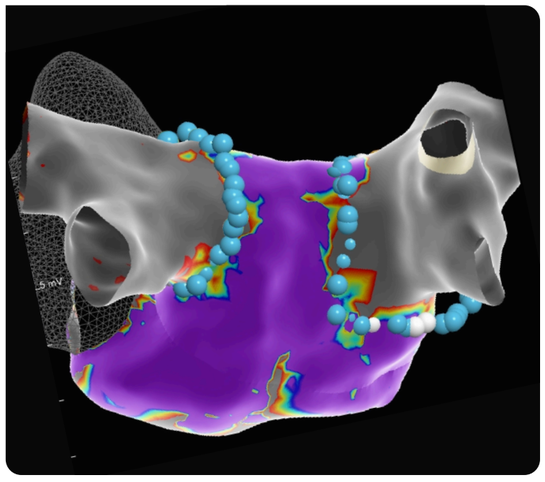
PI values ≥ 30
Automark distance up to 6 mm resulted in[†]

84.6%

freedom from documented AF/AFL/AT with strict monitoring including weekly TTM (n=26)

96.2%

freedom from repeat ablation at 12 m[‡] (n=25/26)

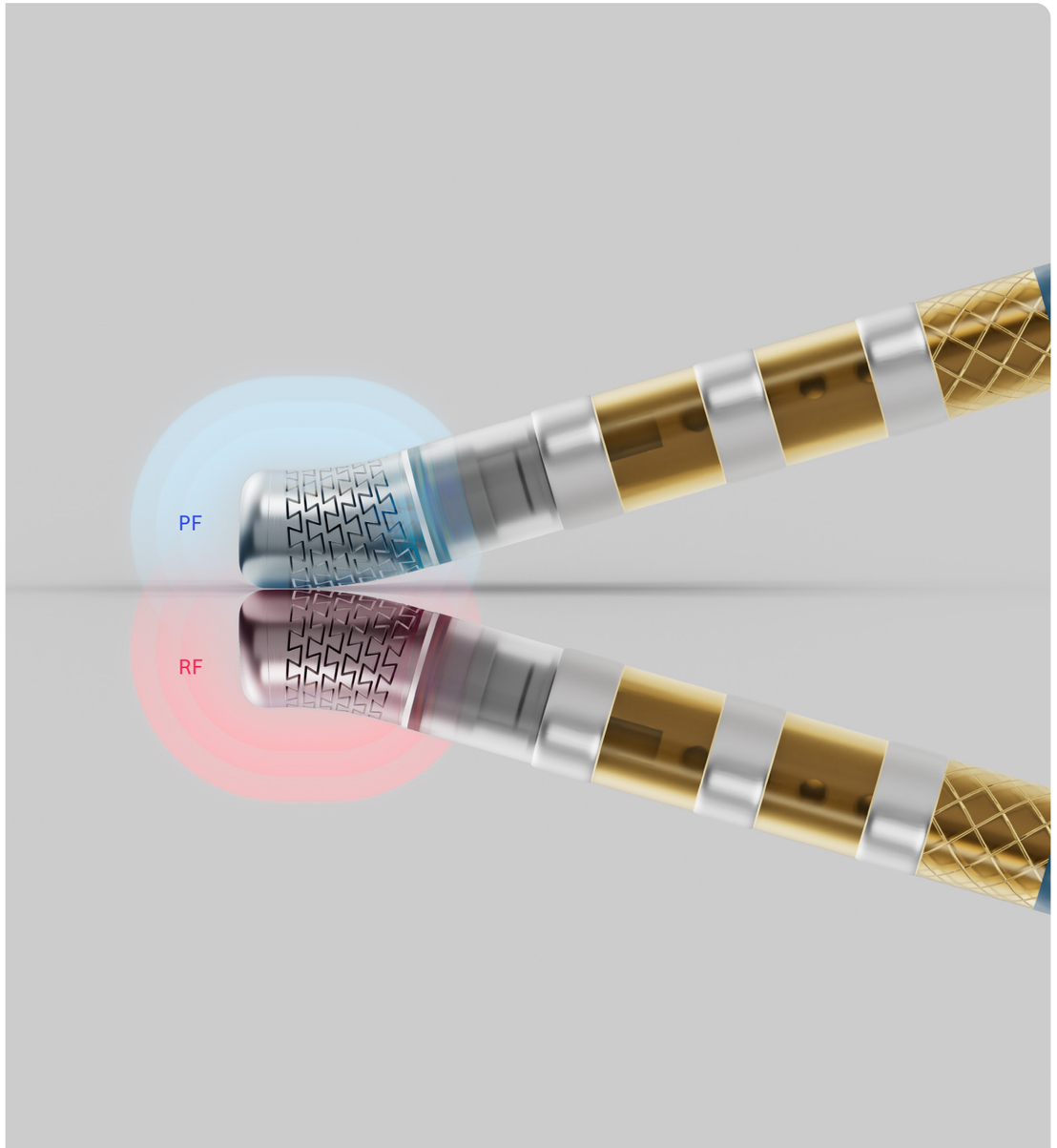


†Retrospective analysis. Over 80% of applications applied with PI greater than or equal to 30 and over 90% AMD thresholds in a retrospective analysis. 77.2% freedom from with low compliance to workflow

