MEDISTIM

Urgent field safety notice (FSN)

Medistim L15 Ultrasound Imaging probes

Instructions for use

1.	**Information on Affected Devices***	
1.1	**Device Type(s)***	
	Intraoperative ultrasound imaging probe	
1.2	**Commercial name(s)**	
	Medistim L15 Ultrasound Imaging probe	
1.3	**Unique Device Identifier(s) (UDI-DI)**	
	07070554100931	
1.4	**Primary clinical purpose of device(s)***	
	Performs intraoperative guidance and quality control during surgical procedures and meet the demands for documentation of surgical procedures.	
1.5	**Device Model/Catalogue/part number(s)***	
	EL100015	

2.	**Reason for Field Safety Corrective Action (FSCA)***	
2.1	**Description of the product problem***	
	The device's Instructions for Use (IFU) provides guidance on reprocessing of the probe before each use. However, the current IFU does not cover certain reprocessing procedures preferred by some hospitals. To address this, Medistim has validated use of an endoscopic washer-disinfector (EWD) for cleaning and disinfection of the device. The IFU has been updated to include the validated method as an approved cleaning and disinfection option followed by sterilization or application of a sterile transducer cover.	
2.2	**Hazard giving rise to the FSCA***	
	If reprocessing is not performed according to the instructions for use, it may result in microbial cross-contamination during surgeries.	

3.	**Type of Action to mitigate the risk***	
3.1	**Action To Be Taken by the User***	
	☒ Take note of amendment/reinforcement of Instructions For Use (IFU) The IFU provided with the device should be replaced with the updated IFU included in this field safety notice.	
3.2	Is customer Reply Required? *	Yes

4.	**General Information***	
4.1	FSN Type*	New
4.2	Further advice or information already expected in follow-up FSN? *	No
4.3	Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Medistim ASA
	b. Address	Økernveien 94, 0579 Oslo, Norway

	c. Website address	www.medistim.com
4.4	The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.5	Name/signature	Tone Veiteberg, VP QA & RA

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. 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.

If you have any questions about this matter, please contact your local Medistim sales representative.

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Customer reply form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSCA25-001
FSN Date*	04.03.2025
Product/Device name*	L15 Ultrasound Imaging probe
Product code	EL100015

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its contents.	
☐	I performed all actions requested by the FSN.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	I do not have any affected devices.	
☐	I have a query please contact me (Enter contact details if different from above and brief description of query)	
Print Name		
Signature		
Date		

*Mandatory information

Please return the completed form to your local Medistim sales representative or to the following e-mail: FCSA25-001@medistim.com
Deadline for returning the customer reply form: 14.03.2025