

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصحة
والرقابة الدوائية
مسقط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 247 dated 27.12.12 Regarding Intersurgical Recall of Intersurgical products containing the Adult Ecolite™ Aerosol Mask from (mfr: Intersurgical Ltd).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information

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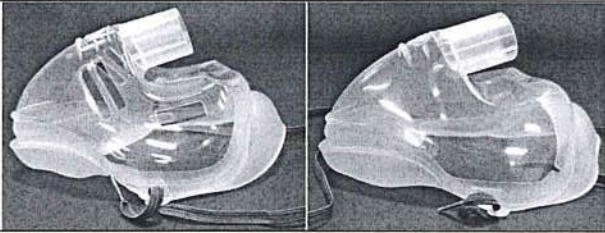
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Circular No. 247/2020

12 -05-1442 H

27 -12-2020

Recall of Intersurgical products containing the Adult Ecolite™ Aerosol Mask from Intersurgical Ltd.

Source	Intersurgical Ltd through their local agent Muscat Pharmacy & Stores LLC.
Product	CIRRUS2 NEBULISER, ADULT, INTERSURGICAL ECOLITE MASK KIT WITH TUBE, 2.1M
Description	Intersurgical products containing the Adult Ecolite™ Aerosol Mask.
Manufacturer	Intersurgical Ltd.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	REF: 1453015 Lot Numbers: 32052973, 32053276, 32053524.
Reason	Intersurgical have received a complaint where a product that should contain an Adult Ecolite™ Aerosol Mask with vents, has been found to contain a similar mask without vents, this would prevent the patient breathing normally. This could result in distress or some form of harm to the patient if unnoticed. It would also prevent the intended treatment being provided to the patient.
Action	1. Immediately quarantine all affected product codes and lot numbers listed above and do not use these devices. 2. Contact the local agent for remedial action.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through an E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General



Relevant Country Contact Name

Tel.: Relevant country telephone

Fax: Relevant country fax

Email: Relevant country email

Intersurgical Ltd, Crane House, Molly Millars Lane,
Wokingham, Berkshire, RG41 2RZ, UK

T: +44 (0)118 965 6300 F: +44 (0)118 965 6356

info@intersurgical.com www.intersurgical.com

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
32052973
32053276
32053524

Manufacturer: Intersurgical Ltd**FSCA identifier:** 301083**Date:** 17/12/2020**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 a complaint where a product that should contain an Adult Ecolite™ Aerosol Mask with vents (Picture 1), has been found to contain a similar mask without vents (Picture 2), this would prevent the patient breathing normally. This could result in distress or some form of harm to the patient if unnoticed. It would also prevent the intended treatment being provided to the patient.

Picture 1: Correct Mask with vents



Picture 2: Mask without vents



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.



Ivan Seniut, Group Quality and Regulatory Affairs Director, Intersurgical