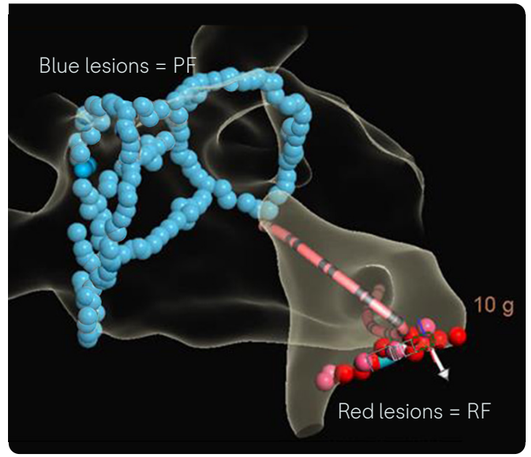
‡After blanking period through 12 months

Built to switch

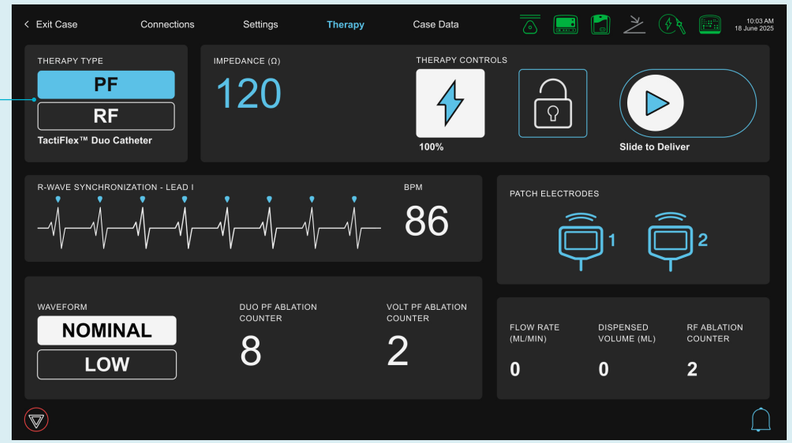
Break free from one-size-fits-all solutions with tailored energy delivery that **adapts to every patient, every procedure, every anatomy**[4,5]



Feel the freedom of choosing the right energy for the right tissue with **the ability to seamlessly switch between PF and RF**[4]



Switch between PF and RF



Optimize patient safety and clinical workflow through sedation-flexible waveforms, astutely engineered to minimize nerve and muscle stimulation - **with or without general anesthesia**[23,24]

34.7% used conscious sedation or deep sedation vs. general anesthesia[28]

CS/DS workflows, compared to GA showed

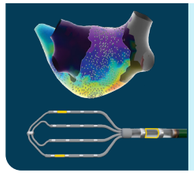
↘7% lower procedure time (8.5 min)[28]

0% no difference in proportion of cases with none or clinically acceptable skeletal muscle recruitment[28**]

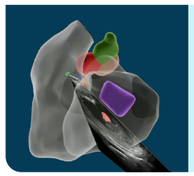
144 patients in 21 centers in Australia and Europe

Liberated from limits

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.



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



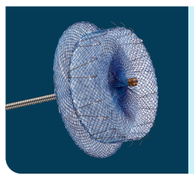
ICE driven intelligence with AI-assisted contouring on ViewFlex™ Xtra ICE Catheter, Sensor Enabled™ - designed to streamline workflows



Unresticted 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 restrictions[25] 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 anticoagulants[26] with the Amplatzer™ Amulet™ LAAO designed for complete closure of the left atrial appendage

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 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.

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5. Data on file 91062308.
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7. Data on file 90985059.
8. Data on file 91057904.
9. Data on file 91104530.
10. Data on file 90985036.
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16. 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.
17. Woods, C., et al. (2025, April 26). Impact of pulsed field ablation using a balloon-in-basket catheter on hemolysis and renal function biomarkers [Poster presentation]. Heart Rhythm Society 2025, San Diego, CA.
18. 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.
19. Nair D et al. Catheter Stability Analysis in Ablation of Paroxysmal Atrial Fibrillation: Impact of a Novel Flexible Electrode Tip. HRS Poster 2023.
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23. Silberbauer J, et al. (2025, April 25) 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.
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25. 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.
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28. Scherr, D. et al. (2025, November). General anesthesia vs. Deep sedation and Conscious Sedation in Subjects Undergoing Pulmonary Vein Isolation with a Novel Flexible-Tip Dual-Energy PF/RF Ablation Catheter [Oral Presentation]. Presented by Daniel Scherr. Asia Pacific Heart Rhythm Society (APHRS) 2025, Yokohama, Japan.

Rx Only. 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.

