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Mason, Ohio 45040
United States
513-755-4100

URGENT: AtriCure Coolrail Linear Pen (MCR1) Advisory Notice Due to Atrio-Esophageal Fistula Occurrences

January 20, 2017

Dear Health Care Professional and/or Risk Manager:

This Advisory Notice (aka Field Safety Notice) is to inform you of a safety issue involving

AtriCure Coolrail Linear Pen (MCR1)

An Atrio-Esophageal Fistula (AEF) resulting in death recently occurred in a patient after the use of this device during the AtriCure sponsored DEEP Pivotal investigational study. Since the Coolrail device was commercialized in 2008, at least nine (9) patients have developed atrio-esophageal fistula and, as a result, four (or 44% of the AEF patients) died.

In the patients who developed AEF, a minimally invasive thoracoscopic ablation procedure was used to treat atrial fibrillation. The Coolrail device is cleared by the FDA to ablate cardiac tissue during cardiac surgery using radiofrequency energy. The safety and effectiveness of the use of the Coolrail device for minimally invasive thoracoscopic ablation procedures or for the treatment of atrial fibrillation (AF) have not been established.

The purpose of this Advisory Notice is to inform users of the Atrio-Esophageal Fistula cases that have occurred with the AtriCure Coolrail Linear Pen. This Urgent Notification is being made with the knowledge of the Food and Drug Administration (FDA). FDA is concerned about the rate of AEF associated with the use of the Coolrail device in minimally invasive, thoracoscopic procedures. Importantly, the safety and effectiveness of the device for treating AF has not been demonstrated.

The following are Signs and Symptoms of AEF and were identified in some patients in the DEEP Pivotal Study and in an extensive literature review:

- Fever
- Dysphagia (Painful or Difficulty Swallowing)
- Persistent Chest Pain (Different from Incisional Pain)
- Seizure(s)
- Change in Mental Status (Confusion)
- Sudden Weakness on One Side of the Body
- Vomiting Blood
- Blood in Stool
- Fainting
- Dyspnea (Shortness of Breath)
- Difficulty Speaking
- Numbness, Tingling Sensation, Dizziness, Double Vision

The DEEP Pivotal study is investigating the use of AtriCure Bipolar system with minimally invasive thoracoscopic approaches for the treatment of subjects with persistent and longstanding persistent AF. The following techniques are being implemented in this study to decrease the risk of AEF; however, their effectiveness is currently unproven:

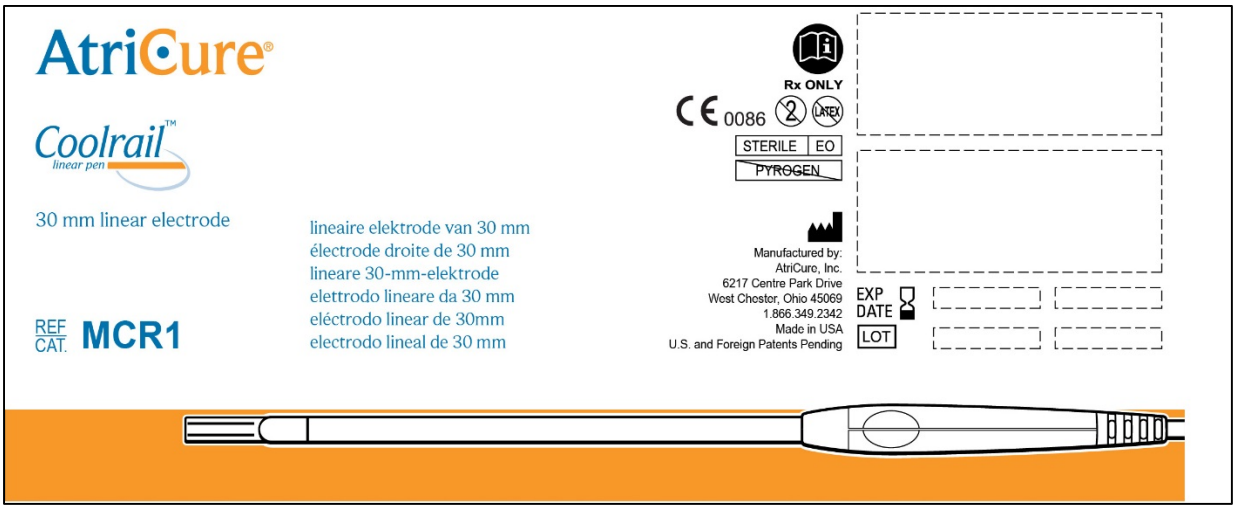
- Determine the location of the esophagus utilizing thoracoscopic visualization and the TEE probe.
- Prior to energy delivery, the Transesophageal echocardiography (TEE) probe should be retracted from the area of ablation as a measure to protect the esophagus and other surrounding tissue structures.

- **Ablation**: Ablations should be visualized and atrial tissue should be elevated up and away from the posterior pericardium with the ablation device(s) in order to avoid collateral injury to surrounding tissue.
- **Post Ablation:** Prior to repositioning the device and prior to resting the atrium onto the posterior pericardium, the device should remain in place for 30 seconds while simultaneously quenching the device, the ablated tissue, and the surrounding tissues with saline. This will allow these areas to adequately cool.
- In addition, it is recommended that a Proton Pump Inhibitor (PPI) be prescribed to the patient for a minimum of seven (7) days prior to the procedure and continued for a minimum of 30 days post-procedure.

Immediately examine your inventory to determine if you have any MCR1 devices. If so, please ensure all users are aware of this Advisory Notice.

All device lot numbers are affected. A sample of the full product label is below**.**

OR



This safety issue will also be posted on AtriCure's website at www.atricure.com/products.
In the event a patient has experienced Atrio-Esophageal Fistula post ablation procedure with the AtriCure Coolrail Linear Pen, please ensure appropriate medical treatment and contact AtriCure, Inc. within 24 hours of

the adverse event by calling 1-866-349-2342, and select option 6 or e-mail pcomplaints@atricure.com or productrecalls@atricure.com.

If you have any questions, call Anupam Bedi (513-755-4563), M-F, 8:30 AM-5:00 PM EST.

Anupam Bedi
AtriCure, Inc.
Director of Quality

Device Notification Acknowledgment Form

AtriCure Coolrail Linear Pen
Product Codes: MCR1

Lots Numbers: All Lot Numbers

Please determine if the affected device is present in your inventory and check the appropriate box. Please return this form by fax to 513-644-1918 or 513-285-3127, or by e-mail productrecalls@atricure.com immediately:

☐ We have the following affected product at our facility and have read the Advisory Notice.
(Please indicate lots and quantities below)

☐ We have no affected product within the scope of this Advisory Notice.

Please print legibly. If needed, you may document on a separate piece of paper.

Product Codes	Lot Number	Quantity On-Hand
Product Code: MCR1 P/N: A000475, A000475-1, A000475-EU		

Institution Information:

(Print Name)	
(Signature)	**(Date)**
(Telephone Number)	**(Email Address)**
(Institution Name)	
(Institution Street Address)	**(Institution City, State, Zip)**