Vision-MR® Ablation Catheter 2.0 Summary of Safety and Clinical Performance

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1. Introduction

1.1 Purpose

This document provides the summary of safety and clinical performance in compliance with MDCG 2019-9.

1.2 Definitions

Term	Definition
Clinical Evaluation	A methodologically sound ongoing procedure to collect, appraise and analyze clinical data pertaining to a medical device and to evaluate whether there is sufficient clinical evidence to confirm compliance with relevant general safety and performance requirements when using the device according to the manufacturer's Instructions for Use. (MEDDEV 2.7/1 rev. 4)
CND Code	"Classificazione Nazionale dei Dispositivi medici" or "National Classification of Medical Devices" codes are the basis for the EUDAMED device database nomenclature. CND codes will be mapped to Global Medical Device Nomenclature (GMDN) for ease of use.
Basic UDI-DI	The Basic UDI-DI is the primary identifier of a device model. It is the device identifier (DI) assigned at the level of the device unit of use. It is the main key for records in the Unique Device Identifier (UDI) database and is referenced in relevant certificates and European Union (EU) declarations of conformity.
EUDAMED	European database on medical devices is a central repository for information on market surveillance. It will function as a registration system, a collaborative system, a notification system, a dissemination system (open to the public), and will be interoperable. (Europa)
Post-Market Clinical Follow-up (PMCF) Study	A study carried out following the CE marking of a device and intended to answer specific questions relating to clinical safety or performance (i.e., residual risks) of a device when used in accordance with its approved labelling. (MEDDEV 2.12/2 rev.2)
Periodic Safety Update Report (PSUR)	Summary of the results and conclusions of Post Market Surveillance (PMS) data along with a rationale and description of any corrective actions taken for products on the market. Manufacturers of class IIb and class III devices shall update the PSUR at least annually. Manufacturers of class IIa devices shall update the PSUR at least every two years.

2. Summary of Safety and Clinical Performance for Healthcare Professionals:

This SSCP is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the Vision-MR Ablation Catheter 2.0.

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

2.1 Device Identification and General Information

Device Identification and General Information	
Device Trade Name(s) and Model Number(s)	Vision-MR Ablation Catheter 2.0 (VMRA102)
Manufacturer	Imricor Medical Systems, Inc. 400 Gateway Blvd. Burnsville, MN 55337, USA
Manufacturer's SRN	US-MF-000017310
BASIC UDI-DI	0854277008VMRA1XXRT
Medical Device Nomenclature (CND Code)	C020301, Cardiac tissue ablation electrocatheters, radiofrequency
Device Class	Class III
Initial Certificate (CE) Issuance	CE-Marked
Authorized Representative	MedR-AR Services Kloosterweg 1 6412 CN Heerlen, NL +31 45 3030 006 SRN: NL-AR-000000120
Notified Body (NB)	TUV SUD Product Service GmbH Zertifizierstellen (0123) Ridlerstraße 65 80339 MÜNCHEN, DE

2.2 Intended Use of the Device

Intended Purpose of the Device	
Intended Purpose / Intended Use	The Vision-MR Ablation Catheter 2.0 is intended for cardiac electrophysiological mapping (stimulating and recording) for the diagnosis of arrhythmias and radiofrequency ablation and treatment of Type I atrial flutter in patients 18 years or older.
Indications for Use	The Vision-MR Ablation Catheter 2.0 is indicated for the diagnosis of arrhythmias and radiofrequency ablation and treatment of Type I atrial flutter.
Intended User	A physician who performs electrophysiology procedures.
Patient Population	Patients age 18 years or older.
Intended part of body/type of tissue applied to or interacted with	Cardiac electrophysiology procedures. The device is inserted into the heart via vasculature access and the distal end of the catheter comes into direct contact with the right atrium.

Contraindications/ Limitations	The Vision-MR Ablation Catheter 2.0 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.

2.3 Device Description

Device Description	
General Description	The Vision-MR Ablation Catheter 2.0 is an MR Conditional 9.5F (3.2mm) catheter with either a 32mm or 48mm curve diameter, a deflectable tip, and two gold electrodes (1.3mm spacing): a 3.7mm tip electrode and a ring electrode. The catheter is designed to facilitate electrophysiological mapping of the heart and to conduct radiofrequency energy to the catheter tip electrode for tissue ablation. The catheter tip electrode incorporates a fiber optic temperature sensor and six holes for irrigation. The distal end of the catheter includes two MR receive coils to allow for active MR tracking. The catheter is a sterile, single-use device. The Vision-MR Ablation Catheter 2.0 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 injection of saline for irrigation. The Vision-MR Ablation Catheter 2.0 must be used with the Advantage-MR EP Recorder/Stimulator System. 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 2.0 interfaces with the Advantage-MR EP Recorder/Stimulator System via sterile accessory cable Vision-MR Ablation Cable Set 2.0.
Operating Principals	Elimination of an arrhythmia can be achieved by destroying a small, but critical, patch of heart tissue responsible for causing the arrhythmia. Once inserted into the heart, the catheter electrodes are used to perform diagnostic analysis to determine the mechanism of the arrhythmia and localize the target tissue to be destroyed. With the tip of the catheter positioned at the critical target tissue, RF energy delivered through the tip electrode of the catheter heats up and destroys a volume of cardiac tissue adjacent to the electrode causing a lesion. This lesion disrupts the electrical path maintaining the arrhythmia thereby eliminating the arrhythmia. Open irrigation applied through the tip electrode is used to facilitate effective RF energy delivery and reduce excessive heating of tissue during ablation. The Vision-MR Ablation Catheter 2.0 is intended to be compatible with and visualized under MRI to guide the procedure while enabling visualization of the soft tissue to which therapy is being applied during the procedure.
Accessories	Advantage-MR® EP Recorder/Stimulator System (AD900) Vision-MR® Ablation Catheter Cable 2.0 (CABA102)
Sterility	Sterile device. Sterilized via 2x EtO
French Size	9.5F
Usable Length	115 cm
Usage	Single use
Electrodes	2

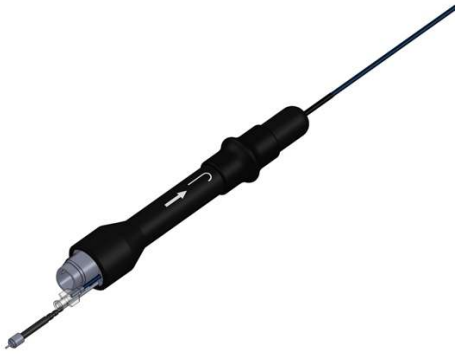
Device Materials

The Vision-MR Ablation Catheter 2.0 is biocompatible as an external communication device in contact with circulating blood for a contact duration of less than 24 hours. Biocompatibility testing was conducted in accordance with ISO 10993 and determined no materials could result in sensitization or an allergic reaction to the patient or user. There are no medicinal, tissue or blood products incorporated in this product. There are no substances that are absorbed by or locally dispersed in the human body and there are no materials in the device that contain or consist of CMR substances or endocrine-disrupting substances.

