

## **URGENT FIELD SAFETY NOTICE**

### **END USERS**

**Commercial name:** Rectal Tubes, Unoversal Drainage Systems, SimpaVac, Sterile Suction Connecting Tubes, Sterile Connecting Pieces, Suction Handles/Sets (FilterFlow™/Deltaflo), Oxygen Catheters, Sterile Nasal Oxygen Cannulas, Sterile Oxygen Connecting Tubes, and Sterile Forceps.

**Issue Date:** 04 Jan 2019

**REF No:** See Attachment A

**FSCA ID:** 2018-005 Phase 3

**Type of action:** Recall / Product Disposal

**Recall Centre email:** [convatecproductrecall@stericycle.com](mailto:convatecproductrecall@stericycle.com)

**Please note that this action only applies to specific product codes and does not affect all product codes of the above-mentioned products.**

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#### **Description of the problem:**

ConvaTec has voluntarily initiated a recall of specific product codes of the above-mentioned products.

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 packaging failed confirming the potential for a breach in the sterile barrier. Using a non-sterile device on a patient may expose the patient to infectious agents increasing the patient risk of developing infection.

ConvaTec has not received any reports of incidents related to the packaging seal issue.

#### **Product Descriptions**

**Rectal Tubes** are single-use devices which are inserted via the rectum to drain faeces, perform lavage, administer medicine and/or enemas to the lower intestine, for colonoscopy exploration and colonic decompression.

**Unoversal Drainage Systems** are intended to be used for wound drainage by means of low vacuum where a medium or small volume of post-operative bleeding is expected. They are single use devices that are intended for use in short-term treatment.

**SimpaVac** is a canister intended for low vacuum post-operative wound drainage in conventional (open) surgery.

**Sterile Suction Connecting Tubes** are intended to connect two existing devices, (e.g. suction handles and canisters), or as an extension between an existing device and a vacuum source.

**Sterile Connecting Pieces** are intended to connect two existing devices such as suction handles and collection canisters.

**Suction Handle/Sets (FilterFlow™/Deltaflo)** is a device intended primarily for orthopaedic surgical procedures to remove and collect debris and bone fragments chips, cement, marrow and blood clots without blocking the suction device, using a combination of suctioning and filtering.

**Oxygen Catheters** are single patient use devices, requiring short-term oxygen therapy and administer oxygen (in low concentration) directly via the nasopharyngeal or nasal route.

**Sterile Nasal Oxygen Cannulas** are intended for direct administration of low concentrations of oxygen via the bi-nasal route.

**Sterile Oxygen Connecting Tubes** are intended for administration of low/medium concentration of oxygen in oxygen therapy. The connecting/extension tubes channel the oxygen from a stationary or mobile oxygen supply unit to the patient via a dispensing device. Dispensing devices can be e.g. oxygen catheters, nasal oxygen cannulas or facemasks. When using connecting/extension tubes between the patient dispensing device and the supply unit, the patient is allowed more freedom of movement without interruption of the oxygen flow.

**Sterile Forceps:** These are single use tweezers for multiple applications. Used in clinical procedures to grasp, manipulate, maneuver or assist with the removal of debris, particulates or wound tissue.


### **Product Identification Procedure**

Only the identified product part codes within this notice may have a potential breach in the sterile barrier packaging.

For this reason and to address any potential risk of harm, all the affected products should **not be used**.

The only way to identify affected product is by comparing Product code/REF and LOT/Batch number to the recalled product list (see Attachment A). There is no other discernable difference between affected and unaffected product.

See Attachment B 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 symbol,  .

**Advice on action to be taken by the end user.**

Our records show that you have taken delivery of affected product. Please follow the steps below:

1. Please stop the use of all affected devices as defined in this document.
2. Check stock and ensure that all affected devices that you have in stock are quarantined.
3. Complete the enclosed 'Recall Response Form for END USERS' which should be forwarded to your distributor **as soon as possible**.
4. Contact your distributor (not Convatec or the Recall center) to arrange return of affected products, if applicable, and to arrange credit. **For replacement products, please place new orders with your distributor using the usual route and procedure.**

**PLEASE PROVIDE A COMPLETED RESPONSE AS SOON AS POSSIBLE.**

Please continue to report any non-recall related information such as any adverse events involving these products to your distributor or the ConvaTec Customer Care Line (refer to the **Regional ConvaTec contact** list for details).

**Transmission of this Field Safety Notice:**


This notice should be sent to all others who have received the affected devices within your organization or to any organization where the affected devices have been transferred.

ConvaTec is committed to providing quality products and services to our customers and we sincerely apologize for any inconvenience this notice may cause.

If you have any questions relating to this recall, please contact the Recall Centre. For other support please contact your distributor or local ConvaTec representative. See **Regional ConvaTec contact** list for details.

