Vision-MR™ Diagnostic Catheter

en	English	Instructions for Use

EC REP

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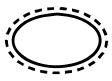
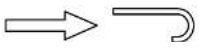
Symbols

	Manufacturer
	Date of manufacture
	Use-by date
	Batch code
	Catalog number
	Sterilized using ethylene oxide
	Do not resterilize
	Do not use if package is damaged and consult instructions for use
	Protect from heat and radioactive sources
	Keep dry
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Caution
	MR Conditional: Use only in 1.5T MRI environment. See MR Conditions for Use section.
	Medical device
	Single sterile barrier system
	Single sterile barrier system with protective packaging outside
	European Conformity
	Authorized representative in the European Community
	Packaging unit
	Spacing of tip electrode
	Tip length
	Usable length
	Catheter marking: Thumb control deflects catheter in specificed direction when pushed forward.
	Unique device identifier
	Importer
	Authorized representative in Switzerland
	Humidity limitation
	Temperature limit
	Atmospheric pressure limitation

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Single Use Only. Do Not Resterilize.

DEVICE DESCRIPTION

The Vision-MR™ Diagnostic Catheter is an MR Conditional 9F (3.0mm) catheter with a deflectable tip and two gold electrodes (1.3mm spacing): a 1.5mm tip electrode and a 1.4mm ring electrode. The catheter is designed to facilitate electrophysiological mapping of the heart (sensing and pacing) during cardiac electrophysiology procedures. The distal end of the catheter includes a receive coil to allow for MR tracking. The catheter is a sterile, single-use device.

The Vision-MR Diagnostic Catheter is a uni-directional deflectable catheter that is 115cm in length. The catheter handle incorporates a thumb control that deflects the catheter when pushed forward.

The Vision-MR Diagnostic Catheter must be used with the Advantage-MR™ EP Recorder/Stimulator. Advantage-MR provides EP recording and cardiac stimulation capabilities and is the interface between the catheter and compatible medical devices, such as MR tracking systems. The Vision-MR Diagnostic Catheter interfaces with the Advantage-MR EP Recorder/Stimulator System via a sterile accessory cable (Vision-MR™ Diagnostic Cable 2.0).

CONTENTS

Vision-MR Diagnostic Catheter

INTENDED PURPOSE/INTENDED USE

The Vision-MR Diagnostic Catheter is intended for cardiac electrophysiological mapping (stimulating and recording) during electrophysiology procedures to diagnose arrhythmias and/or guide therapeutic decisions in patients 18 years or older.

USER INFORMATION

The intended user is a physician who performs electrophysiology procedures.

CONTRAINDICATIONS

The Vision-MR Diagnostic Catheter is contraindicated for use in patients:

- Who have had a ventriculotomy or atriotomy within the preceding eight weeks;
- With a prosthetic valve through which the catheter must pass;
- With an active systemic infection;
- With a myxoma, or an intracardiac thrombus;
- With an interatrial baffle or patch through which the catheter must pass.

MRI CONDITIONS FOR USE

The Vision-MR Diagnostic Catheter is MR Conditional and, as such, is designed to be used safely under MRI when used according to the specified MRI conditions for use.

MR System Requirements:

- Horizontal cylindrical closed bore magnet, clinical MRI systems with a static magnetic field of 1.5 Tesla (T) must be used.
- Gradient systems with maximum gradient slew rate performance per axis of ≤ 200 T/m/s must be used.
- The Digital Amplifier Stimulator (DAS) and DAS Power Supply for Advantage-MR System must reside outside the 100 Gauss maximum magnetic field strength.

MR Scanning Requirements:

- The scanner must be operated in Normal Operating Mode or First Level Controlled Operating Mode; the SAR must be ≤ 4 W/kg.
- There are no scan duration limitations.

Procedure Requirements:

- The Vision-MR Diagnostic Catheter must be used with the Advantage-MR EP Recorder/Stimulator System [(AD001), (AD900)]
- The patient must be in the supine position.
- Femoral access must be used.

Training Requirements:

- A health professional who has completed Imricor's interventional cardiovascular magnetic resonance (iCMR) training must be present during the procedure.

WARNINGS

1. Do not attempt to operate the Vision-MR Diagnostic Catheter prior to completely reading and understanding the Instructions for Use.
2. The Vision-MR Diagnostic Catheter is a single use device. Do not reuse or resterilize the catheter. Reuse or resterilization may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury, illness, or death. Reuse or resterilization may also create a risk of patient or user infections. Contamination of the device may lead to injury, illness, or death of the patient.
3. Only physicians trained in cardiac electrophysiology procedures should use this device. Appropriate clinical instruction in use of the Vision-MR Diagnostic Catheter should also be completed.

4. When used in an MR environment, refer to the MR Conditions for Use section of this IFU.
5. The interaction with implantable devices has not been evaluated by Imricor. Refer to the IFU and MR conditions of use for any implantable devices present.
6. To avoid thromboemboli, anticoagulation should follow standard therapeutic guidelines.
7. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade during catheter advancement. Use appropriate imaging and electrogram data during catheter introduction and advancement to reduce the risk of tissue injury. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
8. Always pull the thumb control back to straighten the catheter tip before insertion or withdrawal of the catheter.
9. Discontinue use of the catheter if the catheter is not functioning properly.
10. Testing has not been conducted on pregnant women. This should be taken into consideration prior to using this device.

