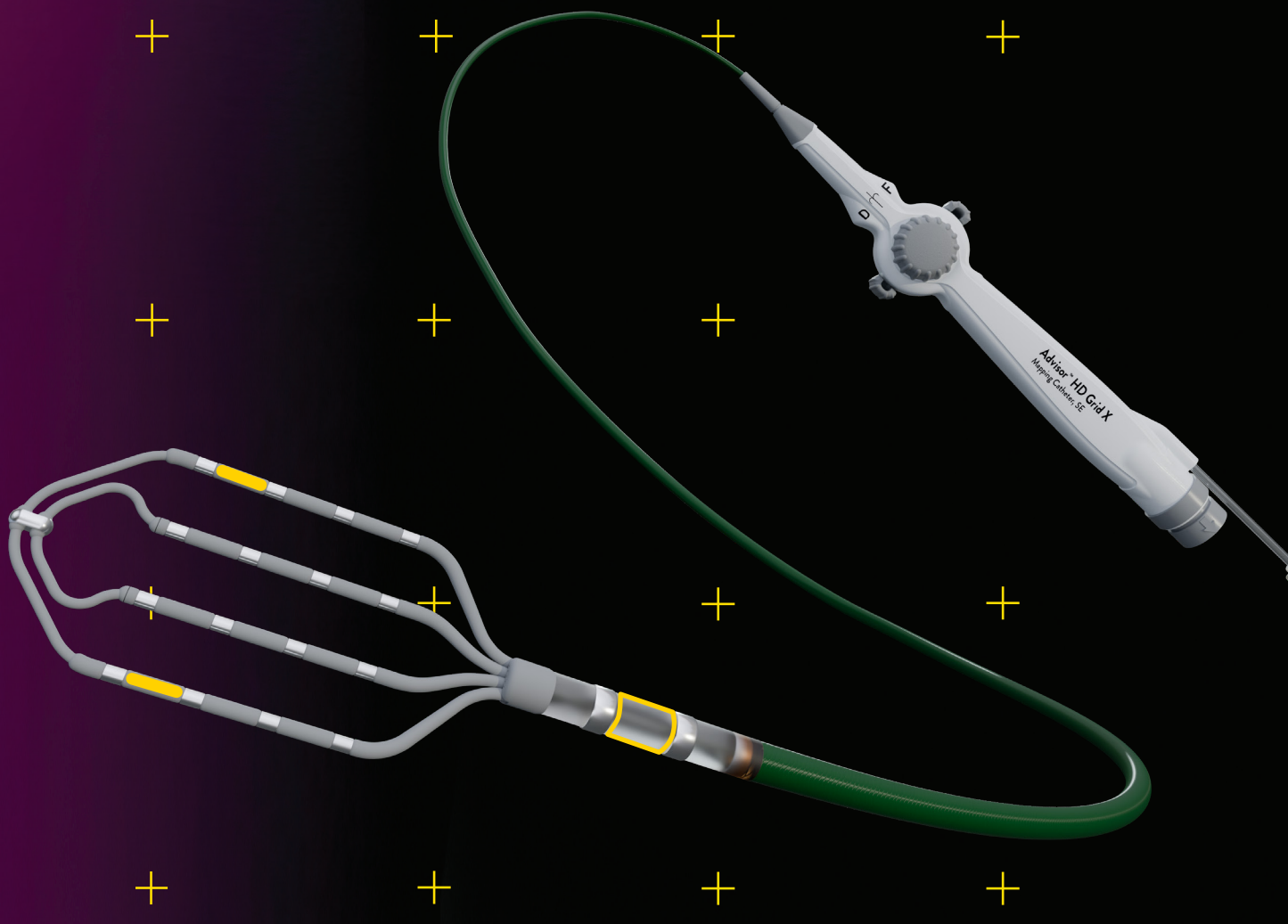
Abbott

BUILDING ON OUR LEGACY OF ENHANCED MAPPING SPEED AND ACCURACY[1]



INTRODUCING: ADVISOR™ HD GRID X MAPPING CATHETER, SENSOR ENABLED™

Experience the power of next-generation technology with the Advisor HD Grid X Mapping Catheter, SE. This advanced tool is now better than ever, offering a boost in **accuracy, speed,** and **versatility**[1].

