# AtriCure

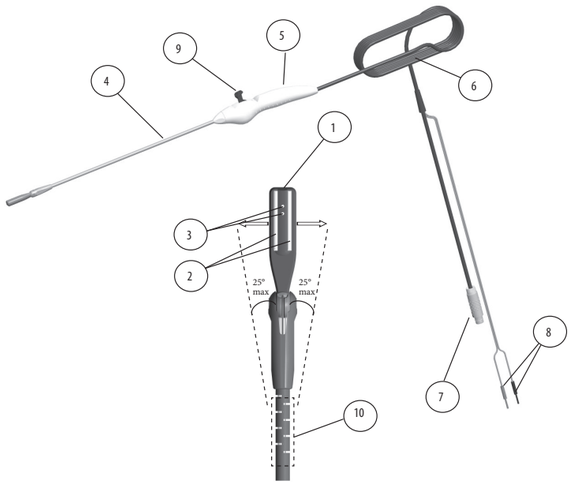
## Isolator™ linear pen

## Instructions for Use

### DESCRIPTION

The Isolator linear pen System is comprised of the AtriCure Ablation and Sensing Unit (ASU) or Multifunctional Ablation Generator (MAG), Isolator linear pen (Pen), Footswitch, Switch Matrix (ASB). The Pen is a single patient use electrosurgical instrument designed for use only with the ASU and ASB or MAG. The Pen is used to ablate cardiac tissues and as a surgical pacing and mapping tool. When the Pen is connected to the ASU or MAG, the generator provides the bipolar radiofrequency (RF) energy flowing between both electrodes of the Pen. The Operator controls the application of this RF energy by pressing the Footswitch. When the Pen is connected to an auxiliary pace, sense, or stimulation device; the Pen is designed to provide temporary pacing or monitoring.

### ISOLATOR LINEAR PEN ILLUSTRATION AND NOMENCLATURE




[1] End Effector
[2] Ablation Electrodes
[3] Sensing Electrodes
[4] Shaft
[5] Handle
[6] Cable
[7] Ablation Connector
[8] Sensing Connectors
[9] Articulation Lever
[10] Malleable Zone

### COMPATIBLE DEVICES

- OSCOR PACE 203 H AND ORLAB

### INDICATION FOR USE

- The Isolator linear pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy.
- The Isolator linear pen may be used for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or recording device.

### CONTRAINDICATIONS

- The device is not intended for contraceptive tubal coagulation (permanent female sterilization).
- Do not ablate directly on the cardiac valves.

### POTENTIAL COMPLICATIONS

Possible complications related to the creation of spot or linear lesions in cardiac and soft tissues are:

- Tissue perforation
- Postoperative embolic complications
- Extension of extracorporeal bypass
- Perioperative heart rhythm disturbance (atrial and/or ventricular)
- Pericardial effusion or tamponade
- Damage to adjacent nerve and/or blood vessels
- Valve leaflet damage
- Conduction disturbances (SA/AV node)
- Acute ischemic myocardial event

### ⚠WARNINGS⚠

Read all instructions carefully for the AtriCure ASU or MAG, Isolator linear pen, ASB Switch Matrix, and any compatible auxiliary device being used prior to using the devices. Failure to properly follow instructions may lead to electrical or thermal injury and may result in improper functioning of the device.

Do not touch the electrodes of the Pen while activating the ASU or MAG. Touching the Pen electrodes during ASU or MAG activation could result in a burn to the operator.

As with other unidirectional devices, do not place anything in front of or behind the target tissue (tissue being ablated). Any tissue within the RF energy field may experience heating and/or tissue damage. Ensure that non-target tissue is adequately separated from the RF field. Ensure non-target tissue is protected from the RF field by carefully placing and orienting the electrodes. Refer to Potential Complications list.

To prevent ineffective cardioversion, always remove the Pen from the patient during defibrillation.

To avoid the risk of patient infection, inspect the product packaging prior to opening to ensure that the sterility barrier is not breached. If the sterility barrier is breached, do not use the Pen.

The Pen device is intended for single use only. Do not RESTERILIZE or REUSE. Resterilization may cause loss of function or injury to patient.

To avoid damage to the device or sterility breach do not drop the Pen. If the Pen is dropped, do not use. Replace with a new Pen.

Ensure the full lengths of both electrodes are in contact with the targeted tissue, prior to, and throughout RF activation. Partial contact of the electrodes may produce perforations in the tissue.

