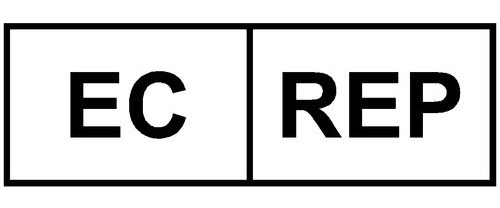
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0123



MedQ Consultants B.V.

Baanstraat 110

NL 6372 AH Landgraaf

+31 45 303 0006



Imricor Medical Systems

400 Gateway Blvd.

Burnsville, MN 55337 USA

+49 30 40 50 45 323

[www.imricor.com](http://www.imricor.com)

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|  |  |
| --- | --- |
| FORM, portrait | Vision-MR™ Ablation Catheter |
| VMR100-01 |
| INSTRUCTIONS FOR USE |

Vision-MR™ Ablation Catheter

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**SYMBOLS**

|  |  |
| --- | --- |
| Caution | Consult Instructions for Use |
| Sterilized with ethylene oxide gas | Manufacturer |
| Use By | European Authorized Representative Service - TSQuality.ch  European Community Authorized Representative |
| Catalog number | FORM, portrait  MR Conditional |
| Batch code | Spacing of tip electrode  SPACING |
| Do not resterilize | Tip length  TIP LENGTH |
| Single use only | Usable length  USABLE LENGTH |
| Do not use if package is damaged | Contents of package  CONTENTS |
| Protect from heat and radioactive sources | What is CE Marking? - CE Mark Certification vs. Self Declaration | ASQ  Notified body CE mark |
| Keep dry |  |

COMPATIBLE EXTERNAL DEVICES & ACCESSORIES

* Advantage-MR EP Recorder/Stimulator System (AD-001). Supplied separately.
* Vision-MR Ablation Cable Set (CAB100). Supplied separately.
* Vision-MR Diagnostic Cable (CAB200). Supplied separately.

PACKAGING

The Vision-MR Ablation 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.

STORAGE

Store the Vision-MR Ablation Catheter in a dry environment protected from heat and radiation at room temperature.

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.**

Please refer to the Advantage-MR EP Recorder/Stimulator System and compatible RF generator instructions for use for directions on proper connection and operation of these devices when used with the Vision-MR Ablation Catheter.

