FSN Ref: 5a_12_FSN_0625
FSCA Ref: 5a_12_FSCA_0625

Date: 2025-06-25

Urgent safety information
Recall
Injection needle

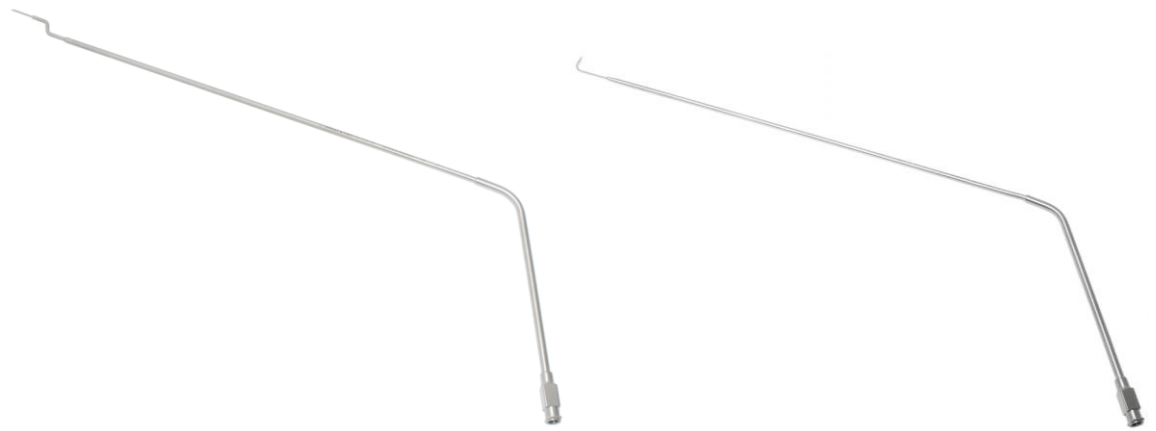
For the attention of: Affected users and distributors

Contact details
Thomas Nüsse SPIGGLE & THEIS Medizintechnik GmbH Burghof 14 51491 Overath Germany Phone: +49 2206 9081 - 26 Mobile: +49 172 4300458 vigilance@spiggle-theis.com

Information about affected product

Product type

Injection needle, bayonet, Luer-Lock, working length 25 cm, total length 31 cm, non-sterile
Injection needle, curved, Luer-Lock, working length 24 cm, total length 31 cm, non-sterile



The product is an injection needle with a Luer-Lock connection for injecting irrigation fluids into tissue and body cavities and for opening body cavities.

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Trade name

Injection needle

Description of the product problem

The affected product is laser-marked, passivated and finally cleaned by a subcontractor. To check the success of the final cleaning, a cytotoxicity test, bioburden, endotoxin and the determination of THC and TOC values are carried out once a year. The batch of injection needles now tested showed cytotoxicity in the tests for the first time. All other tests showed no abnormalities. The cytotoxicity tests were repeated twice with a larger test scope and showed inconclusive results with increased cytotoxicity values in some cases.
The manufacture of the products has not been changed since the last test and no new auxiliary and operating materials have been used. The parameters for laser marking, passivation and final cleaning have also remained unchanged. Cytotoxicity tests are non-specific in-vitro tests that do not allow any statement to be made about the quantity or quality of the contamination. As the cause of the cytotoxicity cannot be determined at present, the injection needles (REF 50-353-23) of the affected batch and the comparable injection needle (REF 50-345-23) are being recalled. As previous batches did not show any abnormalities, these are excluded from the recall.
There are no other comparable complaints about the product that confirm this problem.
The risk can be traced back to an unidentified contamination. Due to regular testing, the risk only exists in the batches affected by the recall.
The resulting potentially very low risk for patients is a possible intolerance reaction or an allergic reaction due to the use of the injection needles in question. We are not aware of any such case to date.

Affected products

REF	LOT		REF	LOT
50-345-23	2230438		50-353-23	(0)2241239
	2240251			

List of measures

1. Please check your stocks for the product affected by the recall. Do not use or distribute the product and quarantine it immediately.
2. If you do not have an inventory of affected products, please check the appropriate box on the customer response form (see Appendix 1) and send the form to the email address provided.
3. If you have a stock of the affected product, please send an e-mail to vigilance@spiggle-theis.com. You will then receive a return number. Please enter this return number in the appropriate section of the enclosed 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 with all details of the product in your area of responsibility that is affected by the recall and send it to vigilance@spiggle-theis.com.
6. Please coordinate the return of the affected products with your customer service representative or your dealer.
7. SPIGGLE & THEIS Medizintechnik GmbH (or the distributor responsible for you) will issue a credit note upon receipt of the products.

Passing on the information described in this form

Please ensure that all users of the above product and other persons to be informed are made aware of this urgent safety notice. If you have passed the products on to third parties, please forward a copy of this information or inform the contact person named above.
Please keep this information at least until the action has been completed.

The competent (regulatory) authority in your country will be informed of this notification to customers.	
List of annexes/attachments:	Appendix 1
Name/Signature	 Thomas Nüsse PRRC

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Appendix 1

Response form for customers
Injection needle recall

Please complete this customer response form in full and return it to us immediately by e-mail: vigilance@spiggle-theis.com

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

☐ We hereby confirm that we have received the Field Safety Notice (FSN) and that we have read and understood its contents.

- We **do not have any affected products** in our organization's inventory.
- If we are a dealer or a purchasing department, we also confirm that we have informed all relevant downstream departments or customers about the recall and that **they also have no affected products in their inventory**.

☐ We confirm that we have received the information in the Field Safety Notice (FSN) and that we have read and understood the content.

- We have **affected products** in our organization.
  All measures described in the FSN have been implemented. The affected products have been quarantined.
- If we are a distributor or a central purchasing department, we have ensured that all measures described in the FSN have been implemented at **our customers or specialist departments** and that the products have been quarantined.
  All affected products from our customers or specialist departments are recorded centrally by us and sent to SPIGGLE & THEIS in a collective delivery.

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

☐ **All final** feedback from our customers or specialist departments has been received.
☐ **Not** all feedback from our customers or specialist departments has been received **yet**.

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

Return number: _____

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

Thank you for your support.