

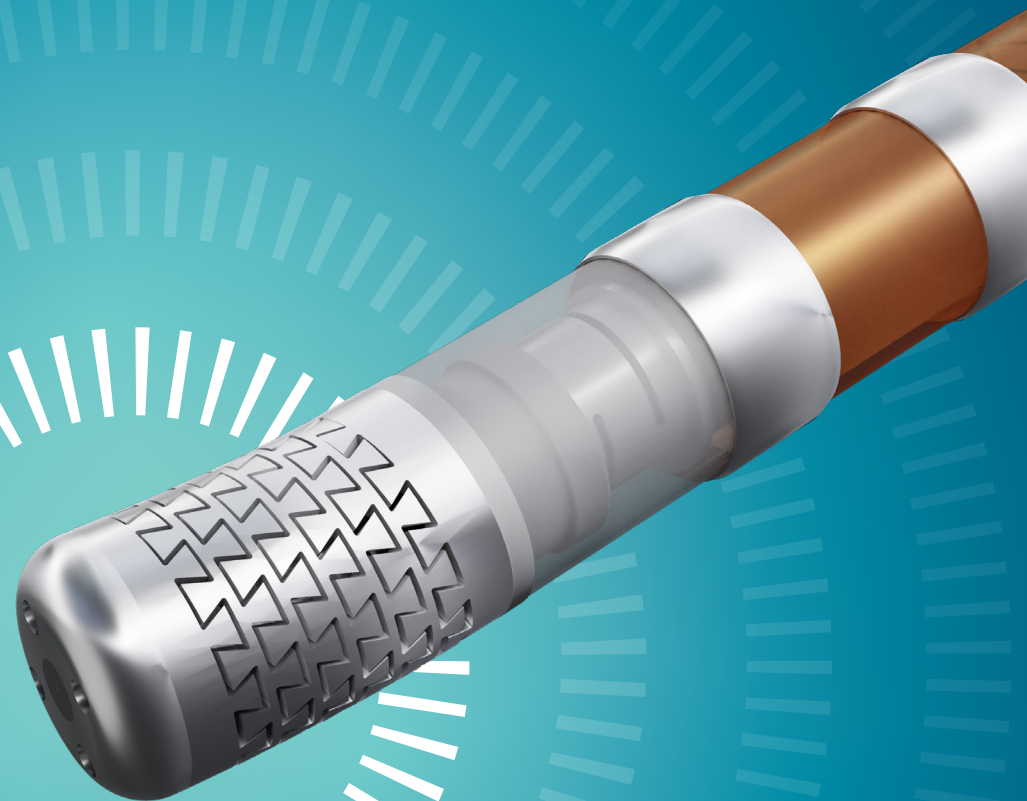


Abbott

KNOW THE FACTS:

