



Occlutech GmbH • Winzerlaer Straße 2 • 07745 Jena • Germany

FSN identifier: FSN –20190611
FSCA identifier: FSCA –20190611

Date: 2019-06-11

To: Distributors, hospitals & physicians

Urgent Field Safety Notice

Affected Product: Occlutech Delivery Set
REF: 51DS011 / LOT: S18084, S18089 and S19009

FSN identifier: FSN-20190611
Type of action: device destruction

Attention: 11F Occlutech Delivery Sets (ODS) having LOT number S18084, S18089 and S19009 contain malfunctioning (leaking) loaders.

Details on affected devices:

Product name: **Occlutech Delivery Set (11F)**
REF: **51DS011**
LOT: **S18084, S18089, S19009**

Description of the problem:

Occlutech Delivery Sets (ODS) contain several components, including a delivery sheath, loader, hemostatic valve, and a dilator. Occlutech became aware that *three lots of the 11F ODS* contain mis-assembled parts that result in a leaking connection between the loader and the hemostatic valve components of the ODS. The presence / absence of such leaks is detected easily during the pre-procedural “flushing” of the device to remove air bubbles.

Actions to be taken by the user:

1. Distributors, physicians and/or hospitals should immediately inspect their current inventories of *11F Occlutech Delivery Sets* and quarantine and permanently dispose of all products with the following Lot Numbers:

S18084, S18089 and S19009

in such a way as to prevent distribution or usage.

2. Distributors, physicians and/or hospitals should immediately complete the attached Product Reconciliation Form “*Att.1 FSN-20190611_Product reconciliation form*” and return completed forms to Occlutech (see “Contact reference person”, below).

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3. Transmission of this Field Safety Notice: (if appropriate): This notice needs to be shared with users (physicians and/or hospitals) of the affected devices. Please assure and maintain awareness of this FSN among user of affected 11F ODS lots to ensure proper quarantining, destruction and disposal of products.

Action to be taken by Occlutech:

Occlutech has taken all necessary steps to notify relevant authorities and has implement corrective and preventive actions.

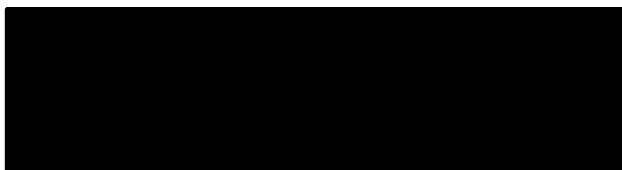
Contact reference person:

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Please do not hesitate to contact Occlutech with question concerning this FSN.

The undersigned hereby confirms that this FSN has been provided to the appropriate responsible person(s) and, if applicable, to the appropriate Regulatory Agencies.



Susann Klebon
Medical Device Safety Officer