

Aptiva Medical S.R.L.  
Via Rembrandt 2  
20148 Milano  
ITALY

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


September 28, 2016

Dear Business Partner,

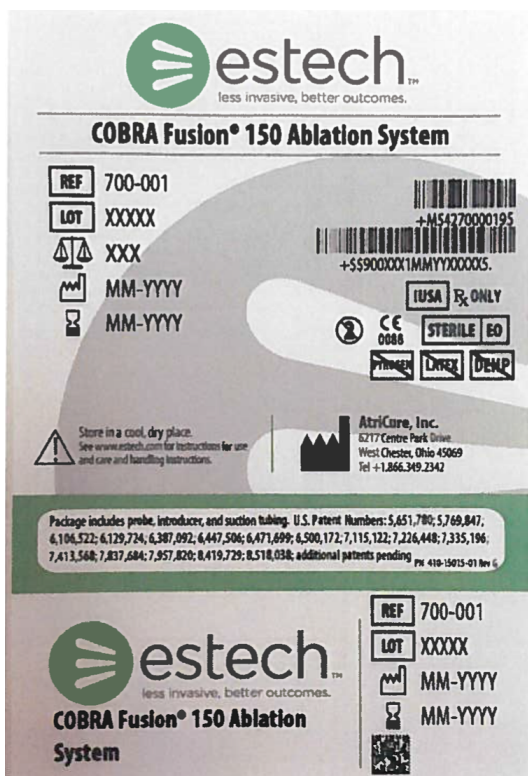
This Advisory Notice (aka Field Safety Notice) is to inform you of a potential issue involving:

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 Sales Support at +31 20 700 5560 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, please call AtriCure Sales Support at +31 20 700 5560, 08:30 – 17:00 Local.



**Anupam Bedi**  
AtriCure, Inc.  
Director of Quality

## Device Notification Acknowledgment Form

**Estech COBRA Fusion – Ablation System**  
**Product Codes: 001-700-001S, 001-700-001MI, 001-700-002, 001-700-003**  
**All lots manufactured prior to February 2016**

Please determine if you have affected product at your facility and check the appropriate box.  
Please return this form immediately by fax to **+31 20 700 5561** or scan this document and e-mail it to **salessupporteu@atricure.com**

- ☐ 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 advisory notice and will not be returning to AtriCure.
- ☐ We have no affected product/lot(s) 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
<b>COBRA Fusion</b>		
<b>001-700-001S</b>		
<b>001-700-001MI</b>		
<b>001-700-002</b>		
<b>001-700-003</b>		

### Institution information:

	<b>RGA-2016-1266</b>
(Name)	(Returned Goods Authorisation (RGA) number)
(Signature)	(Date)
(Telephone number)	(Email Address)
<b>Aptiva Medical S.R.L.</b>	<b>Via Rembrandt 2</b>
(Name Institution)	(Street address)
<b>20148 Milano</b>	<b>ITALY</b>
(City and Postal Code)	

### Return Instructions:

If you would like to return any affected product, contact AtriCure Sales Support at +31 20 700 5560 to start the return process and to have an appropriate replacement sent to your facility.