

Advisor™ HD Grid Mapping Catheter, Sensor Enabled™

Instructions for Use

REF

D-AVHD-DF16

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

TM Indicates a trademark of the Abbott group of companies.

‡ Indicates a third party trademark, which is property of its respective owner.

Pat. <http://www.abbott.com/patents>

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EN: English

Advisor™ HD Grid Mapping Catheter, Sensor Enabled™

Instructions for Use

Description

The Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ is a steerable, flexible, insulated electrophysiology catheter constructed of thermoplastic elastomer material and noble metal electrodes. The shaft curvature is manipulated by the control mechanism located on the handle at the catheter's proximal end. To adjust the curve on the catheter, use the actuator to deflect the catheter in either direction. The catheter is compatible with Abbott Medical visualization and 3D navigation systems.

Table 1. Compatible Systems

System Device	Connect via	System Software
EnSite™ Velocity™ System	Sensor Enabled™ Diagnostic Catheter Cable	v 5.2 or later
EnSite Precision™ System	(D-AVSE-CBL22)	v 2.2 or later

Indications for Use

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

- This device should be used by or under the supervision of physicians thoroughly trained in the techniques of percutaneous electrophysiology studies.
- 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).
- 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.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- This device is intended for one time use only. Do not reprocess or reuse. Reuse can cause device failure, patient injury, and/or the communication of infectious disease(s) from one patient to another.

Caution

- United States law restricts this device to sale by or on order of a physician.
- Read directions prior to use.

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.
- Personnel handling the electrophysiology catheter should wear gloves.
- To maintain optimal patient safety and electrode catheter integrity, do not wipe this catheter with alcohol.
- Excessive bending or kinking of the catheter may cause damage to the catheter.
- Use care to isolate any unused connector pins of the electrogram cable. This will reduce the chances of developing accidental current pathways to the heart.
- 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.
- 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.

Directions

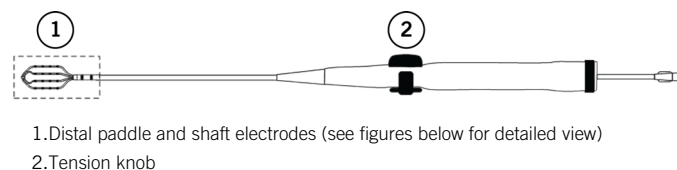
1. Inspect the package prior to use. Do not use if the package is open, damaged, or expired.
2. Remove the catheter from its packaging.
 - Completely remove the tray from the pouch.
 - Remove the handle retainer from the tray before removing the catheter. See Packaging and Shelf-Life (page 3).
 - To prevent potential damage to the distal paddle, lift the catheter up and out of the tray.
3. Inspect the electrodes and catheter carefully for integrity and overall condition.
4. Connect a sterile luer lock syringe filled with saline mix to the luer connection of the catheter. Push the contents of the syringe into the catheter to confirm the irrigation port is open.
5. Connect the catheter to the irrigation system using standard luer fittings. The pump must be able to operate at a minimum flow rate of 2ml/min.
6. Flush the catheter with heparinized saline and purge the tubing and catheter of air bubbles before insertion.
 - To avoid occlusion of the irrigation conduits, the catheter must be continuously irrigated when within the vasculature. Irrigation should only be stopped after removal of the catheter from the body.
7. Insert the distal tip section of catheter into an 8.5 F minimum introducer (not included) using the insertion tool:
 - Prior to insertion, deflect catheter shaft to straight position.
 - Slide the insertion tool over the distal paddle section of the catheter.
 - Insert the insertion tool with the catheter distal end into and through the hemostasis valve of the introducer (not included).
 - Insert catheter through the hemostasis valve.
 - After the catheter is inside the introducer, pull the insertion tool out from the hemostasis valve.
8. Never manipulate the deflectable section of the shaft while within the introducer.
9. Connect to compatible systems using the appropriate cable. Refer to the cable's instructions for use for information about connections.
10. The catheter should be passed from a peripheral vessel to the desired position with the aid of fluoroscopy.
11. To adjust the curve of the distal tip on the catheter, use the actuator to deflect the catheter in either direction.