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. If using the catheter for diagnostic and pacing purposes, connect the catheter via the Vision-MR Diagnostic Cable. Connect the catheter 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.
   1. Connect a syringe filled with room temperature heparinized (1 u heparin/ml) normal saline, to the luer fitting of the Vision-MR Ablation Catheter.
   2. Flush the catheter to purge trapped air bubbles and to verify that the irrigation holes are clear.
   3. Keep the syringe connected to the luer fitting throughout the procedure.
6. If using the catheter for ablation, connect the catheter via the Vision-MR Ablation Cable Set to the PDI. Connect the catheter cable to the “ABL CATH” port on the PDI and the fiber optic cable to the “TEMP” port on the PDI. Ensure the PDI is properly connected to the RF generator and the DAS using the appropriate Advantage-MR interface cables.
   1. Connect the irrigation tubing to a room temperature, heparinized (1 u heparin/ml) normal saline bag using standard hospital practices. Open the stopcock on the end of the tubing set and fill the tubing with saline. Remove any trapped air. Then, close the stopcock.
   2. Load the irrigation tubing in the irrigation pump, open the stopcock, and begin irrigation. Flush the irrigation line until all bubbles have been removed from tubing.
   3. Connect the stopcock on the end of the irrigation tubing to the luer fitting of the Vision-MR Ablation Catheter.
   4. Flush the catheter and tubing to purge trapped air bubbles and to verify that the irrigation holes are clear. If encountering an occlusion error, reduce the flush flow rate and attempt to flush again.
   5. Start continuous irrigation at a low flow rate, such as 2 ml/min.
7. To complete the electrical circuit for the RF generator, connect a dispersive electrode to the RF return port on the PDI. Ensure the return port on the PDI is properly connected to the RF generator using the appropriate Advantage-MR interface cable.
8. SLOWLY insert the Vision-MR Ablation 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.
9. 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.
10. For RF ablation, ensure the compatible RF generator and irrigation pump are configured as described below. Refer to the RF generator, Advantage-MR EP Recorder/Stimulator System, and irrigation pump instructions for use for more information.
    1. Set to power-controlled mode of operation.
    2. Program impedance to function with the impedance of the catheter and cabling in situ.
    3. Enable communication to the irrigation pump.
11. RF ablation application parameters will vary depending on the ablation site, the specific conditions present in each procedure, and the RF generator control circuitry. Recommend setting the initial power to 35 Watts and duration to 60 seconds.
12. During RF ablation, ensure the irrigation flow rate increases to 17 ml/min. It is recommended to ablate point by point.
13. The applied power may be increased as needed to create a transmural lesion. Do not exceed 65 Watts.
14. Monitor the catheter tip temperature throughout the procedure to ensure appropriate tip temperature rise. If the temperature reaches 40° C during RF application, power delivery should be discontinued.
15. After RF current is discontinued, confirm the irrigation flow rate has returned to its low setting (2 ml/min).
16. In the event of a generator cutoff (impedance), the catheter must be withdrawn and the tip electrode cleaned of coagulum, if present, before RF current is reapplied. A sterile gauze pad dampened with sterile saline may be used to gently wipe the catheter tip section clean; do not scrub or twist the tip electrode as damage to the tip electrode bond may occur and loosen the tip electrode. Prior to reinsertion, ensure that the irrigation holes are not occluded by increasing flow rate and verifying flow from each of the irrigation holes.

If irrigation hole occlusion occurs:

1. Fill a 1 or 2 ml syringe with sterile saline and attach to the stopcock on the end of the tubing set.
2. Carefully inject the saline from the syringe into the catheter. A stream of fluid should be visible from all electrode holes.
3. Repeat steps 1 and 2, if necessary, until the holes are cleared.
4. Flush catheter and tubing per standard technique to ensure purging of trapped air bubbles and to verify that the irrigation holes are clear.
5. Ensure the catheter tip is clean.
6. The catheter can now be reintroduced into the patient.
7. Upon completion of procedure, pull thumb control back to straighten catheter tip and SLOWLY withdraw catheter from the cardiovascular system.
8. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

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

Vision-MR™ Ablation Catheter

INSTRUCTIONS FOR USE

**Single Use Only. Do Not Resterilize.**

DEVICE DESCRIPTION

The Vision-MR™ Ablation Catheter is an MR Conditional 9F (3.0mm) catheter with a deflectable tip and two gold electrodes (1.3mm spacing): a 3.7mm tip electrode and a 1.4mm ring electrode. The catheter is designed to facilitate electrophysiological mapping of the heart and to conduct radiofrequency current to the catheter tip electrode for ablation purposes. The catheter tip electrode incorporates a fiber optic temperature sensor and six holes for irrigation. The distal end of the catheter includes two receive coils to allow for MR tracking. The catheter is a sterile, single-use device.

The Vision-MR Ablation 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 catheter handle also incorporates a saline port with a standard luer fitting, which permits the infusion of saline for irrigation.

The Vision-MR Ablation 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 RF generators and MR tracking systems. The Vision-MR Ablation Catheter interfaces with the Advantage-MR EP Recorder/Stimulator System via sterile accessory cables (Vision-MR Ablation Cable Set and Vision-MR Diagnostic Cable).

INTENDED USE AND INDICATIONS FOR USE

The Vision-MR Ablation Catheter is intended for cardiac electrophysiological mapping (stimulating and recording) and radiofrequency ablation for the treatment of Type I atrial flutter in patients age 18 years or older.