We've made advancements to our novel first-generation Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ - which offered a first-of-its-kind electrode configuration for high-density mapping, allowing you to place 16 electrodes where you need them. Our unique first-generation design platform, Advisor HD Grid Mapping Catheter, SE was designed to maneuver bi-directionally within all chambers of the heart.

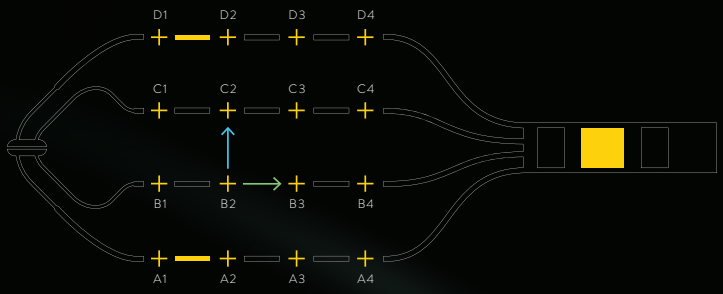
BUILDING ON OUR LEGACY

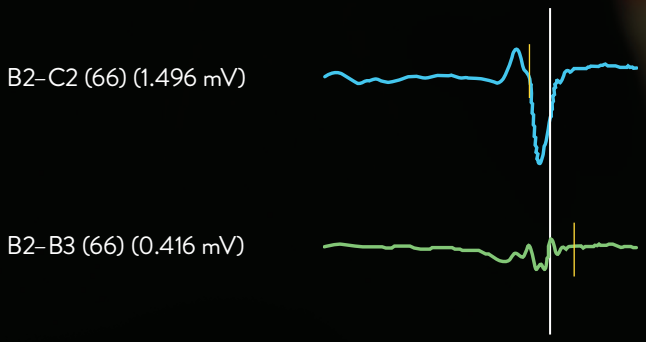
Leveraging our legacy with the Advisor™ HD Grid Mapping Catheter, Sensor Enabled™, we returned to our roots, building on our foundation and drawing strength from our past. The Advisor HD Grid Mapping Catheter, SE **reduces radiation**[2]**, redo AF procedures**[3]**,** and **identifies gaps often missed** by other circular mapping catheters[4].

	 ADVISOR™ HD GRID MAPPING CATHETER, SENSOR ENABLED™	 CIRCULAR MAPPING CATHETERS	
AFIB FLUORO TIME[2]	4.1 MIN	15 MIN	
REDO AF PROCEDURES[3]	6%	20%	
GAPS IDENTIFIED FOLLOWING PVI[4]	81.8%	**CMC10** 36.7%	**CMC20** 38.9%

