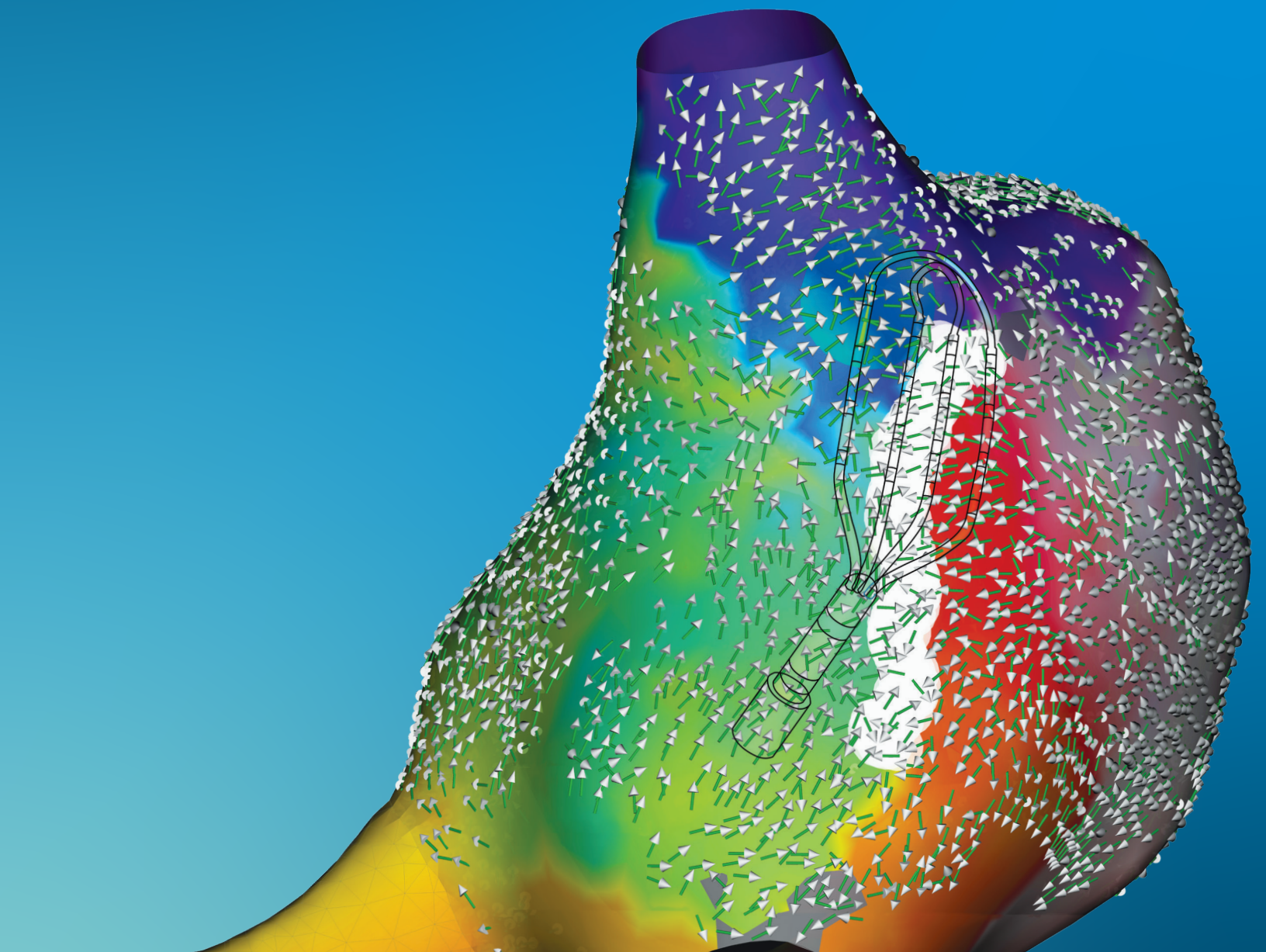
Abbott

BOLD SOLUTIONS TO CHALLENGE AFIB

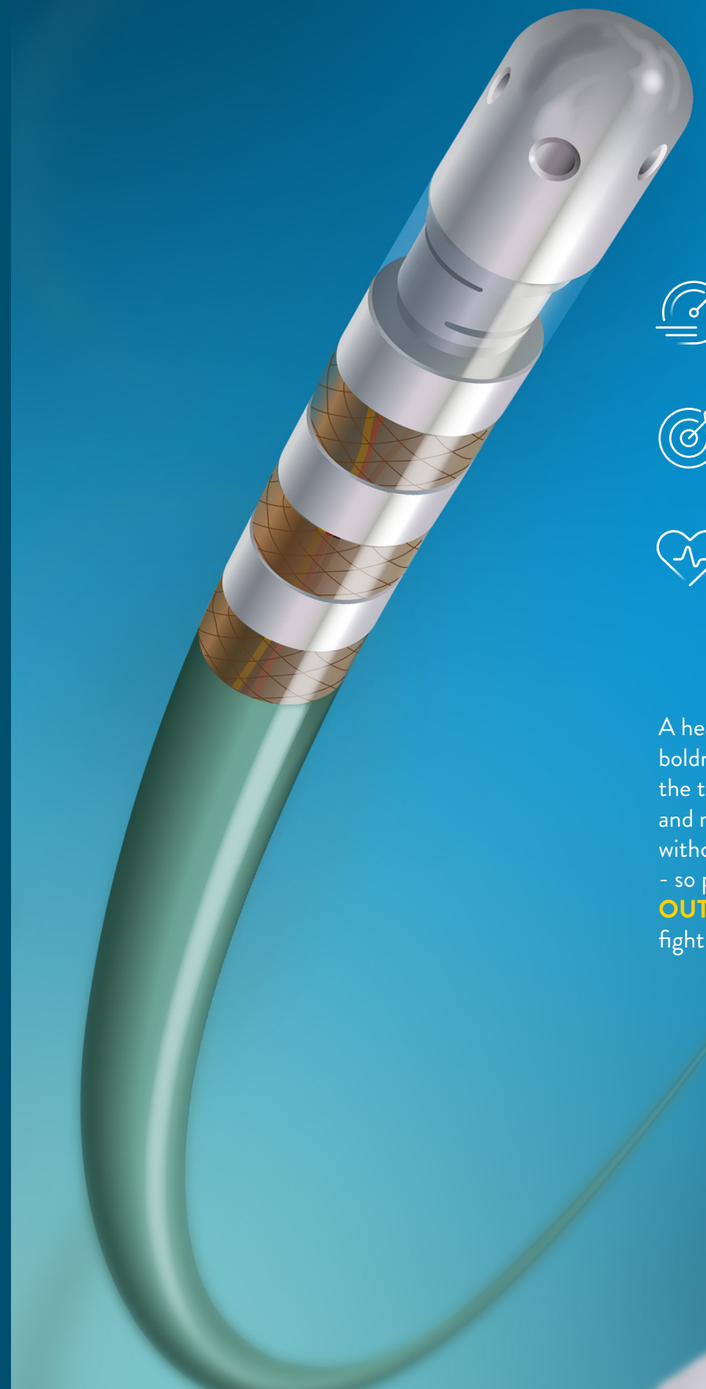


ATRIAL FIBRILLATION:
A GROWING CRISIS

Atrial fibrillation is the fastest growing crisis in EP, with worldwide patient population expected to explode

FROM 37 MILLION TODAY, TO MORE THAN 60 MILLION BY 2050

ABBOTT EP: BOLDLY REDEFINING
THE TECHNOLOGY YOU RELY ON



EFFICIENCY

ACCURACY

PATIENT OUTCOMES

A health crisis scaling so dynamically demands boldness. Abbott partners with EPs to take the tools used to challenge AFib everyday, and redefine them to be more **EFFICIENT** without ever compromising **ACCURACY** - so physicians can deliver better **PATIENT OUTCOMES** and bring boldness to the fight against AFib

