Field Safety Notice (Rev. 2)

Resuscitation and Anesthesia Facemasks

FSN: 2022-001

FSCA: 2022-001

May 24, 2022

Dear Valued Customer,

Name of the affected product:
Therapeutic Respiratory Equipment including single use and reusable non-sterile respiratory products (Masks)

Brand name:
Resuscitation and Anesthesia Facemasks

Manufacturer:
O-Two Medical Technologies Inc.
SRN:

Local distributor:
GCE – Gas Control Equipment
Žižkova 381, 583 01 Chotěboř, Czech Republic

Information on Affected Devices

Device Type(s)

Resuscitation and Anesthesia Facemasks consist of disposable clear PVC masks. Class IIa device.

Primary clinical purpose of device(s)

Resuscitation and Anesthesia Facemasks are intended to be used with automatic ventilator/manual resuscitator or anesthesia machine to provide a mask to face seal which covers both mouth and nose during resuscitation or anesthesia.

Device Model/Catalogue/part number(s)

02FM4999-CS, 02FM500-CS and 02FM5001-CS

Reason for Field Safety Corrective Action (FSCA)

Description of the product problem

There is a discrepancy in the information between outer label and the IFU of the O-two Resuscitation and Anesthesia facemask reference 02FM4999-CS with lot numbers 190604 and 191102. The outer label of the box states that the product is for single use only; however, the IFU indicates that the product can be sterilized by cold chemical method after each use.

Due to a deficiency in our labelling process, the IFU remained without any change. The IFU was updated but not implemented and the information of single-use device was not provided to the customers.

Hazard giving rise to the FSCA

The product was sold as reusable device for more than twenty years and has never had any complaint regarding safety or performance; therefore, we did not identify additional hazard(s). The decision to change from reusable to single-use device is due to commercial reasons and did not affected the clinical performance of the device.

However, to resolve the issue of mislabeling and to prevent misunderstanding regarding the information in the outer pack and IFU, O-Two decided to replace the incorrect IFU with the revised IFU by initiating Field Safety Corrective Action.

Action to be taken

Any hospital, clinic or organization that still has this product in stock, please return them to our distributor, GCE – Gas Control Equipment. The masks that are being reused must be discarded.

This FSN must be transmitted to any organisations where the affected products were distributed or passed on.

Note that the Competent (Regulatory) Authority of your country has been informed about this communication to customers.

We apologize for any inconvenience and thank you for your cooperation during this process.

Hitalo Arume

Regulatory Affairs Specialist

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resuscitation@otwo.com

FSN Acknowledgement form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2022-001
FSN Date*	24 May, 2022
Product/ Device name*	Resuscitation and Anesthesia Facemasks
Product Code(s)	02FM4999-CS, 02FM500-CS and 02FM5001-CS
Batch/Serial Number (s)	190604, 191102, 191202, 200319, 200404 or any lot number you have in your stock.

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

3. Return acknowledgement to Sender	
Email	regulatory@otwo.com
Distributor/Importer Helpline	(905)799-1339
Postal Address	45A- Armthorpe road, Brampton L6T 5M4, CA
Web Portal	https://otwo.com/
Deadline for returning the Distributor/Importer reply form*	30 May 2022 Or 5 calendar days after receiving this FSN

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4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	
☐	I have checked my stock and quarantined inventory	Quantity in stock: Date:
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Quantity: Lot/Serial Number: Date Returned:
☐	I have destroyed affected devices – enter number destroyed and date complete.	Quantity: Lot/Serial Number Date Returned
☐	Neither I nor any of my customers has any affected devices in inventory	
Distributor/Importer name		
Distributor/Importer sign		
Date *		

Mandatory fields are marked with *

It is important that your organization 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.

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