

URGENT FIELD SAFETY NOTICE

Commercial Name: HandyVac™, Guedel Airways and Universal Connector (see Attachment 2 for commercial name and full details)

Issue Date: 07 October 2019
☒ Original Notice ☐ Revised Notice Revision No.: Rev. 1


Reference/REF No: See Attachment 2: Product List

FSCA Ref.: 2019-008-011MA & 013MA

Type of Action: Recall/Product Disposal

Please note that this action only applies to specific product codes of the above-mentioned products.

DESCRIPTION OF THE PROBLEM	<p>ConvaTec has voluntarily initiated a recall of specific product codes of the above-mentioned products.</p> <p>Internal assessment of product packaging integrity has confirmed that these devices are not meeting our expectations or those of our customers. Transportation testing conducted on the product in its current market packaging failed, confirming the potential for a breach in the sterile barrier.</p> <p>ConvaTec has not received any reports of incidents related to the packaging seal issue.</p> <p>Using a non-sterile device on a patient may expose the patient to infectious agents increasing the patient risk of developing infection.</p>
INFORMATION ON AFFECTED DEVICES	<p>HandyVac™ HandyVac™ is a single-use sterile low vacuum wound drainage system for post-operative surgical wound drainage, to drain wound fluids and prevent formation of hematomas, which can delay healing, cause pain or support infection. HandyVac™ consists of a drainage tube connected to a low-vacuum bellows and a drainage bag to collect the drained fluids. It is supplied as a standalone system or together with wound drains or wound drains that are pre-connected to a trocar.</p> <p>Guedel Airways Single-use sterile oropharyngeal airways to maintain a patent airway in unconscious or anaesthetized patients by keeping the airway passage free.</p> <p>Universal Connector Sterile connector with CH 04-18 Christmas Tree connector on one side and Luer slip port on the other side.</p>

PRODUCT IDENTIFICATION PROCEDURE	<p><u>Confirmation of Specific Product Codes and Lot Numbers:</u></p> <p>This issue is limited to specific product codes as identified in Attachment 2.</p> <p>Only the identified product part codes within this notice may have a potential breach in the sterile barrier packaging.</p> <p>For this reason and to address any potential risk of harm, all the affected products should not be used.</p> <p>The only way to identify affected product is by comparing Product code/REF and LOT/Batch number to the recalled product list (see Attachment 1). There is no other discernable difference between affected and unaffected product.</p> <p>See Attachment 1 for examples of package labelling that highlights the location of the product code and LOT/Batch number on the device labels. These are located on the primary packaging and the shipping carton. The product code (reference number) is preceded by the word 'REF' and the LOT/Batch number is preceded by the</p> <p>symbol,  .</p>
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DISTRIBUTOR ACTIONS

1	Verify if you have affected product in your inventory and identify which of your customers have received potentially affected product using Attachment 2: Product List .
2	<p>If you have distributed this product:</p> <ul style="list-style-type: none"> • To other Wholesalers: <ul style="list-style-type: none"> ○ Please forward this Field Safety Notice, including attachments, to them and ask that they follow these Distributor Actions. • To End Users <ul style="list-style-type: none"> ○ Please forward this Field Safety Notice, including attachments, to your end-users and ask that they follow the End User Actions Section (below).
3	<p>If you have received returned product from your customers that they have identified or if you have any stock on hand which you have verified as included in the scope of this Field Safety Notice (as described in Attachment 2: Product List).</p> <ul style="list-style-type: none"> • Immediately stop distributing and quarantine all affected products. • Contact ConvaTec Customer Service for further instructions on how to return affected product and to arrange credit. <p>Products will not be automatically replaced. For replacement product(s), please place new orders with ConvaTec using the usual process. ConvaTec will supply new products as soon as possible.</p>
4	<p>Please complete the Field Safety Notice <u>Distributor Response Form</u> and return to your Customer Service as soon as possible. Include details of product to be returned, if applicable.</p> <p>Please send a complete list of all consignees to your Customer Service as soon as possible. Please indicate if you have sent this Field Safety Notice, including attachments, to your consignees. This information is not required but important to allow ConvaTec to perform effectiveness checks.</p> <p>Please contact your Customer Service if you have any additional questions.</p>