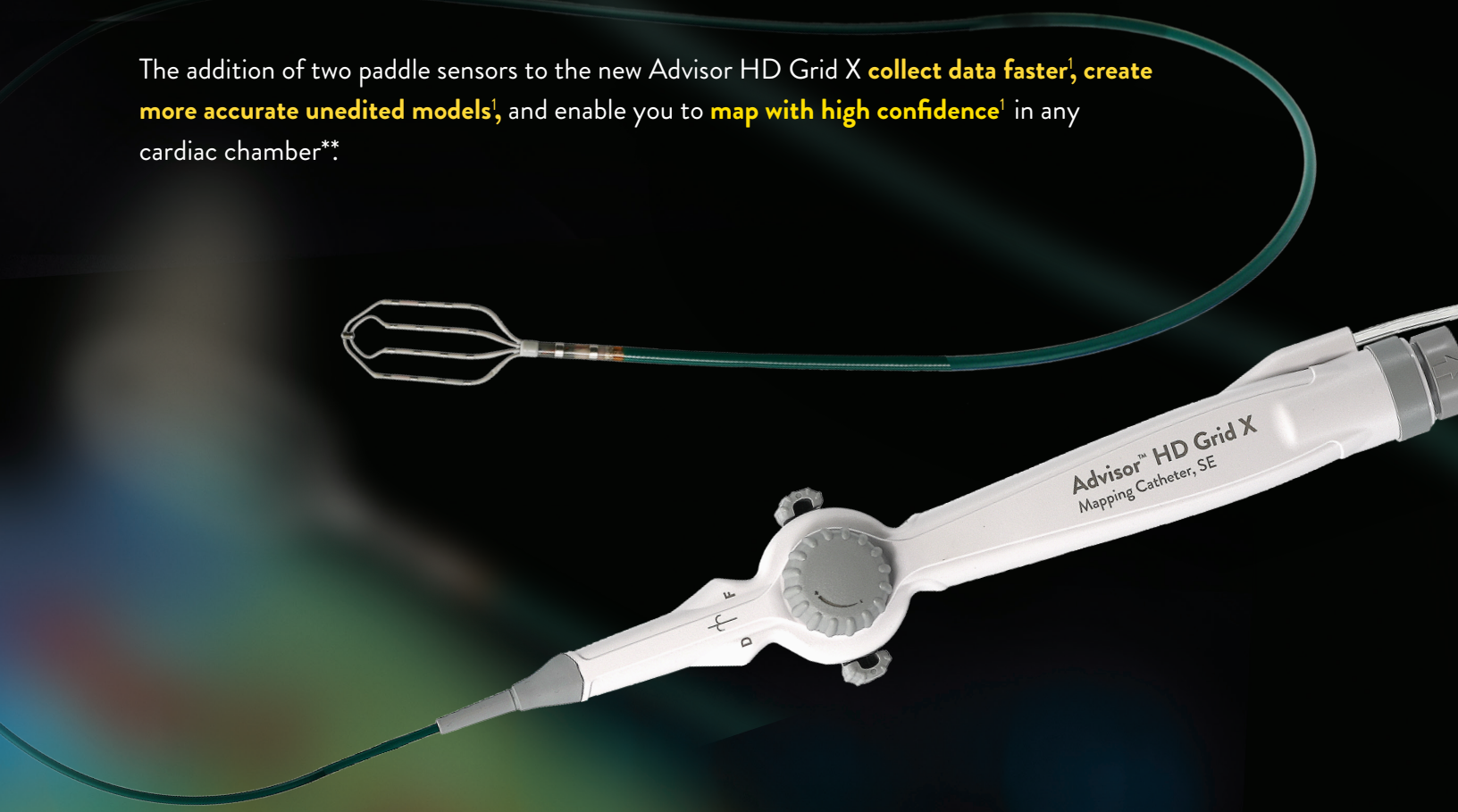
PART OF YOUR ONE SYSTEM SOLUTION

The innovative Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™ leverages the advanced capabilities of the EnSite™ X EP System, compatible with EnSite™ VoXel Mode through its **2 additional sensors.** When paired with the EnSite X EP System, the catheter's grid-pattern displays **true*, localized signals** often missed by traditional mapping catheters.





The addition of two paddle sensors to the new Advisor HD Grid X **collect data faster[1], create more accurate unedited models[1],** and enable you to **map with high confidence**[1] in any cardiac chamber**.



*EnSite Omnipolar Technology captures true signals independent of catheter orientation relative to the wavefront.
**Supported by data from a pre-clinical animal study involving 6 subjects. Results are not necessarily indicative of clinical performance.
A preclinical study with the objective of comparing Advisor HD Grid X Mapping Catheter, SE to Octaray and Advisor HD Grid Mapping Catheter, SE. Four participating independent physicians performed the study protocol with each of the HD Grid X Mapping Catheter, SE, Octaray, and Advisor HD Grid Mapping Catheter, SE catheters within the atria and ventricles of each of six swine study subjects. The protocol measured each catheter on (1) mapping and modeling speed; (2) model accuracy; and (3) ectopic burden.