The table below identifies the raw materials incorporated into the key functional elements either in direct or indirect contact with the human body.

Component	Raw Material	Direct/Indirect Body Contact
Catheter Shaft	Pebax (75D, 55D, 90AE) Blue Pantone 295C Blue Pantone 2945C	Direct
Ring Electrode, 9.5Fr	99.9% Gold	Direct
Tip Electrode, 9.5Fr	99.9% Gold	Direct
Electrode Tip Support	PEEK, natural	Direct
Catheter Shaft Strain Relief	Polyolefin	Direct
Irrigation Lumen, 0.023 ID	Polymide	Direct
Irrigation Hub, 8F	Polycarobonate, clear	Direct
Irrigation Strain Relief	Pellethane	Direct
UV Adhesive, 4306	Cyanoacrylate	Direct
UV Adhesive, 4310	Cyanoacrylate	Direct
UV Adhesive, 4311	Cyanoacrylate	Direct
UV Adhesive, 211-CTH-SC	Urethane	Direct

Device Drawings



2.4 Key Functional Elements

2.4.1. Catheter Control Mechanism

During an interventional procedure, the catheter is physically maneuvered using the following mechanisms:

- Advancement and retraction of the catheter
- Rotation of the catheter
- Deflection of the catheter

The catheter shaft is constructed using industry standard medical grade materials and is reinforced with polymer braiding to provide advancement and torque response similar to existing braided catheters. As is the standard in the industry, advancement of a thumb control mechanism on the catheter handle retracts a pullwire within the catheter shaft and deflects the catheter tip. This deflection action allows the catheter to be directed within the cardiac anatomy.

2.4.2. Catheter Visualization

The Vision-MR Ablation Catheter 2.0 meets the requirements of ISO 10555-1 for conspicuousness in x-ray images. This is accomplished by doping the catheter shaft material with barium sulfate ($BaSO_4$). The catheter electrodes and electrode wire assembly are also visible under x-ray.

The catheter can also be visualized using standard MR imaging techniques by selecting an imaging plane that intersect with or is parallel to a subsection of the catheter shaft. Visualizing the catheter by either voids or local areas of enhancement it creates in MR images is referred to as “passive” tracking or visualization. Passive catheter tracking does not utilize active electronics or communication with the MRI to determine the catheter position. It relies solely on identifying the catheter in MR images of the cardiovascular anatomy.

2.4.3. Active Catheter Imaging

“Active imaging” refers to the process of using MRI signals received by miniature receive coils on a medical device to visualize the position of the device in real-time. During active imaging, the coil appears as bright spot in the MR image. The imaging plane can be either manually or automatically interactively manipulated during imaging to keep the coil in the imaging plane.

To facilitate active imaging, the Vision-MR Ablation Catheter 2.0 has two miniature MRI receive coil integrated into the distal tip of the catheter. When used for active imaging, the receive coils in the catheter are connected to a receive channel of the MRI via Advantage-MR and the MRI interface. This allows the MRI to receive signals from the coil in the catheter.

2.4.4. Active Catheter Tracking

“Active tracking” refers to the process of using MRI signals received by miniature antennas on a medical device to track the position of the device in real-time. It is an automated and continuous process of determining the device position and visualizing the device in MR images or segmented shells representing relevant anatomic structures.

To facilitate active tracking, the Vision-MR Ablation Catheter 2.0 has two miniature MRI receive coils integrated into the distal tip of the catheter. When used for active tracking, each receive coil in the catheter is connected to a receive channel of the MRI via Advantage-MR and the MRI interface. This allows the MRI to receive signals from coils in the catheter.

When actively tracking the catheter, the MRI processes signals received by the miniature receive coils in the catheter to determine the three-dimensional coordinates of each receive coil within the MRI imaging volume. This allows the location of the coils to be identified within the MR system’s field of view.

Commercially available conventional catheters use sensors which are external to the patient for catheter tracking. Some use additional sensors within the catheter. These tracking techniques must all be calibrated and registered to the imaging used during the procedure.

The Vision-MR Ablation Catheter 2.0 uses the MR imaging modality, itself, for tracking. Since the same mechanism generates anatomical images and determines the catheter position, the resulting catheter position is by definition calibrated and registered to the images.

2.4.5. Tip Electrode Temperature Monitoring

The Vision-MR Ablation Catheter 2.0 uses a fiber optic temperature sensor to monitor the tip electrode temperature throughout the procedure. Because the sensor is constructed from fiber and non-metallic, it is

inherently safe for use in the MRI environment. This varies slightly in form but not function from commercially available catheters that use either thermocouples or thermistors to monitor the tip electrode temperature throughout the procedure.

2.4.6. Intracardiac Sensing, Pacing, Mapping, and Ablating

The Vision-MR Ablation Catheter 2.0 facilitates sensing of intracardiac electrograms, cardiac pacing, electroanatomical mapping, and RF ablation for the treatment of type I atrial flutter. A brief description of each of these functions is provided below.

2.4.6.1. Sensing Intracardiac Electrograms

The Vision-MR Ablation Catheter 2.0 is used with Advantage-MR to sense and record intracardiac electrograms. To sense intracardiac electrograms, the catheter acts as a probe and conducts the voltage difference between the catheter electrodes to sensing circuitry in Advantage-MR. Advantage-MR then filters and displays the electrograms. If used with an image guidance system, electrogram measurements taken with Advantage-MR can be sent to the image guidance system and used for electroanatomical mapping.

2.4.6.2. Cardiac Pacing

The Vision-MR Ablation Catheter 2.0 is used with Advantage-MR to deliver bipolar pacing stimuli between the catheter tip and ring electrodes. The programming and electrical stimulus for cardiac pacing is provided by Advantage-MR. The role of the Vision-MR Ablation Catheter 2.0 is to conduct the pacing stimuli from Advantage-MR to cardiac tissue adjacent to the catheter electrodes.