CONTRAINDICATIONS

The Vision-MR Ablation 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 Ablation 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 Ablation Catheter must be used with the Advantage-MR EP Recording/Stimulator System (AD-001)
* 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 Ablation Catheter prior to completely reading and understanding the Instructions for Use.
2. The Vision-MR Ablation 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 ablation procedures should use this device. Appropriate clinical instruction in use of the Vision-MR Ablation 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. Maximum catheter Rated Voltage: 173 Vrms (245 Vpk). Do not use RF generator output power and impedance limit settings which may result in a maximum output voltage exceeding the Maximum catheter Rated Voltage (consult the RF generator IFU for appropriate settings to avoid excessive output voltages).
7. Do not use the temperature sensor to monitor tissue temperature. The temperature provided is the temperature of the catheter tip electrode, not cardiac tissue temperature. The temperature sensor may be used to indicate an increase in the irrigation flow rate.
8. Care should be taken when ablating near structures such as the sino-atrial and atrioventricular nodes.
9. Patients undergoing septal accessory pathway ablation are at risk for complete AV block which requires the implantation of a permanent pacemaker. Patients who experience inadvertent complete AV block as a result of RF ablation may also require permanent pacing.
10. In accordance with hospital protocol, monitor the patient's fluid balance throughout the procedure to avoid fluid volume overload. Some patients may have a reduced ability to handle the increased fluid volume, making them susceptible to developing pulmonary edema or heart failure during or after the procedure. Patients with congestive heart failure or renal insufficiency and the elderly are particularly susceptible. Prior to a procedure, always identify the patient's risk of volume overload.
11. Inspect irrigation saline for air bubbles prior to its use in the procedure. Air bubbles in the irrigation saline may cause emboli.
12. Purge catheter and irrigation tubing with heparinized normal saline.
13. To avoid thromboemboli, anticoagulation should follow standard therapeutic guidelines.
14. 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.
15. Always pull the thumb control back to straighten the catheter tip before insertion or withdrawal of the catheter.
16. The Vision-MR Ablation Catheter is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the catheter and dispersive electrode, particularly when operating the device. During energy delivery, the patient should not be allowed to come in contact with grounded metal surfaces. If temperature does not rise during ablation, discontinue delivery of energy and check set-up.
17. The risk of igniting flammable gases or other materials is inherent in electrosurgery. Precautions must be taken to restrict flammable materials from the electrosurgical suite.
18. Electrodes and probes used for monitoring and stimulating devices can provide paths for high frequency current. The risk of burns can be reduced, but not eliminated, by placing the electrodes and probes as far away as possible from the ablation site and the dispersive electrode. Protective impedance may reduce the risk of burns and permit continuous monitoring of the electrocardiogram during energy delivery.
19. Discontinue use of the catheter if irrigation is occluded or the catheter is not functioning properly.
20. Discontinue ablation if catheter tip temperatures reaches or exceeds 40 °C.
21. Discontinue MR scanning if tip temperature rises while not ablating.

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 part number and lot number 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 proximal handle or cable connector in fluids; electrical performance could be affected.
6. Do not scrub or twist the distal tip electrode during cleaning.
7. Before use, check that irrigation ports are patent by infusion of heparinized normal saline through the catheter and tubing. Maintain continuous irrigation throughout the procedure to minimize the risk of irrigation occlusion.
8. Insert catheter carefully into introducer to avoid damage to distal tip.
9. Use only dispersive electrodes that meet or exceed IEC 60601-2-2 requirements and follow the dispersive electrode manufacturer’s instructions for use.
10. In the event that RF current is disrupted due to a temperature or an impedance rise, the catheter should be removed and the tip cleaned of coagulum, if present. When cleaning the tip electrode, be careful not to twist the tip electrode with respect to the catheter shaft as twisting may damage the bond and loosen the tip electrode. Make sure the irrigation holes are not occluded prior to re-insertion.
11. Apparent low power output, impedance anomalies, or failure of the RF generator to function correctly at normal settings may indicate faulty application of the dispersive electrode(s) or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication of the dispersive electrode or other electrical leads.
12. Electromagnetic interference (EMI) produced by the Vision-MR Ablation Catheter, when used in conjunction with an RF generator during normal operation, may adversely affect the performance of other equipment.

