FSN Ref: PC3688EU FSCA Ref: ECL-FSCA-129

Date: 18-07-2049

Urgent Field Safety Notice
Interoperative Probe Cover PC3688EU

For Attention of*: All healthcare professionals who are responsible for or who use these devices

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

Microtek Medical B.V.
a division of Ecolab
P.O. Box 234 7200 AE Zutphen The Netherlands
Hekkehorst 24, 7207 BN Zutphen The Netherlands
Tel. +31 (0)575 599 200 Fax +31 (0)575 599 299

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Urgent Field Safety Notice (FSN)
Interoperative Probe Cover PC3688EU
Risk addressed by FSN

	1. **Information on Affected Devices***
1	1. Device Type(s)*
	Intraoperative Probe Cover with Long Surgi-tip. Probe Covers are composed of natural or synthetic materials and come in a variety of sizes and shapes to allow these devices to properly fit equipment with diverse shapes and uses. One type of synthetic material that are used is Polyisoprene (PIP). * Intraoperative Probe Covers – For use in biopsy, abdominal surgery, cardiac surgery, vascular surgery, and special procedures The devices cover a transducer / probe and, in some instances, the cables connected to the transducers / probes. These coverings offer a physical barrier between the transducer and the patient Kit
1	2. Commercial name(s)
	Intraoperative ultrasound imaging system transducer cover
1	3. Unique Device Identifier(s) (UDI-DI)
	Not applicable
1	4. Primary clinical purpose of device(s)*
	A device intended to be used as a physical barrier for protection against the effects of environmental exposure (e.g., body fluids, gels) and/or to maintain the required hygienic level of various diagnostic or surgical procedures which utilize a transducer (probe). This is a single use device. (Not to be reprocessed) The devices are further indicated to be used in or on: * Intact or compromised skin * Intra-operatively (e.g., on internal organs.) Product PC3688EU includes warning statement 'Not intended for contact with the Central Nervous System' on product, inner and outer case labels. This warning statement is also translated in all applicable languages on the IFU that is supplied with this product.
1	5. Device Model/Catalogue/part number(s)*
	Interoperative Probe Cover PC3688EU
1	6. Software version
	Not applicable
1	7. Affected serial or lot number range
	Lot Number: 1611753V, 1612016V, 1612154V,1612332V,1712400V, 1712645V, 1712752V, 1712940V, 1713076V, 1713163V, 1713165V, 1813407V, 1813523V, 1813667V, 1813675V, 1813760V, 1813877V, 1813943V, 1814226V, 1914553V, 1914677V
1	8. Associated devices
	Not Applicable

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2	**Reason for Field Safety Corrective Action (FSCA)***
2	1. Description of the product problem*
	There is a very low potential of a bacterial contamination to some batches of the Intraoperative Probe Cover. For precautionary reasons Ecolab decided to initiate a recall.
2	2. Hazard giving rise to the FSCA*
	The hazard caused by the defect is direct exposure of the intra-cardiovascular, intra-lymphatic or neurological system to a level of endotoxins sufficient to produce a pyrogenic response. Endotoxins introduced into the bloodstream or cerebrospinal fluid can result in an inflammatory response causing: fever (pyrogenic reaction), leukopenia or leukocytosis (decreased or increase leukocytes [white blood cells], or lethal shock. Reference: Endotoxin (Lipopolysaccharide (LPS).
2	3. Probability of problem arising
	An assessment of the likelihood of occurrence of the potentially hazardous event resulted in less than 1%.
2	4. Predicted risk to patient/users
	In case of contamination caused by contaminated probe covers, patients would be at greater risk of infection. To avoid the risk a FSN and a recall of the products is initiated
2	5. Further information to help characterise the problem
	In case of the contaminated probe covers are applied, patients would be at greater risk of infection if the precaution advice “Not to be used with the Central Nervous System’ is not strictly followed. Generally, the risk assessment for any potential health hazard linked to the use of the probes results in low risk for the patient and the user.
2	6. Background on Issue
	A microbial contamination source has been identified in a raw material (PIP tips) that is sourced from an external supplier and used in product code PC3688EU.
2	7. Other information relevant to FSCA
	No other information required.

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	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	
3	2. By when should the action be completed?	Customer: 31st July 2019 Distributor: 31st August 2019
3	3. Particular considerations for: Is follow-up of patients or review of patients' previous results recommended? No	
3	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3	6. By when should the action be completed?	ASAP
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?	

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	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:	
	NA	
4	6. Anticipated timescale for follow-up FSN	31st August 2019
4	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Microtek Medical Malta Ltd.
	b. Address	Sorbonne Centre, F20 Mosta TechnoparkMST3000 Mosta, Malta
	c. Website address	N/A
4	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4	9. List of attachments/appendices:	N/A
4	10. Name/Signature	Dieter Wirbals Director Regulatory Affairs Ecolab
		

	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..*

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