PLEASE PROVIDE A COMPLETED RESPONSE AS SOON AS POSSIBLE

RETAILER ACTIONS

1	<p>For Retailers with a physical location (e.g. a “brick and mortar” store)</p> <ul style="list-style-type: none"> • Immediately stop distributing and quarantine all affected products • Please post the Field Safety Notice including Attachment 1 in a conspicuous location in your store. <p>For Retailers, which have a digital location (e.g. an eRetailer)</p> <ul style="list-style-type: none"> • Please forward Attachment 2: Product List showing affected Product Codes/REF No. and LOT Numbers via physical mail or e-mail to End-users.
2	<p>If you have received returned product from your customers that they have identified or if you have any stock on hand which you have verified as included in the scope of this Field Safety Notice (as described in Attachment 1: Product List, contact Customer Services Centre for further instructions on how to return affected product and to arrange credit.</p> <p>Products will not be automatically replaced. For replacement product (s), please place new orders with ConvaTec using the usual process. ConvaTec will supply new products as soon as possible.</p>
3	<p>Please complete the Field Safety Notice Distributor Response Form and return to your Customer Services as soon as possible. Include details of product to be returned, if applicable.</p> <p>Please send a complete list of all consignees to your Customer Service as soon as possible. Please indicate if you have sent this Field Safety Notice, including attachments, to your consignees.</p> <p>This information is not required but important to allow ConvaTec to perform effectiveness checks.</p> <p>Please contact your Customer Service if you have any additional questions.</p>

PLEASE PROVIDE A COMPLETED RESPONSE AS SOON AS POSSIBLE

END USER ACTIONS (CLINICIANS, HOSPITALS, PATIENTS, OTHERS)

1	<p>Our records show that you have taken delivery of affected product. Please stop the use of all affected devices as defined in this document.</p>
2	<p>This issue is limited to specific product codes and lots. Check stock and ensure that all affected devices that you have in stock are quarantined.</p> <p>If you do not know where the product code and/or lot number are located, please refer to Attachment 1: Examples of Labelling.</p> <p>To verify whether your lot is associated with the product included in the scope of this Field Safety Notice use Attachment 2: Product List showing affected Product Codes/REF No. and LOT Numbers.</p>
3	<p>Please complete the enclosed, Field Safety Notice ‘End User Response Form’ and forward it to your distributor as soon as possible.</p> <p>Include details of product to be returned, if applicable.</p> <p>This information is required to allow ConvaTec to perform effectiveness checks.</p>
4	<p>Contact your distributor (or ConvaTec Customer Service if you have purchased the product directly from ConvaTec) to arrange return of affected products, if applicable, and to arrange credit. For replacement products, please place new orders with your distributor or ConvaTec using the usual route and procedure.</p> <p>Please contact your Customer Service if you have any additional questions.</p>

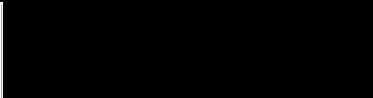
PLEASE PROVIDE A COMPLETED RESPONSE AS SOON AS POSSIBLE

TRANSMISSION OF THIS FIELD SAFETY NOTICE	<p>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. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.</p>
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ConvaTec is committed to providing quality products and services to our customers and we sincerely apologise for any inconvenience this notice may cause.

The relevant National Authorities have been advised about this Field Safety Corrective Action.

AUTHORISATION

<u>Name</u> Diane Baker	<u>Title</u> Director, CCC Franchise Regulatory Affairs and Quality Assurance	<u>Address</u> ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, CH5 2NU, U.K.	
<u>Date</u> 	07 October 2019	<u>Signature</u> 	

cc: Chairman Medical Board and relevant Head-of-Department of affected healthcare facilities

Local Customer Service Contact:**Singapore**

Optimal Medical Products Pte Ltd

Tel: +65 6253 5247

Email: sales@optimalmedical.com.sg

FIELD SAFETY NOTICE DISTRIBUTOR RESPONSE FORM

PLEASE COMPLETE AND RETURN by Fax/Email

Consignee of the device:

Consignee Account No:	
Consignee Name:	
Consignee Address:	

The following products, HandyVac™, Universal Connector, and Guedel Airways, have been distributed to your facility:

Invoice #	Sales Order #	Product Code / REF No.	SAP Code	LOT No.	Quantity Delivered (pieces)

Distributors (Tick all that apply and give details, where applicable)

<input type="checkbox"/>	I confirm the receipt, the reading and understanding of the Field Safety Notice.	
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Add details to Table 1
<input type="checkbox"/>	I have identified customers that received or may have received this device	
<input type="checkbox"/>	I have attached customer list	Add details to Table 2
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date sent:
<input type="checkbox"/>	I have received confirmation of reply from all identified customers	Attach responses
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	

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.

Table 1. Quarantined Inventory: Record quantity (pieces) for each LOT to be returned.

LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand

Table 2. Customer List: Please provide details of affected HandyVac™, Universal Connector, and Guedel Airways products that were distributed to your customers.