United States: Required Safety Information

Indications for Use: The Volt™ PFA Catheter, Sensor Enabled™ is indicated for the treatment of symptomatic, recurrent, drug-refractory paroxysmal or persistent (episode duration less than one year) atrial fibrillation when used in conjunction with a compatible pulsed field ablation (PFA) generator. The catheter is compatible with the EnSite™ X EP System. **Contraindications:** The Volt™ PFA Catheter, Sensor Enabled™ is contraindicated for:• Patients who have had a ventriculotomy or atriotomy within the preceding four weeks. • Patients with prosthetic valves as the catheter may damage the prosthesis. • Patients with an active systemic infection as this may increase the risk for cardiac infection. • Patients with a myxoma or an intracardiac thrombus as the catheter could precipitate an embolus. • Patients unable to receive heparin or an acceptable alternative to achieve adequate anti-coagulation. The transseptal approach is contraindicated in a patient with an interatrial baffle or patch because the opening could persist and produce an iatrogenic atrial shunt. The retrograde trans-aortic approach is contraindicated in patients who have had aortic valve replacement. **Warnings:** Misuse of this device may result in serious complications. Do not alter this device in any way. This device is intended for one time use only; do not reprocess or reuse it. Note the product "Use by" date on the package. Any attempt to resterilize and reuse this system may compromise its integrity. Adverse effects of using nonsterile components may include, but are not limited to: • Local or systemic infection or reaction • Mechanical damage • Inaccurate functionality. For both patients and laboratory staff, cardiac catheterization procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects due to the x-ray beam intensity and duration of the fluoroscopic imaging. Carefully consider the use of this device in pregnant women.This device should be used by physicians trained in the techniques of catheter ablation in a fully equipped electrophysiology laboratory. Do not immerse the proximal handle or cable connectors in fluids; electrical performance could be affected. Do not use excessive force to advance or withdraw the catheter when resistance is encountered. Vascular perforation or dissection is an inherent risk of any catheter placement. Careful catheter manipulation must be performed to avoid device component damage, thromboembolism, cerebrovascular accident, cardiac damage, perforation, pericardial effusion, or tamponade. The safety and long-term effects of lesions created by pulse field ablation have not been established. In particular, the long-term effects of lesions in proximity to the specialized conduction system or coronary vasculature are unknown. The safety and effectiveness of the device has not been established in pregnant women or pre-pubescent children. Careful consideration must therefore be given for the use of the device in pregnant women or prepubescent children. Concurrent use of non-linear catheters within the atrial chamber may increase the risk of entanglement. Catheter entanglement with other device is a possible complication of electrophysiology procedures. To unentangle the Volt™ PFA Catheter, Sensor Enabled™, deflate the balloon and manipulate the opposing catheter to the center of the basket electrodes. Follow any relevant entanglement procedures from the opposing device.Aspiration during catheter introduction or withdrawal is recommended to limit the potential for air ingress into the patient. During catheter preparation, rinsing or submerging the basket in saline reduces the potential for blood coagulation. During catheter preparation, shifting the straightener over the basket removes any residual air remaining in the folds of the balloon and reduces the potential for air embolism.Use of a syringe larger than 12 mL for balloon inflation increases the risk of overinflation. This can result in detachment of the spline electrodes at the distal coupler.Pacemakers and implantable cardioverter/defibrillators can be affected adversely by PFA signals. It is important to: • Have temporary external sources of pacing and defibrillation available during ablation. • Deactivate ICDs because they can discharge and injure the patient or even damage the ICDs during the ablation procedure. • Exercise extreme caution while ablating near atrial or ventricular permanent pacing leads. • Perform complete pacing system analysis on all patients after ablation. **Precautions:** Do not deflect the introducer while the basket is within the deflectable portion of the introducer, as this can cause damage to the introducer deflection mechanism. Do not deflect the Volt™ PFA Catheter, Sensor Enabled™ while the basket is in the introducer, as this can cause damage to the catheter deflection mechanism. The first application of PFA will likely result in a significant reduction of amplitude of PV potentials recorded from the electrodes on the catheter. Do not use this as an immediate indication that no further ablation is necessary. The PFA therapy should be delivered in accordance with the Therapy Delivery Parameters. Advance the catheter slowly through the introducer to minimize the risk of air embolism. Do not attempt to use the device before completely reading and understanding the applicable instructions for use.Inspect the package prior to use. Do not use if the packaging or catheter appears damaged. Inspect all components before use. Excessive bending or kinking of the catheter may cause damage to the catheter. Be careful not to twist the electrodes with respect to the catheter shaft; twisting may damage the electrode bond and loosen the electrodes. Release the steering (make the catheter straight) prior to pulling back the catheter into the introducer. Deflate the balloon before pulling the catheter back into the introducer. Overinflation of the balloon may cause damage to the device. Always straighten the catheter shaft and keep the balloon deflated before insertion or withdrawal.Do not use if the catheter appears damaged, kinked, or if there is difficulty in deflecting the distal section to achieve the desired curve. Do not use if the catheter does not hold its curve or if there is difficulty deflecting the catheter. Do not use if there is difficulty inflating or deflating the balloon. Do not use excessive force to advance or withdraw the catheter while inside the introducer when resistance is encountered to avoid potential damage to the catheter. Do not expose catheter to organic solvents such as alcohol. Catheter advancement must be performed with support from visualization modalities such as Intracardiac echo, fluoroscopy, and or compatible navigation and visualization systems to minimize the risk of cardiac damage, perforation, or tamponade. If other catheters are used concomitantly with the Volt™ PFA Catheter, Sensor Enabled™, only use other catheters in close proximity when the balloon is inflated, and never in tandem with the catheter in the same pulmonary vein. Never retract the catheter into the introducer when another catheter is in close proximity. Never use a loop catheter concomitantly with the Volt™ PFA Catheter, Sensor Enabled™ within the same atrial chamber. Retract the catheter into the introducer before using a loop catheter within the same chamber. Prior to therapy delivery, ensure that the guidewire is not touching the basket electrodes to prevent ineffective therapy. Compliance with intended therapy delivery parameters reduces the potential for hemolysis and acute kidney injury.Ensure that vacuum pressure is relieved and balloon is fully deflated. After deflating the balloon, leave the stopcock open between the syringe and the inflation lumen to prevent catheter damage during catheter withdrawal.It is recommended to withdraw the guidewire into the introducer prior to balloon deflation to avoid potential entanglement with spline electrodes.Ensure even spacing for splines and full balloon inflation to reduce potential for generator fault detection. Ensure connection to center lumen stopcock when attempting to inject contrast. The balloon inflation lumen has a blue/grey striped sleeve to visually distinguish it from the center lumen stopcock.Do not touch the guidewire during therapy delivery. Risk of electric shock to the user is possible under rare circumstances in which the guidewire is in contact with an active therapy electrode(s) and the user. During treatment with the catheter, ensure there is no possibility of contact with electrodes from another catheter. To avoid thromboemboli, intravenous heparin should be used when entering the left heart during ablation. Consult the HRS consensus guidelines for anticoagulation strategies pre-, during, and post-catheter ablation.Individual patient anatomy and physician technique may require procedural variations.Maintain an activated clotting time (ACT) of greater than 300 seconds at all times during use of the catheter. Store in a dry place. After use, the device accessories and packaging should be appropriatelyclassified for disposal, e.g. biohazard, sharps, non-hazardous waste etc.,and carefully disposed of in compliance with facility procedures andapplicable laws and regulations. Catheter materials are not compatible with magnetic resonance imaging (MRI).Potential Adverse Events: The potential adverse events may be related to the ablation catheter(s) and/or the interventional procedure. The severity and/or the frequency of these potential adverse events may vary and may result in prolonged procedure time and/or additional medical and/or surgical intervention, implantation of a permanent device such as a pacemaker, and in rare cases, may result in death. The following adverse events have been documented for catheter ablation procedures: • Abnormal vision • Acute kidney injury • Air embolism • Anesthesia reaction • Angina/chest pain/discomfort • Aorto-right atrial fistula • Arrhythmias, including exacerbation of preexisting atrial fibrillation • Arteriovenous fistula • AV/SA node stunning (asystole) • Bleeding, including major bleeding requiring surgery or transfusion/hematomas/anemia • Cardiac perforation/tamponade • Cardiac embolism • Cardiovascular injury, including atrial trauma and coronary artery/pulmonary vein trauma • COPD exacerbation • Component damage to Implantable Cardioverter Defibrillator(ICD) or implantable pacemaker • Coronary artery spasm • Cytotoxicity/systemic toxicity/sensitization/endotoxin/pyrogen • Death • Dislodgement of ICD or pacing leads • Electrical shock • Endocarditis • Esophageal lesion • Fever • Foreign body embolism • Heart block/unintended ablation • Heart failure • Hemothorax • Hypotension • Infectious pericarditis • Left atrial esophageal fistula • Myocardial infarction • Neck/ back/groin/chest pain/discomfort (general chest pain not associated with MI) • Palpitations • Pericarditis • Pericardial effusion • Phrenic nerve injury • Peripheral vascular dissection/laceration • Pleural effusion • Pneumonia • Pneumothorax • Pseudoaneurysm • Pulmonary edema • Pulmonary embolism • Pulmonary hypertension • Pulmonary vein stenosis • Radiation injury • Respiratory failure/distress/depression/hypoxia • Silent cerebral event/lesion • Stiff Left Atrial Syndrome • Stroke/cerebrovascular accident • Syncope/vasovagal reaction/dizziness • Transient ischemic attack (TIA) • Thromboembolism • Thrombosis/thrombus • Vagal nerve injury including Gastroparesis • Valvular damage or insufficiency

