

URGENT FIELD SAFETY NOTICE

Commercial Name: Convex Two-Piece Skin Barriers i.e. Natura / Surfit / Combihesive Wafers
(see Attachment 3 for commercial name and full details)

Issue Date: 20 September 2019

X Original Notice ___ Revised Notice

Revision No.: Rev. 1 (for EU)

Reference/REF No: See Attachment 3: Product List

FSCA Ref.: 2019-006MA

Type of Action: Customer Notification

FSCA Helpdesk Email: Refer to the “ ‘Regional ConvaTec Contact’ for other support:” section

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

DESCRIPTION OF THE PROBLEM	<p>ConvaTec has voluntarily initiated a Field Safety Corrective Action in the form of a Customer Notification for specific product codes and lots of the above-mentioned Ostomy products.</p> <p>ConvaTec has received complaints associated with use of Convex Two-Piece Skin Barriers where the starter hole (stoma hole) is off-centre on product manufactured from February 2017 to September 2018. Specifically, we have had three instances globally where use of an off-centre Convex Two-Piece Skin Barrier led to a stomal cut. These cuts did not require hospitalization and the end-user was able to resolve the issue. The overall risk of injury is low. However, since this risk can be visually detected, we are taking precautionary measures to notify customers of this matter so that the end-user can thoroughly check their product to see if it: a) was manufactured during this period and b) is visually off-centre.</p>
INFORMATION ON AFFECTED DEVICES	<ul style="list-style-type: none"> • SurFit™/ Combihesive™ Wafers: • System 92 Secure Moldable Convex Durahesive™ Wafer • System 92 Secure Durahesive Wafer with Convex

PRODUCT IDENTIFICATION

How to tell the difference between affected product and unaffected product	<p><u>Confirmation of Specific Product Codes and Lot Numbers:</u></p> <p>This issue is limited to specific product codes and lot numbers, identified in Attachment 3.</p> <p>All customers may refer to Attachment 3 to verify if their product is included in the scope of this Field Safety Notice.</p> <p>Upon request, a customer scope listing based on your receipts will be provided. Please contact your ConvaTec Customer Services Team Member for assistance.</p> <p>For product in scope of this Field Safety Notice, End Users may refer to Attachment 1 for examples of package labeling highlighting the location of the LOT No. and Product Code / REF No.</p> <p><u>Ostomy Product End User Visual Verification of Potentially Affected Product:</u></p> <p>Ostomy Product End Users may refer to Attachment 2 for additional information on how to visually verify potentially affected product and / or contact the FSCA Help Desk should they have additional questions.</p>
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DISTRIBUTOR ACTIONS

