



Occlutech GmbH • Wildenbruchstr. 15 • 07745 Jena • Germany

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FSCA identifier: **FSCA-20160927**

Date: 2016-09-30

Urgent Field Safety Notice

Occlutech LAA Occluder

Type of action: Field Safety Corrective Action

Dear customer,

We are writing to inform you of a product problem that we have identified with the Occlutech LAA Occluder and provide you with the actions that need to be taken immediately to address the issue. These actions are being taken in response to individual reports that we have received, that indicate an increased level of patient risk with the use of the Occlutech LAA Occluder.

ACTIONS TO BE TAKEN BY THE CUSTOMER

- 1. Identify all patients that currently have an Occlutech LAA Occluder implanted and schedule a clinical follow-up to confirm correct placement of the device.**
- 2. Continued follow-ups should be performed as described in the current labeling: at 1 month, 3 months and 12 months after implantation.**

Affected product / articles	30LAA18, 30LAA21, 30LAA24, 30LAA27, 30LAA30, 30LAA33 All Lots/All Serial Numbers/All Sizes
Problem description	<p>Within the LAA trial and commercial use four dislocations have occurred with Occlutech LAA Occluder. The dislocations occurred both during the procedure (after initial release of the device) and at some point in time after the clinical procedure was completed (Follow-up Phase).</p> <p>Our initial review of these cases clearly indicates that an implementation of a more extensive operator training program and clearer guidance is needed to prevent comparable situations in the future.</p>
Additional information	<p>The attached list shows the devices that were delivered to your facility. These devices have not been returned. Please confirm that these devices have been implanted.</p> <p>Please forward us a report of the performed requested follow-up including the result of the placement of the device.</p> <p>Please send the information immediately to the following contact details.</p> <p style="text-align: center;"><i>Customer Service Occlutech International AB La Cours Gata 2 252 31 Helsingborg Sweden</i></p> <p style="text-align: center;"><i>Tel: +46 (42) 33 65 32 Fax: +46 (42) 311 09 70 E-mail: order@occlutech.com</i></p> <p>Please do not hesitate to contact us for further information.</p>
Action taken by Occlutech	<p>Customer Services and Sales & Marketing have been advised to suspend shipping or selling Occlutech LAA Occluder and remaining products on (consignment) stock are being taken out of circulation. Finally, our RA/Q team has taken the necessary steps to advise authorities.</p> <p>Our internal investigations to identify the Root Cause and to implement necessary corrective actions are ongoing.</p>



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We apologize for these inconveniences and are working to resolve the issue as soon as possible. We trust that this document clarifies all concerns.

Sincerely,