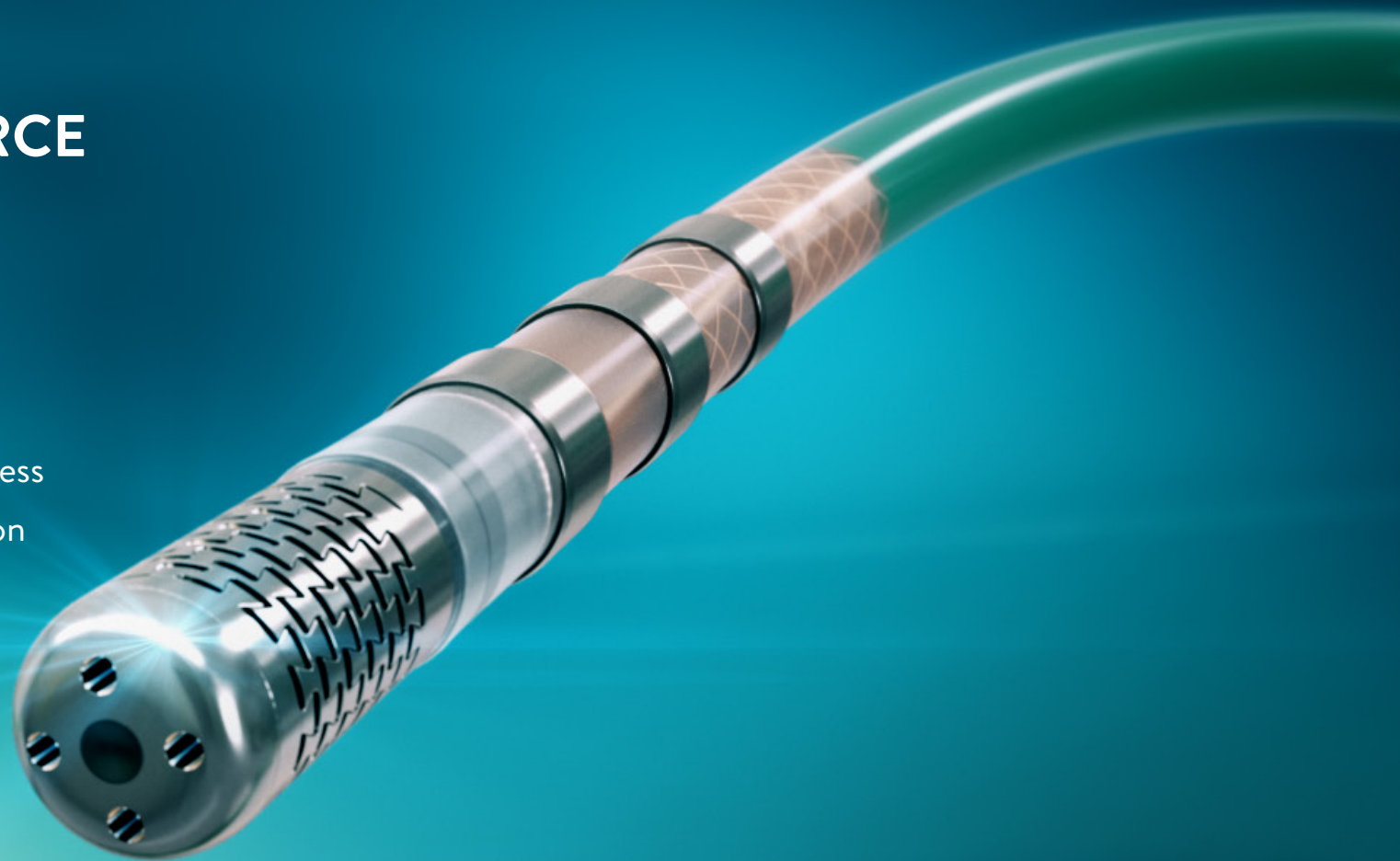
**7 REASONS TACTIFLEX™
ABLATION CATHETER,
SENSOR ENABLED™**

PREVAILS OVER QDOT‡



THE FIRST AND ONLY CONTACT FORCE CATHETER WITH A FLEXIBLE TIP.

BACKED BY EXPLICIT DATA, TactiFlex™ Ablation Catheter, Sensor Enabled™ allows you to advance safety, stability and success in RF ablation, making it the best-in-class RF ablation catheter on the market, and your solution for today's ablation procedures.



Redefine how you perform high-power short-duration RF ablation procedures with TactiFlex Ablation Catheter, SE, **PREVAILING OVER QDOT[‡] IN SEVEN DISTINCT CATEGORIES** - supported by **CLINICAL EVIDENCE AND REAL-WORLD EXPERIENCE.**

1

SUPERIOR TIP STABILITY



REDUCE LAB TIME THROUGH OPTIMAL LESION CREATION

SUPPORTING SAFE AND EFFICIENT LESION
CREATION WITH UP TO 2X GREATER STABILITY[†]



Ablate with predictability and confidence through greater tip-tissue stability and excellent footprint

Help ease function and promote predictable
lesion size with greater stability



The flexible tip enhances
stability at the tip-tissue
interface by **UP TO 2X**
with a displacement force of

