EXTRUDAN®
more Sustainable Medical Devices
Est. 1984

INTERSURGICAL®
BEATMUNGS-PRODUKTE GMBH
Siegburger Str. 39
53757 Sankt Augustin
Tel.: 02241-25690 | Fax: 02241-2569222
anfrage@intersurgical.de

20.02.2023

FIELD SAFETY NOTICE

FSN - 1/2022 – A

Expanded Recall

Dear Sir or Madam,

From the information we obtained, it appears that you have the product listed below.

Identification of affected medical device:

Product name: Connecting Tube

Model: Connecting Tube; FINGERTIP – FUNNEL – MULTILUMEN TUBE

Basic UDI-DI: 59077466MLTUBE2J

REF: 1300.1800.80.ML

UDI: 5907746600592

Affected LOTs numbers: **220210/9 , 220310/3 , 220428/60**

Extrudan is now expanding the Recall to include LOT: **220707/3**

Description of the problem:

During the checking of the portable suction pumps, the leakage problem occurred. After connecting the suction tube, the system indicated a malfunction. According to the information gathered from the customers and tests performed on the non-conforming products, the connection between the tube and the connector is not stable which causes leakage. To ensure continued safety, Extrudan decided to recall all affected devices from the above-mentioned LOTs.

Measures to be taken:

1. Please check your inventory to see if you have any products of the above reference and LOTs numbers and sort them out to ensure that the products are not used.

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2. If the above-mentioned products are in your inventory inform your distributor **Intersurgical GmbH**.
3. Please complete and return the reply form (Appendix A) to confirm that you have read and understood the contents of this Field Safety Notice and send it to **Intersurgical GmbH** by email or fax.
4. Dispose the non-conforming medical devices in-line with local and Government guidelines. You will receive a credit note for the disposed goods.

Please ensure that all users of the above products in your organization and other persons to be informed are made aware of the recall. If you have passed products on to third parties, please forward a copy of this information to them.

Please keep this information at least until the action has been completed at your site.
The BfArM was informed about the safety corrective action and recall.

Contact person from the manufacturer side:

Quality Manager - [redacted]
Dąbrówka ul. Polna 5,
62-070 Dopiewo, POLAND
Phone: +48 61 814 33 58

Please do not hesitate to contact us if you have any further questions or require further information.
Please accept our apologies for any inconvenience that our product caused you.
We would like to thank you for your understanding and cooperation.

For and on behalf of Extrudan Sp. z o.o.

[redacted] Quality Manager

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Appendix C

Customer (Healthcare organization) Reply Form

1. Field Safety Notices (FSN) information	
FSN Reference number*	FSN – 1/2022-A
FSN Date*	20.02.2023
Product/ Device name*	Connecting Tubes FINGERTIP – FUNNEL - MULTILUMEN
Product Code(s)	1300.1800.80 ML
LOT number (s)	220210/9, 220310/3, 220428/60, 220707/3 newly added

2. Customer Details	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation			
☐	*I confirm receipt of the Field Safety Notice and that I read and understood its content.		
☐	*The information and required actions have been brought to the attention of all relevant users and executed		
☐	The following products were identified for disposal (if applicable)	LOT: LOT:	Quantity: Quantity:
☐	All identified products have been disposed of: (if applicable)		
☐	I do not have any affected devices.		
Print Name*			
Signature*			
Date*			

Mandatory fields are marked with *

Return the completed form to your local distributor representative by e-mail anfrage@intersurgical.de or fax: 02241-2569222

Please contact your local distributor representative or Extudan Sp. z o.o. directly for replacement or credits for any defective products identified. Evidence will be required for any quarantined and/or destroyed items.

Deadline for returning the Distributor reply form – 31st March 2023