2.4.6.3. Electroanatomical Mapping

The Vision-MR Ablation Catheter is used with Advantage-MR, an image guidance system, and a 1.5T MRI to generate electroanatomical cardiac maps. An overview of the workflow for MR-guided electroanatomical mapping is provided below.

The MRI is used to generate three-dimensional images of the cardiac anatomy. The images are ten used to segment relevant cardiac structures and produce shells representing the cardiac anatomy. The shells, images of the cardiac anatomy, and the location of the Vision-MR Ablation Catheter 2.0 are displayed by the image guidance system.

The Vision-MR Ablation Catheter 2.0 is then maneuvered within a region of interest to acquire electrograms. Timing and/or delay measurements are taken using Advantage-MR. These measurements are then sent to the image guidance system where they are used to create a color-coded map of cardiac voltage and/or conduction delay. The resulting electroanatomical map is displayed by the image guidance system as a color map on a previously segmented cardiac shell.

2.4.7. RF Ablation

The Vision-MR Ablation Catheter 2.0 is used with Advantage-MR, an RF generator, and an irrigation pump to delivery RF energy for the treatment of type I atrial flutter. To perform cardiac ablation, the catheter is maneuvered to the appropriate location and electrograms are acquired and displayed by Advantage-MR. The intracardiac electrograms are reviewed by a physician to confirm proper positioning of the catheter. Real-time MR imaging may also be used to confirm the catheter position. Once the position of the catheter is confirmed, RF energy is applied by third-party RF ablation generator connected to Advantage-MR and irrigation is provided by a third-party irrigation pump connected via irrigated tubing to the ablation catheter.

The ablation energy is controlled by the ablation generator. The irrigation flow rate is also controlled by the ablation generator, which communicates with the irrigation pump to trigger a high irrigation rate when ablating and a low irrigation rate when not ablating.

The Vision-MR Ablation Catheter 2.0 tip temperature is monitored throughout the procedure and, along with the ablation power, duration and impedance, is displayed by Advantage-MR.

2.5 Risks and Warnings

The risk management activities for the Vision-MR Ablation Catheter 2.0 identified risks applicable to the design and use of the device and determined the overall residual risk. Analysis of the residual risks took into consideration the clinical data from the equivalent device, the current state of the art, preclinical data from the Vision-MR Ablation Catheter 2.0 and equivalent device and scientific literature to determine the acceptability of each residual risk. The device labeling is suitable to address the intended use and residual risks of the device. The residual risks are address in the IFU through the warnings, precautions, contraindications, directions for use and list of potential adverse events.

2.5.1. Potential Adverse Events

The following table categorizes the potential adverse events for the Vision-MR Ablation Catheter 2.0 used for the treatment of type I atrial flutter procedures into one of the following categories: cardiovascular, pulmonary, neurological, anesthesia, or general procedure. The table includes the expected threshold level for each adverse event within a given category. The potential adverse events listed were identified via review of State of the Art, literature, clinical studies for the equivalent device, review of applicable databases and comparable competitive device instructions for use. The Vision-MR Ablation Catheter 2.0 is planned for market release in 2025, therefore there is no sales data available. Sales information will be used to corroborate the threshold levels below once the device is market released.

Adverse Event Category (Threshold Levels)	Adverse Events
Cardiovascular (Reasonably Probable < 1%)	• Arrhythmias (new or exacerbation of existing arrhythmias) • Cardiac arrest • Cardiac thromboembolism • Cardiac perforation/tamponade • Complete heart block (transient/permanent) • Congestive heart failure • Coronary artery injury • Endocarditis • Heart failure • Lead dislodgement or components damage of implantable cardioverter/defibrillator/pacemaker • Myocardial infarction • Pericarditis • Tamponade • Temporary/complete heart block • Valvular damage • Unintended complete or incomplete AV, sinus node or other heart block or damage
Pulmonary (Extremely Unlikely < 0.01%)	• Effusion (pericardial/pleural) • Hemothorax • Leakage of air or blood into the lungs or other organs due to perforation • Pneumothorax • Pneumonia • Pulmonary edema • Pulmonary embolism • Respiratory depression • Worsening chronic obstructive pulmonary disease
Neurological (Extremely Unlikely < 0.01%)	• Cerebrovascular accident (CVA)/stroke • Transient ischemic attack (TIA)
Anesthesia	• Allergic reaction

Adverse Event Category (Threshold Levels)	Adverse Events
(Extremely Unlikely < 0.01%)	• Anesthesia/sedative agent reaction
General Procedure (Reasonably Probable <10%)	• Air embolism • Arteriovenous fistula • Chest pain/discomfort • Death • Fluid volume overload • Hematoma • Hospitalization (initial/prolonged) • Hypertension • Hypotension • Infections • Major bleeding/hemorrhage • Nerve injury (phrenic/vagus/diaphragmatic paralysis) • Pseudoaneurysm • Thrombosis • Thromboembolism • Tissue damage (burn) • Vasovagal reactions • Vessel trauma (perforation/dissection/rupture/obstruction)

The occurrence rates of the residual risks will be reviewed on a continuous basis to determine if a harm is occurring more than expected. If a harm is occurring more than expected the risk analyses will be updated and the overall benefit-risk analysis will be reassessed.

2.5.2. Warnings

1. Do not attempt to operate the Vision-MR Ablation Catheter 2.0 prior to completely reading and understanding the Instructions for Use.
2. For single use only. Do not reuse, reprocess, or resterilize the catheter. Reuse, reprocessing, 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, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
3. Contents are supplied STERILE using an EO process. Do not use the device after the “Use By” date. Do not use if sterile barrier is damaged as use of non-sterile devices may result in patient injury. If damage is found, contact Imricor.
4. Only physicians trained in cardiac electrophysiology procedures should use this device. Appropriate clinical instructions in use of the Vision-MR Ablation Catheter 2.0 should also be completed.
5. When used in an MR environment, refer to the MR Conditions for Use section of this IFU.
6. 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. Imaging guidance and care must be taken during advancement, manipulation, and withdrawal to avoid lead dislodgement. It is important to have external sources of pacing and defibrillation available.
7. To avoid thromboemboli, anticoagulation should follow standard therapeutic guidelines.
8. 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.
9. Always pull the thumb control back to straighten the catheter tip before insertion or withdrawal of the catheter.