Indications for Use: The Current™ PFA Generator is indicated for use with compatible ablation catheters for the treatment of cardiac arrhythmias. **Contraindications:** There are no known contraindications specific to the use of the Current™ PFA Generator itself. However, users should read and understand the specific indications, contraindications, warnings, and precautions included with any cardiac ablation catheter used in conjunction with the Current™ PFA Generator. **Warnings:** Misuse of this device may result in serious complications. This device must be used by, or under the supervision of, physicians trained in the techniques of percutaneous electrophysiology studies. For both patients and laboratory staff, cardiac catheterization procedures present the potential for significant X-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects due to the X-ray beam intensity and duration of the fluoroscopic imaging. Carefully consider the use of this device in pregnant women. The safety and effectiveness of the device is not established in pregnant women or prepubescent children. Carefully consider the use of this device in pregnant women or prepubescent children. Pacemakers and implantable cardioverter/defibrillators can be affected adversely by PFA signals. It is important to: Have temporary external sources of pacing and defibrillation available during ablation. Deactivate ICDs because they can discharge and injure the patient or even damage the ICDs during the ablation procedure. Exercise extreme caution while ablating near atrial or ventricular permanent pacing leads. Perform complete pacing system analysis on all patients after ablation. Ablation within and near the coronary arterial vasculature is associated with myocardial infarction and death. The long-term risk of lesions created by PFA is not established. When using an EP recording system, the equipment must be front-end isolated or have an isolated patient cable and comply with the IEC 60601-1 safety requirements for medical electrical systems. Failure of the Current™ PFA Generator can result in an unintended power output increase or the inability to remove power when commanded. In case of system malfunction, attempt to stop PFA delivery by pressing the Standby button on the front panel or turning off the power switch on the rear panel. If those attempts do not turn off the power, disconnect the power cord. Failure to do so can result in operator or patient harm. The Current™ PFA Generator is not suitable for use within Oxygen Rich Environments or in the presence of flammable gasses, including flammable anesthetic mixtures with air, oxygen, or nitrous oxide. Avoid using this equipment adjacent to or stacked with other equipment because it can result in improper operation. If such use is necessary, observe all equipment involved to verify that they are operating normally. To avoid the risk of electric shock, only connect this equipment to a mains power supply with protective earth. Use of accessories, transducers, and cables other than those specified can result in improper operation due to increased electromagnetic emissions or decreased electromagnetic immunity of this equipment. Do not use portable RF communications equipment (including peripherals, such as antenna cables and external antennas) closer than 30 cm (12 in.) to any part of the Current™ PFA Generator (including cables specified by the manufacturer) because it can result in degradation of the equipment. During treatment, ensure there is no possibility of contact with electrodes from another catheter. Do not open the Current™ PFA Generator in attempt to access its internal components. Opening the device may result in personal injury and damage to the generator. Do not position the Current™ PFA Generator so that it is difficult to disconnect the equipment from the mains supply. Do not modify the Current™ PFA Generator. **Precautions:** Federal (USA) law restricts this device to sale by or on order of a physician. Do not attempt to operate the Current™ PFA Generator before reading this IFU thoroughly. Read, understand, and follow the Current™ PFA Generator IFU carefully. For future reference, keep this IFU in a convenient, readily accessible place. During use of the catheter in the left side of the heart, therapeutic anticoagulation needs to be achieved. Anticoagulation treatment must adhere to the ESC/ AHA/ACC or any other consensus guidelines to avoid thromboemboli. Do not immerse cable connectors in fluids; electrical performance can be affected adversely. The Current™ PFA Generator defaults to the nominal waveform unless the user selects the lower waveform. The Current™ PFA Generator is capable of delivering high voltage. Improper handling of the catheter can result in patient or operator injury, particularly when operating the device. During high voltage delivery, do not allow the patient to contact grounded metal surfaces. Place a non-conductive material between the patient and grounded metal surfaces. Electrode attachments are to be as close to the operating field as possible. Place connecting cables so contact with the patient or other leads is avoided. Advance the catheter with support from visualization modalities such as intracardiac echo (ICE), fluoroscopy, and compatible navigation and visualization systems to minimize the risk of cardiac damage, perforation, or tamponade. Accessory equipment connected to the analog and digital interfaces must comply with the respective IEC standards (IEC 60950 for data-processing equipment and IEC 60601-1 for medical equipment). Apparent low voltage output or failure of the equipment to function correctly at normal settings may indicate failure of an electrical lead. Do not increase the voltage before checking for obvious defects or misapplication. Place the unit so the airflow around it is adequate for cooling. Inspect and test reusable cables and accessories regularly. Only connect items that are specified as part of the system. To reduce the risk of accidental burns, avoid skin to skin contact (for example, between the arms and body of the patient) by inserting dry gauze. Place monitoring electrodes as far as possible from surgical electrodes when surgical equipment and physiological monitoring equipment are used simultaneously. This equipment generates, uses, and can radiate energy. If not installed and used in accordance with the instructions, this equipment may be interfered with by, or cause harmful interference to, other equipment in the vicinity, even if the other equipment complies with CISPR emission requirements. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to devices, which can be determined by turning the equipment off and on, the user is encouraged to correct the interference by one or more of the following measures:Reorient or relocate the receiving device. Increase separation between the equipment. Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected. Consult the manufacturer for help. Follow the system installation to achieve optimal use. In the event of an error or warning message, check the programmed ablation parameters against the specific ablation catheter IFU before continuing delivery of ablation energy to the patient. To ensure electrical safety, do not use the USB ports to connect this device to other non-Abbott Medical powered devices. When using non-Abbott Medical devices, the USB ports should only be used with port powered devices such as a USB flash drive, keyboard, or mouse. The USB ports are not electrically isolated. Do not touch the USB port and the patient simultaneously. To ensure electrical safety, do not touch the HDMI ports and the patient simultaneously; the HDMI ports are not electrically isolated. External monitors/ switches/hubs that are non-Abbott Medical devices must be IEC 62368 compliant. If the system is used with an uninterruptible power supply, this device should not be connected to an external monitor. The user is responsible for compliance with IEC 60601-1 safety requirements for medical electrical systems and IEC 60601-1 Edition 3.1, Clause 16 when connecting this device to other devices. Monitoring systems incorporating high-frequency current-limiting devices are recommended. Studies have shown that smoke generated during electrocautery procedures can be potentially harmful to patients and the surgical team. These studies recommend adequately ventilating the smoke by using a surgical-smoke evacuator or other means. Do not operate or position the Current™ PFA Generator and its accessories within the vicinity of magnetic resonance imaging (MRI) equipment. The Current™ PFA Generator and its accessories have not been evaluated for safety, functionality, or compatibility within the MRI environment. Interaction with MRI equipment may adversely impact the Current™ PFA Generator's performance, degrade MRI quality, and result in patient harm. Do not clean the electrical contacts/pins of the connectors. Do not clean system components with bleach. Do not apply cleaners while the system is warm to the touch. Do not sterilize system components. Do not immerse system components in liquid. Turn off and disconnect power to the Current™ PFA Generator before cleaning it. Do not autoclave any Current™ PFA Generator component. Autoclaving may damage the system components. Dispose of/recycle packaging materials according to any applicable facility procedures and local regulations. At the end of useful life, classify the hardware for disposal/recycle (example: electrical equipment, non-hazardous waste, and so forth) and dispose of/recycle the hardware according to any applicable facility procedures and local regulations. The IFU is recyclable. **Potential Adverse Events:** The potential adverse events may be related to the ablation catheter(s) and/or the interventional procedure. The severity and/or the frequency of these potential adverse events may vary and may result in prolonged procedure time and/or additional medical and/or surgical intervention, implantation of a permanent device such as a pacemaker, and in rare cases, may result in death. The following adverse events have been documented for catheter ablation procedures: • Abnormal vision• Acute kidney injury • Air embolism• Anesthesia reaction • Angina/chest pain/discomfort • Aorto-right atrial fistula • Arrhythmias, including exacerbation of preexisting atrial fibrillation • Arteriovenous fistula • AV/SA node stunning (asystole) • Bleeding, including major bleeding requiring surgery or transfusion/hematomas/anemia • Cardiac perforation/tamponade • Cardiac embolism • Cardiovascular injury, including atrial trauma and coronary artery/pulmonary vein trauma • COPD exacerbation • Component damage to Implantable Cardioverter Defibrillator(ICD) or implantable pacemaker • Coronary artery spasm • Cytotoxicity/systemic toxicity/sensitization/endotoxin/pyrogen • Death • Dislodgement of ICD or pacing leads • Electrical shock • Endocarditis • Esophageal lesion • Fever • Foreign body embolism • Heart block/unintended ablation • Heart failure • Hemothorax • Hypotension • Infectious pericarditis • Left atrial esophageal fistula • Myocardial infarction • Neck/ back/groin/chest pain/discomfort (general chest pain not associated with MI) • Palpitations • Pericarditis • Pericardial effusion • Phrenic nerve injury • Peripheral vascular dissection/laceration • Pleural effusion • Pneumonia • Pneumothorax • Pseudoaneurysm • Pulmonary edema • Pulmonary embolism • Pulmonary hypertension • Pulmonary vein stenosis • Radiation injury • Respiratory failure/distress/depression/hypoxia • Silent cerebral event/lesion • Stiff Left Atrial Syndrome • Stroke/cerebrovascular accident • Syncope/vasovagal reaction/dizziness • Transient ischemic attack (TIA) • Thromboembolism • Thrombosis/thrombus • Vagal nerve injury including Gastroparesis • Valvular damage or insufficiency.

