Rev 1: September 2018
FSN Ref: 403646 FSCA Ref: 403646

Date: 07:03:2023

Urgent Field Safety Notice

Intersurgical Clear-Therm 3 HMEF with luer port, Superset™ catheter mount and elbow

For Attention of*: All clinical staff, Managers and users of the above product

Contact details of local representative (name, e-mail, telephone, address etc.)*
Miriam Nolan Intersurgical Ireland Ltd 249 Corporate Park 2 Blanchardstown Dublin 15 D15 XY68 Ireland **Email:** MN@intersurgical.ie **Tel. No:** +353870685089

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Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	HMEF and combined Catheter mount
1.	2. Commercial name(s)
	Clear-Therm 3 HMEF with luer port, Superset™ catheter mount and elbow
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	To reduce risk of bacterial and viral contamination of patients, medical devices and equipment, whilst also reducing moisture and heat loss from the patient's respiratory gases within anaesthesia, critical and respiratory care breathing systems
1.	5. Device Model/Catalogue/part number(s)* Ref; 1541974
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range **Ref; 1541974** Lot: 1230176
1.	8. Associated devices
	N/A.

2. **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*
	We have received reports of foam dust particles on the machine side housing of the HMEF and in the packaging, where it may come into contact with the patient side connection.
2.	2. Hazard giving rise to the FSCA*
	Whilst aesthetically undesirable the observed dust within the HMEF housing and packaging is unlikely to be released during use or compromise the patient's airway. However, there remains a possibility that it could come into contact with the patient.
2.	3. Probability of problem arising
	1:10,000 - 1:1,000
2.	4. Predicted risk to patient/users
	Moderate risk of harm and possible occurrence.

2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Intersurgical has received reports, where unacceptable amounts of dust particles from the foam HME element have been found in the machine side housing or in the packaging of the products. In all reports it has been visually obvious and noticed either whilst still in the pack, or during pre-use checks. This issue has been due to a process non-conformity during the manufacture of the HME material.
2.	7. Other information relevant to FSCA The manufacturing process for the HME material has been investigated and resolved.

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

Identify and immediately quarantine all affected codes and lot numbers listed above and do not use these devices. Please complete the Reply Form to confirm the products have been disposed of locally or to arrange collection of the devices and a credit. If you have no affected devices in stock, please confirm this using the Reply Form. Return the completed Reply Form to MN@intersurgical.ie.

Please continue to report to Intersurgical any adverse events involving this product.

3.	2. By when should the action be completed?	Immediately on receipt of this FSN and ongoing until no affected stock listed in this FSN is remaining.
3.	3. Particular considerations for: Is follow-up of patients or review of patients' previous results recommended? Not applicable.	
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?	One month of receipt of the FSN
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?	
	No	

	4. General Information*	
4.	1. FSN Type*	New - Recall
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? *	No
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. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Intersurgical Ireland Ltd
	b. Address	249 Corporate Park 2, Blanchardstown, Dublin 15, D15 XY68, Ireland
	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:	Customer Reply Form
4.	10. Name/Signature	**Ivan Seniut** **Group Quality and Regulatory Affairs Director** **Duly authorised for and on behalf of Intersurgical Ltd**
		

	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..*

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