Occlutech GmbH • Wildenbruchstr. 15 • 07745 Jena • Germany

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FSCA identifier: **FSCA-20170112** Date: 2017-01-23

Urgent Field Safety Notice

Review of Occlutech® Occluder Set Inventory

Type of Action: Field Safety Corrective Action

Dear Customer,

This notice is being sent in response to an isolated report Occlutech has received on the inadvertent use of an expired pusher cable.

Occlutech would like to advise you and end-users to carefully review the Occlutech occluder set labels prior to use, in accordance with the Instructions for Use. In addition, we ask that you take immediate action as set forth below.

ACTIONS TO BE TAKEN BY THE CUSTOMER

1. **Immediately check the expiration dates of the Occlutech occluder and of the pusher cable as printed on the outer box-label of all products in your current inventory.**
2. **If one of the expiration dates is exceeded, block and remove the Occlutech occluder set containing the expired product from your inventory.**
3. **Return the affected Occlutech product sets to Occlutech (see "Return Information / Action by Customer").**
4. **Vigilantly monitor your inventory to make certain that neither of the two expiry dates have been exceeded and handle Occlutech product sets containing expired products according to routine procedure.**

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Affected Product / Articles	**Pusher cables: Flex-Pusher I, Flex-Pusher II, Occlutech Occlusions Pusher** **All Lots/All Serial Numbers/All Sizes** **Occluders:** **Figulla Flex I ASD, Figulla Flex II ASD,** **Figulla Flex I PFO, Figulla Flex II PFO,** **Figulla Flex I UNI, Figulla Flex II UNI,** **Occlutech PDA Occluder,** **Occlutech PLD Occluder,** **Occlutech mVSD Occluder,** **Occlutech FASD Occluder** **All Lots/All Serial Numbers/All Sizes**
Problem Description	A customer inadvertently used an expired Occlutech Flex II Pusher cable and noticed doing so shortly after the implantation procedure. There was no impact on the patient, the procedure, or the product performance. Occlutech occluders and compatible pusher cables are packaged together into an Occlutech product set which also contains the Instructions for Use and the Patient Information card. The outer label on the Occlutech product set clearly shows the expiration dates of both the occluder and the pusher cable. As these dates can differ from each other it is important to check both dates to not miss the shortest expiration date.
Return Information / Action by Customer	If you have identified an Occlutech product set that contains an expired product, please: (1) Remove the Occlutech product set from your inventory; (2) Notify the Occlutech Customer Services (order@occlutech.com) to obtain a Returned Goods Authorization ("RGA"); (3) Return all affected Occlutech product sets to Occlutech: Customer Service Occlutech International AB La Cours Gata 2 252 31 Helsingborg Sweden Tel: +46 (42) 33 65 32 Fax: +46 (42) 311 09 70 E- mail: order@occlutech.com

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Action Taken by Occlutech	Occlutech has notified relevant authorities and will implement a revised Occlutech product set label showing only the shortest expiry date.

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,

[redacted]

Susann Klebon
Safety Officer for Medical Devices
Occlutech GmbH