



Occlutech GmbH ■ Winzerlaer Straße 2 ■ 07745 Jena ■ Germany

FSN identifier: FSN-2026-001  
FSCA identifier: FSCA-2026-001

Date: 2026-07-01

To: Distributors, Hospitals, Physicians

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## **Field Safety Notice**

**Affected Product: Figulla Flex II ASD Occluder and its Procedure Pack**  
**REF: 29ASD12, 29ASD15, 29ASD19**

**FSN Identifier : FSN 2026-001**  
**Type of action: Notification of labelling discrepancy**

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### **Attention:**

Occlutech is providing information on a discrepancy in labelling regarding compatible Occlutech Delivery Set III (ODS III) sizes for certain Figulla Flex II ASD and its Procedure Packs. This labelling discrepancy does not pose an inherent risk as the product is safe to use with corresponding information on the label.

### **Details on affected devices:**

Product name: Figulla Flex II ASD Occluder and its Procedure Pack  
Please refer to Attachment *FSN-2026-001\_List of affected products* for further product details

Dear Customer,

This Field Safety Notice is to inform you that Occlutech has initiated a voluntary Field Safety Notice for the products listed on the Attachment *FSN-2026-001\_List of affected products*. This Field Safety Notice is limited to the serial numbers listed in the attachment.

### **Description of the problem:**

Labels for two different compatible Occlutech Delivery System (ODSIII) sizes are visible on the Tyvek pouch of the affected products (implants). The implant is compatible with both ODS III sizes, which was demonstrated in bench tests. Therefore, this labelling discrepancy does not pose an inherent risk as the implant is safe to use with either information on the label.

### **Actions to be taken by the distributors, physicians and/or hospitals:**

1. Inform clinicians and users of the label discrepancy regarding compatible ODS III sizes.
2. A written confirmation of the receipt, the reading and understanding of this Field Safety Notice should be provided to [order@occlutech.com](mailto:order@occlutech.com), or to your local sales representative compiling the attached confirmation form. If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.



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**Recommendation:**

Either the distributor or hospital should attach a copy of this Field Safety Notice to the outer box of any affected products to serve as a reminder.

**Transmission of this Field Safety Notice:**

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 Figulla Flex II ASD Occluder and its Procedure Pack products to ensure proper use 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:**

**Customer Service**

Occlutech International AB  
Landskronavägen 2  
SE-252 32 Helsingborg  
Sweden  
Tel: +46 766 36 72 00  
E- mail: [order@occlutech.com](mailto:order@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.

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*Vice President Regulatory Affairs and Quality*  
*Occlutech GmbH*



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Attachment *FSN-2026-001\_List of affected products*

| Serial Number | REF     | Product name / description     | Manufacturing date | Expiry date |
|---------------|---------|--------------------------------|--------------------|-------------|
| 2548291526_02 | 29ASD15 | Figulla Flex II ASD, size 15   | 2022-06-23         | 2027-05-25  |
| 2547291248_01 | 29ASD12 | Figulla Flex II ASD, size 12   | 2022-03-31         | 2027-03-02  |
| 2548291526_01 | 29ASD15 | Figulla Flex II ASD, size 15   | 2022-06-23         | 2027-05-25  |
| 2548291526_04 | 29ASD15 | Figulla Flex II ASD, size 15   | 2022-06-23         | 2027-05-25  |
| 2548291535_02 | 29ASD15 | Figulla Flex II ASD, size 15   | 2022-07-07         | 2027-06-08  |
| 2548291535_03 | 29ASD15 | Figulla Flex II ASD, size 15   | 2022-07-07         | 2027-06-08  |
| 2547291969_01 | 29ASD19 | Figulla Flex II ASD, size 19,5 | 2022-04-13         | 2027-03-15  |
| 2547291247_01 | 29ASD12 | Figulla Flex II ASD, size 12   | 2022-04-05         | 2027-03-07  |
| 2548291535_01 | 29ASD15 | Figulla Flex II ASD, size 15   | 2022-07-07         | 2027-06-08  |



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## FSN Confirmation form

| 1. Field Safety Notice (FSN) information |                                                   |
|------------------------------------------|---------------------------------------------------|
| FSN Reference number                     | FSN-2026-001                                      |
| FSN Date                                 | 2026-06-25                                        |
| Product/ Device name                     | Figulla Flex II ASD                               |
| Affected articles / REF                  | 29ASD12, 29ASD15, 29ASD19                         |
| Affected LOT / SN Number                 | See <i>FSN-2026-001_List of affected products</i> |

| 2. Customer (Distributor / Hospital / Physician) identification* |  |
|------------------------------------------------------------------|--|
| Customer / Organisation Name                                     |  |
| Customer / Organisation Address                                  |  |
| Department/Unit (if applicable)                                  |  |
| Contact Name                                                     |  |
| Title or Function                                                |  |
| Telephone number                                                 |  |
| Email                                                            |  |

| 3. Confirmation*                                                                                                                                                                                                        |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| With my signature below I confirm receipt, the reading and understanding of the Field Safety Notice. I confirm that I followed the recommendation to attach a copy of the Field Safety Notice to the outer product box. |  |
| Print Name                                                                                                                                                                                                              |  |
| Signature                                                                                                                                                                                                               |  |
| Date                                                                                                                                                                                                                    |  |



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| 4. Return acknowledgement to sender        |                                                                      |
|--------------------------------------------|----------------------------------------------------------------------|
| Email                                      | <a href="mailto:info.mdso@occlutech.com">info.mdso@occlutech.com</a> |
| Postal Address                             | Occlutech GmbH<br>Winzerlaer Straße 2<br>07745 Jena<br>GERMANY       |
| Fax                                        | +49 (3641) 508 358                                                   |
| Deadline for returning the completed form* | 10 days after receipt the Field Safety Notice                        |

*Mandatory fields are marked with \**

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the actions.