

Urgent Field Safety Notice

Recall of

DynaMesh®-IPST-R visible surgical meshes for parastomal hernia repair in Italy

July 7th, 2023

FEG Textiltechnik reference: R-2023-30-FSCA
EU-Single registration number (SRN): DE-MF-000005284

Dear Madam/Sir,

With this Urgent Field Safety Notice (FSN), FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH informs you about the voluntary recall of **DynaMesh®-IPST-R visible** in Italy. The affected devices are surgical meshes used for parastomal hernia repair.

Issue description:

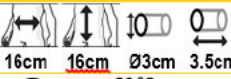
A user reported to us that a **DynaMesh®-IPST-R visible** device was found in a **DynaMesh®-IPST visible** packaging during a surgery. The labels on the outer and inner packaging did not match. Based on this report, we suspect that there is a second product with incorrect labels: A **DynaMesh®-IPST-R visible** packaging with a **DynaMesh®-IPST visible** inside. In the hypothetical case that a surgeon uses the **DynaMesh®-IPST visible** instead of the **DynaMesh®-IPST-R visible**, we do not expect to see any deterioration in performance or safety of the device since both are indicated for parastomal hernia repair. However, the application of the device with respect to the surgical technique differs. In a worst-case scenario the physician may decide to abort the surgery in the absence of the correct product. Since this type of surgery is typically performed in patients who are already very sick, postponing the surgery may have particularly detrimental effects. Therefore, FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH recalls in total seven (7) **DynaMesh®-IPST-R visible** surgical meshes delivered to Italy where one of the seven potentially includes a **DynaMesh®-IPST visible** surgical mesh inside the packaging. This voluntary recall affects only the item code with associated lot number listed below.

Packaging process improvements have been implemented to remediate this issue.






Identification of the affected medical device:



- Product name: DynaMesh®-IPST-R visible
- REF: IP113316F1
- LOT: 4021/1105/9
- Expiry date: 2027-11
- Manufacturing date: 2022-12
- Country delivered: Italy

The package label contains the following contents:

DynaMesh® - IPST-R visible 

2027-11



    

(01)04250274706399 (17)271100(10)402111059 (01)04250274706399(17)271100(10)402111059

Vertrieb durch / distributed by **DAHLHAUSEN®** P.J. Dahlhausen & Co. GmbH 50996 Köln / Germany Emil-Hoffmann-Str. 53 Tel.: +49 (2236) 3913 0 Fax: +49 (2236) 3913 109 www.dahlhausen.de Art. Nr. 2610780315 PZN

DynaMesh® - IPST-R visible E83 Rev02
2023-20660

REF IP113316F1 **LOT** 4021/1105/9 **2022-12**
03x16x16cm (L3.5) **BX** 1 EA

en Mesh implant for parastomal hernia repair
it Impianto a rete per la riparazione dell'ernia parastomale

Required actions for customers in Italy:

- Please check whether the affected products are in your stock. If so, please quarantine the affected products to prevent usage and further delivery.
- Please inform your customers about the measure and retrieve all affected products.
- Please return all affected products to FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH as soon as possible.
- Please fill the Distributor Reply Form and return it to FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH within 10 business days.
- This FSN should be passed on to all those who need to be aware within your organization. If you have passed on affected products, please forward this FSN to those recipients.

Additional information:

FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH has notified the Competent Authority of your country of this action.

Please keep this information at least until the measure has been completed.

We regret any inconvenience this action may cause. If you have question regarding this Urgent Field Safety Notice please contact Michael Krumbiegel via +49 241 1892374-13 or m.krumbiegel@dyna-mesh.com.

Thank you very much for your cooperation!

Sincerely,

FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH

Distributor Reply Form

1. Field Safety Notice (FSN) information		
FSN Reference number	R-2023-30-FSCA	
FSN Date	July 2023	
Product/ Device name	DynaMesh®-IPST-R visible	
Product Code(s)	IP113316F1	
Batch/Serial Number (s)	4021/1105/9	
2. Distributor/Importer Details		
Company Name*		
Address*		
Shipping address if different to above		
Contact Name*		
Title or Function		
Telephone number*		
Email*		
3. Return acknowledgement to Sender		
Email	u.schuette@dyna-mesh.com	
Phone	+49 241 1892374-54	
Postal Address	Prager Ring 70, 52070 Aachen, Germany	
Deadline for returning the Distributor/Importer reply form	10 business days after receipt of FSN	
4. Distributors/Importers (Tick all that apply)		
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
<input type="checkbox"/>	I have identified customers that received or may have received this device	
<input type="checkbox"/>	I have attached customer list	
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication:
<input type="checkbox"/>	I have received confirmation of reply from all identified customers and saved the corresponding documentation locally.	
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		
Signature*		
Date *		

Mandatory fields are marked with *