

**FB 8.5.8  
Field Safety Notice (FSN)**

Date: 2023-07-28	Type of measure: <b>Recall</b>
FSN/FSCA-REF.-Nr.: AE-CO-013-2023	

**Urgent field safety notice (FSN)  
Recall action - measures required**

Dear Customer,

Si Us Instruments GmbH has issued a voluntary recall for the product listed below.  
issued.

According to our records, you have received products from one of the LOT numbers listed below.

**We urge you not to use any of these suction cannula and to return the suction cannula still in your inventory.**

Product	Cannula tip closed with side openings, scaled, OD 2.4 mm, length 100 mm
Article-no.	SUXCA1494
Unique Device Identifier(s) (UDI-DI)	n.a.
Medical intended use	Blunt hollow needle for tissue-friendly aspiration of secretions and fluids.
Batch / LOT-Number	2405205233C
Expiry date	2025-05-23
Date of delivery	Various

**Defects in the product, the cause of the security message**

Si Us Instruments GmbH is recalling the product listed above after a customer reported that the suction cannula was found to be contaminated (cleaning residue) in the primary/sterile packaging (peel bag) during an obligatory visual inspection (incoming goods inspection) and the product was reported/complained to us accordingly. As an immediate measure / action, the affected suction cannulas were immediately blocked by the customer for further use.

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**Emanating risk from the product**

All affected customers were immediately contacted by telephone in advance of this urgent safety notice and instructed to block the potentially affected products.

Since the suction cannulae in question were blocked for further use immediately after the above-mentioned defects were discovered and were not put to use, none of the following consequences could have occurred, either directly or indirectly:

- (a) the death of a patient, user or other person,
- (b) the temporary or permanent serious deterioration of the state of health of a patient, user or other person,
- (c) a serious risk to public health.

**Instructions for action / Necessary measures**

The product must be discarded. Discarded products must be returned to the manufacturer according to the instructions for use.

Upon receipt of the returned affected products, you will receive a credit note.

Please pass on this safety information to all persons within your company to all persons within your company or in other companies to whom potentially affected products have been passed on and who need to be informed about the Urgent Safety Information. need to be informed.

Please keep this information at least until the measure has been completed.

The Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this Urgent Safety Information.

For all inquiries the followings contacts are available	
Department	Customer service
E-mail	info@si-us-instruments.de
Customer hotline	+49 30 351 364 36
Address	Si Us Instruments GmbH Max-Planck-Str. 3 12489 Berlin Deutschland
Website	www.si-us-instruments.de
Fax	+49 30 690 887 10
Available Monday to Friday from 09:00 a.m. to 05:00 p.m.	

**FB 8.5.8**  
**Field Safety Notice Customer Reply**  
**Returning Form**

**Safety Information from Si Us Instruments GmbH - For Urgent Attention**

<b>Field Safety Notice (FSN) information</b>	
FSN Reference number*	AE-CO-013-2023
FSN Date*	28.07.2023
Product/ Device name*	Cannula tip closed with side openings, scaled, OD 2.4 mm, length 100 mm
Product Code(s)	SUXCA1494
Batch/Serial Number (s)	2405205233C

<b>Customer Details</b>	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

<b>Customer action undertaken on behalf of Healthcare Organisation</b>				
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):

## FB 8.5.8 Field Safety Notice Customer Reply Returning Form

		N/A	Comments:
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:
		N/A	Comments:
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
<input type="checkbox"/>	Other Action (Define):		
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A	
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query	
Print Name*			
Signature*			
Date*			

Return acknowledgement to sender	
Email	info@si-us-instruments.de
Customer Helpline	+49 30 351 364 36
Postal Address	Si Us Instruments GmbH Max-Planck-Str. 3 12489 Berlin Germany
Web Portal	www.si-us-instruments.de
Fax	+49 30 690 887 10
Deadline for returning the customer reply form*	<b>04.08.2023</b>

Mandatory fields are marked with \*

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.