Urgent Field Safety Notice

Recall of

DynaMesh®-IPST surgical meshes for parastomal hernia

January 10th, 2024

FEG Textiltechnik reference: R-2024-01-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 a specific batch of **DynaMesh®-IPST** containing one (1) erroneously labelled device. During the preparation of this Urgent Field Safety Notice, the erroneously labelled device has already been identified. **DynaMesh®-IPST** surgical meshes are used for parastomal hernia prevention and repair.

Issue description:
During an inventory, it was discovered that there was a discrepancy between products in the sterile warehouse and products shipped with two model numbers of DynaMesh®-IPST. We suspected that one of the delivered packages contained a different product from what was stated on the label (*i.e*. DynaMesh®-IPST Ref IP070417F1 LOT 3523/1107/2 with the packaging label showing DynaMesh®-IPST Ref IP070316F1 LOT 3523/1107/2). The two products differ in size: According to the label, the expected product DynaMesh®-IPST with REF IP070316F1 has a base area of 16 x 16 cm and a funnel diameter of 3 cm. The incorrectly packaged product DynaMesh®-IPST with REF IP070417F1 has a base area of 17 x 17 cm and a funnel diameter of 4 cm.

If a larger funnel diameter is used, there is an increased risk of occurrence or recurrence of a parastomal hernia. Therefore, FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH prepared a recall of 31 DynaMesh®-IPST surgical meshes with REF IP070316F1, one of which was suspected to be the faulty DynaMesh®-IPST surgical mesh with REF IP070417F1 inside the packaging. This voluntary recall affected only the item code with associated lot number listed below. During the preparation of this Urgent Field Safety Notice, the faulty DynaMesh®-IPST surgical mesh with REF IP070417F1 with the packaging label showing DynaMesh®-IPST with REF IP070316F1 was found in a delivery to a distributor in Germany. **As the wrongly labelled DynaMesh®-IPST surgical mesh has been found, no further actions are necessary from your side**. **No further products need to be returned. All DynaMesh®-IPST surgical meshes, including devices with the REF IP070316F1 and LOT 3523/1107/2 identified below can be used according to the instructions for use.**

This letter serves as a notification for your records regarding the retrieval of one non-implanted product. Please share this notice with those who need to be aware within your organization.

Packaging process improvements are currently investigated to prevent similar issues in the future.

DynaMesh®
by FEG Textiltechnik
Forschungs- und Entwicklungs-
gesellschaft mbH

Prager Ring 70
52070 Aachen, Germany
Tel: +49-(0)241-18 92 37 4-0
Fax: +49-(0)241-18 92 37 4-59

www.dyna-mesh.com
Geschäftsführer:
Dr.-Ing. Boris Obolenski
Dipl.-Ing. Stefan Schneemelcher

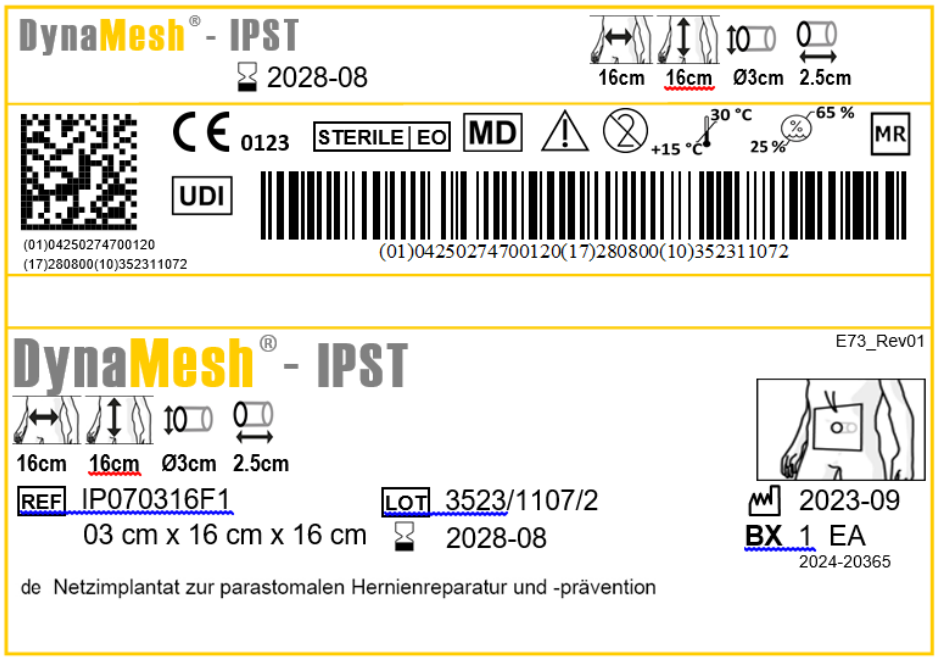
Amtsgericht: Aachen
HRB 5252
USt.-Id.-Nr. DE 153211727
Steuernummer: 20159583245

Bankverbindung:
Aachener Bank e.G.
SWIFT-BIC GENODED1AAC
IBAN DE92 3906 0180 1123 9850 24

Identification of the affected medical device:

- Product name: **DynaMesh®-IPST**
- REF: IP070316F1
- LOT: 3523/1107/2
- Expiry date: 2028-08
- Manufacturing date: 2023-09

The package label contains the following information:



Additional information:

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

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

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