

FSN Ref.: RAN 21019

Date: 25.03.2021

Urgent Field Safety Notice

Biopsy Handy and Puncture Sheath

For Attention of: User and distributors

Contact details (name, e-mail, telephone, address etc.)
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Customer Contact: Kerstin Lindstedt
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SOMATEX Medical Technologies GmbH

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Germany

Urgent Field Safety Notice


Biopsy Handy and Puncture Sheath

Risk of unsterility

1. Information on Affected Devices	
1. Device Type	Biopsy needles
2. Commercial name(s)	Biopsy Handy Puncture Sheath
3. Primary clinical purpose of device(s)	The Biopsy Handy is used to extract histologically usable tissue material from a variety of soft tissue and organs. The Puncture Sheath is intended for soft tissue biopsy in conjunction with the biopsy needles used for taking samples.
4. Device Model/Catalogue/ part number(s) and LOT Numbers	<p>Biopsy Handy:</p> <p>REF 900118 – LOT 20051271S REF 900126 – LOT 20061291S REF 900128 – LOT 2003735S REF 900128 – LOT 20051280S REF 900130 – LOT 20092038S REF 900134 – LOT 20061361S REF 900136 – LOT 20051183S REF 900136 – LOT 20061353S REF 900144 – LOT 20092225S</p> <p>Puncture Sheath:</p> <p>REF 170257 – LOT 2004926S REF 170257 – LOT 20061423S REF 170259 – LOT 200103S REF 170259 – LOT 20071562S REF 170261 – LOT 200105S REF 170261 – LOT 20092043S REF 170269 – LOT 20092116S</p>

2. Reason for Field Safety Notice (FSN)	
1. Description of the product problem	There is a potential risk that the sterilization process was not successful and the products are therefore potentially unsterile.
2. Hazard giving rise to the FSCA (Field Safety Corrective Action)	Using a non-sterile product poses a risk of infection for the patient.

3. Type of Action to mitigate the risk	
1. Action To Be Taken by the User and Distributors	<input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Cease use <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> for distributors: complete the distributor reply form (page 4 and 5) of this documents and submit it to SOMATEX – contact information see page 1 <input checked="" type="checkbox"/> for user: complete the user reply form (page 6 and 7) of this documents and submit it to your distributor – contact information see page 7
2. Is User and Distributor Reply Required	Yes. Information shall be sent to SOMATEX (for distributors) or to the distributor (for user), if affected products are used or still on stock. This information shall be sent as soon as possible.

4. General Information	
1. FSN Type	New
2. Further advice or information already expected in follow-up FSN?	The evaluation of the sterilization cycles is currently ongoing. As soon as possible after finishing the evaluation, the customers with stock will be contacted again for further actions.
3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
Name / Signature	 <hr/> Jörg Heise Managing Director

Transmission of this Field Safety Notice
<p>This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (as appropriate)</p> <p>Please transfer this notice to other organizations on which this action has an impact. (as appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.</p>

Field Safety Notice Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	RAN 21019
FSN Date*	25.03.2021
Product/ Device name*	Biopsy Handy Puncture Sheath
Product Code(s) and Batch/LOT Number (s)	Biopsy Handy: REF 900118 – LOT 20051271S REF 900126 – LOT 20061291S REF 900128 – LOT 2003735S REF 900128 – LOT 20051280S REF 900130 – LOT 20092038S REF 900134 – LOT 20061361S REF 900136 – LOT 20051183S REF 900136 – LOT 20061353S REF 900144 – LOT 20092225S Puncture Sheath: REF 170257 – LOT 2004926S REF 170257 – LOT 20061423S REF 170259 – LOT 200103S REF 170259 – LOT 20071562S REF 170261 – LOT 200105S REF 170261 – LOT 20092043S REF 170269 – LOT 20092116S

2. Distributor Details	
Company Name	
Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Return acknowledgement to Sender	
Email	k.lindstedt@somatex.com
Distributor Helpline	+49(0)30 3198225-34
Postal Address	SOMATEX Medical Technologies GmbH Hohenzollerndamm 150/151 14199 Berlin Germany
Web Portal	www.somatex.com
Deadline for returning the Distributor reply form	As soon as possible

4. Distributors (to be completed by the Distributor - Tick all that apply)		
<input type="checkbox"/>	I confirm the receipt, the reading and understanding of the Field Safety Notice.	
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Distributor to enter quantity and date
<input type="checkbox"/>	I have identified customers that received or may have received this device	
<input type="checkbox"/>	I have attached customer list	
<input type="checkbox"/>	I have informed the identified customers of this FSN with page 1-3 and page 6-7	Date of communication:
<input type="checkbox"/>	I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	
	Print Name	
	Signature	
	Date	

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.

Field Safety Notice User Reply Form

5. Field Safety Notice (FSN) information	
FSN Reference number*	RAN 21019
FSN Date*	25.03.2021
Product/ Device name*	Biopsy Handy Puncture Sheath
Product Code(s) and Batch/LOT Number (s)	Biopsy Handy: REF 900118 – LOT 20051271S REF 900126 – LOT 20061291S REF 900128 – LOT 2003735S REF 900128 – LOT 20051280S REF 900130 – LOT 20092038S REF 900134 – LOT 20061361S REF 900136 – LOT 20051183S REF 900136 – LOT 20061353S REF 900144 – LOT 20092225S Puncture Sheath: REF 170257 – LOT 2004926S REF 170257 – LOT 20061423S REF 170259 – LOT 200103S REF 170259 – LOT 20071562S REF 170261 – LOT 200105S REF 170261 – LOT 20092043S REF 170269 – LOT 20092116S

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

7. Customer action undertaken on behalf of Healthcare Organisation		
<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 identified and quarantined affected devices - enter number of devices	Qty: Lot Number:
		Qty: Lot Number:
		Qty: Lot Number:
		N/A Comments:
<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		

8. Return acknowledgement to sender	
Email	
Customer Helpline	
Postal Address	
Web Portal	
Fax	
Deadline for returning the customer reply form	

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.