



Occlutech International AB

FSN identifier: FSN-2025-001
FSCA identifier: FSCA-2025-001

Date: 2025-02-13

To: Distributors, Hospitals, Physicians

Urgent Field Safety Notice

Affected Product: Delivery cable Flex-Pusher II (51FP100) in combination with Delivery system ODSIII 6F (98DS006 & 98US006) and ODSv1 6F (51US006).

Flex-Pusher II (51FP100) is part of the Procedure Pack with REF: 29ASD06F, 29ASD07F, 29ASD09F, 29ASD10F, 71VSD06F, 89VSD08SF, 84VSD08F, 90VSD08LF

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Notification on the Delivery cable Flex-Pusher II (51FP100) and 6F Delivery system compatibility

Attention:

Occlutech is providing an updated guidance on the Flex-Pusher II delivery cable and delivery system compatibility. Certain Procedure Packs containing Flex-Pusher II (51FP100) have a 6F size recommendation of Occlutech Delivery Set III (ODS III) and Occlutech Delivery Set (ODSv1) that may lead to incompatibility.

Details on affected devices:

Product name: **Procedure Packs containing Flex-Pusher II (51FP100)**
Please refer to *Attachment FSN-2025-001_List of affected products*.

Dear Customer,

This Field Safety Notice is to inform you that Occlutech is voluntarily recalling the procedure packs listed on the *Attachment FSN-2025-001_List of affected products*. We ask that you take note of the recommendations as described below. This Field Safety Notice is limited to the serial numbers mentioned on the list attached to this Field Safety Notice.

Description of the problem:

Occlutech has identified that certain Procedure Packs containing Flex-Pusher II (51FP100) affected by this corrective action have a size recommendation of 6F for ODSIII and ODSv1 on the label of the Procedure Pack box and the sterile pouch of the implant that might lead to incompatibility.

This could happen because the interface between the Flex-Pusher II delivery cable and the ODS (III or v1) Delivery Set is determined by the interaction between the inside diameter of the Delivery Set and the outside diameter of the Delivery cable. When both diameters are at their nominal values, compatibility is assured. However, as tolerances are considered, the dimensions of each device may vary within specified limits: in case of Flex-Pusher II (51FP100) at the upper end tolerance interval and ODS 6F (ODSIII 6F (98DS006 & 98US006)) and ODSv1 6F (51US006)) at the lower end tolerance interval, potential compatibility issues may occur.

Consequences to the patient that may result from the use of the affected device:

- Prolonged procedure: This problem may cause difficulties to push the Flex-Pusher II through the Loader or the Sheath of the Delivery Set. A change of Delivery Set and implant might be necessary which could lead to a prolonged procedure.
- No defect closure (unsuccessful procedure) if there is no second or alternative device available.
- Embolization due to potential inner lumen sheath particles.

The severity of these adverse health consequences is rated as temporary injury.

Any implanted devices are not affected by this issue and do not carry any risk for patient health.

To date, there have been four complaints associated with this incorrect compatibility. No patient adverse events or injury have been reported.

Actions to be taken by the physicians, hospitals and distributors:

1. Check your inventory and determine if you have any of the affected procedure packs: 29ASD06F, 29ASD07F, 29ASD09F, 29ASD10F, 71VSD06F, 89VSD08SF, 84VSD08F, 90VSD08LF.
2. In this case, please quarantine them and contact your direct Occlutech representative to return the products.
3. Please inform clinicians and users who may have the affected procedure packs if you have further distributed them.
4. A written confirmation of the receipt, the reading and understanding of the Field Safety Notice should be provided to info.mdso@occlutech.com, compiling the attached confirmation form. Please also refer to the contact information mentioned at the end of this letter. If you have any questions or would like assistance with this Field Safety Notice, please contact your direct Occlutech representative.



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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 users of the affected devices.

Action to be taken by Occlutech:

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

Contact reference Customer Service:

Occlutech International AB
Landskronavägen 2
SE-252 32 Helsingborg,
Sweden

Contact Email address: order@occlutech.com
Contact Phone Number: +46 76636 7200

Medical Device Safety Officer
E- mail: info.mdso@occlutech.com

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

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