PRECAUTIONS

1. Do not use the product after its use-by date.
2. Inspect all components before use. Do not use if the package or items in the package appear damaged or defective. Contact Imricor Medical Systems, Inc. with the model number, lot number, and unique device identifier (UDI) from the package label if the seal or package is damaged or if there are any concerns regarding product integrity.
3. Do not expose the catheter to organic solvents such as alcohol.
4. Do not autoclave the catheter.
5. Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
6. Do not scrub or twist the distal tip electrode with respect to the catheter shaft during cleaning as twisting may damage the bond and loosen the tip electrode.
7. Insert the catheter carefully into the introducer to avoid damage to the distal tip.

POTENTIAL ADVERSE EVENTS

Potential adverse events that may be associated with cardiac catheterization include:

- Air embolism
- Allergic reaction
- Anesthesia/sedative agent reaction
- Arrhythmias (new or exacerbation of existing arrhythmias)
- Arteriovenous fistula
- AV block
- Cardiac perforation/tamponade
- Cerebrovascular accident (CVA)/stroke
- Chest pain/discomfort
- Death
- Endocarditis
- Hematoma
- Hemothorax
- Hospitalization (initial/prolonged)
- Infections
- Lead dislodgement or component damage of implantable cardioverter/defibrillator/pacemaker
- Major bleeding/hemorrhage
- Myocardial infarction
- Nerve injury (phrenic/vagus/diaphragmatic paralysis)
- Pericarditis
- Pneumothorax
- Pseudoaneurysm
- Pulmonary embolism
- Thrombosis
- Thromboembolism
- Tissue damage (burn)
- Transient ischemic attack (TIA)
- Valvular damage
- Vasovagal reactions
- Vessel trauma (perforation/dissection/rupture/obstruction)

EXPECTED CLINICAL BENEFITS

The Vision-MR Diagnostic Catheter provides multiple benefits including confirmation of arrhythmia treatment and elimination of exposure to ionizing radiation for patients and clinicians. Confirmation of diagnosis and treatment for various arrhythmias is achieved using pacing and sensing techniques within the heart. Additionally, the Vision-MR Diagnostic Catheter is safe for use in the MR environment. Real-time, MR-guided procedures allow clinicians to leverage superior anatomical imaging of the heart while eliminating exposure to ionizing radiation for patients and clinicians in successful cases.

COMPATIBLE EXTERNAL DEVICE AND ACCESSORIES

- Advantage-MR EP Recorder/Stimulator System [(AD001),(AD900)]. Supplied separately.
- Vision-MR Diagnostic Cable 2.0 (CABD102). Supplied separately.

PACKAGING

The Vision-MR Diagnostic Catheter is provided in sterile (EO) packaging. The catheter is secured in a plastic tray, sealed in a Tyvek® pouch and packaged inside a box.

ENVIRONMENTAL PARAMETERS

	Temperature (°C)	Humidity (%)	Atmospheric Pressure (kPa)
Transport	–29–60	25–85	80–106
Storage	15–25	40–60	80–106
Operating	15–40	30–75	80–106

DIRECTIONS FOR USE

Proper operational procedures and sterile techniques are the responsibility of the medical professional. The following procedures are provided for information only. Each physician must apply the information in these instructions according to professional medical training and experience.

Refer to the Advantage-MR EP Recorder/Stimulator System instructions for use for directions on proper connection and operation of these devices when used with the Vision-MR Diagnostic Catheter.

WARNING: Discontinue use of the catheter if the catheter is not functioning properly.

1. Patient preparation must be performed with MR conditional tools, if performed in the MR environment. In the absence of MR conditional tools, patient preparation must be performed outside of the MR environment. Any introducer or short sheaths that remain in the patient within the MR environment must contain no metallic components, including braiding.
2. Create a vascular access in a large, central vessel using aseptic techniques.
3. Remove catheter from package and place in a sterile work area.
4. If using in conjunction with a sheath, verify compatibility by advancing the catheter through the sheath prior to insertion.
5. Connect the catheter via the Vision-MR Diagnostic Cable 2.0. Connect the cable to the "CATH 2" port on the Advantage-MR Patient Device Interface (PDI). Ensure the PDI is properly connected to the Digital Amplifier Stimulator (DAS) using the appropriate Advantage-MR interface cables.
6. *Slowly* insert the Vision-MR Diagnostic Catheter via the access site and advance the catheter to the area under investigation. Use appropriate imaging and electrograms to aid in proper positioning. A compatible sheath may be used in this process at the physician's discretion.
7. The catheter tip can be deflected to facilitate positioning by using the thumb control to vary tip curvature. Pushing the thumb control forward causes the catheter tip to deflect. When the thumb control is pulled back, the tip straightens.
8. Upon completion of procedure, pull thumb control back to straighten catheter tip and SLOWLY withdraw catheter from the cardiovascular system.
9. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

A summary of safety and clinical performance can be found at www.imricor.com/manuals.

SERIOUS INCIDENT REPORTING

Any serious incident that has occurred in relation to this device should be reported to Imricor Medical Systems and the competent authority of the Member State in which the user and/or patient is established.

WARRANTY

For device warranty information, visit www.imricor.com/warranty.

For patent information, visit www.imricor.com/patents