Total duration of ablation(s) per lesion not to exceed recommended ablation time. Do not overlap ablations by more than 50%. Ablations exceeding recommended time and/or overlap may produce perforations in tissue.

Do not connect the ASB or MAG auxiliary device cable to supply mains (line voltage) operated equipment without verifying isolation of the connected equipment to EN60601-1. Supply mains operated equipment may introduce dangerous leakage currents into the heart.

Electrosurgery should be used with caution in the presence of internal or external pacemakers and/or internal cardiac defibrillators (ICD). Interference produced with the use of electrosurgical devices can cause devices such as a pacemaker and/or ICD to deliver inappropriate therapy or fail to deliver appropriate therapy.

### ⚠PRECAUTIONS

- Use of the Pen should be limited to properly trained and qualified medical personnel. Proper surgical procedures and techniques are the responsibility of the medical professional. Understanding the proper use of the auxiliary equipment Oscor and ORLab is also the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of any procedure based on their own medical training and experience, and the type of surgical procedure.
- The ablation and sensing electrodes must be kept clean of debris during surgery to avoid loss of power. Before activating the ASU or MAG, inspect the electrodes of the Pen for foreign matter. Foreign matter captured on the tip will adversely affect the ablation.
- The Pen should only be used with compatible axillary approved cardiac pacing and sensing devices.
- Ablation with the Pen is only compatible with the AtriCure ASU and ASB or MAG. Use of the Pen with another manufacturer's ablation generator may damage the device.
- The Pen has an eight hour useful life that is tracked by the ASU or MAG. If the Pen is plugged in after it has reached its time limit expiration, the Pen will no longer function and the ASU or MAG will display a message indicating that the Pen must be replaced.
- The Pen is to be used with the ASB in ablation mode only. The ablation electrodes are not to be used for pacing, sensing, or stimulation.
- Use of the ablation electrodes and sensing electrodes simultaneously may produce erroneous data from the auxiliary device.
- Do not bend shaft past 25 degrees from neutral position. Only bend the shaft in the malleable zone.
- Do not touch the electrodes of the Pen to metal staples or clips, or to sutures while activating the ASU or MAG.
- Do not immerse the entire pen in liquids as this may damage the device.
- Do not allow the connectors of the Pen to get wet, as this may affect the device performance.
- Use caution during device insertion, removal, articulation, and if bending the malleable portion of the shaft with surgical tools.

### INSTRUCTIONS FOR USE

**Pacing and Mapping Mode**

1. Inspect the package and product to ensure the expiration date has not passed and no damage occurred to the product during shipping and handling.
2. Using sterile technique, remove the Pen from its packaging.
3. Connect the Pen Sensing Connectors to the auxiliary pace, sense, or stimulation device.
4. Turn on the auxiliary pacing or sensing equipment and ensure proper connections to check electrical continuity. For detailed instructions refer to auxiliary pacemaker manual.
5. Settings and procedures for the auxiliary device are determined according to the instructions for use provided with the auxiliary device. Set auxiliary device to atrial asynchronous mode (sensing disabled or increased to maximum value).

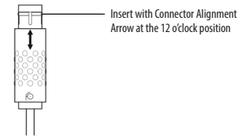
**Note:** The Pen will pace when the auxiliary device is in the ON position.

6. Identify and expose the sites for pacing and sensing using standard surgical techniques. Use the articulation lever to orient the end-effector. If necessary, bend the malleable zone of the shaft laterally to orient the end-effector. Under direct visualization, place the sending electrodes against the targeted tissue. Assure both sensing electrodes are in contact with targeted tissue.
7. Ensure the pacing is only on when the end effector is in contact with the targeted tissue. The device will pace when the auxiliary device pacing is on.
8. For sensing (mapping), place the sensing electrodes onto the targeted tissue to display the electrogram (EGM).
9. Upon completion of the surgical procedure, disconnect the Pen from the auxiliary device. Discard the Pen after use. Follow local governing ordinances and recycling plans regarding disposal or recycling of device component.

### INSTRUCTIONS FOR USE

**Cardiac Ablation Mode**

1. Using sterile technique, remove the Pen from its packaging. With the Connector Alignment Arrow symbol, in the 12 o'clock position, push the Ablation Connector into the Pen receptacle on the front of the ASU, ASB or MAG. Verify that the connections between the Pen and the generator are secure. If the connections are loose, do not use the Pen. Inspect the cable and do not use the Pen if the cable is frayed or the insulation is damaged.




