	FSN (EC template)	FSN reference nr.: 202203
		Date: 25-11-2022

Urgent Field Safety Notice
Radial Fiber TXMF600R

For Attention of *: [purchasing department or person responsible for quality and regulatory requirements](#)

Contact details

Tobrix BV

Van Dijklaan 27
5581 WG Waalre
The Netherlands
Tel: +31 40 223 0773
Email: koen@tobrix.com

Dear Customer,

We, Tobrix BV, are conducting a field safety corrective action concerning LOT **2111049** of the 600mu radial fiber **TXMF600R**.

Please read this letter carefully and take the appropriate action as outlined in part 3


Urgent Field Safety Notice (FSN)

Radial Fiber

Risk addressed by FSN

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	Sterile surgical laser fiber 'radial fiber' 600mu for EVLA treatments
1	2. Commercial name(s)
.	Radial fiber
1	3. Unique Device Identifier(s) (UDI-DI)
.	n/a
1	4. Primary clinical purpose of device(s)*
.	Endovenous laser ablation
1	5. Device Model/Catalogue/part number(s)*
.	TXMF600R
1	6. Software version
.	n/a
1	7. Affected serial or lot number range
.	LOT: 2111049
1	8. Associated devices
.	n/a

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	Tip breaks of with little force
2	2. Hazard giving rise to the FSCA*
.	The broken tip can remain in the patient. If this occurs close to the crosse it may present a hazard, requiring surgical removal of the tip
2	3. Probability of problem arising
.	2 out of 50 known incidences, so 4%
2	4. Predicted risk to patient/users
.	Severity is low, probability is 4% so risk is low
2	5. Further information to help characterise the problem
.	
2	6. Background on Issue
.	Incident was reported by healthcare facility after 2 incidences. In both cases the tip broke off shortly after starting lasering.
2	7. Other information relevant to FSCA
.	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

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3. Type of Action to mitigate the risk*		
3.	1. Action To Be Taken by the User* <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input 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 Devices can be returned to our office at: Van Dijklaan 27 5581WG Waalre The Netherlands	
3.	2. By when should the action be completed?	Identify and quarantine device ASAP. Return device within one week if possible
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes Please respond before 02-12-2022
3.	5. Action Being Taken by the Manufacturer <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 checked="" type="checkbox"/> Other <input type="checkbox"/> None LOT will be removed and investigated for cause.	
3	6. By when should the action be completed?	Specify where critical to patient/end user safety
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	3. For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	...
		...

	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.