Instructions for Use
Reprocessed IntellaMap Orion
High Resolution Mapping Catheter

Reprocessed Device for Single Use

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

DEVICE DESCRIPTION

The Reprocessed IntellaMap Orion High Resolution Mapping Catheter is an 8.5F(ø 2.82 mm) , 115 cm working length, 64-electrode steerable catheter. The basket-shaped distal region consists of 8 splines that comprise the electrode array (1). The proximal end has a handle that extends to a cable with a connector. The handle includes bi-directional articulation controls (2,3) and a deployment slider (4) that activates the electrode array into a basket shape once inside the heart. A flushing port (5) extends from the back of the connector (6) for connection to a continuous pressurized saline drip. The catheter is supplied with an 8.5F insertion sleeve (7) for insertion through the hemostasis valve of an introducer sheath. A sensor in the catheter tip enables the position of the distal region of the catheter to be tracked in space when used with the Rhythmia Mapping System.

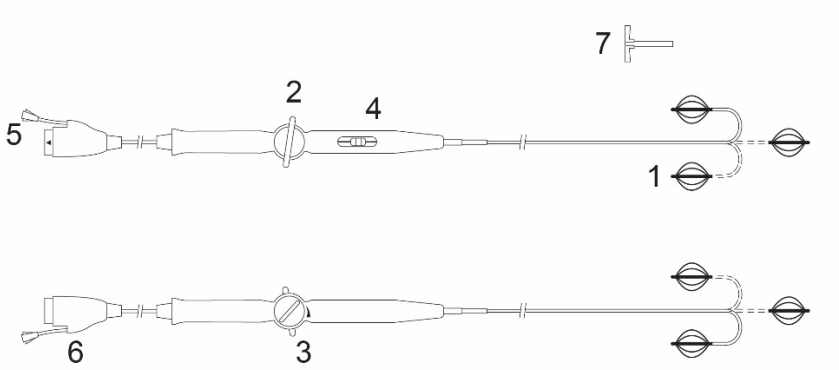

Figure 1. (1) Electrode Array shown deployed and in 3 different articulation positions (2) Articulation level (3) Articulation tension adjustment knob (4) Deployment slider (5) Flushing port (6) Connector (7) Insertion Sleeve

INDICATIONS FOR USE

The Reprocessed IntellaMap Orion High Resolution Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart.

CONTRAINDICATIONS FOR USE

The Reprocessed IntellaMap Orion catheter should not be used in:

- Patients who are not candidates for transvascular catheter procedures.
- Patients with a hypercoagulable state or who cannot tolerate heparin anticoagulation therapy.
- Patients with prosthetic or stenotic valves, in the chamber where prosthetic or stenotic valve reside.
- Patients with active systemic infection.

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- Pediatric patients.
- Pregnant and/or nursing patients.
- Patients with any other condition where catheter manipulation may not be safe.
- The catheter should not be used for Radio Frequency (RF) ablation.
- The catheter should not be used inside an MRI machine.

WARNINGS

- This equipment should be used by or under the supervision of physicians trained in cardiac catheterization procedures.
- Keep the connector dry; wet connector pins may affect performance. Do not allow the handle or cabling to be immersed in fluid.
- Do not use the catheter to deliver ablation therapy.
- Do not expose the catheter to alcohol or other cleaning solvents.
- Do not operate the catheter against resistance. If resistance is felt during advancement , retraction, articulation, deployment or undeployment, stop and evaluate device location under fluoroscopy.
- Do not advance or retract the catheter through a sheath when deployed or articulated.
- In order to reduce the risk of clot formation:
    - Maintain an Activated Clotting Time (ACT) of greater than 300 seconds at all times during use of the catheter, and
    - Continuously flush the electrode array with saline via the irrigation port at the proximal end.
- Do not use the catheter with equipment (such as stimulation or recording systems) that is not isolated.
- Tactile feedback of reprocessed device may vary during use.

PRECAUTIONS

- Do not attempt to operate the catheter prior to completely reading and understanding these directions for use.
- Personnel handling the electrophysiology catheter should wear gloves.
- Do not immerse the electrical connectors in fluids or solvents. If these components get wet, electrical performance may be compromised. Do not expose the catheter or cable to organic solvents such as alcohol.
- To avoid cardiac damage, do not use excessive force when manipulating the catheter in vivo. Specifically, use caution when maneuvering while undeployed. Note that mapping and recording data do not require the use of force on the tissue.
- Always undeploy the catheter prior to removal from the patient. Use visualization (such as fluoroscopy) to verify undeployment.
- Always move the articulation control lever to its neutral position to straighten the catheter prior to removal from the patient.
- Only use guiding sheaths with curves that allow passage of the catheter without using excessive force.
- When used with a steerable guiding introducer sheath:
    - Ensure under fluoroscopy that the guiding introducer sheath distal end is straight or, if necessary, only minimally curved prior to advancing or retracting the catheter through the sheath.
    - Do not articulate the sheath while the catheter array is inside the articulating section.
- Do not deploy or articulate the catheter while the distal end is inside a sheath.
- Do not apply RF energy on an ablation catheter that is in direct contact with the electrodes on the catheter.
- To prevent entanglement, use care when using the catheter in the proximity of other catheters.
- When pacing, verify desired waveform is observed.

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- Prior to insertion into vasculature, ensure removal of all air from the catheter lumen; use a pressured saline bag to flush saline through the catheter shaft and electrode array.
- Remove the catheter in case of an observed malfunction.

