

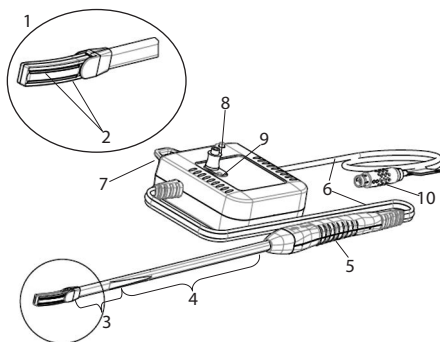
AtriCure®

Coolrail® linear pen Instructions for Use

DESCRIPTION

The AtriCure® Coolrail® linear pen System is comprised of the AtriCure Ablation and Sensing Unit (ASU), Coolrail® linear pen, Footswitch, and AtriCure Switch Matrix (ASB). The Coolrail® linear pen is a sterile, single-use electrosurgical instrument designed for use with the ASU and ASB. The Coolrail® linear pen is used for the ablation of cardiac tissue. The device is designed with internally cooled electrodes to produce continuous, full thickness lesions on the beating heart. The ASU delivers bipolar radiofrequency (RF) energy, which flows between the internally cooled electrodes of the Coolrail® linear pen. The Operator controls the application of energy by pressing the Footswitch.

Coolrail® LINEAR PEN ILLUSTRATION AND NOMENCLATURE



- | | |
|-------------------------------|-------------------|
| 1. End Effector | 6. Cable |
| 2. Electrodes | 7. Pump Box |
| 3. Malleable portion of shaft | 8. Injection Port |
| 4. Rigid portion of shaft | 9. Vent |
| 5. Handle | 10. Connector |

INDICATION FOR USE

The Coolrail® linear pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy.

CONTRAINDICATIONS

The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

POTENTIAL COMPLICATIONS

Potential Adverse events with surgical RF ablation of cardiac and soft tissues, apart from those that may occur as a result of surgical/mechanical manipulation of the target tissues, include, but are not limited to:

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



WARNINGS

- Ensure the full lengths of both electrodes are in contact with the targeted tissue prior to and throughout RF activation. Partial contact of electrodes may produce perforations in the tissue.
- 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 such as the esophagus is adequately separated from the RF field. Ensure non-target tissue is protected from the RF field by carefully placing and orienting the electrodes.
- Do not perform ablations directly on the atrial appendage. Clotting may occur.
- Do not touch the electrodes of the Coolrail® linear pen while activating the ASU. Touching the Coolrail® linear pen electrodes during ASU activation could result in an electrical shock or burn to the operator.
- Do not touch the electrodes of the Coolrail® linear pen to metal staples or clips, or to sutures while activating the ASU. This may damage the Coolrail® linear pen or tissue, or result in an incomplete ablation.
- Do not use abrasive cleaners or electrosurgical tip cleaners to clean

debris from the electrodes. Use of abrasive cleaners or electrosurgical tip cleaners can damage the electrodes and result in device failure. Use saline-soaked gauze for cleaning debris. Do not turn on ASU while cleaning the device.

- Total duration of ablation(s) per lesion not to exceed recommended ablation time. Do not overlap ablations by more than 50%.
- Do not immerse the Coolrail® linear pen in liquids as this may damage the device.
- To avoid shock/burn hazards, always wear the appropriate surgical gloves when using the Coolrail® linear pen and ASU.
- Do not use the Coolrail® linear pen for coagulation or ablation of veins or arteries.
- To avoid shock/burn hazards, always remove the Coolrail® linear pen from the patient during defibrillation.
- No representation or warranty is made that failure or cessation of function of the device will not result in an adverse event or that medical complication (including tissue perforation) will not follow the procedure, or that the use of the device will in all cases restore adequate cardiac function.
- 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 Coolrail® linear pen.
- Only use sterile water when filling the Pump Box. Other fluids may affect the performance of the device.
- The Coolrail® linear pen device is intended for single-use only. Do not resterilize. Resterilization may cause loss of function or injury to patient.
- Do not allow the connectors of the Coolrail® linear pen to get wet. Wet connectors may affect the device performance.
- Do not connect the ASB auxiliary device cable to supply mains (line voltage) operated equipment without verifying isolation of the connected equipment to EN60601-1-1. Supply mains operated equipment may introduce dangerous leakage currents in the heart.
- An auxiliary device may have an adverse effect on nearby radio or TV transmissions. There may also be cases when nearby electrical appliances adversely influence the auxiliary device, causing data errors or malfunction.



