FSN Ref: 1b_01_FSN_0331
FSCA Ref: 1b_01_FSCA_0331

Date: 2023-04-11

Urgent safety information
Recall
Sterilisation containers for middle ear implant length measurement dummies

For the attention of: Affected users and distribution partners

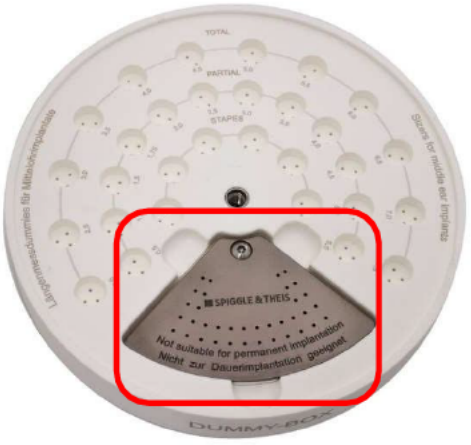
Contact details

[redacted]
SPIGGLE & THEIS Medizintechnik GmbH
Burghof 14
51491 Overath
Germany
Phone: +49 2206 9081 –[redacted]
Mobile:[redacted]
vigilance@spiggle-theis.com

Information about the affected product

Product type

Sterilisation containers for middle ear implant length measurement dummies, non-sterile



The product concerned is a sterilisation container for the sterile reprocessing (cleaning, disinfection, sterilisation) of middle ear implant length measurement dummies made of titanium.

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Commercial name

Sterilisation containers for middle ear implant length measurement dummies (dummy box)

Description of the product problem

One of our customers has alerted us to a problem with regard to the reprocessing of middle ear implant length measurement dummies within the sterilisation container. After cleaning in the cleaning and disinfection unit, liquid residues remained in the container; the presence of these residues made it impossible to guarantee safe and sterile reprocessing of the middle ear implant length measurement dummies.
There are no other comparable complaints about the product that would confirm this problem. Nevertheless, SPIGGLE & THEIS Medizintechnik GmbH decided to make a design change to further minimise potential weak points. However, a review of the reprocessing routine after the design change revealed that despite successful cleaning of the products, sterilisation of the middle ear implant length measurement dummies in the sterilisation container cannot be ensured.
The hazard can be traced back to the design of the sterilisation container. The risk exists for all batches produced to date.
The resulting risk to patients is possible bacterial infection or pyrogenic reactions from the use of non-sterile middle ear implant length measurement dummies in the middle ear. So far, we are not aware of any such cases, however.

Affected products

REF	LOT
DUMMY BOX	All

List of measures

1. Please check your stocks for the products affected by the recall. Do not use or distribute the products any more and quarantine them immediately.
2. If you do not have any stock of the affected products, please tick the appropriate box on the customer response form (see Annex 1) and send the form to the e-mail address provided.
3. If you do have any stock of the affected products, please send an e-mail to **vigilance@spiggle-theis.com.** You will then receive a return authorisation number. Please enter this number in the designated section of the attached customer response form.
4. As a retailer: Forward this safety information to all customers who have received a product affected by this safety information.
5. Please complete the customer response form and provide all the details on the products within your domain of responsibility that are affected by the recall, and then send the form to **vigilance@spiggle-theis.com.**

6. Please coordinate the return of the affected products with your customer service representative or your retailer.
7. SPIGGLE & THEIS Medizintechnik GmbH (or the distributor responsible for you) will issue you a credit note upon receipt of the products.

Passing on the information described in this form

Please ensure that all users of the above-mentioned product and other people who need to be informed are made aware of this urgent safety notice. If you have passed products on to third parties, please forward a copy of this information or inform the contact named above.
Please keep this information at least until the measure is completed.

The competent (regulatory) authority in your country has been informed of this notification to customers.	
List of annexes/attachments:	Annex 1
Name/signature	[redacted] [redacted] PRRC

FSN Ref: 1b_01_FSN_0331
FSCA Ref: 1b_01_FSCA_0331

Annex 1

Customer response form
Recall
Sterilisation containers for middle ear implant dummies

Please complete this customer response form in full and return it to us immediately by e-mail: 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 we have read and understood its contents. We further confirm that we do NOT have any affected products in our organisation's stock.	☐ We confirm that we have received the information in the Field Safety Notice (FSN) and that we have read and understood the contents. We further confirm that we either HAVE the affected products in our organisation's stock or have passed them on to consumers. All required measures from the FSN have been completed. All affected products have been quarantined and the products with the lot numbers listed below will be returned.

Product number (REF)*	Batch (LOT)	Number of boxes / number of units of product

- - Please enclose a copy of this completed response form with your return shipment.
- * If you are returning more than 3 products, please indicate the exact number in a separate attachment.

Return authorisation number: _____

Name of the institution (e.g. name of hospital, retailer)	
Address of the institution	
Telephone number / fax	
E-mail address	
Form completed by _____ Name (in block capitals) _____ Signature, date	

Many thanks for your support.

FSN Ref: 5a_14_FSN_0331
FSCA Ref: 5a_14_FSCA_0331

Date: 11 April 2023

Urgent safety information
Recall
Middle ear implant length measurement dummies

For the attention of: Affected users and distribution partners

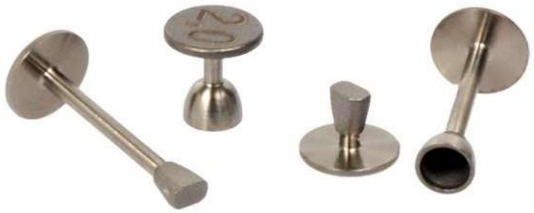
Contact details
[redacted]
SPIGGLE & THEIS Medizintechnik GmbH
Burghof 14
51491 Overath
Germany
Phone: +49 2206 9081 – [redacted]
Mobile: [redacted]
vigilance@spiggle-theis.com

Information about the affected product

Product type

Middle ear implant length measurement dummies, non-sterile

The products concerned are titanium middle ear implant length measurement dummies that are used to measure the required implant length.



Commercial name

Length measurement dummy for PORP/TORP implants

FSN Ref: 5a_14_FSN_0331
FSCA Ref: 5a_14_FSCA_0331

Description of the product problem

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Affected products

REF	LOT	REF	LOT
11000-D20	All	12000-D05	All
11000-D25	All	12000-D10	All
11000-D30	All	12000-D15	All
11000-D35	All	12000-D17	All
11000-D40	All	12000-D20	All
11000-D45	All	12000-D25	All
11000-D50	All	12000-D30	All
11000-D55	All	12000-D35	All
11000-D60	All	12000-D40	All
11000-D65	All	12000-D45	All
11000-D70	All	12000-D50	All
11000-D75	All	12000-D55	All

List of measures

1. Please check your stocks for the products affected by the recall. Do not use or distribute the products anymore and quarantine them immediately.

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Address of the institution	
Telephone number / fax	
E-mail address	

Form completed by

_____ Name (in block capitals)

_____ Signature, date

Many thanks for your support.