

Date: 05-02-2020

Urgent Field Safety Notice
Needle guide bushings for stereotactic breast biopsy

For Attention of*:



Director of Breast Imaging
Director of Radiology
Director of Biomedical Engineering

Contact details of local representative (name, e-mail, telephone, address etc.)*

Turon MedTech AB
Kardavagen 21
SE-43232 Varberg
Sweden
+46 (0)340 84060


bushing@turonmedtech.com

Urgent Field Safety Notice (FSN)
Needle guide bushings for stereotactic breast biopsy
may fail

1. Information on Affected Devices*	
1	<p>1. Device Type(s)*</p> <p>Sterile needle guide bushings for one-time use. These bushings are delivered sterile in pairs, i.e. one package includes two (2) bushings, according to picture 1. When using the stereotactic breast biopsy device, these bushings are used to guide the biopsy needle through the needle holder according to picture 2.</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>Picture 1</p> </div> <div style="text-align: center;">  <p>Picture 2</p> </div> </div>
1	<p>2. Commercial name(s)</p> <p>CYTOGUIDE Needle guide bushes: GA12, GA14, GA16, GA18, GA20, GA20 OPEN & GA22.</p>
1	<p>3. Unique Device Identifier(s) (UDI-DI)</p> <p>N/A</p>
1	<p>4. Primary clinical purpose of device(s)*</p> <p>Needle guide bushings</p>
1	<p>5. Device Model/Catalogue/part number(s)*</p> <p>040301, 040302, 040307, 040308, 040309, 040311 & 040312</p>
1	<p>6. Software version</p> <p>N/A</p>
1	<p>7. Affected serial or lot number range</p> <p>All bushings with these article numbers</p>
1	<p>8. Associated devices</p> <p>N/A</p>

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	Some bushings have a material defect, which makes them brittle. The degree of this material defect varies. However, some of them, may break during normal usage in the field. This has happened and has consequently been reported.
2	2. Hazard giving rise to the FSCA*
.	When a bushing breaks, parts of it may fall on the breast, i.e. around the needle's entry into the breast. This may require the biopsy operator to clean the breast, remove the needle and replace the bushing. This could lead to extended surgery time and a potentially stressful situation for both patient and operator. No injuries have been reported due to this issue.
2	3. Probability of problem arising
.	N/A

3. Type of Action to mitigate the risk*			
3.	<p style="color: red; font-weight: bold;">1. Action To Be Taken by the User*</p> <p> <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input checked="" type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Follow patient management recommendations </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p> <p> <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p> If you have any of these bushings remaining, we strongly advise you, to stop using them. We will immediately and free of charge send you replacement bushings in stainless steel. For replacement please send an email to bushing@turonmedtech.com and you will get immediate respond with replacement instructions. </p> <p> Note that these stainless-steel bushings will be delivered nonsterile. A sterilization instruction will come with the bushings. </p>		
3.	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 40%; padding: 5px;">2. By when should the action be completed?</td> <td style="padding: 5px; text-align: center;">2020-04-30</td> </tr> </table>	2. By when should the action be completed?	2020-04-30
2. By when should the action be completed?	2020-04-30		
3.	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%; padding: 5px;">3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)</td> <td style="padding: 5px; text-align: center;">See 3.1 & 3.2</td> </tr> </table>	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	See 3.1 & 3.2
3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	See 3.1 & 3.2		
3.	<p style="font-weight: bold;">4. Action Being Taken by the Manufacturer</p> <p> <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>As an immediate action we have stopped delivery of these bushings until the issue is mitigated.</p>		
3	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 40%; padding: 5px;">5. By when should the action be completed?</td> <td style="padding: 5px; text-align: center;">2020-05-31</td> </tr> </table>	5. By when should the action be completed?	2020-05-31
5. By when should the action be completed?	2020-05-31		
3.	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%; padding: 5px;">6. Is the FSN required to be communicated to the patient /lay user?</td> <td style="padding: 5px; text-align: center;">No</td> </tr> </table>	6. Is the FSN required to be communicated to the patient /lay user?	No
6. Is the FSN required to be communicated to the patient /lay user?	No		
3	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 100%; padding: 5px;">7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?</td> </tr> <tr> <td style="padding: 5px; text-align: center;">N/A</td> </tr> </table>	7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	N/A
7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?			
N/A			

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.* Work in process regarding information to authorities	
4.	8. List of attachments/appendices:	
4.	9. Name/Signature	Göran Ekström and Martin Gröndahl Managing Director Business Developer
		

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations 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>

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.