BOLD SOLUTIONS TO CHALLENGE AFIB

Only Abbott offers a holistic portfolio with solutions for every step in your procedure journey

ACCESS

Agilis™ NxT Steerable Introducer

IMAGING

ViewMate™ Ultrasound System

ViewFlex™ Xtra Intracardiac Echocardiography (ICE) Catheter

TRANSSEPTAL

BRK™ Transseptal Needles

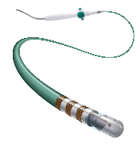
MAPPING

Advisor™ HD Grid Mapping Catheter, Sensor Enabled™

EnSite™ X EP System

ABLATION

FlexAbility™ Irrigated Ablation Catheter, Sensor Enabled™



TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™

LAAO

Amplatzer™ Amulet™ LAA Occluder

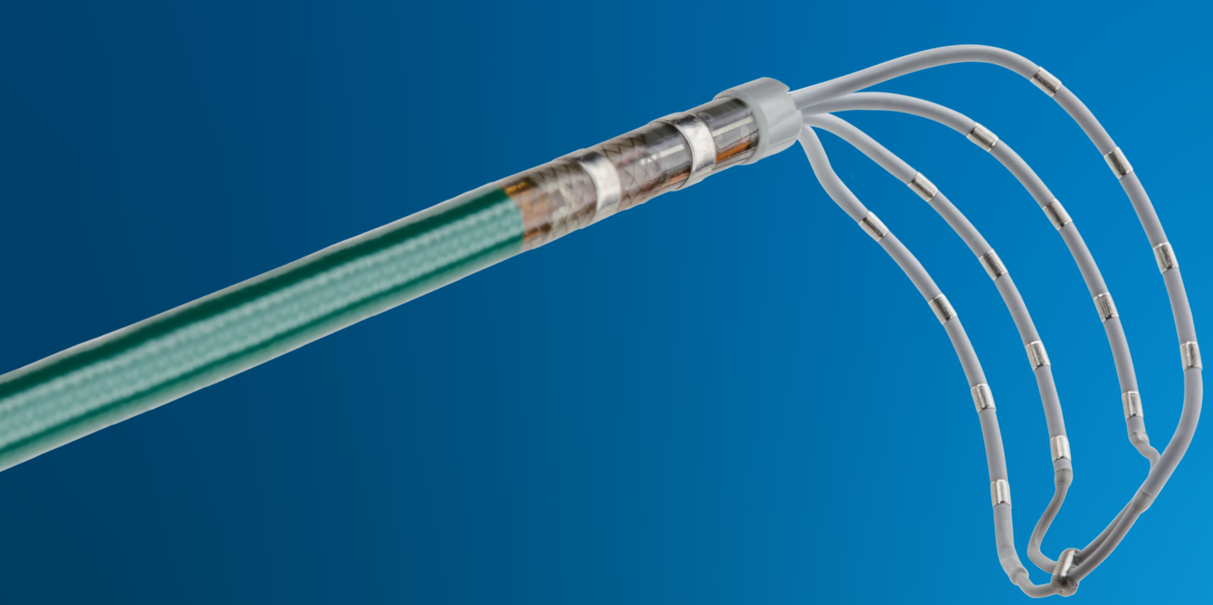
VASCULAR CLOSURE

Perclose™ Prostyle™ Suture-Mediated Closure System

MONITORING

Jot Dx™ Insertable Cardiac Monitor

ABBOTT - A BOLD PARTNER IN THE FIGHT AGAINST AFIB



YOU RELY ON TECHNOLOGY
THAT DRIVES EFFICIENCY

GET IN AND OUT OF YOUR LAB IN LESS TIME

Unleash the bold power of the grid with Advisor™ HD Grid Mapping Catheter, Sensor Enabled™. Advisor™ HD Grid Mapping Catheter, SE redefines lab efficiency with **SHORTER PROCEDURE TIMES** than circular mapping catheters.