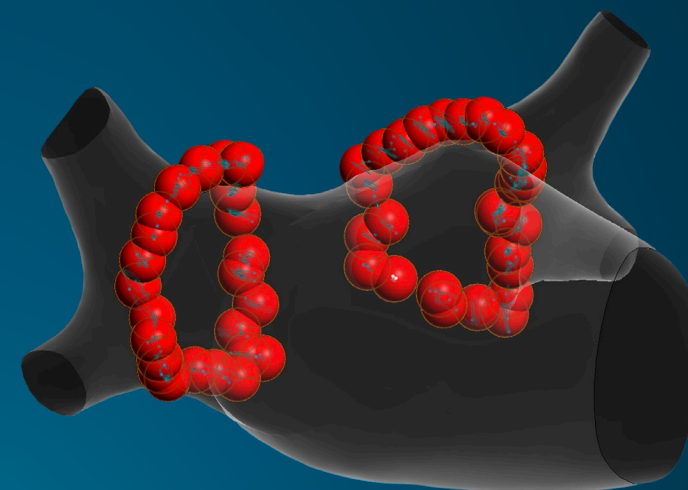
~24G^{1}**



A fixed tip catheter with
properties similar to QDOT[†]
demonstrated a displacement
force of

~12G^{1}**

Maximize lesion efficacy with parallel
configuration and optimal ablation
area footprint



Note: These values are at 10 G of CF and in parallel catheter orientation.

2

EXCELLENT SIGNAL QUALITY

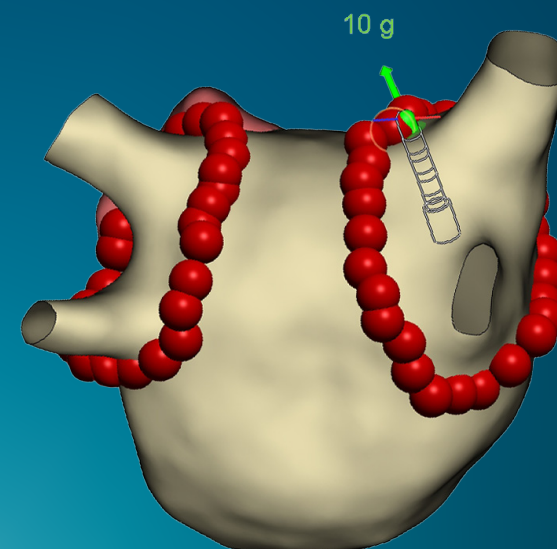


Experience excellent signal quality **ON OR OFF ABLATION** allowing confident lesion creation

TactiFlex™ Ablation Catheter, Sensor Enabled™ features provide high quality bipolar and unipolar signals for monitoring signal attenuation during RF delivery

- A novel flexible tip design to enhance the tip-to-tissue interface for reliable signal quality
- An increase in catheter stability for signal consistency
- A reduced flow rate and a low noise floor of the EnSite™ X EP System for greater signal clarity

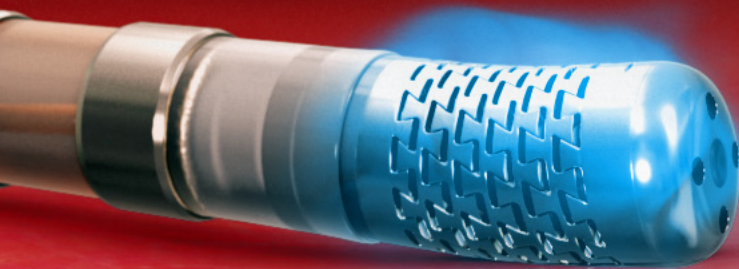
QDOT⁺ features microelectrodes at the distal tip of catheter



Actual signal from TactiFlex Ablation Catheter, SE DURING ABLATION

3

DIRECTED IRRIGATION FLOW



OPTIMIZE SAFETY IN TRANSMURAL ABLATION

LIMIT STEAM POP PREVALANCE WITH DIRECT
TISSUE COOLING²



Optimize safety during ablation with targeted cooling
at the tip-to-tissue interface

Reinforce safety with directed
tissue cooling to reduce steam
pop prevalence compared to
a solid tip catheter²

Protect patients during
ablation by reducing fluid
loading with low irrigation
flow rates

