
Urgent FIELD SAFETY NOTICE

OxyMask
CS202200044
Device Destruction

Date: 01-June-2021

Attention: Hospithera nv (The Surgical Company be)
Lenniksebaan 451
1070 Brussels, Belgium

Description of the problem:

Southmedic Inc. is conducting a Field Safety Corrective Action of a specific lot number of the Southmedic OxyMask, part number OM-1125-14 (lot number W73887) (see **Details on affected device** for details that will allow for easy identification of the affected device). The reason for this Field Safety Corrective Action is due to possible disconnection of the oxygen tubing from the mask's elbow. Disconnection would result in a loss of device function and insufficient oxygen delivery to the patient. It is likely that patients may not experience any adverse events and are able to switch to a new oxygen delivery device, but critical and dependent patients may experience a greater detriment in oxygen saturation during this switch-over which could lead to life-threatening events.

Details on affected devices:

Our records indicate that the following products are affected:

Part Number	Lot Number	PO#	Cases Shipped
OM-1125-14	W73887	142311	6
		142816	4

The lot number may be identified on the carton and bag labels.

Advice on action to be taken by the user:

A **Distributor/Importer Reply Form** has been provided on **pages 3 and 4**. After checking your inventory, please complete this form and fax to the attention of Tish Whitehead at 705-728-9537. **Please advise as soon as possible if customers had received product.** If this is the case, please provide the attached "Urgent Field Safety Notice (FSN)" to these healthcare professionals and request product return from these end users.

Please dispose of any existing inventory and any customer returns.

If there are any regulatory questions, please contact Tish Whitehead, at (800)-463-7146 ext 342 or at regulatoryaffairs@southmedic.com.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.



Southmedic Incorporated
Head Office: 50 Alliance Blvd., Barrie, Ontario, Canada L4M 5K3
1-705-726-9383 1-800-463-7146 Fax: 1-705-728-9537
www.southmedic.com ISO 13485



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

Contact reference person:

For questions about product disposition, please contact:

Genna Woodrow

Customer Service

Phone: (800) 463-7146 ext 307

Fax: (705) 728-9537

Email: gwoodrow@southmedic.com

For any regulatory questions, please contact:

Tish Whitehead

Vice President, Quality & Regulatory Affairs

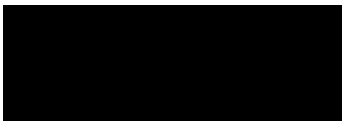
Phone: (800) 463-7146 ext 342

Fax: (705) 728-9537

Email: regulatoryaffairs@southmedic.com

The undersigned confirms that the applicable National Competent Authority will be made aware of the Field Safety Corrective Action.

We apologize for any inconvenience this action may cause. Your immediate attention is appreciated.



Tish Whitehead

Vice President, Quality & Regulatory Affairs

Southmedic Inc.

Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	CS20220004401
FSN Date*	25-May-2021
Product/ Device name*	OxyMask
Product Code(s)	OM-1125-14
Batch/Serial Number (s)	W73887

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	Customer Service: gwoodrow@southmedic.com Regulatory Affairs: regulatoryaffairs@southmedic.com
Distributor/Importer Helpline	Customer Service: (800) 463-7146 x307 Regulatory Affairs: (800) 463-7146 x342
Postal Address	50 Alliance Blvd, Barrie. Ontario L4M 5K3 Canada
Deadline for returning the Distributor/Importer reply form*	04-June-2021

4. Distributors/Importers (Tick all that apply)	
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.
	Distributor/Importer to complete or enter N/A

<input type="checkbox"/>	I have checked my stock and quarantined inventory	Lot #: W73887 (OM-1125-14) Quantity: _____ Date: _____
<input type="checkbox"/>	I have identified customers that received or may have received this device	
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication: _____
<input type="checkbox"/>	I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Lot #: W73887 (OM-1125-14) Quantity: _____ Date Destroyed: _____
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		
Signature*		
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.