AVERAGE REDUCTION OF PROCEDURE TIME
34.1 MINUTES[1]

KNOW YOU'RE DOING IT RIGHT THE FIRST TIME

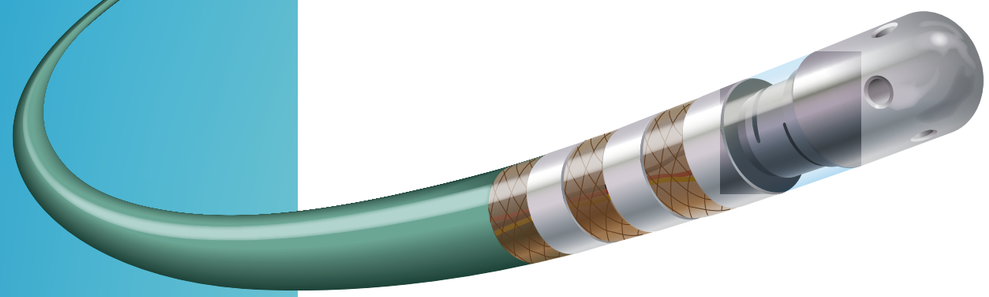
Within Abbott's EP portfolio of products, there are bold solutions that redefine what is possible in delivering care that **REDUCES REPEAT VISITS**

REDO AF PROCEDURES[2]

Reduce patient **HEALTHCARE UTILIZATION** when ablating with TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™

OVER 53%

Reduction of all-cause annual event rates (event per patient per year) observed at 15-month[3]

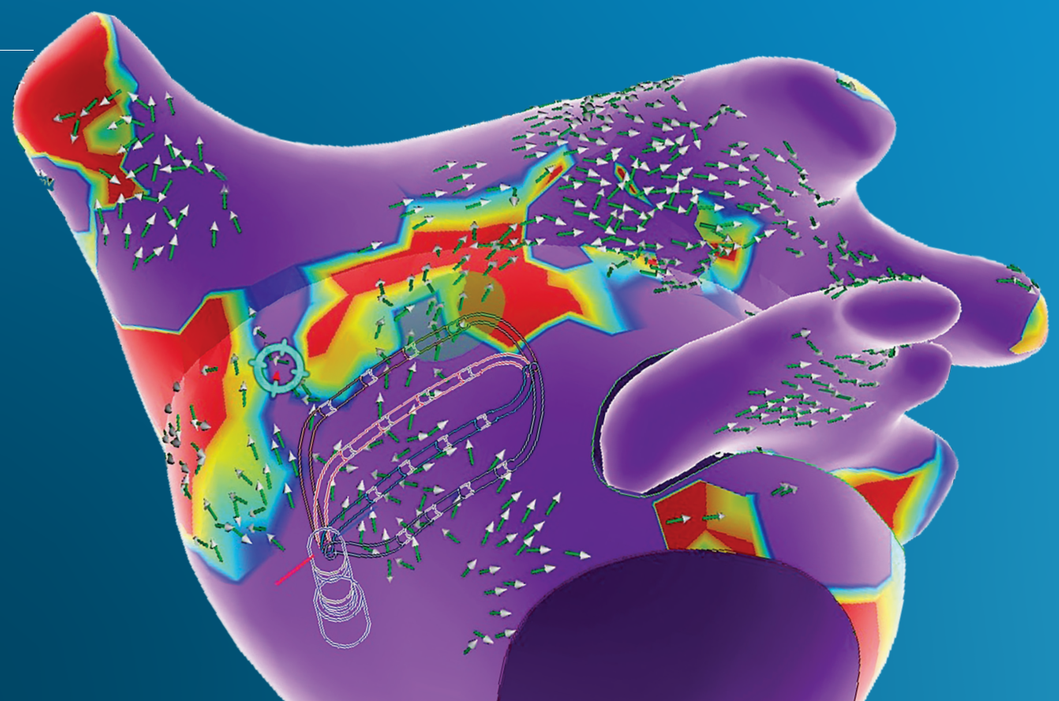


YOU RELY ON TECHNOLOGY BOLD ENOUGH **NOT TO COMPROMISE BETWEEN EFFICIENCY AND ACCURACY**

Abbott has worked with electrophysiology partners to ensure that our solutions challenge AFib with technology that redefines lab efficiency and SIGNAL ACCURACY