NOTE: The bi-directional handle has an adjustable tension control knob that allows the operator to use the actuator and deflectable section in an unlocked state or adjust the tension to where the actuator and deflectable section are locked in place. The amount of friction increases as the knob is rotated clockwise until it reaches the fully plus (+) position.
12. Prior to withdrawal, deflect catheter shaft to straight position. Re-insert the insertion tool into the hemostasis valve prior to removing the catheter from the introducer.
13. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

Electrode Identification

Orientation of the Electrodes

Figure 1. Advisor™ HD Grid Mapping Catheter, Sensor Enabled™



The EnSite Precision™ and EnSite™ Velocity™ Systems have two options for displaying the electrodes on the distal paddle and shaft. The figures below show electrode numbering in the different display views.

Figure 2. With the tension knob facing upwards, electrodes on the A spline are located on the bottom of the paddle.

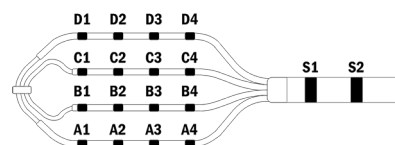
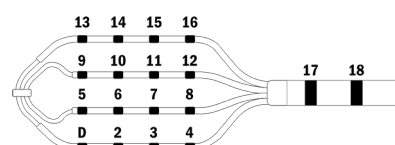


Figure 3. With the tension knob facing upwards, electrodes on the D through 4 spline are on the bottom of the paddle.



Connection to Other Equipment

The catheter may be connected to a commercially available EP recording system and navigation and visualization system using the connection cable. All systems must be patient isolated. For instructions regarding the use of these systems with the catheter, refer to the system's instructions for use.

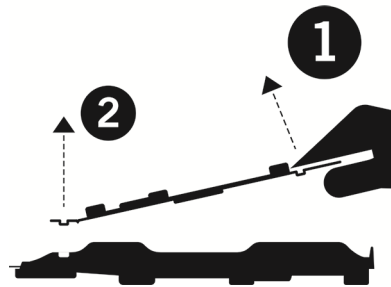
Packaging and Shelf-Life

The catheter packaging is designed to prevent crushing of the product, to minimize product exposure to the atmosphere, and to provide for aseptic product transfer. It is recommended that the product remain in the unopened package until time of use. Contents are sterile if the package is unopened and undamaged. Do not resterilize. The expiration date is marked on the outside of the package. The product should be stored in a cool, dry location.

The instructions for use is recyclable. Dispose of used product and packaging following standard solid biohazard waste procedures.

To remove the catheter from its tray, remove the handle retainer from the tray then lift the catheter up and out of the tray. See figure below.

Figure 4. Remove catheter from tray



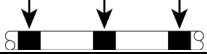
Warranty

Abbott Medical warrants that its products shall be free from defects in materials and workmanship under normal use. This warranty does not exceed the "Expiration" date stated on any product labeling. The authorized uses and approved methods of use of each of our products is set forth in the related "Instructions for Use" that accompany each product. Abbott Medical disclaims any responsibility and liability for the use of its products in a manner that has not been authorized or approved. Abbott Medical's liability under this warranty is limited to replacing its products. The foregoing warranty excludes and is in lieu of all other warranties whether expressed or implied including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Abbott Medical disclaims any liability for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this product, other than as expressly provided by specific law. Abbott Medical neither assumes nor authorizes any other person to assume for it any other or additional liability for loss, damage, or expense in connection with this product. For more details please review complete Abbott Medical warranty policy available from Abbott Medical or on the back of an Abbott Medical invoice.

Symbols

NOTE: The symbols section contains all the symbols that may be used on product labels. Product is labeled as required.

Symbol	Description
	Caution, consult accompanying documents
	Quantity
	Keep dry
	Keep away from sunlight
	Catalog number
	Batch code
	Unique Device Identification
	Do not reuse
	Do not resterilize
	Sterilized using ethylene oxide

Symbol	Description
	CAUTION: Federal law (U.S.) restricts this device to sale by or on the order of a physician.
	Manufacturer
	Date of Manufacture
	Manufacturing facility
	Authorized European representative
	Consult instructions for use
	Follow instructions for use on this website
	Electrodes
	Spacing
	Number of electrodes
	Do not use if package is damaged
	Use by
	Length
	Temperature limitations
	Humidity limitation
	Outer Diameter
	Non-pyrogenic
	Diagnostic Catheter
	High Density Mapping Catheter
	Conformité Européenne (European Conformity). Affixed in accordance with European Council Directive 93/42/EEC (NB 2797) and 2011/65/EU. Hereby, Abbott Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.



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