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Relevant Country Contact Name
Tel.: Relevant country telephone
Fax: Relevant country fax
Email: Relevant country email

Urgent Recall Notice (This supersedes the previous FSN dated 15/07/2019)

Devices:

REF	DESCRIPTION
1941199	FILTA-THERM HMEF WITH LUER PORT, SUPERSET CATHETER MOUNT, DOUBLE SWIVEL ELBOW, FLIP TOP CAP AND 22F - 22M/15F
3521000	SUPERSET DOUBLE SWIVEL CATHETER MOUNT 22F - DOUBLE FLIP TOP CAP - 22M/15F, 70MM-150MM

LOT numbers:

1941199	31852854, 31858636, 31953249, 31954693
3521000	2180327, 2180571, 2181474, 2181503, 2181825, 2182119, 2182852, 2183518, 2190008, 2190350, 2190531, 2191025, 2191410

Manufacturer: Intersurgical Ltd

FSCA-identifier: 226766 **Date:** 25/07/2019

Attention: Medical Device Safety Officers (MDSO)

Distribution: All Critical Care clinical staff, all Anaesthesia clinical staff, managers and users of the above products

Type of action: The removal of all products and lot numbers listed above to prevent their possible use.

Description of the problem: We have received complaints about cracked ports in the swivel elbow where the flip cap is inserted, and these cracks leak if they reach a significant size. The percentage of cracked products in any lot may vary between 0% and approximately 10%. The cracks were not present at the time of manufacture, but have occurred later on during storage.

In a worst case scenario, leakage from a crack could result in the prescribed ventilation not being delivered to the patient. If this leak were left undetected it could lead to the patient becoming hypoxic and hypercapnic which would have a detrimental impact upon the patient's respiratory function and vital signs.

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Action to be taken by the user:

Immediately quarantine all affected products and lot numbers listed above and do not use these devices. Please contact Intersurgical using the Response Form to confirm these have been disposed of locally or arrange collection of the devices and credit. If you have no affected devices in stock, please confirm this using the Response Form.

Corrective Action being taken by manufacturer Intersurgical:

We have stopped production of the affected component where the problem has been identified, however in the meantime we are able to use components manufactured at a different site to minimise disruption in supply to our customers.

Transmission of this Recall Notice:
This notice should be transmitted to all those who need to be aware within your organisation, or to any organisation where these potentially affected devices have been transferred.

Intersurgical apologises for any inconvenience this may cause. If you have any questions, please contact your distributor or local Intersurgical representative.

The relevant National Authorities have been advised about this Field Safety Corrective Action.

Please maintain awareness of this Recall Notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Ivan Seniut, Group Quality and Regulatory Affairs Director, Intersurgical

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Response Form

Devices:

REF	DESCRIPTION
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Manufacturer: Intersurgical Ltd

FSCA-identifier: 226766 **Date:** 25/07/2019

Hospital Name: _____

Hospital Address: _____

Please tick one of the following options:

☐ We do not have any remaining stock of the affected products.
☐ We have quarantined our remaining stock of the following affected products and have disposed of these locally or wish to return them. Please arrange credit.

(Please complete the section below, and send it back to the contact above).

I confirm that I have quarantined the following products and lot numbers.

REF	LOT	Quantity of products per LOT number
[add more rows as required]		

Form Completed and Returned by:

Name: …….. **Phone No: ……..**

Position: ……. **E-mail: ……**

Date: ……