10. Do not modify this equipment without authorization from Imricor Medical Systems as this may void the warranty.
11. Maximum catheter rated voltage: 200 Vrms (283 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.
12. 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.
13. Care should be taken when ablating near structures such as the sino-atrial and atrioventricular nodes.
14. Prior to procedure, always identify the patient's risk of volume overload. 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.
15. Inspect irrigation saline for air bubbles prior to its use in the procedure. Air bubbles in the irrigation saline may cause emboli.
16. Purge catheter and irrigation tubing with saline (heparinized per standard hospital practices).
17. The Vision-MR Ablation Catheter 2.0 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.
18. 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.
19. Electrodes and probes used for monitoring and stimulating devices can provide paths for high frequency current. The risks 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.
20. Continuously monitor the tip temperature while ablating. If ablation temperature data appears to be higher or lower than expected, turn off ablation power.
21. Discontinue ablation if catheter tip temperatures reaches or exceeds 40˚ C.
22. Discontinue MR scanning if tip temperature rises while not ablating.
23. Ablating at higher power (>50 W) may lead to steam pops, which have been associated with tissue perforation. Use caution when ablating at higher power.
24. Testing has not been conducted on pregnant women. This should be taken into consideration prior to using this device.
25. Discontinue use of the catheter if irrigation is occluded or the catheter is not functioning properly.

2.5.3. Precautions

1. Inspect all components before use for any defects or physical damage. Do not use if defective or damaged devices.
2. Do not expose the catheter to organic solvents such as alcohol.
3. Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
4. Do not scrub or twist the distal tip electrode as twisting may damage the bond and loosen the tip electrode.
5. Before use, check that irrigation ports are patent by infusion of saline (heparinized per standard hospital practices) through the catheter and tubing. Maintain continuous irrigation throughout the procedure to minimize the risk of irrigation occlusion.
6. Insert catheter carefully into introducer to avoid damage to distal tip.

7. Use only dispersive electrodes that meet or exceed IEC 60601-2-2 requirements and follow the dispersive electrode manufacturer's instructions for use.
8. 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 char/coagulum, if present. When cleaning the tip electrode, do not scrub or twist the distal tip electrode as twisting may damage the bond and loosen the tip electrode. Make sure the irrigation holes are not occluded prior to re-insertion.
9. Apparent low power output, high impedance readings, or failure of the RF generator to function correctly at normal settings may indicate faulty application of the dispersive electrodes 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.
10. Electromagnetic interference (EMI) produced by the Vision-MR Ablation Catheter 2.0, when used in conjunction with an RF generator during normal operation, may adversely affect the performance of other equipment.

2.5.4. Safety (Other)

There are no field safety corrective action (FSCA) or field safety notices (FSN) for the Vision-MR Ablation Catheter 2.0.

2.6 Summary of Clinical Evaluation and Post Market Clinical Follow-Up (PMCF)

The Vision-MR Ablation Catheter 2.0 was assessed and endorsed by the notified body on the basis of equivalence. The Vision-MR Ablation Catheter 2.0 is considered clinically, technologically, and biologically equivalent to the Vision-MR® Ablation Catheter (Basic UDI-DI 0854277008VMR1XXEV). The equivalent device is manufactured by Imricor Medical Systems. The Vision-MR Ablation Catheter SSCP is not currently available in EUDAMED. This section includes a summary of the pertinent clinical data for the Vision-MR Ablation Catheter 2.0 and the equivalent device.

2.6.1. Summary of Clinical Investigation (Equivalent Device)

A premarket clinical investigation (IMR-2016) was performed for the equivalent device, the Vision-MR Ablation Catheter (VMR100-01). 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 18 years or older.

The study was a non-randomized, single arm cohort study. A total of thirty-six (36) subjects with type I atrial flutter were enrolled in the study, with thirty-five subjects being ablated with the Vision-MR Ablation Catheter. Subjects had follow-up visits 7-days, 3-months and 6-months post procedure. One subject was enrolled but was withdrawn from the study prior to catheter insertion. The study included the following study objectives and endpoints:

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.

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 I atrial flutter at 3-months post procedure.

Secondary Performance Endpoint: Chronic success defined as freedom from recurrence of type I atrial flutter at 6-moths 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.

Inclusion Criteria:

- First time indication for ablation of type I atrial flutter
- Age 18 or above
- Patients willing and able (mentally and physically capable per physicians' discretion) to understand the investigational nature, potential risks and benefits of the study and able to provide written informed consent to participate in the study and agree to comply with the follow-up visits and evaluation
- Patients able to receive anticoagulation therapy to achieve adequate anticoagulation

Exclusion Criteria:

- Contraindicated for MRI diagnostic exam
- A cardiac ablation or cardiac surgery within 180 days prior to enrollment
- Documented intracardiac thrombus, tumor, bleeding, clotting or other abnormality that precludes catheter introduction and placement
- Myocardial infarction within 60 days prior to enrollment
- Current unstable angina
- History of cerebrovascular event (within 180 days prior to enrollment)
- Patients with an ejection fraction less than or equal to 35% within 90 days prior to enrollment
- Permanent leads in or through the right atrium

- Clinically significant structural heart disease (including tricuspid valve regurgitation, tricuspid valve stenosis or other congenital heart disease) that would preclude catheter introduction and placement, as determine by the Investigator
- Uncompensated congestive heart failure (NYHA Class III or IV)
- Arrhythmia is secondary to electrolyte imbalance, thyroid disease, or other reversible or non-cardiovascular cause
- Known or sensitivity to heparin or warfarin
- Active or systemic infection
- Any other significant uncontrolled or unstable medical condition (including but not limited to hypertension and diabetes)
- Contraindicated for conventional ablation procedure due to known allergy against radiocontrast agents or renal insufficiency with glomerular filtration rate < 30ml/min/1,73m^2
- Women who are pregnant or plan to become pregnant within the course of their participation in the investigation or who are breastfeeding
- Life expectancy of less than 12 months
- Patients with prosthetic valves
- Contraindicated for transfemoral venous access
- Older than 75 years
- Current enrollment in any other clinical investigation

Results:

Subject Demographics:

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

Characteristics	Values
Male (%)	35 (97.2)
Age (years)*	68.0 ± 6.6
Height (cm)*	177.5 ± 8.5
Weight (kg)*	90.9 ± 16.0

*Mean ± SD

Primary Acute Performance Endpoint:

	# 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:

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

Secondary Performance Endpoint:

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

Primary Safety Endpoint:

	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 the table below. These events were a result of hospitalization and/or medical intervention.