Indication: TactiFlex™ Duo Ablation Catheter, Sensor Enabled™ is indicated for use in cardiac electrophysiological mapping and ablation for the treatment of drug-refractory recurrent symptomatic paroxysmal atrial fibrillation and concomitant atrial flutter, when used in conjunction with a compatible radiofrequency (RF) or pulsed field (PF) generator and three-dimensional mapping system. **Contraindications:** Do not use in patients with active systemic infection, intracardiac thrombus or myxoma, prosthetic heart valves, recent ventriculotomy or atriotomy (<4 weeks), inability to receive adequate anticoagulation, or in patients for whom the specified transseptal or retrograde approaches are contraindicated. Use in the coronary vasculature is contraindicated. **Warnings**: Application of RF energy on the left atrial posterior wall exceeding 40 W in power, or use of contact force ≥15 g, increases the risk of esophageal perforating complications including atrio-esophageal fistula and death. Application of RF energy outside of the power and duration recommendations may increase the likelihood of steam pop occurrence. The combination of intracoronary placement of the ablation catheter and RF energy application has been associated with myocardial infarction and death. Contact force accuracy above 50 g has not been established. Increased contact force may increase the risk for perforation during manipulation of the catheter. Cases of delayed onset of atrio-esophageal fistula (AEF) have been reported in association with radiofrequency catheter ablation procedures. While rare, AEF is associated with significant morbidity and mortality. A high index of suspicion for AEF should be maintained in patients who present with symptoms including but not limited to fever, neurological deficits, hematemesis, septic shock, and dysphagia in the several weeks after a left atrial ablation procedure. Inspect tubing, connections, and saline irrigation for air bubbles prior to and throughout its use in the procedure. Air or bubbles in the saline irrigation may cause emboli, potential injury, or fatality. To avoid thromboemboli, intravenous heparin should be used when entering the left heart during ablation. Patients undergoing septal accessory pathway ablation are at risk for complete AV block which requires the implantation of a permanent pacemaker. Permanent pacing may be required in patients who experience inadvertent complete AV block as a result of RF ablation. Implantable pacemakers and implantable cardioverter/defibrillator (ICDs) may be adversely affected by RF or PFA current. It is important to: have temporary external sources of pacing and defibrillation available during ablation, temporarily reprogram the pacing system to minimum output to minimize risk of inappropriate pacing, exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent leads, program the ICD to the OFF mode during the ablation procedure, perform complete implantable device analysis on all patients after ablation. Take precautions to avoid injuring the phrenic nerve, including pacing to identify the proximity of the nerve, and, when using RF, appropriately reducing power. Caution should be taken when placing lesions in the proximity of the specialized conduction system. Collateral anatomical structures need to be considered (e.g. phrenic nerve, coronary arteries and native conduction system) while manipulating catheters and prior to ablation. PF energy should not be applied to the cavotricuspid isthmus. Ablations in areas adjacent to the coronary arteries may lead to coronary artery spasm and/or injury, and the resulting myocardial injury may be fatal. **Precautions:** Use the catheter only in a fully equipped electrophysiology laboratory. It is recommended that the laboratory should include corresponding equipment including, but not limited to, fluoroscopy, stimulator, recording, defibrillator or ultrasound/intracardiac echocardiography (ICE) units. The PFA therapy should be delivered in accordance with Therapy Delivery Parameters. The first application of PFA will likely result in a significant reduction of amplitude of PV potentials recorded from the electrodes on the catheter. Do not use this as an immediate indication that no further ablation is necessary. During treatment with the catheter, ensure there is no possibility of contact with the electrodes or guidewire from another catheter. Always straighten the catheter tip before insertion or withdrawal. If irrigation flow is interrupted, immediately inspect and re flush the catheter outside of the patient. Re-establish irrigation flow prior to placing catheter in the body. Irrigated ablation systems have been shown to create larger lesions than standard radiofrequency ablation catheters. Be careful when ablating near electrically vulnerable, thin walled, or other arterial structures. **Potential Adverse Events:** Potential adverse events include, but are not limited to, death, stroke, transient ischemic attack (TIA), atrio-esophageal fistula (AEF)/esophageal injury, phrenic nerve injury/diaphragmatic paralysis, and serious cardiovascular complications including cardiac tamponade, cardiac perforation, myocardial infarction, heart block requiring permanent pacemaker implantation, pulmonary vein stenosis, thromboembolism, and major bleeding or vascular access complications. Refer to the Instructions for Use for a complete list of adverse events.