2. Use the articulation lever to orient the end-effector. If necessary, bend the malleable zone of the shaft laterally to orient the end-effector. Under direct visualization, place the ablation electrodes against the targeted cardiac tissue. Assure both electrodes are in contact with targeted tissue.
3. **Ablation technique:**

   3.1. Apply constant firm pressure to the tissue without movement. Maintain full contact of the electrode surface with the tissue. A lesion is approximately 20 mm x 8 mm.
   3.2. If creating connecting linear lesions, overlap the contiguous ablations at most 50% to ensure a continuous and complete lesion.

Lesion Depth*

| Ablation Time (s) | 20 | 30 | 40 | Repeat 40s ablation |
|---|---|---|---|---|
| Lesion Depth (mm) | 4.5-4.9 | 5.1-5.5 | 5.7-6.0 | 6.6 - 6.9 |

*Data was obtained from ablations performed on excised bovine myocardium and represent 95% confidence intervals. Results may vary based on live tissue properties.

4. Press the Footswitch to activate the ASU or MAG.
5. When the Footswitch is pressed, the ASU or MAG will emit an audible tone indicating that current is flowing between the ablation electrodes of the Pen and through the tissue.
6. Inspect the surgical area to ensure adequate ablation.
7. Between ablations, wipe the ablation electrodes clean with a saline-soaked gauze pad. **Important:** For optimal performance, keep the Pen electrodes clear of coagulum. To ensure the electrodes are clear of coagulum:

   7.1. Use saline-soaked gauze to clean the electrodes after each ablation. The coagulum is much easier to remove within the first several seconds after ablation. In a brief period of time, the coagulum may dry, making removal of coagulum more difficult.
   7.2. Check both electrodes before each ablation to ensure that the gold of the electrode is visible and coagulum is removed.
   7.3. If the Pen is idle between ablations, place the ablation electrodes onto saline-soaked gauze to prevent any coagulum not cleaned off the electrodes from drying.

8. Repeat ablation if necessary.

   8.1. If multiple repeat ablations are performed, ensure the ablation electrodes are cooled to maintain adequate lesion depth. Cooling may be achieved by immersing the End Effector in a saline or sterile water bath.

9. Upon completion of the surgical procedure, disconnect the Pen from the ASU/ASB or MAG and auxiliary device and discard the Pen after use. Follow local governing ordinances and recycling plans regarding disposal or recycling of device component.

### HOW SUPPLIED

The Isolator linear pen is supplied as a STERILE instrument and is for single patient use only.

Sterility is guaranteed unless the package is opened or damaged. Do not resterilize.

### RETURN OF USED PRODUCT

If for any reason this product must be returned to AtriCure, Inc., a return goods authorization (RGA) number is required from AtriCure, Inc., prior to shipping.

If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment; and it should be properly labeled with an RGA number and an indication of the biohazardous nature of the contents of shipment.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from AtriCure, Inc.

⚠**CAUTION:** It is the responsibility of the health care institution to adequately prepare and identify the product for shipment.

### DISCLAIMER STATEMENTS

Users assume responsibility for approving the acceptable condition of this product before it is used, and for ensuring that the product is only used in manner described in these instructions for use, including, but not limited to, ensuring that product is not re-used.

Under no circumstances will AtriCure, Inc. be responsible for any incidental, special or consequential loss, damage, or expense, which is the result of the deliberate misuse or re-use of this product, including any loss, damage, or expense which is related to personal injury or damage to property.

**Explanation of symbols on package labeling**

Refer to the outer package label to see which symbols apply to this product.

**EXPLANATION OF SYMBOLS ON PACKAGE LABELING**

**REFER TO THE OUTER PACKAGE LABEL TO SEE WHICH SYMBOLS APPLY TO THIS PRODUCT.**

| | | | |
|---|---|---|---|
| | Non-Pyrogenic | | Caution |
| STERILE EO | Sterilized by Ethylene Oxide | | Follow instructions for use |
| | Do Not Re-Use | | Manufacturer |
| Rx ONLY | Caution: Federal Law (US) restricts this device to sale by or on the order of a physician | LATEX | Not made with natural rubber latex |
| LOT | Lot Number | | Do not resterilize |
| | Use by Date | | Do not use if package is damaged |

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