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Urgent Recall Notice

Type of Action: RECALL

Devices: The following Intersurgical products containing the Adult Ecolite™ Aerosol Mask.

REF:	DESCRIPTION
1453015	CIRRUS2 NEBULISER, ADULT, INTERSURGICAL ECOLITE MASK KIT WITH TUBE, 2.1M

LOT NUMBERS
32052758
32052973
32053066
32053274
32053276
32053357
32053524

Manufacturer: Intersurgical Ltd

FSCA identifier: 301083-A **Date:** 11/02/2021

PLEASE NOTE: THIS RECALL NOTICE SUPERSEDES THE PREVIOUS NOTICE ID: 301083 DISTRIBUTED ON THE 17/12/20202, AS IT NOW INCLUDES THE FOUR ADDITIONAL POTENTIALLY AFFECTED LOT NUMBERS HIGHLIGHTED.

Attention: Medical Device Safety Officers (MDSO)

Distribution: All Respiratory Care Units, Hospital Wards and Departments, Emergency Departments, Intensive Care Units, Ambulance/Paramedic staff, Community Nurses, Home Users/Carers, GP Surgeries, Clinics and all users of the above products.

Type of action:
All users of the product and lot numbers listed above must follow the instructions described in the Actions section below before use.

Description of the problem: We have received complaints where a product that should contain an Adult Ecolite™ Aerosol Mask with vents/exhalation ports (Picture 1), has been found to contain a similar mask without vents/exhalation ports (Picture 2), this would prevent the patient breathing normally. If a mask without vents/exhalation ports is not identified and subsequently used on a patient, in situations where the patient cannot or does not remove the mask themselves this could result in distress, harm or potential fatality. It would also prevent the intended treatment being provided to the patient.

Picture 1: Correct Mask with vents/exhalation ports

Picture 2: Mask without vents/exhalation ports

Action to be taken by the user:
Immediately quarantine all affected product codes and lot numbers listed above and do not use these devices. Please contact Intersurgical using the Response Form below to confirm these have been disposed of locally or arrange collection of the devices and credit. If you have no affected devices in your stock, please confirm this also using the Response Form.

Corrective Action being taken by manufacturer Intersurgical:
We have already reviewed the manufacturing process and implemented actions to prevent this error in the future.

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

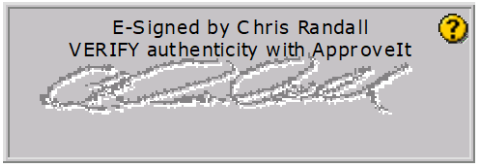
Transmission of this Field Safety Notice:

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 Field Safety Notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.



Chris Randall, Quality Manager, Intersurgical

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Urgent Recall Notice Response Form

Devices: The following Intersurgical products containing the Adult Ecolite™ Aerosol Mask.

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Hospital/Facility Name: _____

Hospital/Facility Address: _____

_____

Please complete the section below, and send it back to priority@intersurgical.co.uk

☐ 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 for credit.

☐ We have quarantined our remaining stock of the following affected products and wish to return them for credit.

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

REF	LOT	Quantity of products per LOT number
1453015		
[add more rows as required]		

Form Completed and Returned by:

Name: ……

Position: ……

Phone No: ……

E-mail: ……

Date: ……..