PRECAUTIONS

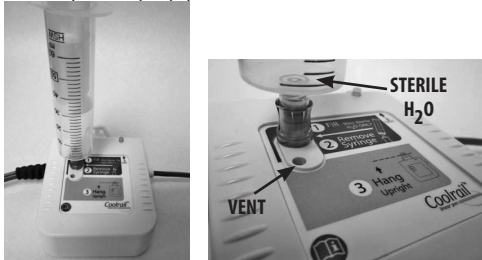
- This device is designed for use on the beating heart. Use of this device on the arrested heart has not been studied.
- To ensure a continuous ablation, assure the full length of both electrodes is in full contact with the targeted tissue during RF activation
- Read all instructions carefully for the AtriCure ASU, Coolrail® linear pen, and AtriCure Switch Matrix, prior to using the device. Failure to properly follow instructions may result in improper functioning of the device and may lead to electrical or thermal injury.
- Use of the Coolrail® linear pen should be limited to properly trained and qualified medical personnel. Proper surgical procedures and techniques are 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.
- Patient and procedure selection is solely a medical responsibility and the outcome is dependent on many variables including patient pathology, and surgical and perfusion procedures.
- Variations in specific procedures may occur due to individual physician techniques and patient anatomy.
- To avoid damage to the device, do not drop or toss the Coolrail® linear pen. If the Coolrail® linear pen is dropped, do not use. Replace with a new Coolrail® linear pen.
- Do not use the Coolrail® linear pen in the presence of flammable materials.
- The Coolrail® linear pen is only compatible with the AtriCure Generator (ASU) and AtriCure Switch Matrix (ASB). Use of the Coolrail® linear pen with another manufacturer's generator may damage the device and result in patient injury.
- Before activating the ASU, inspect the electrodes for foreign matter. Foreign matter on the tip may adversely affect the ablation. Use saline-soaked gauze for cleaning debris off of the electrodes.
- The Coolrail® linear pen has an eight hour useful life that is tracked by the ASU. The device will no longer function after it has reached its time limit expiration and the ASU will display a message indicating that the Coolrail® linear pen must be replaced.
- It is the responsibility of the user to dispose of this device in accordance with local regulations.
- Excessive bending of the malleable shaft will cause the shaft to harden and may increase the potential for breakage.

INSTRUCTIONS FOR USE

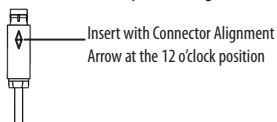
1. Examine the packaging of the device to ensure the sterility of the product has not been breached. Remove the sterilized instrument from its package per standard sterile technique.
2. Place the Pump Box on a flat surface prior to priming the system.
3. Fill a syringe with 30cc of sterile water in order to prime the pump system.

NOTE: Do not use saline, as device performance may be affected.

4. Placing the tip of the syringe into the Injection port of the Pump Box, prime the pump system with sterile water.



5. Fill the pump system until sterile water flows from the vent. This may require slightly more than 30cc of sterile water.
6. Remove the syringe from the injection port.
7. With the Connector Alignment Arrow symbol in the 12 o'clock position, push the Connector into the "Pen" receptacle on the front of the ASB. Verify proper ASB connections by consulting the ASB package insert. Verify that the connections between the Coolrail® linear pen and the ASB are secure. If the connections are loose, do not use the Coolrail® linear pen. See Figure 3.