POTENTIAL ADVERSE EVENTS

Potential adverse events that may be associated with catheterization and/or cardiac ablation include:

* Air embolism
* Allergic reaction
* Anesthesia/sedative agent reaction
* Arrhythmias (new or exacerbation of existing arrhythmias)
* Arteriovenous fistula
* Cardiac perforation/tamponade
* Cardiac thromboembolism
* Cerebrovascular accident (CVA)
* Chest pain/discomfort
* Complete heart block (transient/permanent)
* Congestive heart failure
* Coronary artery injury
* Death
* Effusion (pericardial/pleural)
* Endocarditis
* Fluid volume overload
* Heart failure
* Hematoma
* Hemothorax
* Hospitalization (initial/prolonged)
* Hypertension
* Hypotension
* Infections
* Lead dislodgement or component damage of implantable cardioverter/defibrillator/pacemaker
* Leakage of air or blood into the lungs or other organs due to perforation
* Major bleeding/hemorrhage
* Myocardial infarction
* Nerve injury (phrenic/vagus/diaphragmatic paralysis)
* Pericarditis
* Pneumonia
* Pneumothorax
* Pseudoaneurysm
* Pulmonary edema
* Pulmonary embolism
* Respiratory depression
* Skin burns
* Tamponade
* Temporary complete heart block
* Thrombosis
* Thromboembolism
* Transient ischemic attack (TIA)
* Unintended complete or incomplete AV, sinus node or other heart block or damage
* Valvular damage
* Vasovagal reactions
* Vessel trauma (perforation/dissection/rupture/obstruction)
* Ventricular tachycardia/fibrillation
* Worsening chronic obstructive pulmonary disease

CLINICAL STUDIES

Objective

The objective of the study was to evaluate the safety and performance of the Vision-MR Ablation Catheter for the treatment of type I atrial flutter. The clinical study was conducted using the IBI 1500T11 RF Generator and Cool Point Irrigation Pump. Ablation parameters may vary based on specific RF generator used.

1. Study Design

The study was a non-randomized, single arm cohort study. There was no randomization or stratification of the study population.

**Study Endpoints:**

The endpoints for the study were as follows:

**Primary Acute Performance Endpoint**: Acute success defined as the demonstration of bidirectional cavo-tricuspid isthmus block after radiofrequency application in the cavo-tricuspid isthmus.

**Primary Chronic Performance Endpoint**: Chronic success defined as freedom from recurrence of type 1 atrial flutter at 3-months post procedure.

**Secondary Performance Endpoint**: Chronic success defined as freedom from recurrence of type 1 atrial flutter at 6-months post procedure.

**Primary Safety Endpoint**: The rate of serious adverse events (SAEs) related to the device or procedure assessed at the 7-day follow-up.

**Subject Accountability:**

Table 1: Subject Accountability and Disposition

|  |  |
| --- | --- |
|  | **Number** |
| Subjects enrolled in study | 36 |
| Excluded subjects – enrolled but in whom investigational catheter was not inserted | 1 |
| Subjects ablated with Vision-MR Ablation Catheter | 35 |

**Subject Demographics:**

The table below summarizes the demographic information of all subjects who enrolled in the study (n=36).

Table 2: Subject Demographics

|  |  |
| --- | --- |
| **Characteristics** | **Values** |
| Male (%) | 35 (97.2) |
| Age (years) \* | 68.0 6.6 |
| Height (cm) \* | 177.58.5 |
| Weight (kg) \* | 90.9 16.0 |

\* Mean SD

1. Results

The tables below describe the procedural data.

