Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
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 109 **dated** 28/7/2024 **Regarding NCMDR Recall of BLUperc® Percutaneous Dilation Tracheostomy Kit from (mfr: Smith's Medical International Limited).**

Copy to:

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

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Sultanate of Oman
Ministry of Health
Drug Safety Center
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سلطنة عُمان
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Circular No. 109/ 2024

22 -01-1446 H
28-07-2024

Recall of BLUperc® Percutaneous Dilation Tracheostomy Kit from Smith's Medical International Limited.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21122
Product	BLUperc® Percutaneous Dilation Tracheostomy Kit.
Description	Tracheotomy.
Manufacturer	Smith's Medical International Limited.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	SKU/List/Model Number (Lot/Serial Number): 101/561/090 (4439066)
Reason	The potential for a disconnection of the pilot balloon from the tracheostomy inflation line within specific lots.
Action	1. Please discontinue use and discard all stock of the affected lot. If, due to extenuating circumstances, an alternative device cannot be used, all instructions, including warnings and cautions contained in the Instructions for Use Documentation must be followed with heightened awareness when checking the device prior to use and while in use. 2. Contact the local agent for remedial action.
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 the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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URGENT: FIELD SAFETY NOTICE

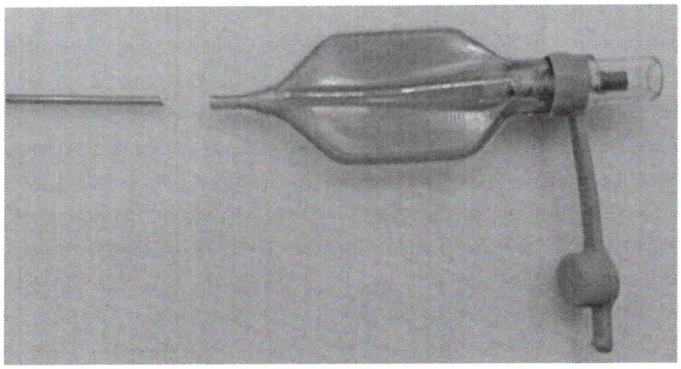
BLUselect® Tracheostomy Tube Kits , BLUselect® Suctionaid® Tracheostomy Tube Kits, BLUgriggs® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with BLUselect® Tracheostomy Tube with or without Forceps, BLUperc® Dilation Procedural Tray with Single Stage Dilator Products, BLUperc® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with or without BLUselect® Tracheostomy Tube

04 July 2024

Dear Valued BLUSelect® Customers,

Smiths Medical, Inc. is issuing this Urgent Field Safety Notice to notify you of a potential defect with the following BLUSelect®, BLUgriggs® and BLUperc® products listed in *Attachment 1_Affected Product*. This letter details the issue and the required steps for you to complete.

Issue:
Smiths Medical has identified the potential for a disconnection of the pilot balloon from the tracheostomy inflation line within specific lots of the BLUSelect®, BLUgriggs® and BLUperc® products because of a manufacturing defect. See the photo example of the issue below.



Potential Risk:
If the pilot balloon used to inflate the tracheostomy cuff becomes detached from the inflation line, the **cuff pressure may not be maintained which can lead to inadequate ventilation of, and increased risk of** aspiration to the patient. To date, Smiths Medical has received thirteen (13) reports of serious injury and zero (0) deaths associated with this issue.

Affected Product:

SKU/List/Model Number	Lot/Serial Number	Shipped Quantity
101/561/090	4439066	1

Smiths Medical Actions:
Smiths Medical is sending this notification to all BLUSelect®, BLUgriggs® and BLUperc® customers who received products from Smiths Medical listed in *Attachment 1_Affected Product*. Smiths Medical will provide replacement product(s) or credit to affected customers upon receipt of a completed response form to certify product destruction.

Customer Required Actions:

When using the device, all instructions, including warning and cautions contained in the Instructions for Use Documentation must be followed with heightened awareness. Please complete the following actions listed below

1. Check all inventory locations within your institution for the affected catalog numbers and lot numbers listed in the notification and discontinue use. Discard all affected products following your institution's process for discarding. If discarding is not immediately possible at your facility, then the product should be quarantined until disposal.