ADVERSE REACTIONS

Potential adverse events associated with cardiac catheter procedures include but are not limited to the following conditions: stroke, cardiac tamponade, perforation, myocardial infarction, pulmonary embolism, and death. Complications reported included also: air embolism, arrythmia, AV fistula, hematomas, hemothorax, pneumothorax, pseudoaneurysm, thromboembolism, valvular damage, vascular bleeding, and vasovagal reactions.

DIRECTIONS

- The package label is detachable and may be affixed to the medical record of the patient.
- Inspect the catheter and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the catheter is damaged or if the package is compromised, do not use the catheter. Return the catheter to Innovative Health. **Do not attempt to resterilize**.
- Using proper sterile technique, remove the catheter and insertion sleeve (7) from its package and place it in a sterile work area.
- Inspect the electrodes and catheter carefully for integrity, continuity of leads and overall condition.
- Deploy and undeploy the catheter one time to test deployment function. To deploy, pull back the deployment slider (4) until the middle of the slider is aligned with the nominal deployment marking on the handle. To undeploy, push the deployment slider forward until the array is closed.
- Articulate the catheter in both direction by rotating the articulation lever (2) to test the articulation mechanism.
- **Conditioning and Connection to a Rhythmia Mapping System**
    - Connect the catheter connector to the mating Rhythmia umbilical cable. Align the two connectors and press them together until they lock firmly.
    - Connect the umbilical cable to a Rhythmia hardware, and condition the catheter according to the direction for use supplied with the hardware.
    - Confirm correct connection to a Rhythmia Mapping System hardware prior to use. For guidance, refer to the mapping system's directions for use.
- **Preparation for Insertion**
    - Prepare a saline bag under 250 mmHg-300 mmHg pressure, with an IV administration line attached. Ensure that all air is expelled from the IV tubing.
    - Connect the irrigation port on the catheter connector to the pressurized saline bag. Open the line fully to allow flow into the catheter. Inspect the handle for any liquid leaks and stop using the catheter if leaks are observed.
    - Ensure that all air is expelled from the IV tubing and flushing port, including the luer connection, and allow saline to drip from the electrode array.
    - Submerge the insertion sleeve in a bowl of saline and ensure that no bubbles are attached to the inside of the sleeve.
    - Submerge the electrode array in the same bowl of saline. Deploy the catheter and ensure there are no air bubbles attached to the array. Undeploy the catheter, keeping the array submerged.
- **Insertion**
    - Follow standard procedure for vessel puncture and placement of introducer sheaths. Ensure that all air is removed from the introducer sheath. The catheter can be inserted through commercially available 8.5F or larger short or long introducer sheath.
    - While submerged in saline, verify that no bubbles are attached to the sleeve or catheter and slide the insertion sleeve over the distal end of the catheter with the tabs facing the handle. Push the sleeve back over the catheter shaft until the electrode array is fully covered and only the distal tip is visible.
    - Insert the catheter and sleeve so that the sleeve just breaches the introducer's valve. Keeping the insertion sleeve in place and under fluoroscopy guidance, continue advancing

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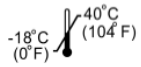
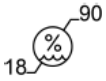
the catheter through the sleeve and introducer sheath until it reaches the desired location in the heart.
    - Pull the insertion sleeve back out of the introducer valve and towards the proximal end of the catheter. The sleeve can be reused as needed during the same procedure.
- **During use – Flushing**
    - Ensure that fluid is dripping at approximately 1 cc/min through the irrigation line at all times when the catheter is in vivo.
- **During use – Electrode Array Deployment**
    - Deploy and undeploy the electrode array as needed by slowly pulling or pushing the deployment slider (4), respectively. Do not use excessive force.
      Note that undeploying the array causes the tip of the catheter to move forward. Always perform deployment and undeployment under fluoroscopy or other imaging techniques to ensure that the array does not generate excessive force on cardiac tissue structures.
    - A marking on the handle indicates the nominal deployment state for mapping.
- **During use – Bi-direction Articulation**
    - Articulate the tip of the catheter as needed by rotating articulation lever (2) in the handle in the direction of desired motion. The articulation tension adjustment knob (3) can be used to tighten or loosen the articulation lever as needed.
- **During use – Catheter Removal**
    - Undeploy the electrode array.
    - Move the articulation control lever to its neutral position.
    - Remover the catheter.
    - Disconnect the catheter from the umbilical cable. To disconnect, rotate the connector coupling ring in the direction of the arrow and pull the two connectors apart.
    - Upon use, please return the device per Innovative Health's Instructions.

Rx only	Federal Law in the USA restricts this device to sale by or on the order of a physician
STERILE EO	Sterilized by Ethylene Oxide Gas
REF	Catalog Number
SN	Serial Number
LOT	Lot Number
	Use by Date
	Do Not Reuse
	Do Not Resterilize
	Consult Instructions for Use
	Keep Product Dry
	Keep Away from heat and sunlight
	Do Not Use if Package is Damaged
	Non-pyrogenic
	Temperature limit
	Humidity limitation

As the reprocessor, Innovative Health is solely responsible for this device. All Original Manufacturer (OM) information is provided for device identification and may contain trademarks from third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with Ethylene Oxide (EO) gas. Even though the product is processed in compliance with all applicable laws and regulations relating to EO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with EO. The packaging may expose you to EO, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

IntellaMap Orion is a registered trademark of Boston Scientific.

Please refer to www.innovative-health.com for product warranty.

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