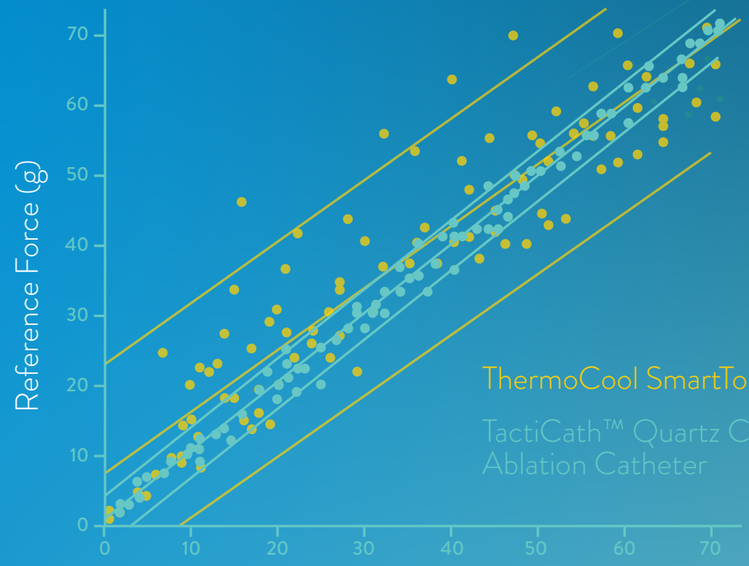
Boldness is **SEEING EVERY SIGNAL IN 360 DEGREES** with EnSite™ Omnipolar Technology; capturing signals no other mapping technology can detect

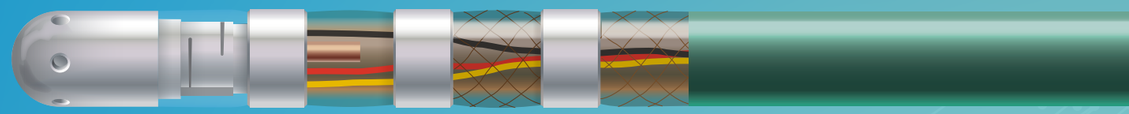
EnSite™ Omnipolar Technology helps electrophysiologists challenge AFib with **INSTANT NEW PERSPECTIVE OF WAVEFRONT DIRECTION** with activation direction arrows displayed beat-by-beat



ACCURACY MATTERS **IN ABLATION THERAPIES**

Abbott's EP portfolio is bold enough to complement accuracy in signal quality with **ACCURACY IN CONTACT FORCE** during ablation





UP TO 6X GREATER ACCURACY IN CONTACT FORCE SENSING WITH THE TACTICATH™ CONTACT FORCE ABLATION CATHETER, SENSOR ENABLED™ TIP IN LATERAL ORIENTATION [4,5]

YOU RELY ON TECHNOLOGY THAT **DELIVERS BETTER PATIENT OUTCOMES**

We design for BOLD results that help physicians give their patients better outcomes that last

FREE YOUR PATIENTS FROM ATRIAL ARRHYTMIAS

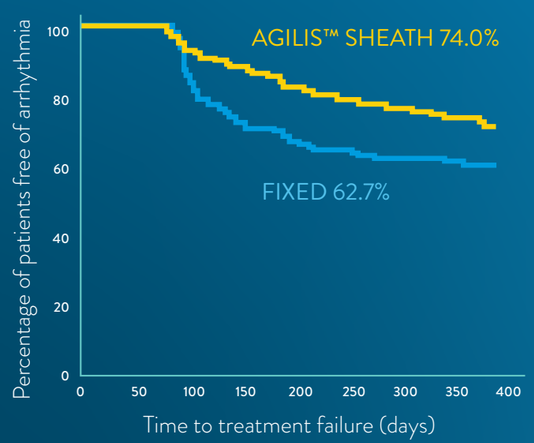
12-month freedom from atrial Arrhythmias with Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ [2]