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

The first four SAEs 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. Results of the study were published in Paetsch et al.

No clinical investigations were conducted for the Vision-MR Ablation Catheter 2.0 for the indication of type I atrial flutter before CE-marking.

2.6.2. Summary of Literature Review

A literature review was performed for ablation catheters indicated for type I atrial flutter. The purpose of the literature review was to evaluate published clinical literature relevant to the state of the art, safety, efficacy and clinical benefits of ablation catheters indicated for type I atrial flutter.

Clinical literature, TPLC data, MAUDE data, and competitive device IFUs reported on types of adverse events and technical complications related to ablation catheters indicated for type I atrial flutter. The data summarized in the report provides benchmarks for measuring and comparing the safety and performance of the Imricor Vision-MR Ablation Catheter 2.0 and demonstrates the effectiveness of the predicate devices when used to facilitate radiofrequency ablation of type I atrial flutter. Information regarding State of the Art and possible diagnostic and therapeutic alternatives can be found in Section 2.7. References to the articles selected as part of this literature review are located in Section 4 of this SSCP.

2.6.3. Summary of Preclinical Animal Data

Two system level preclinical animal studies were performed to evaluate the feasibility of treating type I atrial flutter with the first-generation Vision-MR Ablation Catheter in a clinical iCMR laboratory. In total, ten swine underwent a cardiac mapping ablation procedure designed to mimic all aspects of the workflow for treating type I atrial flutter in an MR EP interventional laboratory.

Three additional preclinical animal studies were performed using the Vision-MR Ablation Catheter 2.0. The first animal studied evaluated the feasibility of the second-generation ablation catheter to achieve its intended use while the remaining animal studies evaluated lesion creation using the second-generation catheter at clinically relevant ablation powers.

2.6.4. Post Market Clinical Data

The Vision-MR Ablation Catheter 2.0 is planned for market release in 2025, therefore there is no post market clinical data at this time. Data from the Post Market Clinical Follow-Up study described in Section 2.6.6.1 will be added to this section upon study completion.

Post-market surveillance activities for the Vision-MR Ablation Catheter 2.0 are documented in the Vision-MR Ablation Catheter PSUR. This data will be used to identify new or changed likelihoods of residual risks, significant increase in the frequency or severity of incidents, and any identified adverse trends.

2.6.5. Summary of Clinical Performance and Safety

The data presented in the clinical evaluation report supports the conclusion that the Vision-MR Ablation Catheter 2.0 is safe and performs as intended. Evaluation of the clinical and preclinical data from the equivalent device, preclinical testing of the Vision-MR Ablation Catheter 2.0 as well as clinical data from the literature, adequately establishes the clinical safety, performance, and MR Conditional use of the Vision-MR Ablation Catheter 2.0.

The risks associated with the use of the device are acceptable when weighed against the benefits to the patient and the current knowledge/state of the art. The data relevant to the Vision-MR Ablation Catheter 2.0 is sufficient to demonstrate safety and performance of the device per the intended use as well as compliance with the General Safety and Performance Requirements.

The device labeling is suitable to address the intended use and residual risks of the device. The residual risks are addressed in the IFU through the warnings, precautions, contraindications, directions for use and list of potential adverse events. The residual risks identified for the Vision-MR Ablation Catheter 2.0 are consistent with ablation catheter currently on the market for the treatment of type I atrial flutter and are acceptable for CE Marking. The residual risks will be actively updated based on the results of post market clinical follow-up and post market surveillance activities.

The clinical data reviewed in the clinical evaluation is sufficient to demonstrate the safety and performance of the device for the intended purpose of cardiac electrophysiological mapping (stimulating and recording) and radiofrequency ablation for the treatment of type I atrial flutter.

2.6.5.1. Safety Analysis

Potential adverse events listed in Section 2.5.1 were identified via a literature view and assessment of comparable competitive device instructions for use. The list of potential adverse events was corroborated by reviewing the procedural and device related adverse events from the clinical investigation (IMR-2016) for the equivalent device described in Section 2.6.1 and preclinical animal testing described in Section 2.6.3.

The Vision-MR Ablation Catheter 2.0 is designed to align with the current knowledge and state of the art ablation catheter functionality. As a result, the use errors expected with the Vision-MR Ablation Catheter 2.0 and mechanical, biological, electromagnetic, and functional hazards are like those expected with conventional ablation catheters. The MR safety design risks related to the use of this device in the MR environment are unique to this catheter and the first-generation Vision-MR Ablation Catheter.

When cardiac electrophysiology procedures are performed in the conventional fluoroscopy lab, there is a risk of exposure to ionizing radiation for both the patient and operator. When used in the MR environment, the risk of exposure to ionizing radiation is eliminated, but new risks related to operating in the MR environment appear. These risks are controlled by the design of the Vision-MR Ablation Catheter 2.0 and verified via bench testing in accordance with MR ASTM standards listed in Section 2.9. The Vision-MR Ablation Catheter 2.0 has no restrictions as to where it can be used within the MR scanner room as long as it is used with the Advantage-MR EP Recorder/Stimulator System and with a 1.5T MR Scanner.

Post market clinical study data and post market surveillance information will be collected to corroborate the safety analysis performed. Details of the planned post market activities are in Section 2.6.6.

2.6.5.2. Performance Analysis

The Vision-MR Ablation Catheter 2.0 is intended for cardiac electrophysiological mapping (stimulating and recording) and radiofrequency ablation for the treatment of type I atrial flutter. The performance of the device was evaluated in a clinical study for the equivalent device, the Vision-MR Ablation Catheter.

The primary performance endpoints in the prospective pre-market clinical study of the Vision-MR Ablation Catheter included one acute and one chronic endpoint. The primary acute performance endpoint was the rate of

acute clinical success defined as the demonstration of bidirectional block after radiofrequency ablation along the cavotricuspid isthmus with the Vision-MR Ablation Catheter.

	# Success / # Subjects Ablated	%	2-sided Exact Binomial 95% Confidence Limits
Bidirectional block of the cavotricuspid isthmus with the Vision-MR Ablation Catheter	32/35	91.4%	(0.77, 0.98)

Complete bidirectional conduction block of the cavotricuspid isthmus was defined as a descending wave front on the lateral atrial wall up to the line of block during proximal coronary sinus pacing representative of a reserved atrial depolarization sequence.