Measure temperature
changes accurately



TactiFlex™ Ablation
Catheter, SE

Allows directed irrigation through
a novel flexible laser-cut tip design

Demonstrated a median fluid
delivery of **436 ml** for all
procedures⁴

Features temperature sensors
proximal to tissue surface



QDOT+

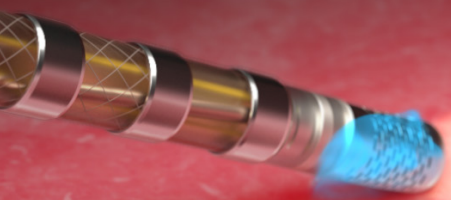
Fixed tip delivers uniform cooling of
the catheter tip

The median fluid delivery was
500 ml³ for all procedures

Introduced 6 TC 120 degrees
apart at the distal and proximal
to catheter tip

4

HIGH FIRST-PASS PV ISOLATION (FPI)



RELIABLE RESULTS, THE FIRST TIME

ACHIEVE 81.8% FIRST-PASS SUCCESS VS.
67.4% WITH QDOT^{±3,4}



Support improved PVI outcomes during your cases with contiguous and durable lesions through high first-pass PVI isolation (FPI) with TactiFlex™ Ablation Catheter, Sensor Enabled™

Create more opportunities for PVI success

81.8%

TactiFlex Ablation Catheter, SE performs at an **81.8%** FPI success rate at 40–50W⁴

67.4%

QDOT[±] Micro demonstrates a **67.4%** success rate at 90W³

Deliver results with an effective workflow with TactiFlex Ablation Catheter, SE and EnSite™ X EP System

- Support safe and optimal therapy with RF time recommendations backed by clinical trial data
- Boost confidence in lesion accuracy with AutoMark distance default settings

5

EFFICIENT PROCEDURES



MORE CONTROL OVER YOUR TIME

REDUCE PROCEDURE TIMES BY ALMOST 16%
VS. QDOT^{†3,4}



Maximize resources and enhance the treatment experience by reducing procedure times and maximizing patient safety utilizing a high-power short duration workflow with TactiFlex™ Ablation Catheter, Sensor Enabled™

Enhance care and efficiency with the potential of shorter procedures

111
MIN⁴

132
MIN³

Reduce radiation exposure by lowering fluoroscopy times

4
MIN⁴

9.1
MIN³

Promote safe and effective lesion creation with shorter total ablation times – from first to last ablation

43
MIN⁴

65
MIN³

Limit fluid delivery via irrigation to enhance patient safety

378
MLS⁴

500
MLS³



TactiFlex Ablation Catheter, SE (40–50W)⁴



QDOT[†] (Qfficiency; 90W + 25–50W)³

6

SEAMLESS INTEGRATION WITH THE ENSITE™ X EP SYSTEM



GREATER PREDICTABILITY FOR EASE OF USE CONTACT FORCE ARROW AND DEFLECTION DIRECTION INDICATOR



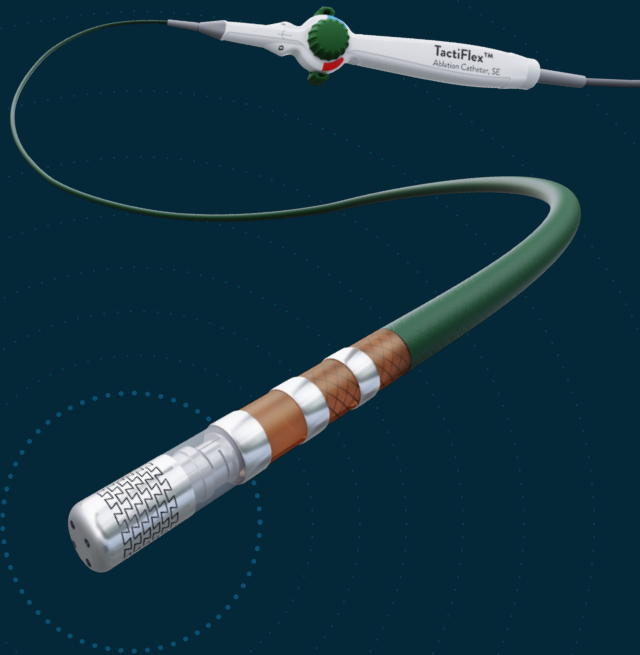
Ablate with efficiency and efficacy by integrated design. Add TactiFlex™ Ablation Catheter, Sensor Enabled™ to your EP lab, with enhanced EnSite X EP System software including EnSite™ Aid Module