ADVISOR™ HD GRID X MAPPING CATHETER, SENSOR ENABLED™ IS DESIGNED TO LEAD IN SPEED AND ACCURACY*[1]

In a pre-clinical, head-to-head comparison, Advisor HD Grid X Mapping Catheter, SE beats Octaray‡[1] in 3 key areas:

30%

MORE ACCURATE UNEDITED MODELS
than Octaray‡[1]

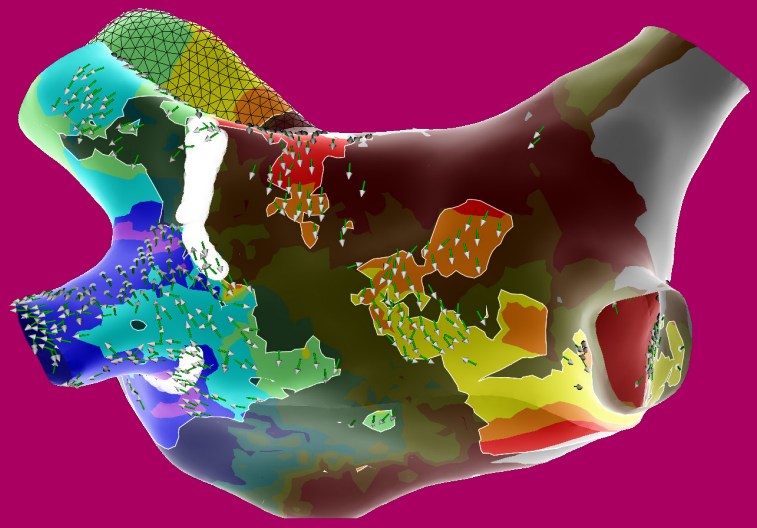
48%

FASTER MAPPING
than Octaray‡[1]

54%

LESS ECTOPY
than Octaray‡[1]

Reduce procedure time[1] with Advisor HD Grid X Mapping Catheter, SE's **expedited data collection and enhanced unedited map quality**[1].



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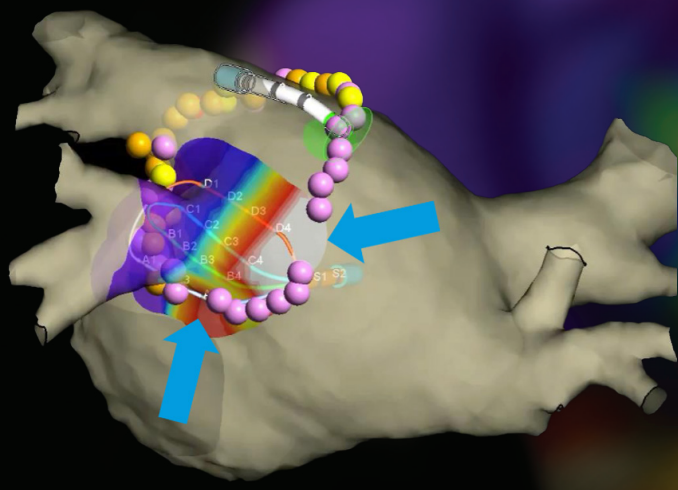
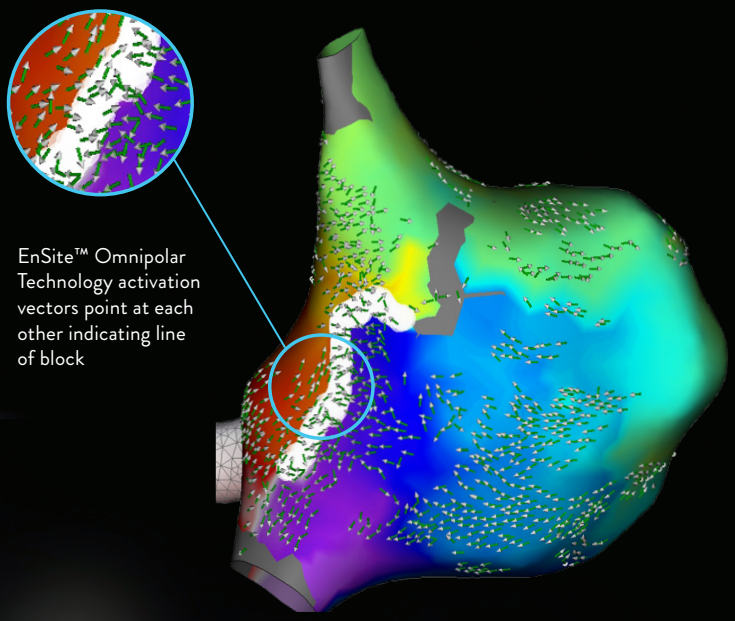
A preclinical study with the objective of comparing Advisor HD Grid X Mapping Catheter, SE to Octaray and Advisor HD Grid Mapping Catheter, SE. Four participating independent physicians performed the study protocol with each of the HD Grid X Mapping Catheter, SE, Octaray, and Advisor HD Grid Mapping Catheter, SE catheters within the atria and ventricles of each of six swine study subjects. The protocol measured each catheter on (1) mapping and modeling speed; (2) model accuracy; and (3) ectopic burden.