2. Share this notification with all potential users of the device to ensure they are aware of this notification and proposed mitigations. If the devices are used at another location, please ensure this communication is delivered there.

3. Complete and return the attached Customer Response Form to EMEA-FSN@icumed.com within 10 days of receipt to acknowledge your understanding of this notification.

4. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them and request that they complete the response form and return it to **YOU**. Then the **DISTRIBUTOR** must complete a SINGLE form with the required details and return to EMEA-FSN@icumed.com

For further inquiries, please contact Smiths Medical using the following information:

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@icumed.com	To report adverse events or product complaints
Customer Service	https://www.icumed.com/about-us/contact-us	Questions about product replacement and/or credit.

Your country regulatory agency has been notified of this action

Smiths Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important **matter. We appreciate your cooperation.**

Sincerely,

Andy Mathein
Vice President of Quality

Enclosures:

- Customer Response Form (See Below)
- Affected Product List (Attachment 1)

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URGENT: FIELD SAFETY NOTICE – RESPONSE FORM

BLUselect® Tracheostomy Tube Kits , BLUselect® Suctionaid® Tracheostomy Tube Kits, BLUgriggs® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with BLUselect® Tracheostomy Tube with or without Forceps, BLUperc® Dilation Procedural Tray with Single Stage Dilator Products, BLUperc® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with or without BLUselect® Tracheostomy Tube

4 July 2024

Check your inventory and complete the information below, even if you do not have the affected product. *Failure to complete all sections of this page may result in improper, delayed or denied credit.*

Please return the completed form to EMEA-FSN@icumed.com, If you have questions about this form please contact EMEA-FSN@icumed.com or your local sales representative.

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

Please select one:

☐ I have **NO** affected products (complete and return this form to the e-mail address above)

☐ **YES**, I have affected products, I have notified users in my facility and I have followed the instructions provided to me and destroyed all affected items (see table below)

If you have affected product on hand, please complete table 1 below:

TABLE 1

Item / SKU Number	Lot Number	Quantity in inventory (Eaches)	Quantity Destroyed (Eaches)	Date of Destruction

If you have distributed the product further, please complete table 2 below with collated information received from your customers and respond to ICU Medical with the overall information.

TABLE 2

Item / SKU Number	Lot Number	Quantity destroyed locally (Eaches)	Date of Destruction

Adverse events and complaints associated with the use of this product should be reported and emailed to Smiths Medical's Global Complaint Management Department at globalcomplaints@icumed.com.

ADDITIONAL AFFECTED PRODUCT DESTROYED

Item / SKU Number	Lot Number	Quantity in inventory (Eaches)	Quantity Destroyed (Eaches)	Date of Destruction

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Devices Sector

قطاع الأجهزة الطبية

NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Back

Reference Number: mdprc 016 07 24 000
Date submitted: 7/9/2024

Manufacturer:	Smith's Medical International Limited
Device Type:	BLUperc® Percutaneous Dilation Tracheostomy Kit
Description:	Tracheotomy
Medical Device Identifier:	SKU/List/Model Number (Lot/Serial Number): 101/561/090 (4439066)
Reason of Field Safety Corrective Action:	The potential for a disconnection of the pilot balloon from the tracheostomy inflation line within specific lots.
Remedy Action:	Please discontinue use and discard all stock of the affected lot. If, due to extenuating circumstances, an alternative device cannot be used, all instructions, including warnings and cautions contained in the Instructions for Use Documentation must be followed with heightened awareness when checking the device prior to use and while in use.
Athorized Representative/Importer/Distributor:	Almadar medical Est.
Report Source:	NCMDR
Source Ref. Number:	SA-08-07-24-499
SFDA Comments:	SFDA urges all healthcare providers that have devices subjected to this safety alert to contact the company.
Attachments:	Smiths Medical International Limited.pdf

View History