Advisor HD Grid Mapping Catheter, SE
87%

Circular Mapping Catheter
75%

Freedom of arrhythmia at 12 mo with Agilis™ NxT Steerable Sheath[6]

Protocol Defined Treatment Success by Sheath Usage – All Subjects



BETTER OUTCOMES FOR BOTH **PAROXYSMAL AND PERSISTENT AFIB**

Safe and effective AFib treatment with TactiCath™ Ablation Catheter, Sensor Enabled

Improved quality of life for patients at least 12 months following ablation[7]

PAROXYSMAL AFIB
92.4%

PERSISTENT AFIB
94.4%
Improved quality of life scores noted as AFEQT

Freedom from symptomatic recurrance of paroxysmal AFib[8]
82.2%

Freedom from symptomatic recurrance of persistent AFib at 15 months[8]
90%

References

1. Abbott. Report on file. 90299533
2. Day, J. D., Crandall, B., Cutler, M., Osborn, J., Miller, J., Mallender, C., & Lakkireddy, D. (2020). High Power Ultra Short Duration Ablation with HD Grid Improves Freedom from Atrial Fibrillation and Redo Procedures Compared to Circular Mapping Catheter. Journal of Atrial Fibrillation, 13(2).
3. Persist-End Final Clinical Study Report (Abbott report CL1013884).
4. Bourier, F., Gianni, C., Dare, M., Deisenhofer, I., Hessling, G., Reents, T., . . . Al-Ahmad, A. (2017). Fiberoptic contact-force sensing electrophysiological catheters: how precise is the technology? Journal of Cardiovascular Electrophysiology, 28(1), 109-114.
5. Bourier F, Deisenhofer I, Hessling G, et al. Contact-force sensing electrophysiological catheters: How accurate is the technology? [Abstract PO03-170]. Presentation at HRS 2016, San Francisco, CA, May 4-7, 2016. Heart Rhythm. 2016;13(5 Suppl 1):S318-S319.
6. Abbott. Data on File. Document 90569806.
7. Mansour, M. (2014) TOCCASTAR: Preliminary Results of the First Prospective Randomized Study of a Contact Force Sensing Ablation Catheter for the Treatment of Paroxysmal AF. Presented at HRS 2014. San Francisco, California.
8. Lo MY, Sanders P, Sommer P, Kalman JM, Siddiqui UR, Sundaram S, Piorkowski C, Olson N, Madej SM and Gibson DN. Safety and Effectiveness of a Next-Generation Contact Force Catheter. JACC: Clinical Electrophysiology. 2021;0.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at manuals.sjm.com or eifu.abbottvascular.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

