FSN Ref: 7c_03_FSN_0624
FSCA Ref: 7c_03_FSCA_0624

Date: 2022-06-28

Urgent Field Safety Notice (FSN)
Dringender Sicherheitshinweis
ENT-single-use suction tube, rhinology

For Attention of: Affected users and distributors

Contact details
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Information on Affected Devices

Device Type

ENT-single-use suction tubes, angled, rounded tip, suction control on side 100x 2.5 mm, sterile, 50 pieces/box
ENT-single-use suction tubes, angled, rounded tip, suction control on side 100x3.0 mm, sterile, 50 pieces/box
ENT-single-use suction tubes, angled, rounded tip, suction control on side 100x4.0 mm, sterile, 50 pieces/box

The products are single-use suction tubes for the removal of liquids/tissue, e.g. from the surgical field, in the areas of ENT respectively head and neck surgery. In particular, the products affected by this FSCA are sinus suction tubes, purpose-built for use in the paranasal sinuses. Sinus suction tubes have an olive, which is attached distally to ensure atraumatic use on patients.

Commercial name

ENT-single-use suction tube, rhinology

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Description of the product problem

Through one of our customers, we have become aware of a problem with our ENT-single-use suction tubes with a (distal) rounded tip.
In a few products, the rounded tip can detach from the shaft.
The hazard can be traced back to an error in the assembly of the shaft and olive. The risk exists only for the batches identified as affected.
The resulting risk for the patient, is that the tip could be left behind in the treated area or could be aspirated, which may lead to a severe health impairment for the patient.
To date are we not aware of such a case.

Affected Products

REF	LOT
3010025	20181130
3010030	20181130
3010040	20181130

List of measures

1. Please check your inventory regarding the product affected by the recall. Stop using or distributing the affected LOT numbers and quarantine them immediately.
2. If you do not have an inventory of affected products, please tick the appropriate box on the Customer Reply Form (see Annex 1) and send it to the e-mail address indicated.
3. If you have a stock of affected products, please send an email to vigilance@spiggle-theis.com. You will then receive a return number. Please enter this return number in the intended section of the enclosed Customer Reply Form.
4. As a distributor: Forward this safety information to all customers who have received a product affected by this safety information.
5. Please fill in the Customer Reply Form with all details of the products in your area of responsibility that are affected by the recall action and send it to vigilance@spiggle-theis.com.
6. Please coordinate the return of the affected products with your Customer Service representative or your distributor.
7. SPIGGLE & THEIS Medizintechnik GmbH (or the distributor responsible for you) will issue you a credit note upon receipt of the products.

Disclosure of the information described on this form

Please ensure that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Safety Notice. If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated above.
Please keep this information at least until the measure has been completed.

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
List of attachments/appendices:	Annex 1
Name/Signature	
	… … Medical Device Safety Officer

Annex 1

Customer Reply Form
RECALL – ENT-single-use suction tube, rhinology

Please fill out this customer reply form completely and send it back to us immediately via Email: vigilance@spiggle-theis.com

Please tick the box that applies to you and complete the following fields.

☐ We hereby confirm that we have received the Field Safety Notice information (FSN) and that the contents have been read and understood. We further confirm that we have NO affected products in our organization's inventory.	☐ We confirm that we have received the Field Safety Notice information (FSN) and that the contents have been read and understood. We further confirm that we either DO HAVE affected products at our organization's inventory or have distributed them to end customers. All measures requested by the FSN are completed. All affected products have been quarantined and the products with the LOT numbers listed below will be returned.

Product Code (REF)*	Batch (LOT)	Quantity boxes / Quantity product

- Please enclose a copy of this completed customer reply form with the return shipment.

* If you return more than 3 products, please list the numbers in an attachment.

Return number: _____

Institution Name (e.g. name of hospital, distributor)	
Institution Address	
Telephone Number/ Fax	
Email Address	
Form filled in by Name (in block letters)	Signature, Date

Many thanks for your kind support.