Indications: The EnSite™ X EP System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated. The EnSite™ X EP System provides information about the electrical activity of the heart and displays catheter location during conventional electrophysiological (EP) procedures. **Warnings:** For patient safety, any connections that directly connect the patient to the EnSite™ X EP System must be routed through the appropriate modules: EnSite™ X EP System SurfaceLink Module, EnSite™ X EP System 20 pin Catheter Input Module, EnSite™ X EP System 80-pin Catheter Input Module and Direct Connect Ports on the EnSite™ X EP System Amplifier. When using the EnSite™ X EP System, full protection against the effects of cardiac defibrillator discharge and other leakage currents is dependent upon the use of appropriate cables. Refer to the ablation catheter IFU for a listing of adverse events related to the use of this device in conjunction with ablation, as a part of the diagnosis and treatment of cardiac arrhythmias. Non-SE catheters cannot collect location data and should not be used for navigation in VoXel Mode because they do not have a magnetic sensor. However, they can be visualized and display intracardiac signals. Only connect items that have been specified as part of the EnSite X EP System or compatible with the EnSite X EP System to the multiple socket-outlets. The EnSite™ X EP System model display should be used in conjunction with conventional EP techniques to confirm catheter location. The AutoMark feature does not indicate lesion effectiveness. AutoMarks are placed based on user-defined parameters for catheter stability and RF metrics only. PFA AutoMarks are placed based on electrode location and user-defined PFA metrics only. Sudden impedance changes of the body or catheter electrodes caused by the connection of other devices (e.g., stimulator, defibrillator, and other devices) may create a location shift. The 2D and 3D LivePoint Displays should not be used as the primary / sole display of tissue proximity during an Electrophysiology study. Refer to the Current PFA Generator IFU for warnings related to the Volt ™ LivePoint Display. **Precautions:** Ensure that surface electrodes, Patient Reference Sensors, and associated connectors do not contact one another, electrical ground, or metallic objects. Do not operate the EnSite™ X EP System Field Frame within 10 m of another operating Field Frame. Do not place the EnSite™ X EP System Field Frame Cable inside the measurement volume or wrap it around the EnSite™ X EP System Field Frame, as it may create a magnetic interference. Metallic equipment used in close proximity to the magnetic field during the procedure, such as a sterile drape holder, may cause metal distortion. Do not place tool cables within 30 mm of the EnSite™ X EP System Field Frame Cable. If placed this close-particularly if the cables are parallel to each other the tool cable may become subject to electromagnetic interference. Do not use the EnSite™ X EP System for magnetic catheter localization or magnetic data collection (NavX SE or EnSite VoXel point collection) if other magnetic fields are present.

