AtriCure®

7555 Innovation Way
Mason, Ohio 45040
United States
513-755-4100

URGENT: COBRA Fusion Ablation System Advisory Notice Due to Potential Magnet Dislodgement

September 21, 2016

Dear Health Care Professional and/or Risk Manager:

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

Estech COBRA Fusion Ablation System

All lots manufactured prior to February 2016. This information can be identified as the symbol for "date of manufacture" on the product label as:

MM-YYYY **(e.g. "MM-YYYY" will be 02-2016 for product manufactured in February 2016)**

A sample of the full product label is below.

The purpose of this Notice is to raise awareness of a potential issue regarding the COBRA Fusion Ablation System. The magnet and/or magnet cap at the distal end of the device could potentially dislodge and separate from the body of the device, and remain behind when the device is removed from the patient. In this event, the magnet and/or magnet cap would need to be removed prior to completion of the surgical procedure. Failure to remove the magnet and/or magnet cap from the body cavity prior to closure could potentially cause permanent impairment of body function or permanent damage to a body structure. No serious injuries or deaths have been reported to AtriCure as of the date of this notice, September 21, 2016.

This Urgent Notification is being made with the knowledge of the Food and Drug Administration (FDA). Adverse reactions or quality problems experienced with the use of this product should be reported to AtriCure as a product complaint.

Immediately examine your inventory and determine if you have any COBRA Fusion Ablation System devices with a manufacture date prior to 02-2016. If so, please ensure that all users of the affected devices are aware of this Advisory Notice. If you may have further distributed this product, please identify your customers and notify them at once of this Advisory Notice. Your notification to your customers should include a copy of this Notice.

Please contact AtriCure customer service at 1-866-349-2342, and select option 6 if you would like to return any affected product(s). Please also complete and return the enclosed Device Notification Acknowledgement Form as soon as possible.

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

Estech COBRA Fusion Ablation System
Product Codes: *see below*

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Please determine if you have affected product at your facility and check the appropriate box. Please return this form by fax to 513-644-1918 or 513-285-3127 immediately:

- ☐ We have the following affected product/lot(s) at our facility and will return the product to AtriCure.
  (Please indicate lots and quantities below)
- ☐ We have affected product/lot(s) within the scope of this recall and will not be returning to AtriCure.
- ☐ We have no affected product/lot(s) within the scope of this recall.

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

Product Codes	Lot Number	Quantity On-Hand
700-001 700-001S 700-001MI 700-002 700-003		

Institution Information:

(Print Name)	(Return Goods Authorization (RGA) Number)
(Signature)	(Date)
(Telephone Number)	(Email Address)
(Institution Name)	
(Institution Street Address)	(Institution City, State, Zip)

Return Instructions:

- If you would like to return any affected product, contact AtriCure Customer Service at 1-866-349-2342 to receive a Return Goods Authorization (RGA) Number and to have an appropriate replacement sent to your facility.