
To: Distributor, hospitals, physician

Urgent Field Safety Notice

Affected product: Occlutech Delivery Set, long version (110cm)
FSN identifier: FSN-20190411
Type of action: Recall of products

Attention: The Occlutech Delivery Set long version (110cm) may contain malfunctioning dilator

Details on affected devices:

Product name: **Occlutech Delivery Set**
REF: **51ES006, 51ES007, 51ES008, 51ES009, 51ES010, 51ES011**
LOT: **All for models listed**

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 the dilator tip of the 110cm (long) ODS (REF 51ESXXX) may malfunction (dilator tip detachment). In the event a dilator tip detaches during a procedure, there is a risk of the detached dilator tip embolizing into the patient's circulation, potentially causing lasting injury.

Advise on action to be taken by the user:

1. Distributors, physicians and/or hospitals should immediately inspect current inventories of Occlutech Delivery Sets and quarantine products with the following REF numbers:

51ES006, 51ES007, 51ES008, 51ES009, 51ES010 and 51ES011

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-20190411_Product reconciliation form*" and return completed forms to Occlutech (see "Contact reference person", below).
3. Distributors, physicians and/or hospitals should, within 10 working days, return the affected product(s) to Occlutech:

Occlutech GmbH
Attn. Susann Klebon
Winzerlaer Straße 2
07745 Jena
Germany

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be shared with distributors and users (physicians and/or hospitals) of the affected devices. Please maintain awareness on this notice to ensure the return of affected devices to Occlutech.

Action to be taken by Occlutech:

Occlutech has taken the necessary steps to notify relevant authorities.
Occlutech has initiated activities internally to implement corrective and preventive actions.

Contact reference person:

Susann Klebon
Medical Device Safety Officer
Regulatory Affairs
Occlutech GmbH
Winzerlaer Straße 2
07745 Jena
GERMANY

Tel: +49 (3641) 508 339
Fax: +49 (3641) 508 358
E- mail: susann.klebon@occlutech.com

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

The undersign confirms that this notice has been provided to the appropriate responsible person, or if applicable to the appropriate Regulatory Agencies.



Susann Klebon
Medical Device Safety Officer