

Urgent Field Safety Notice

Please confirm receipt of this communication to mcorcoran@cardia.com. Cardia is committed to patient safety and appreciates swift attention to this notice. Further contact information can be found at the end of this document.

Product: Ultraseal Left Atrial Appendage Closure Device

BfArM Number 03207/20

Cardia Incident Number MDI01-20

Date: 08-Apr-2020

Attention: Ultrasept LAA Closure Devices users, Generation I

Issue Description:

A manufacturing defect may be present in a small percentage of the initial lots manufactured, which can lead to wire fractures. These fractures can lead to the separation of the distal and proximal sections of the device. If this occurs, the proximal section of the device can embolize. Fractures have been noted in 3 out of 750 devices representing a rate of 0.4%.

These fractures may not be noted during routine follow-up. In one case, the patient had routine follow-ups through twelve months but the fracture was not noted in the six- or twelve-month examinations. A subsequent review of those imaging studies determined that the fracture occurred between three- and six-months post implant.

Product Scope:

All models of the Ultraseal LAA Closure Device with serial numbers up to 750 are potentially affected by this issue.

Product Name	Model Number	Serial Numbers
Ultraseal LAA Closure Device	LAA-16, LAA-18, LAA-20, LAA-22, LAA-24, LAA-26, LAA-28, LAA-30, LAA-32	0001 to 0750

Advised action to be taken by the user:

Patients implanted with these devices should have an additional imaging study to confirm that fracture has not occurred.

Cardia has confirmed that product potentially affected by this issue was been removed from circulation in early 2018. The Competent Authority of your country has been notified.

Please share this communication within your organization, with other organizations where

affected devices have been transferred, and any other associated organizations that may be impacted by this action.

Please maintain a copy of this letter for your records.

Contact reference person:

Please contact the following person if a fracture is discovered or for further information.

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