Acute clinical success was achieved with the study device in 32 of 35 subjects treated. In the 32 subjects where, acute procedural success was achieved, bidirectional conduction block was confirmed with the study device using the method described above. In the three procedures where, acute success was not achieved with the study device, the clinical ablation procedure was terminated prior to achieving conduction block, and the subject was transferred to a conventional fluoroscopy lab.

Two procedures characterized as acute failures were terminated after the subject developed an arrhythmia other than type I atrial flutter during the clinical ablation procedure. Development of the secondary arrhythmia made it impossible to confirm bidirectional conduction block of the isthmus without cardioversion. Because cardioversion was outside of the CIP scope, the subject was transferred to a conventional EP lab to receive cardioversion. For the purpose of simplicity, once sinus rhythm was reestablished in the conventional lab, treatment for type I atrial flutter was completed using conventional devices.

In the third procedure characterized as an acute failure, the investigational procedure was terminated, after several ablations were attempted with the study device, and no observable tip electrode temperature rise was observed. After the investigational procedure was terminated and the patient had been transferred to a conventional EP lab, the physician observed that the return electrode had been placed on the subject's lower calf near the ankle. Per the return electrode IFU, it is recommended the return electrode be placed in close proximity to the surgical site and to avoid bony prominences. The subject was ultimately successfully treated with commercially available devices, after repositioning the return electrode. Placement of the return electrode on a remote and bony location may have resulted in insufficient tip temperature rise and corresponding lesion formation during the investigational procedure. Following the procedure, the catheter and ablation generator were tested and found to be functioning properly.

The primary chronic performance endpoint was the chronic success rate defined as freedom from recurrence of type I atrial flutter at 3-months post procedure. A summary of the primary chronic performance endpoint is provided below.

	# Success / # Subjects Ablated	%	2-sided Exact Binomial 95% Confidence Limits
Freedom from recurrence of type I atrial flutter at 3 months post-procedure for acute success procedures	32/32	100%	(0.89, 1.00)
Freedom from recurrence of type I atrial flutter at 3-moths post-procedure for all procedures	35/35	100%	(0.90, 1.00)

The primary chronic performance endpoint was evaluated for 35 of the 35 subjects treated in the study. At the 3-month follow-up, all 35 subjects remained free from recurrence of type I atrial flutter. The 35 subjects evaluated at the 3-month follow-up included the 32 subjects in which acute success was achieved with the investigational catheter and 3 subjects that were treated with a non-investigational catheter.

The performance of the Vision-MR Ablation Catheter 2.0 was also evaluated in multiple preclinical animal studies. The objective of the first animal study was to evaluate the feasibility of the second-generation ablation catheter to achieve its intended use with an increased shaft size of 9.5F. The study demonstrated that the ablation catheter could be visualized under MR imaging, maneuver to the relevant anatomy for treatment of atrial flutter, sense cardiac electrical signals, stimulate cardiac tissue, measure tip electrode temperature, and deliver RF ablative energy. Additionally, the preclinical lesion studies evaluated the safety and efficacy of lesion creation using the second-generation ablation catheter and demonstrated the Vision-MR Ablation Catheter 2.0's ability to create lesions in a predictable manner between 25W and 65 W at the duration of 60 seconds

The first-generation Vision-MR Ablation Catheter is currently being used in a post market clinical follow-up (PMCF) study. The study is currently enrolling patients and collecting data related to the safety and efficacy of the Vision-MR Ablation Catheter during type I atrial flutter. After approval of the second-generation ablation catheter the study may be updated to collect data on the safety and efficacy of the Vision-MR Ablation Catheter 2.0.

The results of the clinical investigation for the equivalent device, preclinical animal studies, and Vision-MR Ablation Catheter PMCF study demonstrate that the Vision-MR Ablation Catheter 2.0 meets its intended performance of electrophysiological mapping (stimulating and recording) and radiofrequency ablation of the treatment of type I atrial flutter.

2.6.5.3. Expected Benefits

The table below details the expected benefits for the Vision-MR Ablation Catheter 2.0 and associated acceptance criteria. The acceptance criteria are derived from the state of the art.

Benefit	Measurable Parameter	Acceptance Criteria (from state of the art)	Imricor Data
Procedural Safety	Cardiovascular serious adverse event (CSAE) rate	The range of rates of cardiovascular serious adverse events* according to the state of the art (0.9% - 8.3%).	The predicate device, the Vision-MR Ablation Catheter, achieved a rate of 0% CSAE during the IMR-2016 premarket trial. The predicate device has achieved a rate of 0% CSAEs during the currently enrolling PMCF trial as of March 15, 2023.
Acute treatment of type I atrial flutter	Achievement of bidirectional conduction block	The range of acute success for catheter ablation of type I atrial flutter according to the state of the art is (85% - 93.3%).	The predicate device, the Vision-MR Ablation Catheter, achieved acute success in 91.4% of patients during the IMR-2016 premarket trial. The predicate device has achieved acute success in 90.91% of patients in the currently enrolling PMCF trial as of March 15, 2023.
Freedom from recurrence of type I atrial flutter	Freedom from recurrence of type I atrial flutter at 3-months post procedure.	The range of freedom from recurrence of type I atrial flutter according to the state of the art is (85.3% - 96.6%).	The predicate device, the Vision-MR Ablation Catheter, achieved acute success in 100% of patients during the IMR-2016 premarket trial. The predicate device has achieved acute success in 93.33% of patients in the currently enrolling PMCF trial as of March 15, 2023.

Benefit	Measurable Parameter	Acceptance Criteria (from state of the art)	Imricor Data
Elimination of exposure to ionizing radiation in successful cases for patients and clinicians	Measurement of fluoroscopy time per procedure	The lowest total fluoroscopy time reported for comparable device according to the state of the art was (17 ± 19 minutes) with a range of (2-46 minutes).	Total fluoroscopy time for type I atrial flutter procedure using the Vision-MR Ablation Catheter was (0.12 ± 0.46 minutes) with a range of (0-3 minutes).
	Number of patients requiring x-ray for procedure	Indirect measurement: Physicians have been able to achieve zero-fluoroscopy use in 57.6% of atrial flutter procedures.	91.4% of patients using the predicate device, the Vision-MR Ablation Catheter, achieved zero-fluoroscopy use during an atrial flutter procedure during the IMR-2016 premarket trial.

