

URGENT: cryoICE RECALL NOTIFICATION DUE TO POTENTIAL STERILITY BREACH

November 21, 2014

Dear Health Care Professional and/or Risk Manager:

This is to inform you of a product recall (aka Field Safety Notice) involving:

AtriCure cryoICE cryo-ablation probe (CRYO2); Lot numbers 26500 through 53607

See product label below.



This recall has been initiated due to a packaging defect that could potentially compromise the sterility of this device. Use of a non-sterile device could potentially cause permanent impairment or life-threatening injury. Immediately examine your inventory, quarantine any affected product subject to this recall, and return to AtriCure. As of November 21, 2014, no injuries, impairments, or deaths have been reported.

In addition, if you are a distributor of this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Any units from the affected lots should be returned to AtriCure, Inc. Please contact AtriCure's toll-free Recall Hotline at 844-783-5302 to initiate a return. Please also complete and return the enclosed Device Notification Acknowledgement Form as soon as possible. Your assistance is appreciated and necessary to prevent potential patient harm.

If you have any questions, please call the toll-free Recall Hotline (844-783-5302), M-F, 8:00 AM-8:00 PM EST.

Sincerely,

Anupam Bedi
AtriCure, Inc.
Director of Quality

Device Notification Acknowledgment Form

AtriCure product CRYO2 – AtriCure cryoICE Cryo-Ablation Probe
Product Code: A000683
Lot Numbers: 26500 through 53607

Please determine if you have affected lot numbers and check the appropriate box. Please return this form immediately by fax to 513-644-1918 or 513-644-4456, or scan and email to abedi@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 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 Code	Lot Number	Quantity On-Hand
CRYO2 – A000683		

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:

Please call the toll-free Recall Hotline (844-783-5302) to initiate a return. AtriCure will provide you with a Return Goods Authorization (RGA) number and ship a replacement CRYO2 to your facility.