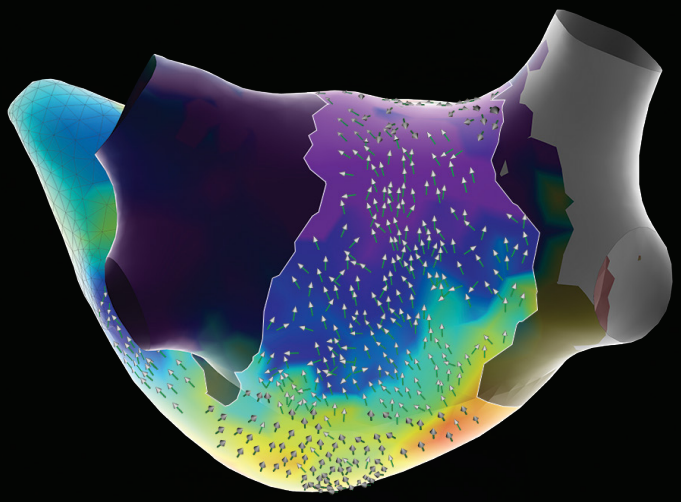
EnSite™ LiveView Dynamic Display **overcomes bipolar blindness**[5] with every beat by displaying mapping data in real-time, beat-by-beat, from the Advisor HD Grid X Mapping Catheter, SE's precise location.





EnSite™ Omnipolar Technology activation vectors point at each other indicating line of block

See every signal in 360 degrees with EnSite™ Omnipolar Technology, capturing signals that no other mapping technology can see**.



Simply, objectively and automatically assess near field signals by isolating **true*, localized signals** with the automated point annotation of EnSite™ OT Near Field software.

Dive into the forefront of cutting-edge mapping technology where unmatched speed, pinpoint accuracy, and unwavering confidence meet.

Get Advisor HD Grid X Mapping Catheter, SE in your lab today.

*EnSite Omnipolar Technology captures true signals independent of catheter orientation relative to the wavefront.

*Supported by data from a pre-clinical animal study involving 6 subjects. Results are not necessarily indicative of clinical performance.
**Every signal can be defined as any signal seen on the RAI window recorded by the Advisor HD Grid Mapping Catheter, SE when the map polarity is set to omnipolar.