United States: Required Safety Information

Indications: The TactiCath™ Quartz Contact Force Ablation Catheter and TactiCath™ Ablation Catheter, Sensor Enabled™ are indicated for use in cardiac electrophysiological mapping and for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used in conjunction with a compatible RF generator and three-dimensional mapping system. **Contraindications:** Do not use for any of the following conditions: certain recent heart surgery; prosthetic valves; active systemic infection; use in coronary vasculature; myxoma or intracardiac thrombus, or an interatrial baffle or patch; retrograde trans-aortic approach in patients with aortic valve replacement. **Warnings:** It is important to carefully titrate RF power; too high RF power during ablation may lead to perforation caused by steam pop. Contact force in excess of 70 g may not improve the characteristics of lesion formation and may increase the risk for perforation during manipulation of the catheter. 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 may be adversely affected by RF current. Always verify the tubing and catheter have been properly cleared of air prior to inserting the catheter into the vasculature since entrapped air can cause potential injury or fatality. The temperature data transmitted by the sensor in this catheter is representative of the irrigated electrode only and does not provide tissue temperature data. **Precautions:** The long-term risks of protracted fluoroscopy and creation of RF induced lesions have not been established; careful consideration must be given for the use of the device in prepubescent children. When using the catheter with conventional EP lab system or with a 3-D navigational system, careful catheter manipulation must be performed, in order to avoid cardiac damage, perforation, or tamponade. Always maintain a constant saline irrigation flow to prevent coagulation within the lumen of the catheter. Care should be taken when ablating near structures such as the sino-atrial and AV nodes. **Potential Adverse Events:** Potential adverse events include, but are not limited to, cardiovascular related complications, including groin 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 attack; esophageal fistula, or death.

Indications: The Advisor™ HD Grid Mapping Catheter, Sensor Enabled™, is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart. **Contraindications:** The catheter is contraindicated for patients with prosthetic valves and patients with left atrial thrombus or myxoma, or interatrial baffle or patch via transseptal approach. This device should not be used with patients with active systemic infections. The catheter is contraindicated in patients who cannot be anticoagulated or infused with heparinized saline. **Warnings:** 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, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Careful consideration must therefore be given for the use of this catheter in pregnant women. Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures. Vascular perforation or dissection is an inherent risk of any electrode placement. Careful catheter manipulation must be performed in order to avoid device component damage, thromboembolism, cerebrovascular accident, cardiac damage, perforation, pericardial effusion, or tamponade. Risks associated with electrical stimulation may include, but are not limited to, the induction of arrhythmias, such as atrial fibrillation (AF), ventricular tachycardia (VT) requiring cardioversion, and ventricular fibrillation (VF). Catheter materials are not compatible with magnetic resonance imaging (MRI). **Precautions:** Maintain an activated clotting time (ACT) of greater than 300 seconds at all times during use of the catheter. This includes when the catheter is used in the right side of the heart. To prevent entanglement with concomitantly used catheters, use care when using the catheter in the proximity of the other catheters. Maintain constant irrigation to prevent coagulation on the distal paddle. Inspect irrigation tubing for obstructions, such as kinks and air bubbles. If irrigation is interrupted, remove the catheter from the patient and inspect the catheter. Ensure that the irrigation ports are patent and flush the catheter prior to re-insertion. Always straighten the catheter 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 and/or if any of the irrigation ports are blocked. Catheter advancement must be performed under fluoroscopic guidance to minimize the risk of cardiac damage, perforation, or tamponade.

Indications: The Agilis™ NxT Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart. Contraindications: The Agilis™ NxT Steerable Introducer is contraindicated for known or suspected atrial myxoma, Myocardial Infarctions within the last two weeks, Unstable angina, Recent Cerebral Vascular Accident (CVA), Patients who do not tolerate anticoagulation therapy, Patients with an active infection and Presence of atrial thrombus. **Warnings:** Do not alter this device in any way. Only those physicians who are trained in transseptal procedures and SJM catheter delivery systems should use this device. Do Not reuse this device. Thorough cleaning of biological and foreign material is not possible. Adverse patient reactions may result from reuse of this device. Maintain continuous hemodynamic monitoring throughout procedure. Always observe acceptable hemodynamics prior to advancing the dilator or any other component. **Precautions:** US federal law restricts this device to sale by or on the order of a physician. Carefully read instructions before use of device to help reduce potential risks and complications associated with transseptal procedures, such as air emboli and/or perforation of the aorta and left atrium (LA). (Perforation of the aorta and LA not included for 82 cm device). Inspect all components before use. Do not use if package or items in kit appear to be damaged or defective. The French size specified represents the inner diameter of the introducer sheath. Potential adverse events: Cardiac perforation, Embolus, Cerebrovascular accident, Death, Atrial fibrillation, Dissection and Heart block.

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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