COHEREX
MEDICAL

URGENT FIELD SAFETY NOTICE

Coherex WaveCrest® Left Atrial Appendage (LAA) Occlusion System (32 mm)
Catalog No: WCR1523
Lot Number: All

May 7, 2018

Dear Valued Customer,

The purpose of this communication is to inform you that Coherex Medical is initiating a voluntary recall of the following device:

Coherex WaveCrest® Left Atrial Appendage (LAA) Occlusion System (32 mm) Catalog number WCR1523

This letter provides important information about the products subject to this action and instructions on returning them to Coherex Medical if you have any devices in your possession.

Overview:
At Coherex Medical, we have an ongoing commitment to patient safety and continuously monitor the performance of our products to ensure we meet customer expectations.

The Coherex WaveCrest left atrial appendage (LAA) closure device is used to occlude the left atrial appendage and minimize the risk of stroke in patients with Atrial Fibrillation (AF). While deploying the device to its intended location, the physician may need to recapture the device into the delivery sheath.
Coherex Medical has recently identified that when attempting to recapture the 32-mm device, the tip of the delivery sheath may fold or buckle resulting in increased retraction force and difficulty or failure to recapture the device. Complications such as vascular injury, cardiac tamponade, pericardial effusion, head injury, hemorrhage, major bleeding, and prolonged surgery are highly unlikely but may occur due to this issue. The device works as intended; this issue is related to interaction between the delivery sheath and the 32-mm device when they are used as a combination. This issue has not been observed with the 22-mm nor the 27-mm devices.

Two cases have been reported to Coherex in which the device could not be recaptured during deployment. No adverse events were associated with these cases. However, due to the potential safety risk associated with the inability to recapture the device, we decided to prevent further use of the 32mm device with any of the currently available delivery sheaths.
The device works as intended once implanted. Patients who have had a 32-mm device implanted are not at any additional risk.

Lots Subject to Removal:
All Lots of Catalog Number WCR1523

Why Are You Being Contacted:
You are receiving this letter because our records indicate you have received devices subject to this recall.

Coherex Medical
3598 West 1820 South
Salt Lake City, UT 84104
Website: Coherex.com
Tell: (800) 390-9107

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What Actions Are Required

- Complete Business Reply Form (BRF) and return it to your local Coherex representative.
- Evaluate your current inventory of the 32-mm Coherex occluder catalog number WCR1523. If you have inventory from all lots of this product code, remove and return products immediately.
- To return the products, complete the BRF and follow the product return instructions contained within. Contact your local Coherex Representative if further assistance is needed to complete the BRF or if you have questions on product return.
- Complete the BRF within three (3) business days even if you no longer have inventory of the identified products.
- Ensure that anyone in your facility who needs to be aware of this notification reads this letter carefully.
- Maintain a copy of this communication where the inventory of lots identified in this letter is located until all products are returned.

Available Assistance:
For questions related to this issue and product recall please contact your local Coherex representative.

The appropriate Health Authorities have been notified and are aware that Coherex Medical is voluntarily recalling this product.

Coherex Medical regrets any inconvenience that this field action may cause. Patient health and safety is our first priority. We know that you place high value in our products and we appreciate your cooperation in this matter.

Respectfully yours,

V. Kastin

Vadim Kastin
Sr. Director, Quality & Compliance

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