1. Abbott. Report on file. 91060435. A preclinical study with the objective of comparing Advisor HD Grid X Mapping Catheter, SE to Octaray and Advisor HD Grid Mapping Catheter, SE. Four participating independent physicians performed the study protocol with each of the HD Grid X Mapping Catheter, SE, Octaray, and Advisor HD Grid Mapping Catheter, SE catheters within the atria and ventricles of each of six swine study subjects. The protocol measured each catheter on (1) mapping and modeling speed; (2) model accuracy; and (3) ectopic burden.
2. Olson N, Lo M, Zahwe F, Gururaj A, Martel JA, Bernard ML, Tao C and Venkataraman R. The effect of dynamic mapping data on procedure efficiency in radiofrequency ablation of patients with atrial fibrillation. Abstracts from the 26th Annual International Atrial Fibrillation Symposium. Journal of Cardiovascular Electrophysiology. 2021;32:1467-1515.
3. 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).
4. Porterfield C, et al. Comparison of Gap Identification Using Three Technologies for Confirmation of Pulmonary Vein Isolation. Abbott. Data on File: MAT-2002108 v1.0
5. Deno DC, Bhaskaran A, Morgan DJ, Goksu F, Batman K, Olson GK, Magtibay K, Nayyar S, Porta-Sánchez A, Laflamme MA, Massé S, Aukhojee P, Nair K, Nanthakumar K, High Resolution, Live, Directional Mapping, Heart Rhythm (2020), doi: https://doi.org/10.1016/ j.hrthm.2020.04.039.

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 Advisor™ HD Grid X 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. Patients unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation. **Warnings:** Persons with a 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: Acrylonitrilebutadienestyrene (ABS Cycolac) – Loctite Adhesive – Pellethane – Platinum Iridium alloy – Polyimide – Polyether block amide (PEBAX) – Polyethylene (High Density Polyethylene, HDPE) – Titanium. Cardiac catheterization procedures present the potential for significant xray 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 xray beam intensity and duration of the fluoroscopic imaging. Careful consideration must therefore be given for the use of this catheter in pregnant women. The safety and effectiveness of the device has not been established in pregnant women or prepubescent children. Careful consideration must therefore be given for the use of the device in pregnant women or prepubescent children. 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). Do not use force to advance or withdraw catheter when resistance is encountered. Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected. **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 reinsertion. Use the straightener during the insertion process to avoid damage to the hemostasis valve. Always straighten the catheter before insertion or withdrawal. Catheter advancement must be performed under fluoroscopic guidance to minimize the risk of cardiac damage, perforation, or tamponade. Compatible navigation and real time visualization systems may also be considered. Do not use if the catheter appears damaged, kinked, or if there is difficulty in deflecting the distal section to achieve the desired curve. Catheter materials are not compatible with magnetic resonance imaging (MRI). One or more components of this device may contain the following substance defined as CMR 1B in a concentration above 0.1% weight by weight: Nmethyl2pyrrolidone (NMP): Chemical Abstracts Service (CAS) No. 872504; EC No. 2128281. Based on a quantitative toxicological assessment it has been determined that NMP released from this device is unlikely to cause adverse reproductive effects. **Potential Adverse Events:** Complications related to the use of the device include, but are not limited to, the following: New or worsening of existing arrhythmia including Atrial fibrillation, Ventricular tachycardia requiring cardioversion, Supraventricular tachycardia (SVT) and Ventricular fibrillation Cardiac perforation including Pericardial effusion or Cardiac tamponade Bleeding including access site Hemorrhage / bleeding, Ecchymosis and Hematoma Vascular access complications or peripheral vascular injury including Femoral artery dissection, Dissection, Arteriovenous fistula and Pseudoaneurysm formation Pulmonary vein stenosis, Heart failure, Volume overload, Hypotension, Embolism, Cerebrovascular accident (CVA)/stroke, Infection, Pneumonia, Pulmonary edema, Immunological reaction, Pain and Pericarditis.

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 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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