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

**Authorisation:**

<u>Name</u> Duncan Rowley	<u>Title</u> Senior Director, Quality, Regulatory & Clinical, EMEA & CCC	<u>Address</u> ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, CH5 2NU, U.K.	
<u>Date</u> 04 Jan 2019	<u>Signature</u>		

**Recall Centre: Dedicated help desk for this Field Safety Corrective Action:**

Tel: +44 208 6101 608

Fax: +44-207 6601 568

Email: [convatecproductrecall@stericycle.com](mailto:convatecproductrecall@stericycle.com)**'Regional contact' for other support:****Singapore**

Tel: +65 6253 5247

Fax: +65 6251 4248

Email: [REDACTED]

cc: Chairman Medical Board and relevant Head of Departments



Please answer each of the following.

1.  We do NOT have any affected product(s).
2.  We have the following affected product(s):

Record quantity (pieces) for each LOT to be disposed:

LOT No.	Units on Hand	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:











<b>Name (CAPITAL LETTERS):</b>	
<b>Position:</b>	
<b>Company Name:</b>	
<b>Address:</b>	
<b>Phone No:</b>	
<b>Signature:</b>	
<b>Date (dd/mmm/yyyy):</b>	

**Recall Centre: Dedicated help desk for this Field Safety Corrective Action:**  
 Tel: +44 208 6101 608  
 Fax: +44-207 6601 568  
 Email: [convatecproductrecall@stericycle.com](mailto:convatecproductrecall@stericycle.com)

**Attachment A: List showing affected Product Codes/REF and batches in Singapore.**

<b>Product Code / REF No.</b>	<b>Product Name</b>	<b>LOT No.</b>
13001182	UNO MINIVAC SET REDON DRN CH6(50/200)	192062 195242 301428 303951 307795 308069 314969 315284 165661 166258
13002182	MINI SET DE REDON CH08	150531 153978 170092 179531 320239
14012182	UNO RECTAL TUBE CH25/40CM(100/600) AUS	167732 179453 181569 234456 236044 241403 245292 7D01679 7G01112
14016182	UNO RECTAL TUBE CH28/40CM(50/400) AUS	152640 158868 172866 215156 220572 7A01842 7B02811 7F00124

Attachment B: Example of Package Labelling

For the Affected product	
The shipper label	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="border: 1px solid black; padding: 2px;">REF</div> <div style="font-size: 2em; font-weight: bold;">29001182</div> <div style="color: red; font-size: 0.8em;">← Product code</div> </div> <p>GB Twin nasal oxygen cannula  D Sauerstoff-Brille  F Lunette a oxygene  NL Zuurstofbril  I Cannula per ossigenoterapia</p> <p>Made in Belarus  <b>CH 10 210CM</b></p> <p style="text-align: center; font-size: 1.5em; font-weight: bold;">6 X 50</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  </div> <div style="text-align: center;">  </div> <div style="font-size: 0.8em;">             ConvaTec Limited              First Avenue              Deeside Industrial Park              Deeside, Flintshire, CH5 2NU, UK           </div> </div> <hr/> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">  <p>2012-04</p> </div> <div style="text-align: center;"> <div style="border: 1px solid black; padding: 2px;">LOT</div> <div style="font-size: 1.5em; font-weight: bold;">630904</div> <div style="color: red; font-size: 0.8em;">← Lot/Batch Number</div> </div> </div> <div style="text-align: center; margin-top: 5px;">  <p>2017-03</p> </div> <div style="text-align: center; margin-top: 5px;"> <p>EAN No. 05705243273444</p> </div> <hr/> <div style="text-align: center;">  <p style="font-size: 0.7em;">(01)05705243273444(17)170331(10)630904 v.05</p> </div>
The market unit label	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="font-size: 1.5em; font-weight: bold;">50</div> <div style="border: 1px solid black; padding: 2px;">REF</div> <div style="font-size: 1.5em; font-weight: bold;">29001182</div> <div style="color: red; font-size: 0.8em;">← Product Code</div> <div style="text-align: right;"> <p>CH 10 210CM</p> </div> </div> <p>GB Twin nasal oxygen cannula  D Sauerstoff-Brille  F Lunette a oxygene  NL Zuurstofbril  I Cannula per ossigenoterapia</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  </div> <div style="text-align: center;"> <div style="border: 1px solid black; padding: 2px;">LOT</div> <div style="font-size: 1.5em; font-weight: bold;">630904</div> <div style="color: red; font-size: 0.8em;">← Lot/Batch Number</div> </div> <div style="font-size: 0.8em;">             ConvaTec Limited              First Avenue              Deeside Industrial Park              Deeside, Flintshire, CH5 2NU, UK           </div> </div> <div style="display: flex; justify-content: space-between; align-items: center; margin-top: 10px;"> <div style="text-align: center;"> <p>EAN No. 05705243273437</p>  <p style="font-size: 0.7em;">(01)05705243273437(17)170331(10)630904</p> </div> <div style="text-align: center;">  <p>2012-04</p> </div> <div style="text-align: center;">  <p>2017-03</p> </div> <div style="text-align: center;">  </div> </div> <p style="text-align: right; font-size: 0.8em;">v.05</p>