Vision-MR™ Ablation Catheter 2.0

MR
1.5 T

en English Instructions for Use

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

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

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SYMBOLS

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

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a. Fill a 1 ml or 2 ml syringe with sterile saline. Disconnect the irrigation tubing from the luer of the catheter and attach the syringe to the luer of the catheter.
b. Carefully inject the saline from the syringe into the catheter. A stream of fluid should be visible from all electrode holes.
c. Repeat steps a and b, if necessary, until the holes are cleared.
d. Disconnect the syringe and reconnect the irrigation tubing to the luer of the catheter.
e. Flush catheter and tubing per standard techniques to ensure purging of trapped air bubbles and to verify that the irrigation holes are clear.
f. Ensure the catheter tip is clean and start continuous irrigation at the low flow rate.
g. The catheter can now be reintroduced into the patient.

17. Upon completion of procedure, to remove the catheter, pull thumb control back to straighten catheter tip and SLOWLY withdraw catheter from the cardiovascular system.
18. When disconnecting the fiber optic connector, advance the bayonet collar toward the receptacle, then rotate counterclockwise and pull away from the receptacle to fully disconnect.
19. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

SERIOUS INCIDENT REPORTING

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

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

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

Single Use Only. Do Not Resterilize.

DEVICE 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 infusion 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.

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 age 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.

CONTRAINDICATIONS

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.

PATIENT TARGET GROUP

Patients age 18 years or older.

USER INFORMATION

The intended user is a physician who performs electrophysiology procedures.

MRI CONDITIONS FOR USE

The Vision-MR Ablation Catheter 2.0 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:

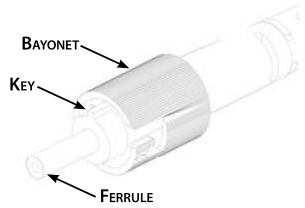
- The Vision-MR Ablation Catheter 2.0 must be used with the Advantage-MR EP Recorder/Stimulator System
- The patient must be in the supine position.
- Femoral access must be used.

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 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 instruction 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 a 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 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.



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

1. For RF ablation, make sure the compatible generator and pump are configured as described below. Refer to the compatible generator, pump, and tubing set instructions for use for more information.
   a. Set to Power Control mode.
   b. Set the maximum temperature to 40 °C.
   c. Set low flow rate to 2 ml/min and high flow rate to 17 ml/min.
   d. Load the irrigation tubing onto the irrigation pump.
   e. Connect the irrigation tubing to saline (heparinized per standard hospital practices).
2. 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.
3. Create a vascular access in a large, central vessel using sterile techniques.
4. Open Vision-MR Ablation Catheter 2.0 and Vision-MR Ablation Cable Set 2.0 packages and transfer the contents to the sterile field maintaining sterile techniques.
5. Connect the catheter via the Vision-MR Ablation Cable Set 2.0 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.
6. 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.
7. Connect the tubing to the luer fitting of the Vision-MR Ablation Catheter 2.0.
8. Flush the catheter and tubing using a flush flow rate up to 40ml/min to purge trapped air bubbles and to verify that the irrigation holes are clear. If encountering a high pressure error, reduce the flush flow rate and attempt to flush again.
9. Start continuous irrigation at the low flow rate.
10. SLOWLY insert the Vision-MR Ablation Catheter 2.0 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.
11. 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.
12. 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 30 Watts and duration to 60 seconds.
13. It is recommended to ablate point by point.
14. The applied power may be increased as needed to create a transmural lesion.

    WARNING: Ablating at high power (> 50W) may lead to steam pops, which have been associated with tissue perforation. Use caution when ablating at higher power.

15. 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.
16. In the event of a generator cutoff (temperature or impedance), pull thumb control back to straighten catheter tip and SLOWLY withdraw catheter. Inspect tip electrode for char/coagulum. If present, gently wipe with a sterile gauze dampened with sterile saline; 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:

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.

- C. 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.

EXPECTED CLINICAL BENEFITS

The Vision-MR Ablation Catheter 2.0 is used for radiofrequency ablation treatment of type I atrial flutter. The benefits of catheter ablation treatment for type I atrial flutter include improved quality of life, reduction of symptoms associated with atrial flutter, and the potential for improved cardiac function. While the Vision-MR Ablation Catheter 2.0 can be used in either the MR or x-ray environment; real-time, MR-guided procedures allow clinicians to leverage superior anatomical imaging of the heart while eliminating exposure to ionizing radiation for patients and clinicians.

COMPATIBLE EXTERNAL DEVICE AND ACCESSORIES

The Vision-MR Ablation Catheter 2.0 is an applied part and must be connected to a defibrillation proof Type CF port of the Advantage-MR System.

The following devices and/or equipment are used with the Vision-MR Ablation Catheter 2.0 but sold separately. Consult the manufacturer's instructions for use for the compatible devices and/or equipment.

Device/Equipment Type	Name(s)/Requirements
EP recording and stimulator system	Advantage-MR EP Recorder/Stimulator System (AD900)
Accessory cable	Vision-MR Ablation Cable Set 2.0 (CABA102)

PACKAGING

The Vision-MR Ablation Catheter 2.0 is provided in sterile (EO) packaging. The catheter is secured in a plastic tray, sealed in a Tyvek® pouch and packaged inside a box.

ENVIRONMENTAL PARAMETERS

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

ELECTROMAGNETIC INTERFERENCE (EMI)/ ELECTROMAGNETIC COMPATIBILITY (EMC)

Consult the Advantage-MR EP Recorder/Stimulator IFU for guidance and manufacturer's declaration of EMC.

CATHETER TIP TEMPERATURE ACCURACY

The Vision-MR Ablation Catheter 2.0 tip temperature is measured and displayed on the Advantage-MR EP Recorder/Stimulator. Consult the Advantage-MR EP Recorder/Stimulator IFU for catheter tip temperature specifications.

DIRECTIONS FOR USE

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

Refer to the Advantage-MR EP Recorder/Stimulator System 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 2.0.

While connecting the fiber optic connector on the catheter to the female receptacle on the fiber optic extension cable, ensure that the raised metal key on the connector is aligned with the mating slot prior to insertion. If necessary, rotate the bayonet collar until the raised metal key is visible.- Once aligned, advance and rotate the bayonet collar clockwise on the connector to achieve a locked connection.

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 (> 50W) 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 the device.
25. Discontinue use of the catheter if irrigation is occluded or the catheter is not functioning properly.

PRECAUTIONS

1. Inspect all components before use for any defects or physical damage. Do not use 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.

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 arrest
- 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/spasm)
- 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.

A. 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) *	177.5 ± 8.5
Weight (kg) *	90.9 ± 16.0

* Mean ± SD

B. 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 (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