Easily track procedural progress with a unified data display and indicator lights

- EnSite X EP System links the contact force value to the force arrow on a single display. Color catheter deflection indicators on the catheter handle match indicators appearing on the screen display
- CARTO⁺ presents the force arrow and contact force values separately. Color deflection indicators display on the screen only

7

PROCEDURAL COSTS



LOWERING ABLATION COSTS, INCREASING OPERATIONAL EFFICIENCY

OVER \$72,000 SAVED PER 100 CASES VS. QDOT^{‡5}



Save \$72,600 in procedural costs^{‡5}



Minimize your per-unit catheter cost for ongoing savings

- TactiFlex™ Ablation Catheter, Sensor Enabled™ is **\$100 LESS THAN QDOT[‡] MICRO⁵**
- This equates to a savings of **\$10,000 FOR 100 CASES**



Save time, personnel resources and costs involved in new capital equipment purchases

- TactiFlex Ablation Catheter, SE is compatible with the current version of our Ampere™ RF Generator, requiring no additional capital equipment purchase
- QDOT[‡] Micro requires a new capital purchase at an estimated **\$40,000**



Create cost-efficiencies with a one-time cable purchase

- TactiFlex Ablation Catheter, SE requires the purchase of a single nondisposable nonsterile cable
- QDOT[‡] Micro requires two cables, including a disposable two-time use cable, for an **ADDITIONAL \$22,000** per 100 cases

FEATURE		CONTRIBUTING FACTORS	 TACTIFLEX™ ABLATION CATHETER, SENSOR ENABLED™	 QDOT‡
1	CATHETER–TISSUE CONTACT	CATHETER STABILITY	UP TO 2X GREATER STABILITY through a flexible laser-cut tip ¹	Fixed tip
		ACCURACY OF CONTACT SENSING	Fiberoptic sensor	Electro-mechanical sensor
2	REAL-TIME EGM FEEDBACK	BI- AND UNIPOLAR SIGNAL QUALITY DURING RF DELIVERY TO MONITOR ABLATION PROGRESS	Comprehensive approach based on 4 factors: tip design, catheter stability, reduced flow rate, EnSite™ X EP System low noise floor	3 microelectrodes at distal tip of catheter allowing monitoring of signal attenuation during ablation
3	ACTIVE COOLING OF CATHETER TIP	IRRIGATION EFFICIENCY	Directed and distributed irrigation	Distributed irrigation
4	PVI SUCCESS	FIRST PASS PV ISOLATION (FPI)	81.8%⁴ (40-50W)	67.4% ³ (90W)
5	PROCEDURE EFFICIENCY	MEDIAN TOTAL PROCEDURE TIME, INCLUDING 20 MINUTE WAITING TIME	120 MIN⁴ (for all procedures) 111 MIN⁴ (for high-power procedures)	132 min ³
6	EASE-OF-USE	CONTACT FORCE ARROW	EnSite™ X EP System displays contact force value to the force arrow	CARTO‡ displays force arrow and contact force values separately
		CATHETER DEFLECTION INDICATOR	Color indicators on handle matching display on screen	Color indicators display on screen
		SET UP	Only requires a one time purchase of an ablation cable	Requires a new generator and a new extension cable, in addition to a one time purchase of an ablation cable
7	COST REDUCTION	COST FOR 100 CASES ⁴	\$371.1M	\$443.7M

*QDOT[†] Qfficiency times includes non-PV ablation targets in 39.8% of participants.

