7555 Innovation Way
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www.atricure.com

URGENT Advisory Notice
AtriCure COBRA Fusion Ablation System Instructions for Use (IFU) Update Due to Thromboembolic Event Occurrences

Date: January 22, 2018

Attention: 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 COBRA Fusion Ablation System

Reason for this Communication:
AtriCure has identified a potential safety issue regarding thromboembolic events (TE) occurring in cardiac surgical procedures using the COBRA Fusion device. AtriCure has received 35 reports of thromboembolic events (34 strokes and 1 Transient Ischemic Attack (TIA)), since worldwide introduction of the device in March 2012. This represents a TE adverse event rate of 0.42% of the 8404 units sold. Of the 35 reported cases, 4 resulted in patient deaths and 31 resulted in serious injuries. The majority of these events occurred during stand-alone off-pump procedures where cardio pulmonary bypass (CPB) was not utilized as outlined below:

	Events
Stand-alone, Off-Pump	29
Concomitant, On-Pump	6
Total Reported Events	35

Based upon review of the TE events, AtriCure believes that patients undergoing ablation with the Fusion device may be at an elevated risk for TE while not on CPB. The standard of care for patients undergoing cardiac surgery on CPB includes a comprehensive anti-coagulation protocol to prevent clot formation. When undergoing cardiac surgery off CPB, it is not standard of care for patients to receive this same comprehensive anti-coagulation protocol. As a result, AtriCure is updating their instructions for use to ensure that appropriate anti-coagulation management is considered.

Instructions for Use (IFU) Update:
AtriCure is providing modifications to the existing Cobra Fusion Instruction for Use (IFU), to address contributing TE Factors associated with stand-alone off-pump procedures. These are in addition to the warnings and precautions that are present within the current IFU.

Modifications to Warnings:
When utilizing the Cobra Fusion device in a stand-alone off-pump (without CPB) procedure, the following should be considered:

- Physicians should consider a comprehensive anti-coagulation protocol including pre-operative, intra-operative and post-operative anti-coagulation management to prevent potential thromboemboli.

Modifications to Precautions:

- Post-operative anti-coagulation therapy for protection against thromboemboli is inclusive of the bridging period between the end of the procedure and until effective therapeutic levels of Oral Anticoagulation (OAC) are achieved.

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Impacted Product*:*
The COBRA Fusion device is indicated to ablate cardiac tissue during cardiac surgery using radiofrequency energy. The safety and effectiveness of the use of the COBRA Fusion device for the treatment of atrial fibrillation (AF) has not been established. The impacted product is detailed in the table below:

Product *(See Attachment A for sample labels)*	**Catalog# (Ref)**	**UDI**	**Lots**
COBRA Fusion 50	700-002	00818354012811	All lots within expiry
COBRA Fusion 150	700-001	None	
COBRA Fusion 150	700-001S	00818354012828	
COBRA Fusion 150 (International Only)	700-001MI	00818354013016	

Reason for this Update:

When undergoing cardiac surgery utilizing CPB, the standard of care is for patients includes a comprehensive anti-coagulation protocol to prevent clot formation and therefore patients ablated with the Fusion device while on CPB are appropriately anti-coagulated prior to the ablation, during the ablation and following the ablation. Further, following discontinuation of CPB, patients remain in a state of hypo-coagulopathy for several hours. When performing cardiac surgery ablation procedures without CPB, it is not standard of care for patients to receive this same comprehensive anti-coagulation protocol. Other contributing factors to be considered include the following:

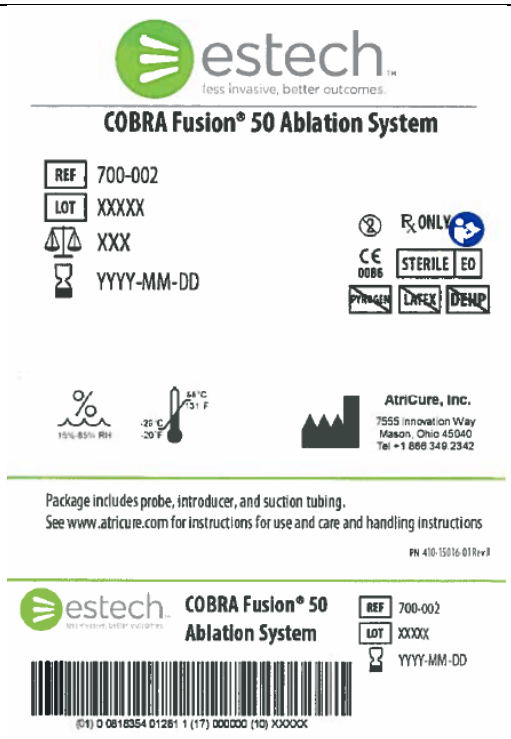
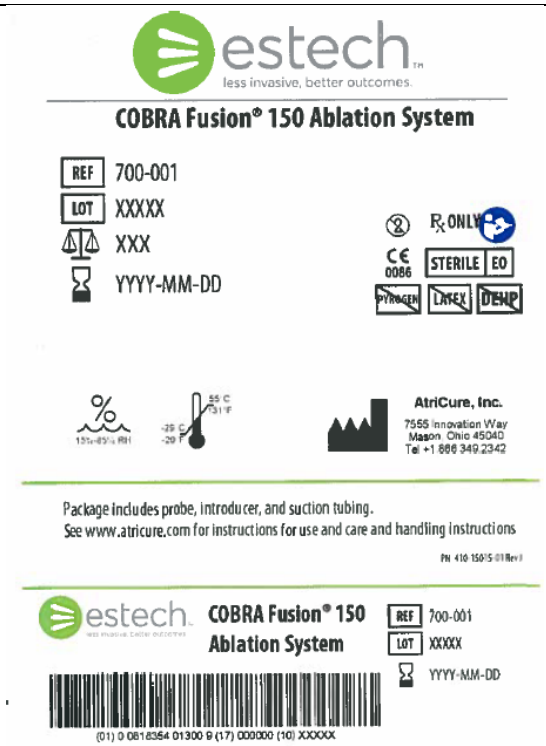
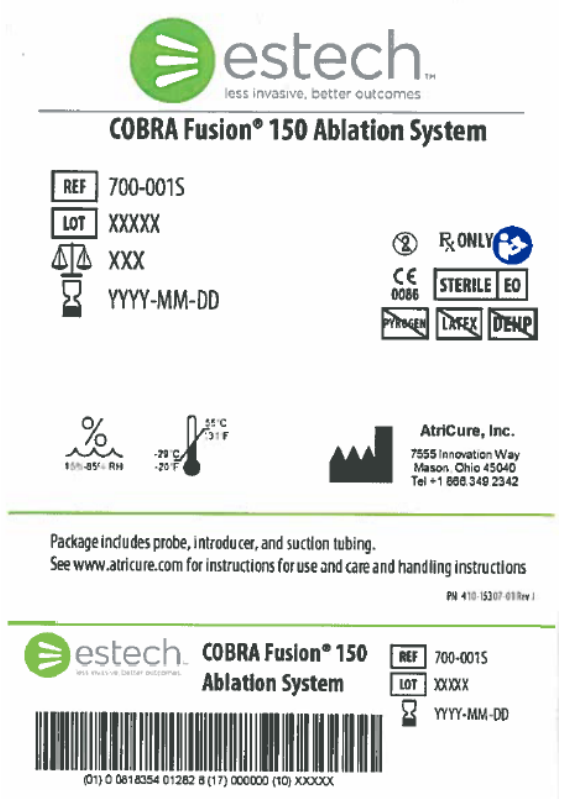
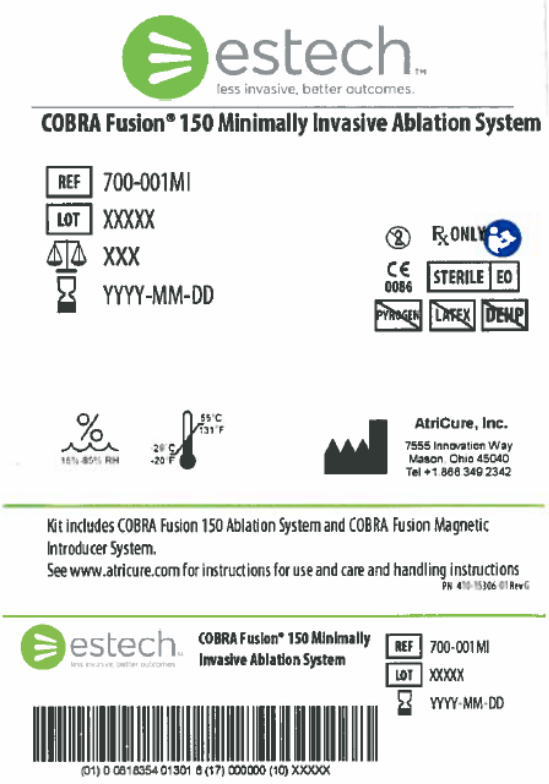
1. CHADS2 score > 2
2. Pre-operative anti-coagulation management

Action Needed:

- Read and follow the revised Instructions for Use "IFU" enclosed when using the Cobra Fusion. See Attachment C, document P001331, revision B.
- Report any post ablation thromboembolic event with the Cobra Fusion, to AtriCure by phone at 1-866-349-2342 (select option 6) or e-mail to pcomplaints@atricure.com.
- Return the attached Acknowledgement Form. See Attachment B.

Contact Information:
If you have any questions, please contact Rob Cantu, Vice President of Quality at (1-513-644-4245) from 9-6pm ET on Mondays - Fridays. You may also contact customer service at (1-866-349-2342) any time of day, your message will be forwarded to Quality Assurance for review promptly. This advisory issue will also be posted on AtriCure's website at www.atricure.com/products.

Attachment A –Cobra Fusion Ablation System Label Samples

700-002 COBRA Fusion 50	700-001 COBRA Fusion 150
	
700-001S COBRA Fusion 150	**700-001MI COBRA Fusion 150 (International Only)**
	

Attachment B – Device Notification Acknowledgment Form

COBRA Fusion Ablation System

Product Model	Product Codes
COBRA Fusion 50	700-002
COBRA Fusion 150	700-001
COBRA Fusion 150	700-001S
COBRA Fusion 150 (International Only)	700-001MI

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 immediately by fax to 513-895-9085, or by e-mail productrecalls@atricure.com:

☐ 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.

Institution Information:

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

Attachment C –Cobra Fusion Ablation System Instructions "IFU"

Includes highlights of the modifications