*The definition of Cardiovascular Serious Adverse Events (CSAEs) is unique to the clinical investigation protocol of each study. In general, the definition includes adverse events related to the cardiovascular system that result in death, a life-threatening complication or a persistent or significant disability/incapacity that requires inpatient hospitalization or prolonged hospitalization.

2.6.5.4. Benefit-Risk Assessment

The clinical data from literature and the expert guidelines establish catheter ablation as the current state of the art treatment of atrial flutter. In addition, they establish the irrigated RF ablation catheter as the current state of the art tool for catheter ablation. Irrigated RF ablation catheters similar to the Vision-MR Ablation Catheter 2.0 have been in commercial use for more than 15 years, yet other than the first-generation Vision-MR Ablation Catheter have been limited to use under fluoroscopy and x-ray. The benefits of catheter ablation using irrigated RF ablation catheters is well established and outweighs the risks, including the risk of exposure to ionizing radiation incurred through the use of x-ray for imaging and guidance of the catheter.

The primary benefit of catheter ablation for the treatment of atrial flutter is the elimination of the arrhythmia; it is a curative therapy. Eliminating the arrhythmia may improve the quality of life for the patient depending on the level of symptoms presented. In addition, catheter ablation may reduce or eliminate the need for anti-arrhythmic medication.

In addition to being an irrigated RF ablation catheter, the Vision-MR Ablation Catheter 2.0 is designed to be MR Conditional, which permits it to be used safely in the MR environment. Being safe for use in the MR environment offers the immediate benefit of a radiation free environment for patients and physicians. MR imaging during the procedure also allows for real-time soft tissue imaging of the cardiac anatomy and substrate. Soft tissue imaging has the potential to improve first-time success rates of ablation procedures by providing ablation lesion visualization and verification. In addition, real-time assessment of cardiac substrate has the potential to allow physicians to deliver individualized ablation therapy strategies.

The data presented in this report includes prospective clinical data for the equivalent device that demonstrates the Vision-MR Ablation Catheter 2.0 is safe for cardiac electrophysiological mapping and radiofrequency ablation for the treatment of type I atrial flutter under MR guidance. The MR safety, electromagnetic safety, and biological characteristics for the equivalent device were consistent throughout the development of the device and are significantly similar to the device under evaluation. In addition, the same sterilization method, 2x ethylene oxide, was used for both devices. Therefore, all exposure of the device to patients can be assessed for complications related the MR, electromagnetic and biological safety of the device as well as the overall procedural use in the MR environment.

Based on the evaluation of clinical data relevant to the Vision-MR Ablation Catheter 2.0, there is no need for additional pre-market clinical data to support the safe use of the device. Post market clinical data will be

gathered for the Vision-MR Ablation Catheter 2.0 to corroborate the safety and performance of the device. Information on the post market clinical activities and frequencies can be found in the Vision-MR Ablation Catheter 2.0 PMCF plan.

The labeling identifies the intended use, warnings, precautions, direction for use and MR conditions of the device. The IFU includes a list of potential adverse events associated with cardiac catheterization, which is consistent with ablation catheters currently on the market. The labeling is consistent with the current state of the art, the risk management report, verification and validation data and the clinical data appraisal performed in Section 8.2.

Taking into consideration the clinical data from the equivalent device, the current state of the art, the preclinical data, scientific literature analysis, and the assessment of potential adverse event data, the benefits outweigh the overall residual risks of using the Vision-MR Ablation Catheter and the device is determined to have a high level of safety consistent with stakeholder expectations. The overall residual risk for the Vision-MR Ablation Catheter 2.0 is acceptable.

2.6.6. Post Market Clinical Follow-Up

The table below summarizes the activities that will be conducted as part of the post market clinical follow-up (PMCF).

Activity #	Planned Activity	Aim of Activity
1	PMCF study	• Confirming the safety and performance of the device • Identify previously unknown side effects or monitoring the identified side effects and contraindications • Identify and analyze emergent risks based on factual evidence • Ensure the continued acceptability of the benefit risk ratio
2	Screen scientific literature	• Ensure the continued acceptability of the benefit-risk ration of the device • Identify and analyze emergent risks based on factual evidence
3	Actively monitor suitable registers	• Identify possible systematic misuse or off-label use of the device, with a view to verify that the intended purpose is correct • Identify and analyze emergent risks based on factual evidence

2.6.6.1. Post Market Clinical Follow-Up Study

Post market clinical data will be collected to support the lifetime of the device. The VISABL-AFL clinical investigation will include a safety and performance population of prospectively enrolled subjects to corroborate the safety of the Vision-MR Ablation Catheter 2.0. A safety population of 91 subjects will be treated with the Vision-MR Ablation Catheter 2.0.

Objectives	Description
Primary Efficacy Objective	Demonstrate efficacy of type I atrial flutter ablation performed with the Vision-MR Ablation Catheter 2.0 and Osypka HAT 500 RF generator and irrigation pump.
Secondary Efficacy Objective	Assess the chronic efficacy of type I atrial flutter ablations performed with the Vision-MR Ablation Catheter 2.0 and Osypka HAT 500 RF generator and irrigation pump.
Safety Objective	Demonstrate an acceptable safety profile of type I atrial flutter ablation performed with the Vision-MR Ablation Catheter 2.0 and Osypka HAT 500 RF generator and irrigation pump.

Endpoints	Description	Acceptance Criteria
Primary Efficacy Endpoint	Confirmation of bidirectional conduction block of the CTI following the last RF application with the Vision-MR Ablation Catheter 2.0 and Osypka HAT 500 RF generator and irrigation pump.	Performance goal of a lower, one-sided 95% confidence bound of 80% success rate for acute bi-directional block.
Secondary Efficacy Endpoint	Chronic success, defined as freedom from recurrent, type I atrial flutter at 3 months (90 days) post procedure.	Characterization of freedom from recurrence at 3 months post procedure.
Safety Endpoint	Composite of the following serious adverse events through 7 days post-procedure: -Cardiac perforation/tamponade -Cerebrovascular accident (CVA) -Transient Ischemic Attack (TIA) -Complete heart block -Myocardial infarction -Pulmonary embolism -MR-related serious adverse event -Unanticipated device related serious adverse event -Death	Performance goal of an upper one-sided 95% confidence bound of 7% for the rate of subjects experiencing at least one of the composite serious adverse events adjudicated by an independent clinical events committee.