Indications: The Agilis™ NxT Steerable Introducer Dual-Reach™ is indicated for the introduction of various cardiovascular catheters into the heart, including the left side of the heart, during the treatment of cardiac arrhythmias. **Contraindications:** The Agilis™ NxT Steerable Introducer Dual-Reach™ is contraindicated for: Previous interatrial septal patch. Known or suspected atrial myxoma. Acute myocardial infarction. Unstable angina. Recent cerebral vascular accident (CVA). Patients who do not tolerate anticoagulation therapy. Patients with an active infection. Presence of an intracardiac thrombus. **Warnings:** Do not alter this device in any way. This device must be used by board-certified electrophysiologists, or EP fellows in training, in a fully-equipped operational EP laboratory. This device is intended for one time use only; do not reprocess or reuse it. Note the product "Use by" date on the package. Any attempt to resterilize and reuse this system may compromise its integrity. Adverse effects of using nonsterile components may include, but are not limited to: Local or systemic infection or reaction, Mechanical damage, Inaccurate functionality. Always aspirate, insert and withdraw components, and exchange catheters slowly to minimize the risk of air emboli. Aspirate all air before fluid infusion from the sideport. Provide continuous heparinized saline infusion while the introducer remains in the vessel. Fibrin may accumulate in or on the introducer tip during the procedure. To prevent dislodgement of potential thrombus, aspirate when removing dilator or catheter. Before removing the steerable introducer, reinsert the guidewire through the introducer, reintroduce the dilator over the guidewire, straighten the steerable introducer, then remove the dilator, guidewire, and introducer as a unit. Maximum in-vivo time: 7 hours. Read the IFU carefully before using this device to help reduce the potential risks and complications associated with the transseptal technique, such as air emboli and perforation of the aorta and left atrium. Aspirate and saline flush the introducer frequently to minimize the potential for thrombus formation. Do not use the introducer without a catheter or dilator supporting the lumen. Use of the introducer directly over a wire without a catheter or dilator supporting the