Customer Name	Product Code / REF No.	SAP Code	LOT No.	Quantity (pieces)

FORM Completed and Returned From:	
Name (CAPITAL LETTERS):	
Position:	
Company Name:	
Address:	
Phone No:	
Signature:	
Date (dd/mmm/yyyy):	

FIELD SAFETY NOTICE CUSTOMER RESPONSE FORM
PLEASE COMPLETE AND RETURN by Fax/Email

Consignee of the device:

Consignee Account No:	
Consignee Name:	
Consignee Address:	

The following products, HandyVac™, Universal Connector, and Guedel Airways have been distributed to your facility:

Invoice #	Sales Order #	Product Code / REF No.	SAP Code	LOT No.	Quantity Delivered (pieces)

Customer action undertaken on behalf of Healthcare Organisation (Tick all that apply)		
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understand its content.	
<input type="checkbox"/>	I performed all actions requested by the FSN.	
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Add details to Table 1
<input type="checkbox"/>	No affected devices are available for return	

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.

Table 1. Quarantined Inventory: Record quantity (pieces) for each LOT to be returned.

LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand

FORM Completed and Returned From:	
Name (CAPITAL LETTERS):	
Position:	
Company Name:	
Address:	
Phone No:	
Signature:	
Date (dd/mmm/yyyy):	

Local Customer Service Contact:

Singapore

Optimal Medical Products Pte Ltd

Tel: +65 6253 5247

Email: sales@optimalmedical.com.sg

List of Attachments

Attachment 1: Examples of Labelling and Affected Product

Attachment 2: Product List showing affected Product Codes/REF No. and LOT Numbers

Attachment 1: Examples of Labelling and Affected Product

For the AFFECTED product

...the shipper labelling will include the product code and lot number.

See example labels to the right.

Product Code (REF/SKU)

Lot Number

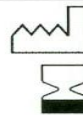
REF 84061181

GB Unometer bag 2000
S Unometerpåse
DK Unometerpose 2000
FIN Unometerpussi
NO Unometerpose 2000
Made in Belarus

2 X 100



ConvaTec Limited
First Avenue
Deeside Industrial Park
Deeside, Flintshire, CH5 2NU, UK



2012-04

2017-03

LOT 632574

EAN No. 05705243208804



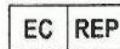
(01)05705243208804(17)170331(10)632574

v.04

...the market unit labelling will include the product code and lot number.

100 REF 84061181

GB Unometer bag 2000
S Unometerpåse
DK Unometerpose 2000
FIN Unometerpussi
NO Unometerpose 2000



UNOMEDICAL A/S
Aaholmvej 1-3, Østved
4320 LEJRE DENMARK

LOT 632574



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EAN No. 05705243208798



(01)05705243208798(17)240731(10)632574

2019-08

2024-07



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Attachment 2: Product List showing affected Product Codes/REF No. and LOT Numbers

PURPOSE

This attachment is a listing of affected products included in the scope of this Field Safety Notice, which has been organized by Product Code. Within each product code, the lot numbers are organized numerically, smallest to largest.

Please contact your ConvaTec Customer Service Team Member for assistance.

Column Header	Details	What Level of Packaging includes this information?
Product Code	The Product Code is also known as the Catalog Number, or the SKU.	This number is included on the Shipper Label and the Market Unit Label.
Product Description	<p>The Product Description is a description of the finished product from the internal ConvaTec system, SAP. It is a brief, coded description of the product.</p> <p>Utilizing the first line item example, Product Code 84062182, Batch: 156697, UNOMETER BAG 3L BO (50/100) INT:</p> <ul style="list-style-type: none"> • REF: Product code • Batch: Lot number • UNOMETER BAG: UnoMeter™ 500 • BO(50/100): with Bottom Outlet (pack of 50/100) 	A description of the material is on the Shipper Label and on the Market Unit Labeling; however, the description on these labels may not exactly match (verbatim) the Material Description as listed in this attachment.
Lot Number	A traceable number which is specific to the product.	This number is included on the Shipper Label and the Market Unit Label.

Attachment 2: Product List showing affected Product Codes/REF No. and LOT Numbers		
<i>Product Code</i>	<i>Product Description</i>	<i>Batch/Lot</i>
84010182	Catheter Connector UNO CONN CH04-CH18(100/800) INT	196869
		204020
		211197
		211651
		219167
		223011
		303471
		303530
		304780
		321887

Note: This is the list of affected product lots imported and distributed in Singapore. There are other product models and product lots affected globally. If in doubt, please check with your distributor or ConvaTec.