**At 10 g of contact force, TactiFlex™ Ablation Catheter, Sensor Enabled™ is 2X MORE STABLE than QDOT[†], requiring 24g of force to displace the catheter compared to only 12g for QDOT[†]

1. 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.
2. Tranter, John H., Zada Thamavong, and Jeffrey Fish. “PO-02-076 AN INVESTIGATION OF LESION EFFICACY AND SAFETY WITH THE TACTIFLEX™ SE ABLATION CATHETER.” Heart Rhythm 20.5 (2023): S342-S343.
3. Very High-Power Short-Duration, Temperature-Controlled Radiofrequency Ablation in Paroxysmal Atrial Fibrillation: The Prospective Multicenter Q-FFICIENCY Trial. Osorio et al., JACC: Clinical Electrophysiology. April 2023 9(4):468-480 Language: English. DOI: 10.1016/j.jacep.2022.10.019, Database: ScienceDirect
4. Nair, D. G., Martinek, M., Colley, B. J., Sundaram, S., Sharma, S., Morales, G. X., ... & Lo, M. Y. (2023). Safety and Effectiveness of the First Contact Force Ablation Catheter with a Flexible Tip. Heart Rhythm O2 (published online ahead of print 31 Oct). Available at: <https://doi.org/10.1016/j.hroo.2023.10.006>.
5. Clarivate Pricetrack.

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: The TactiFlex™ Ablation Catheter, Sensor Enabled™ is indicated for use in cardiac electrophysiological mapping and for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation and concomitant atrial flutter, when used in conjunction with a compatible RF generator and three-dimensional mapping system. **Contraindications:** Do not use for any of the following conditions: recent ventriculotomy or atriotomy heart surgery; prosthetic valves; active systemic infection; use in coronary vasculature; myxoma or intracardiac thrombus, transseptal approach with an interatrial baffle or patch; retrograde trans-aortic approach in patients with aortic valve replacement; patients unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation. **Warnings:** The temperature data transmitted by the sensor in this catheter is representative of the irrigated electrode only and does not provide tissue temperature data. Application of RF energy on the left atrial posterior wall exceeding 40 W in power, or use of contact force ≥15g, 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. Patients undergoing septal accessory pathway ablation are at risk for complete AV block which requires the implantation of a permanent pacemaker. Implantable pacemakers and implantable cardioverter/defibrillator (ICDs) may be adversely affected by RF current. The combination of intracoronary placement of the ablation catheter and RF energy application has been associated with myocardial infarction and death. 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. Increased contact force may increase the risk for perforation during manipulation of the catheter. Contact force in excess of 20 g may not significantly change the characteristics of lesion formation. Contact force accuracy above 50 g has not been established. Caution should be taken when placing lesions in the proximity of the specialized conduction system. To avoid thromboemboli, intravenous heparin should be used when entering the left heart during ablation. Always maintain a constant saline irrigation flow to prevent coagulation within the lumen of the catheter. When using the catheter with conventional EP lab system (using fluoroscopy to determine catheter tip location) or with a 3D navigational system, careful catheter manipulation must be performed, especially when used in combination with a long sheath, in order to avoid cardiac damage, perforation, or tamponade. **Precautions:** 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, cardiovascular related complications, including hematoma, pericardial effusion and infection. More serious complications are rare, which can include damage to the heart or blood vessels; blood clots (which may lead to stroke); tamponade; severe pulmonary vein stenosis; heart block; myocardial infarction; esophageal fistula, or death.

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. The use of this device in conjunction with radio frequency ablation, as a part of the diagnosis and treatment of cardiac arrhythmias, may pose an increased risk of adverse events such as cardiac perforation, myocardial infarction, air embolism, and hematoma requiring surgical repair and/or blood transfusion. 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. 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. Precautions: Ensure that surface electrodes, Patient Reference Sensors, and associated connectors do not contact one another, electrical ground, or metallic objects. EnSite™ X EP System components should be connected to power through an isolation transformer or the multiple socket outlet supplied with the system carts. Connecting equipment directly to a wall outlet may result in excessive leakage current. 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 in the presence of other magnetic fields. Do not drop the EnSite™ X EP System Field Frame or subject it to impact. Physical damage to the EnSite™ X EP System Field Frame may alter the EnSite™ X EP System Field Frame's factory calibration.

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