8. Hang the Pump Box upright on the handle of the ASU or ASB using the hook on the top of the Pump Box. If necessary, the handle of the ASU or ASB can be rotated to a horizontal position.



9. Rotate the ASB knob to indicate "Pen" for ablation.
10. If desired, bend the malleable portion of the shaft of the Coolrail® linear pen into the desired configuration and position the distal tip into 1 of 3 set locations (-25°, 0°, 25°).
11. Identify and expose the sites to be ablated using standard surgical techniques. Place the electrodes against the targeted tissue under direct visualization of the surgeon. **Assure the full lengths of both electrodes are in contact with the targeted tissue.**
12. Press and hold the Footswitch to activate the ASU and deliver RF energy to the tissue. Do not move the device during ablation.
13. When the RF is activated, the ASU will emit an audible tone indicating that current is flowing between the selected electrodes and through the tissue. The audible tone will change pitch every 10 seconds to indicate ablation time.

NOTE: The internal pump will continue to run after the RF activation has stopped.

14. The depth of the lesion will be determined by the duration of activation. The following table lists anticipated lesion depths at various ablation times:

Cardiac Tissue Lesion Depth (mm)*

Duration (seconds)	20	30	40
Tissue Thickness (mm)	4.1 - 4.5	4.8 - 5.2	5.1 - 5.4

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

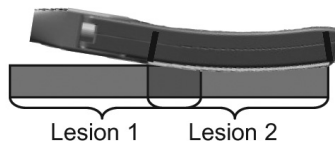
15. Inspect the surgical area to ensure adequate ablation.
16. Between ablations, wipe the distal tip clean with a saline-soaked gauze pad.
- NOTE:** For optimal performance, keep the Coolrail® linear pen electrodes clear of coagulum. The coagulum is much easier to remove within the first several seconds after ablation. In a brief period of time, the coagulum may dry making removal more difficult.
17. Inspect electrodes before each ablation to ensure the surface of the electrode is clean and coagulum is removed.
18. Repeat ablation if necessary.

NOTE: If an E03 error is indicated on the ASU and the LED light is illuminated on the pump box, a hi-temp error has occurred indicating that the end effector has overheated, or the cooling system has

malfunctioned. The system will not operate until either the root cause of overheating is corrected, or the CoolRail device is replaced.

As soon as an E03 error and LED light is indicated, troubleshoot by ensuring that the fluid cable is not kinked or occluded and that there is a sufficient amount of sterile water in the pump box. If an obvious cause of overheating is not quickly identified and the E03 error persists more than 2 minutes, replace the device and return the product to AtriCure for further analysis of the malfunction. For any other errors seen on the ASU during use, reference the ASU user manual.

19. If a continuous lesion is required, always overlap the ablations by 5-10 mm using the black marker as the ablation location indicator. The location indicated by the distal end of the previous ablation should overlap to the proximal end of the next ablation.



20. Upon completion of the surgical procedure, disconnect the Coolrail® linear pen from the generator and discard the Coolrail® linear pen after use. Follow local governing ordinances and recycling plans regarding disposal or recycling of device component.

HOW SUPPLIED

The AtriCure Coolrail® 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 re-sterilize.

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 bio-hazardous 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 the manner described in these instructions for use, including but not limited to, ensuring that the 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.

	Non-Pyrogenic		Lot Number
	Sterilized by Ethylene Oxide		Use-by Date
	Single Use Only		Caution
	Caution: Federal Law (US) restricts this device to sale by or on the order of a physician		Not made with natural rubber latex
	Follow Instructions for Use		Manufacturer
	Do Not Re-Sterilize		Do Not Use if Package is Damaged



Manufactured by:

AtriCure Incorporated
 7555 Innovation Way
 Mason, Ohio 45040 USA
 Customer Service: 1-866-349-2342 (toll free)
 1-513-755-4100 (phone)