Table 3: Ablation Parameter Data

|  |  |  |
| --- | --- | --- |
| **Description** | **Mean SD** | **Range** |
| # RF applications/procedure  (n=35 procedures) | 16 9 | 6-38 |
| Ablation duration (sec)/application  (n=546 RF applications) | 44 20 | 1-60 |
| Maximum power (Watts)/application  (n=546 RF applications) | 58 4 | 45-65 |
| Maximum temperature (C)/application  (n=546 RF applications) | 36 2 | 33-42 |

Table 4: Procedure Time

|  |  |  |
| --- | --- | --- |
| **Description** | **Mean SD** | **Range** |
| Total procedure time/procedure (min)  (n=35 procedure) | 47.8 28.1\* | 19-166\* |
| Ablation duration (sec)  (n=35) | 716.2 362.2 | 300-1619 |

\* One procedure was performed for presentation at a conference with a procedure time of 166min. Without this, the Mean SD would be 44 19 with a range of 19-88.

**Primary Acute Performance Endpoint:**

The primary acute performance endpoint was the acute success defined as the demonstration of bidirectional cavo-tricuspid isthmus block after radiofrequency application in the cavo-tricuspid isthmus with the investigational catheter

Table 5: Primary Acute Performance Outcome

|  |  |  |  |
| --- | --- | --- | --- |
|  | **# Success / # Subjects Ablated** | **%** | **2-sided Exact Binomial 95% Confidence Limits** |
| Bidirectional block of the cavo-tricuspid isthmus with the investigational catheter | 32/35 | 91.4% | (0.77, 0.98) |

**Primary Chronic Performance Endpoint:**

The primary chronic performance endpoint was the chronic success rate defined as freedom from recurrence of type 1 atrial flutter at 3-months post procedure.

Table 6: Primary Chronic Performance Outcome

|  |  |  |  |
| --- | --- | --- | --- |
|  | **# Success / # Subjects Ablated** | **%** | **2-sided Exact Binomial 95% Confidence Limits** |
| Subjects in whom BDB was achieved acutely and for whom 3-month data was available. | 32/32 | 100% | (0.89, 1.00) |

**Secondary Performance Endpoint:**

The secondary performance endpoint was the chronic success rate defined as freedom from recurrence of type 1 atrial flutter at 6-months post procedure.

Table 7: Secondary Performance Outcome

|  |  |  |  |
| --- | --- | --- | --- |
|  | **# Success / # Subjects Ablated** | **%** | **2-sided Exact Binomial 95% Confidence Limits** |
| Subjects in whom BDB was achieved acutely and for whom 6-month data was available. | 30/31 | 96.8% | (0.83, 1.00) |

**Primary Safety Endpoint:**

The primary safety endpoint was the rate of serious adverse events (SAEs) related to the device or procedure assessed at 7-day follow-up.

Table 8: Primary Safety Outcome

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Number of Subjects Experiencing SAEs** | **%** | **2-sided Exact Binomial 95% Confidence Limits** |
| Procedure or device related serious adverse events | 4/35 | 11.4% | (0.03, 0.27) |

The serious adverse events observed during the 7-day follow-up are summarized in Table 9. These events were a result of hospitalization and/or medical intervention.

Table 9: Serious Adverse Events Observed Within 7-day Post Ablation

|  |  |
| --- | --- |
| **Event** | **% (n=35)** |
| Groin Hematoma | 1 (2.9) |
| Pseudoaneurysm | 2 (5.7) |
| AV Fistula | 1 (2.9) |
| Device Replacement | 1 (2.9) |

One subject is listed more than once in the above table

The first four SAEs listed were related to the procedure; specifically, the vascular access site. All four of these events were resolved without further complication. The fifth SAE was a device replacement as a result of replacing the introducer sheath which caused the study device to become unsterile during the procedure.

1. Study Conclusion

The analysis of the Vision-MR Ablation Catheter protocol endpoints for safety and performance demonstrates a reasonable assurance of the safety profile and performance for the Vision-MR Ablation Catheter.