

Date: 25.07.2022

Urgent Field Safety Notice

For temporary non-use of the following medical devices.

Tumark Vision

For Attention of: User and distributors

Contact details (name, e-mail, telephone, address etc.)
Customer Contact: [REDACTED] [REDACTED] [REDACTED] [REDACTED] SOMATEX Medical Technologies GmbH Hohenzollerndamm 150/151 14199 Berlin Germany

Urgent Field Safety Notice (FSN)

For temporary non-use of the following medical devices.

Tumark Vision

1. Information on Affected Devices*	
1.	1. Device Type(s)* Biopsy Clipmarker
1.	2. Commercial name(s)* Tumark Vision
1.	3. Unique Device Identifier(s) (UDI-DI) REF 271589: 04250195611086 REF 271590: 04250195607836
1.	4. Primary clinical purpose of device(s)* The Tumark Vision is intended for the percutaneous marking of soft tissue, such as breast tissue.
1.	5. Device Model/Catalogue/part number(s)* Tumark Vision: REF 271589 – LOT 52173 REF 271589 – LOT 52161 REF 271590 – LOT 52146

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* During internal tests, it was found that the lot numbers of the products listed above may contain production residues that are potentially cytotoxic.
2.	2. Hazard giving rise to the FSCA* risk of infection or reaction to the clip marker

3. Type of Action to mitigate the risk*	
3.	1. Action To Be Taken by the User/Distributor* <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification / inspection <input checked="" type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment / reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None <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 <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

3.	2. By when should the action be completed?	As soon as possible
3.	3. Particular considerations for:	Implantable device
	Based on the information we have reviewed thus far, we believe that patient health risk concerns are insufficient to recommend taking any action or intervention for patients who have been implanted with the affected LOT number. Patients who have received treatment with an affected LOT number should continue to be monitored according to standard medical best practices.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	5. Action Being Taken by the Manufacturer* <input type="checkbox"/> Product Removal <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> Other <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> None Blocking of the affected lot numbers and further investigation; Follow up communication with customers post investigation	

4. General Information*		
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. Name/Signature	<div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div>

Transmission of this Field Safety Notice	
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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.*

Field Safety Notice
Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	RAN 22066
FSN Date*	25.07.2022
Product/ Device name*	Tumark Vision
Product Code(s) and Batch/LOT Number (s)	REF 271589 – LOT 52173 REF 271589 – LOT 52161 REF 271590 – LOT 52146

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

3. Return acknowledgement to Sender	
Email	████████████████████
Distributor Helpline	+49(0)30 3198225-47
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 22066
FSN Date*	25.07.2022
Product/ Device name*	Tumark Vision
Product Code(s) and Batch/LOT Number (s)	REF 271589 – LOT 52173 REF 271589 – LOT 52161 REF 271590 – LOT 52146

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	As soon as possible

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.