Southmedic

Urgent FIELD SAFETY NOTICE

OxyMask $EtCO_2$
CS202000032
Device Destruction

Date: 30-May-2019

Attention: Medival – Medica Valeggia s.p.a.
Via San Crispino, 33
Padova, Italy 35129

Description of the problem:
Southmedic Inc. is conducting a Field Safety Corrective Action of a specific lot number of the Southmedic $EtCO_2$ OxyMask, part number OM-2125-8 (lot number W52497) and OK-2125-8 (lot number W54153) (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 occlusion of the CO_2 sampling line. When connected to an $EtCO_2$ monitor, line occlusion may lead to an 'occlusion'-type error on the monitor. This does not affect the masks' ability to provide oxygen delivery.

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

Part Number	Lot Number	PO#	Cases Shipped
OM-2125-8	W52497	3900103 A	5
		3900184 A	4
OK-2125-8	W54153	3900216 A	1

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

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 Authorities 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*	CS20200003203
FSN Date*	30-May-2019
Product/ Device name*	OxyMask $EtCO_2$
Product Code(s)	1. OM-2125-8 2. OK-2125-8
Batch/Serial Number (s)	1. W52497 (OM-2125-8) 2. W54153 (OK-2125-8)

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*	10-June-2019

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

☐	I have checked my stock and quarantined inventory	Lot #: W52497 (OM-2125-8) Quantity: Date: Lot #: W54153 (OK-2125-8) Quantity: Date:
☐	I have identified customers that received or may have received this device	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Lot #: W52497 (OM-2125-8) Quantity: Date Destroyed: Lot #: W52497 (OM-2125-8) Quantity: Date Destroyed:
☐	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.

FSN Ref: CS20200003203 FSCA Ref: CS202000032

Date: 30-May-2019

Urgent Field Safety Notice
OxyMask™ $EtCO_2$

For Attention of*: **Healthcare Professionals**

Contact details of local representative (name, e-mail, telephone, address etc.)*
Medival – Medical Valeggia s.p.a. **Via San Crispino, 33** **Padova, Italy 35129** **Phone: +39 (0) 4977 5477**

FSN Ref: CS20200003203 FSCA Ref: CS202000032

Urgent Field Safety Notice (FSN)
OxyMask™ $EtCO_2$
Potential for Occlusion in the CO_2 Sampling Line

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The OxyMask™ $EtCO_2$ device is an oxygen mask, provided with oxygen tubing and a CO_2 sampling line. It is provided non-sterile and it is not intended to be sterilized.
1.	2. Commercial name(s)
	OxyMask™ $EtCO_2$, OxyMask™ $O_2/EtCO_2$ Adult
1.	3. Primary clinical purpose of device(s)*
	The OxyMask™ $EtCO_2$ is a minimal contact, open oxygen delivery device for use with USP medical grade oxygen and for monitoring breathing by providing a means to sample exhaled CO_2.
1.	4. Device Model/Catalogue/part number(s)*
	1. OM-2125-8 2. OK-2125-8
1.	5. Affected serial or lot number range
	Lot Number: 1. W52497 2. W54153

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	There is a potential for an occlusion in the CO_2 sampling line for this device.
2.	2. Hazard giving rise to the FSCA*
	The potential occlusion may impact the ability to sample exhaled CO_2, which may consequently impact the quality of the capnograph waveforms. There is no impact to the device's capability for oxygen delivery.
2.	3. Predicted risk to patient/users
	An occluded CO_2 sampling line does not directly yield any adverse health consequences if the OxyMask™ $EtCO_2$ is used within the constraints of the established intended use (i.e., it is not used to detect hypercapnia). $EtCO_2$ monitoring by health care professionals is focused on tracking the changes to the waveforms provided on the capnograph. There is the potential for respiratory depression if health care professionals are unable to detect changes in the CO_2 waveforms due to an occluded sampling line. However, if an occluded CO_2 sampling line was connected to the capnograph, no waveform would be displayed, which should lead to an alarm from the capnography indicating an issue to the monitoring health care professional. This should occur immediately upon connection before use on the patient.

FSN Ref: CS20200003203 FSCA Ref: CS202000032

3. Type of Action to mitigate the risk*			
3.	1. Action To Be Taken by the User* ☑ Identify Device ☐ Quarantine Device ☑ Return Device ☐ Destroy Device **The user must return the device to the distributor identified in page 1 of this FSN.**		
3.	2. By when should the action be completed?	As soon as possible	
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)		Yes
3.	4. Action Being Taken by the Manufacturer ☑ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None **The distributor has been instructed to remove the affected product from the market and dispose of it.**		
3	5. By when should the action be completed?	As soon as possible	
3.	6. Is the FSN required to be communicated to the patient /lay user?		No

4. General Information*		
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Southmedic Inc.**
	b. Address	**50 Alliance Blvd., Barrie, Ontario, Canada, L4M 5K3**
4.	4. The Competent (Regulatory) Authority of your country shall be informed about this communication to customers. *	
4.	5. Name/Signature	**Tish Whitehead** **VP, Quality & Regulatory Affairs** 

FSN Ref: CS20200003203 FSCA Ref: CS202000032

Transmission of this Field Safety Notice	
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

FSN Ref: CS20200003203 FSCA Ref: CS202000032

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	CS20200003203
FSN Date*	30-May-2019
Product/ Device name*	OxyMask $EtCO_2$
Product Code(s)	1. OM-2125-8 2. OK-2125-8
Batch/Serial Number (s)	1. W52497 2. W54153

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number: W52497	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number: W54153	Date Returned (DD/MM/YY):
		N/A	Comments:	
☐	No affected devices are available for return/	Customer to complete or enter N/A		

	destruction	
☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		
Signature*		
Date*		

4. Return acknowledgement to sender	
Email	Pre-filled by sender
Customer Helpline	Pre-filled by sender
Postal Address	Pre-filled by sender
Web Portal	Pre-filled by sender
Fax	Pre-filled by sender
Deadline for returning the customer reply form*	Pre-filled by sender

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.