lumen may result in complications that can cause death. For both patients and laboratory staff, cardiac catheterization procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects due to the x-ray beam intensity and duration of the fluoroscopic imaging. Carefully consider the use of this introducer in pregnant women. Persons with known history of allergies to any of the materials listed below may suffer an allergic reaction to this device. Before use, counsel the patient on the materials contained in the device and discuss a thorough history of allergies. This device contains: Polyether block amide (PEBAX), Polytetrafluoroethylene, ABS, Silicone rubber, DOW Corning 360 fluid , HDPE, MDX/hexane solution, Nylon. Precautions: Federal law (U.S.) restricts this device to sale by or on the order of a physician. Only use this device with equipment that complies with international safety standards. Store in a cool, dark, dry place. Inspect all components before use. Do not use if the packaging or items in the kit appear to be damaged or defective. Conditions requiring special consideration when using this product may be, but are not limited to, small left atrium, marked right atrial enlargement, and marked distortion of the thorax configuration (example, kyphosis or scoliosis). Individual patient anatomy and physician technique may require procedural variations. **Potential Adverse Events:** The following potential complications may occur during the use of this device, but are not limited to: Arrhythmia. Bleeding Major: bleeding requiring surgery or transfusion, Hematomas or Anemia. Cardiac perforation: Cardiac tamponade, Pericardial complications, Pericardial effusion Hemopericardium, Pneumopericardium, Pericarditis. Cardiovascular injury: Atrial/ventricular trauma, Great vessel perforation, Valvular damage. Cerebral injury: Asymptomatic cerebral emboli (ACE), Stroke/cerebrovascular accident, Transient ischemic attack (TIA). Coronary artery injury. Embolism: Air embolism, Foreign body embolism, Pulmonary embolism, Thromboembolism, Thrombosis/thrombus. Hypotension: Vasovagal reaction. Immunological reaction: Anesthesia reaction, Anaphylaxis. Infection: Endocarditis, Pneumonia, Sepsis/shock. Organ injury: Esophageal injury, Pleural effusion. Pain: Groin. Peripheral vascular injury: Arteriovenous fistula, Dissection, Laceration, Pseudoaneurysm. Superficial tissue injury. Please consult the respective manufacturer's labeling for adverse events associated with the use of either cardiovascular catheters or endomyocardial biopsy devices.

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