2.7 Possible Diagnostic or Therapeutic Alternatives

An arrhythmia is a heart rate that is too fast, too slow, or irregular in rhythm. Arrhythmias may present symptomatically or asymptomatically and are caused by changes in heart tissue or the electrical signals that control heartbeat; these changes may stem from injury, disease or genetics[1]. Many arrhythmias are harmless, but some can be serious or life-threatening. In general, arrhythmias are categorized by where in the heart the irregularity originates. Atrial flutter is an arrhythmia in which the heart's upper chambers (atria) beat too quickly. In accordance with current treatment guidelines, catheter ablation is considered first-line treatment for atrial flutter[3,4].

The literature confirms the use of radiofrequency catheter ablation as first-line therapy for the treatment of CTI-dependent atrial flutter[5,6]. Furthermore, the efficacy of RF applications and outcomes are influenced by the type of ablation catheter utilized, with large-tip, irrigated catheters being more effective than conventional small-tip, non-irrigated ablation catheters[7].

Clinical efficacy of RF catheter ablation for AFL depends on the creation of contiguous and transmural lesion[8]. To date, methods to measure these lesions are surrogate measures for the assessment of the lesion itself. Achieving bidirectional block is considered the standard for success with low recurrence rates[9].

The clinical data from the instructions for use (IFU) for the predicate devices studied support a follow-up period of 3-6 months when studying type I AFL. The Therapy CoolPath and Blazer OI catheters had 3-month follow-up while the Navistar ThermoCool defined an acute procedural endpoint as a surrogate endpoint for long term freedom from recurrence. Long-term, defined as 6-months post procedure, freedom from recurrence was also collected to enable the FDA to assess whether the surrogate endpoint of 3-months was reasonable. These studies corroborated the analysis of long-term outcomes after catheter ablation of type I AFL that demonstrated there was no increase in the rate of recurrence of AFL over time.

Alternatives to RF ablation for the treatment of AFL include lifestyle changes, pharmacologic therapy, and electrical cardioversion. While these treatment methods have success for the acute treatment of atrial flutter, radiofrequency ablation has shown greater efficacy than both pharmacologic therapy and DC cardioversion coupled with pharmacologic agents for chronic success[6].

Cardiac magnetic resonance (CMR) imaging guidance has led to a shift in ablation procedures from the fluoroscopy lab to the MRI suite. This technique provides enhanced imaging of the anatomy and arrhythmia substrate along with real-time visualization of the intracardiac catheter and ablation lesion formation. These

methods provide the potential to improve first-time success rates of ablation procedures by providing ablation lesion visualization and verification along with an individualized ablation therapy strategy[13,14]. In addition, the use of CMR-guided ablation provides the immediate benefit of a radiation free environment for patients and physicians. The 2017 HRS consensus statement on AF notes that "[MR imaging] is an area of considerable interest that could emerge as an important ablation monitoring and guidance strategy in the future" while the 2019 ESC guideline on SVT affirms that "the vision of a fully-radiation free, magnetic laboratory in the future is not scientific fiction anymore."

2.8 Suggested Profile and Training for Users

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

2.9 Harmonized Standards and/or other Normative Documents

The following standards are applicable to the Vision-MR Ablation Catheter 2.0 concerning the safety and performance of the device:

Document Identifier	Document Name
ASTM D4169-23 [E2024]	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F 2096-11 (2019	Standard Test Method for Detecting Gross Leaks in Porus Medical Packaging by Internal Pressurization (Bubble Leak)
ASTM F 88/F 88M-23	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F2052-15	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment
ASTM F2182-19e2	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
ASTM F2213-17	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
ASTM F2503-23	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
EN 60601-1:2006+A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
BS EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
BS EN 60601-2-2:2017	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
BS EN ISO 10555-1:2013+A1:2017	Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements
ISO 11135:2014 +A1:2019	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11607-1: 2020+A1:2023	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
BS EN ISO 14155:2020	Clinical investigation of medical devices for human subjects — Good clinical practice
BS EN ISO 14644-4:2001	Cleanrooms and Associated Controlled Environments - Part 4: Design, Construction and Start-Up
BS EN ISO 14644-5:2004	Cleanrooms and associated controlled environments Part 5: Operations
BS EN 14698-1:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
BS EN 14698-2:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
BS EN ISO 80369-7:2021	Small-bore connectors for liquids and gasses in healthcare applications. Part 7: Connectors for intravascular or hypodermic applications.
BS EN 556-2001/AC 2006	Sterilization of Medical Devices – Requirements for Medical Devices to be Designated “Sterile” – Part 1: Requirements for Terminally Sterilized Medical Devices
EN IEC 62304:2006+A1:2015	Medical device software – Software life cycle processes
IEC 62366-1:2015	Medical Devices – Part 1: Application of usability engineering to medical devices

Document Identifier	Document Name
BS ENISO 10993-1:2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 10993-4:2017	Biological evaluation of medical devices — Part 4: Section and Tests for interaction with blood
ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for cytotoxicity – In vitro methods
ISO 10993-10:2013 (R2016)	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2018	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
ISO 10993-12:2012	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
ISO 11607-2:2020 +A1:2023	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 14644-1:2015	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2:2015	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
ISO 14971:2019	Medical devices - Application of risk management to medical devices
BS EN 17141:2020	Cleanrooms and Associated Controlled Environments. Biocontamination Control
ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

3. Revision History

SSCP Revision	Date Issued	Change Description	Revision Validated by the Notified Body
A	31 May 2022	Initial Release	☐ Yes ☒ No
B	04 Aug 2023	• Updated intended purpose, indications for use, intended user and patient population. • Updated potential adverse events section. • Removed warning for undergoing septal accessory pathway ablation and added warning for testing on pregnant women. • Updated planned post market clinical follow up study to reflect objectives and endpoints of planned study. • Updated suggested profile and training for users.	☐ Yes ☒ No
C	12 Oct 2023	• Added statement regarding incorporation of sales data to corroborate threshold levels of potential adverse events • Corrected threshold values for cardiovascular events to <1%.	☐ Yes ☒ No
D	5 Feb 2024	• Added Expected Benefits section	☒ Yes Validation language: English ☐ No
E	18 Apr 2025	• Updates made to reflect current market released status of the device and revision of harmonized standards	☒ Yes Validation language: English ☐ No
F	21 Jul 2025	• Updated the warnings and precautions to align with the current IFU • Added reference to the Vision-MR Ablation Catheter 2.0 PSUR • Added English as the validation language	☒ Yes Validation language: English ☐ No

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