
Urgent FIELD SAFETY NOTICE

$EtCO_2$ OxyMask
CS201800149
Device Destruction

Date: 2018-02-14

Attention Valued Customer

Description of the problem:
Southmedic Inc. is conducting a Field Safety Corrective Action of specific lot numbers of the Southmedic $EtCO_2$ OxyMask, part numbers OK-2125-8, OM-2125-8, and OP-2125-8 (see **Details on affected devices** for details that will allow for easy identification of the affected devices). The reason for this Field Safety Corrective Action is due to possible loose or missing CO_2 diffusers which may result in a non-functioning mask.

Details on affected devices:
Our records indicate that the following products are affected:

Part Number	Lot Number
OK-2125-8	W37602 W37898 W40863
OM-2125-8	W36433 W37741 W37998
OM-2125-14	W38338
OM-2325-8	W38340
OP-2125-8	W38005 W39027

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

Advise on action to be taken by the user:
After checking inventory, please provide Southmedic Inc with information regarding the amount of units sent out to distribution centers and/or end users (as applicable) by faxing a completed **Voluntary Recall Notification Form** to Tish Whitehead at 705-728-9537. Please dispose of all of the affected devices. Once disposition is complete, a Certificate of Destruction (page 5) must be completed and sent to Southmedic Inc.

If there are any questions regarding product disposition, please contact Genna Woodrow, customer service at (800)-463-7146 ext 307 or at gwoodrow@southmedic.com.

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

Please transfer this notice to other organisations on which this action has an impact.

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, Regulatory Affairs & Quality Assurance
Phone: (800) 463-7146 ext 342
Fax: (705) 728-9537
Email: tanger@southmedic.com

The undersign confirms that the applicable National Competent Authorities have been 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.

VOLUNTARY RECALL NOTIFICATION
CONFIRMATION FORM

PLEASE COMPLETE THIS FORM AND FAX TO:
FAX: (705) 728-9537
Attn: Tish Whitehead

Distributor Name: _____

Information on the individual completing this form (please print):

Name: _____
Title:_____

Date:_____ Telephone:_____
Fax:_____

If no products are being returned, please check here: ☐

If there is product to be destroyed, please complete the Certificate of Destruction (page 5).

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Information for Units Sent to your Distribution Centers (DC):

Part Number	Lot Number	Name and Location of DC	Number of Units sent to DC	Has the DC been notified of the Recall	Date of Notification to the DC

Information for Units sent to your Customers:

Part Number	Lot Number	Name and location of customer	Number of units sent to customer	Has the customer been notified of the recall	Date of notification to the customer

Please feel free to include additional pages if more space if required for the completion of the document.

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

Certificate of Destruction

Reason for Destruction:	Manufacturer recall – refer to recall notification sent February 2018
Non-Conformance Report #:	N/A

Merchandise:				
Part #	**Lot #**	**Unit of Measure**	**Quantity Destroyed** *(to be completed by the distributor)*	**Customer order #**
		25/box		
		25/box		
		25/box		

It is herby certified that all the devices listed above received from Southmedic Inc. were totally destroyed and disposed of in such a manner as to eliminate any possibility of any part thereof being accessible to any individual under normal circumstances, and eliminate any possibility of any part thereof causing injury to any person.

Full Signatures Required	
Destroyed by:	Destruction Witnessed by:
Title:	Title:
Signature:	Signature:
Date:	Date:
Location of Destruction:	

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