Rev 1: September 2018 FSN Ref: 01 Apr 2024 Destroy FSCA Ref: 01 Apr 2024 Destroy

Date: 03/27/2024

Urgent Field Safety Notice

Device Commercial Name

For Attention of*:Risk Manager, Staff Nurse, Procurement

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

MicroSurgical Technology, 8415 154th Ave. NE, Redmond, WA 98052
Cs: 888.279.3323 p: 425.556.0544 f: 425.556.0437 www.mst-surgical.com

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Rev 1: September 2018 FSN Ref: 01 Apr 2024 Destroy FSCA Ref: 01 Apr 2024 Destroy

Urgent Field Safety Notice (FSN)

Device Commercial Name

Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Trephine blades used in eye surgeries. Products are sold non-sterile and sold in multiple sized and configurations.
1.	2. Commercial name(s)
	Trephine Blades
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	An ophthalmic surgical blade designed to cut and remove circular sections of the cornea (corneal buttons) and/or sclera from a patient to prepare for graft implantation, or from cadaveric donors to obtain grafts. It is typically a sharp, beveled, hollow cylinder, of different diameters, having a circular, saw-like working edge. It is an exchangeable device that may be attached to a manually rotated handle or to a powered rotary surgical handpiece. This device is typically made of high-grade stainless steel.
1.	5. Device Model/Catalogue/part number(s)*
	See Appendix A for comprehensive list of catalogue numbers.
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	All
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Product was listed in the Accutome catalogue as a reusable device. However, the device has never been approved for reuse and is intended for single use only. Device labelling does not indicate that the devices are single use only.
2.	2. Hazard giving rise to the FSCA*
	The hazard giving rise to the FSCA would be a dull edge. This is typically scored a 3 on MST risk management. 3 indicates a moderate issue requiring intervention or change in medical plan.

2.	3. Probability of problem arising
	880 total devices have shipped to customers since January 1st 2019. There have been zero complaints for these devices since then. The probability is 1:1000 based on MST risk evaluation.
2.	4. Predicted risk to patient/users
	From the output of the Health Hazard Evaluation indicate the anticipated risk (product of severity x probability) of patient/end user harm (direct or indirect).
2.	5. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue.
2.	6. Background on Issue
	A customer contacted MST to see if the Trephine could be sterilized using gas sterilization. MST contacted the supplier, Total Titanium. Total Titanium stated at this time that the devices are not intended for reuse as the sharpness of the blade edge could not be guaranteed after use.
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.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device ☐ Quarantine Device ☐ Return Device ☒ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Since the manufacturer has indicated these are single use the devices should be discarded and not reused.	
3.	2. By when should the action be completed?	ASAP

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Rev 1: September 2018 FSN Ref: 01 Apr 2024 Destroy FSCA Ref: 01 Apr 2024 Destroy

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)	No
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None These devices are no longer being offered by MicroSurgical Technology.	
3	6. By when should the action be completed?	Complete
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.	

MICROSURGICAL TECHNOLOGY™

Rev 1: September 2018 FSN Ref: 01 Apr 2024 Destroy FSCA Ref: 01 Apr 2024 Destroy

	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? *	Choose an item.
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	Insert Name and Title here and signature below Carly Hom. Sr. Quality Systems Manager 2024-04-10

	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)

MICROSURGICAL TECHNOLOGY™

Rev 1: September 2018 FSN Ref: 01 Apr 2024 Destroy FSCA Ref: 01 Apr 2024 Destroy

	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..*

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

Appendix A- List of Affected Catalogue Items

AM0570 20	AM0570 67	AM0570 82	AM0570 105
AM0570 25	AM0570 70	AM0570 85	AM0570 110
AM0570 30	AM0570 72	AM0570 87	AM0570 115
AM0570 45	AM0570 75	AM0570 90	AM0570 140
AM0570 50	AM0570 77	AM0570 95	AM0570 150
AM0570 60	AM0570 80	AM0570 100	AM0570 160