

COHEREX

NO. 10 10 10 10 10 10

3588 West 1820 South
Salt Lake City, Utah 84104
USA

Phone: 801-433-9900
Toll Free: 800-390-9107
Fax: 801-433-9901

www.coherex.com

URGENT FIELD SAFETY NOTICE MEDICAL DEVICE – VOLUNTARY FIELD REMOVAL

CohereX WaveCrest® Left Atrial Appendage (LAA) Occlusion System and Delivery Sheath
Catalog No: WCR1503, WCR1513, WCR1523, WCR1530, WCR1540, WCR1541, WCR1551
Lot No: ALL

August 8, 2014

Dear Valued Customer,

The purpose of this communication is to inform you that a voluntary field safety removal of the COHEREX WAVECREST® LEFT ATRIAL APPENDAGE (LAA) OCCLUSION SYSTEM and delivery sheath has been issued. As the manufacturer of the affected products, CohereX Medical, Inc. has informed Biosense Webster, Inc. as the authorized distributor of the affected products in your area of this field action.

CohereX Medical has become aware of an issue with the CohereX Wavecrest® LAA Occlusion System. Specifically two (2) complaints reported that the delivery sheath was damaged by the constrained occluder as it passed through the sheath. The problem does not affect or impose a risk to patients with implanted devices. There have been no injuries associated with this product issue to date.

Overview:

This letter provides important information concerning the voluntary field removal of a potentially defective product and the instructions for returning the affected units of product you may have at your facility.

Details on Affected Products:

Indications for Use:

The CohereX WaveCrest® Left Atrial Appendage Occlusion System is intended to be used for occlusion of the Left Atrial Appendage in patients who have all of the following:

- Non-valvular paroxysmal, persistent, or permanent atrial fibrillation
- LAA anatomy amenable to treatment by percutaneous techniques
- Risk factors for potential thrombus formation in the LAA

Actions requested on your part:

- Read the "Description of the Problem" section below carefully.
- Immediately identify and set aside all affected product (Catalog number WCR1503, WCR1513, WCR1523) and sheath product (Catalog number WCR1530, WCR1540, WCR1541, and WCR1551) listed in a manner that ensures the affected product will not be used. The catalog number is printed on the outer box label and the catheter pouch label.
- Review, complete, sign and return the attached Voluntary Field Removal - Certification Form in accordance with the instructions listed on the form.

August 8, 2014

- Arrange for return of any affected product that you may have in your inventory per the instructions on the Voluntary Field Removal - Certification Form.
- Pass on this notice to anyone in your facility that needs to be informed.
- Maintain a copy of this letter with the affected product.
- Maintain awareness of this notice until all affected product has been returned.

Description of the Problem:

As the delivery system (implant) is passed through the sheath in its constrained state, it has been observed on two (2) separate occasions that damage can result to the inner liner of the sheath causing potential embolic material. To date, there have been no patient injury or adverse events reported as a result of this issue. However, a partial separation of the sheath material could pose a safety risk to the patient. For this purpose, Coherex medical is voluntarily removing all WaveCrest Occlusion Systems and Delivery Sheaths from the field.

Available Assistance:

For questions related to this issue or product returns please contact your Biosense Webster, Inc. sales representative or call Coherex Medical at (800)-390-9107.

For questions related to the Voluntary Field Removal Certification Form and its return, please contact Urs Huettemann, Field Action Coordinator for Coherex Medical, at +49 172 4547005.

Additional Information:

All of the concerned competent regulatory authorities have been notified and are aware that Coherex Medical, Inc. is voluntarily taking this action.

Coherex regrets any inconvenience that this communication may cause. The quality of our products is a top priority. We know that you place high value in our products and we appreciate your cooperation in this matter.

Sincerely,



Vice President, Regulatory Affairs & Quality Assurance
Coherex Medical, Inc.

Enclosures