

## **URGENT Advisory Notice** **AtriCure EPI-Sense® Coagulation System Potential Compromise of Sterile Package Seal**

**Date:** May 29, 2019

**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 EPI-Sense Coagulation System with VisiTrax®**

**Reason for this Communication:**

AtriCure has identified a potential compromise of the sterile package seal for the EPI-Sense Guided Coagulation System. Use of recalled product with a compromised sterile package seal has a worst-case reasonable harm of an infection. AtriCure has not received any reports of any adverse events related to the potential compromise of the sterile package seal.

AtriCure believes that there is a potential for non-sterile product to be delivered to point of use. As a result, AtriCure is proactively requesting devices be returned from five suspect lots for disposition.

**Impacted Product:**

The EPI-Sense Guided Coagulation System with VisiTrax technology is intended for the coagulation of cardiac tissue using Radiofrequency (RF) energy using thoracoscopic, endoscopic, and laparoscopic surgical techniques and may be used for temporary cardiac signal sensing and recording.

<b>Product</b> (See Attachment A for sample labels)	<b>Catalog# (Ref)</b>	<b>UDI</b>	<b>Lots</b>
EPI-Sense Guided Coagulation System	CDK-1413	00818354015249	70638, 71332, 89208, 89938, 90624
EPI-Sense Guided Coagulation System (European configuration)	CDK-1413-EU	00818354015270	89208

**Action Needed:**

- Immediately quarantine any affected product as identified within this Advisory Notice.
- Contact AtriCure product complaints by phone at 1-866-349-2342 (select option 6) or e-mail to [pcomplaints@atricure.com](mailto:pcomplaints@atricure.com) to request a Return Goods Authorization (RGA).
- Return the attached Acknowledgement Form. See Attachment B. The acknowledgement form must be completed and returned even if product is not on hand by selecting the second option.
- Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

**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](http://www.atricure.com/products).

**Attachment A – Epi-Sense Guided Coagulation System Label Samples**

**CDK-1413 & CDK-1413 Product Label**



## Epi-Sense® 3 cm

**REF** CDK-1413

Guided Coagulation System with VisiTrax®  
 Geleid Coagulatiesysteem met VisiTrax®  
 Système de Coagulation Guidé avec Dispositif VisiTrax®  
 Geführtes Gerinnungssystem mit VisiTrax®  
 Sistema per Coagulazione Guidata con VisiTrax®  
 Sistema de Coagulação Guiada com VisiTrax®  
 Sistema de Coagulación con Guía y VisiTrax®

STERILE R
Rx
2
CE  
0086


Contents: (1) CD-1413 device / Inhoud: (1) CD-1413 instrument  
 Contenu : (1) Dispositif CD-1413 / Inhalt: (1) CD-1413 instrument  
 Contenido: (1) Dispositivo CD-1413 / Conteúdo: (1) Dispositivo CD-1413  
 Contenido: (1) Dispositivo CD-1413

AtriCure, Inc.  
 7555 Innovation Way, Mason, OH 45040 USA +1 (866) 349-2342  
Label No. P001351.C

**CDK-1413 – UDI Label**

<b>LOT</b> 123456		<b>REF CAT.</b> CDK-1413	<b>Ass'y No:</b> CDK-1413
<b>EXP DATE</b> 2021-05-01			
			
(01) 0 0818354 01524 9 (17) 210501 (10) 123456			Label P/N: P001148.B

**CDK-1413-EU – UDI Label**

<b>LOT</b> 123456		<b>REF CAT.</b> CDK-1413	<b>Ass'y No:</b> CDK-1413-EU
<b>EXP DATE</b> 2021-05-01			
			
(01) 0 0818354 01527 0 (17) 210501 (10) 123456			Label P/N: P001148.B

**Attachment B – Device Notification Acknowledgment Form  
Epi-Sense Guided Coagulation System**

<b>Product Model</b>	<b>Product Codes</b>
Epi-Sense Guided Coagulation System	CDK-1413
Epi-Sense Guided Coagulation System (European configuration)	CDK-1413-EU

**Lot Numbers: 70638, 71332, 89208, 89938, 90624**

**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](mailto:productrecalls@atricure.com):**

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

<b>Lot Number(s)</b>	<b>Quantity to return</b>

- 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)	