1	<p>Verify if you have affected product in your inventory and identify which of your customers have received potentially affected product using Attachment 3: Product List showing affected Product Codes/REF No. and LOT Numbers.</p>
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 as off-centre 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 3: Product List showing affected Product Codes/REF No. and LOT Numbers), you do not need to open or inspect the product, ConvaTec will accept product returns and provide full credit to customers. Replacement product can be ordered via the normal ordering process.</p> <p>Contact the FSCA Help Desk for further instructions on how to return affected product and to arrange credit.</p>
4	<p>Action: Please complete the Field Safety Notice Distributor Response Form and return to the FSCA Help Desk by fax or email as soon as possible. Include details of product to be returned, if applicable.</p> <p>Action: Please send a complete list of all consignees to the FSCA Help Desk by fax or email 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 the FSCA Help Desk 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"> Please post Attachment 2: Ostomy Product User Letter of this Field Safety Notice 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: Ostomy Product User Letter and Attachment 3: Product List showing affected Product Codes/REF No. and LOT Numbers via physical mail or e-mail.
2	<p>If you have received returned product from your customers that they have identified as off-centre 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 3: Product List showing affected Product Codes/REF No. and LOT Numbers), you do not need to open or inspect the product, ConvaTec will accept product returns and provide full credit to customers. Replacement product can be ordered via the normal ordering process.</p> <p>Contact the FSCA Help Desk for further instructions on how to return affected product and to arrange credit.</p>
3	<p>Action: Please complete the Field Safety Notice Distributor Response Form and return to the FSCA Help Desk by fax or email as soon as possible. Include details of product to be returned, if applicable.</p> <p>Action: Please send a complete list of all consignees to the FSCA Help Desk by fax or email 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 the FSCA Help Desk 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>Based on our records, the product you have received may potentially have an off-centre starter hole (stoma hole) which is visibly off-centre. Example images are provided in Attachment 1: Photographic Examples of Labeling and Affected Product.</p>
2	<p>This issue is limited to specific product codes and lots. Please verify that your lot is associated with the product included in the scope of this Field Safety Notice utilising Attachment 3: Product List showing affected Product Codes/REF No. and LOT Numbers.</p> <p>If you do not know where the product code and/ or lot number are located, please refer to Attachment 1: Photographic Examples of Labeling and Affected Product.</p>
3	<p>Additional supporting information is included for you in Attachment 2: Ostomy Product User Letter. Please provide this to patients via physical mail or e-mail, as applicable.</p>
3	<p>If you have any product you have identified as off-centre in your possession, please contact the FSCA Help Desk.</p> <p>ConvaTec will accept product returns and replace product free of charge. You do not need to open or inspect this product.</p>
4	<p>Action: Please complete the Field Safety Notice End User Response Form and return to the FSCA Help Desk by fax or email as soon as possible. Include details of product to be returned, if applicable.</p> <p>This information is required to allow ConvaTec to perform effectiveness checks.</p> <p>Please contact the FSCA Help Desk 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 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>	<u>Title</u>	<u>Address</u>	
David Pudwill	Senior Director, Ostomy Franchise Regulatory Affairs and Quality	ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, CH5 2NU, U.K.	
<u>Date</u>	20 September 2019	<u>Signature</u>	

List of Attachments

Attachment 1: Photographic Examples of Labelling and Affected Product

Attachment 2: Ostomy Product User Letter

Attachment 3: Product List showing affected Product Codes/REF No. and LOT Numbers

‘Regional ConvaTec Contact’ for other support:

Country	Distributors, Retailers, Wholesalers should contact	End Users should contact
Austria	Stericycle Phone: 0800 281598 E-Mail: Convatec2p@stericycle.com	CIC Team Austria Phone: +43 800 21 63 39 E-Mail: convatec.austria@convatec.com
Belgium	Stericycle Phone: 0800 71 804 E-Mail: Convatec2p@stericycle.com	Francoise Engelen Phone: 0032-476461740 E-Mail: info.convatec@convatec.com
Bulgaria	Stericycle Phone: 44 20 8089 3767 E-Mail: Convatec2p@stericycle.com	Please contact your local distributor
Croatia	Stericycle Phone: 44 20 8089 3767 E-Mail: Convatec2p@stericycle.com	Please contact your local distributor
Czech Republic	ConvaTec Czech Republic Phone: 800321222 E-Mail: info@convatec.cz	ConvaTec Czech Republic Phone: 800122111 E-Mail: info@convatec.cz
Denmark	Stericycle Phone: 80 82 00 54 E-Mail: Convatec2p@stericycle.com	CIC Team Denmark Phone: +45 48167475 E-Mail: convatec.danmark@convatec.com
Estonia	Stericycle Phone: 44 20 8089 3767 E-Mail: Convatec2p@stericycle.com	Please contact your local distributor
Finland	Stericycle Phone: 0800 413608 E-Mail: Convatec2p@stericycle.com	ConvaTec Oy Phone: +358 20 7659630 E-Mail: mail.fi@convatec.com
France	Stericycle Phone: 0 805 08 02 60 E-Mail: Convatec2p@stericycle.com	ConvaTec Customer Service Team Phone: +33800 358 480 E-Mail: fr.serviceclient@convatec.com
Germany	Stericycle Phone: 0800-0008875 E-Mail: Convatec2p@stericycle.com	CIC Team Germany Phone: +49 800 766 200 E-Mail: convatec.servicede@convatec.com
Greece	ConvaTec Customer Support Team Phone: 30-210-6564740 E-Mail: Lila.Karipidi@convatec.com	ConvaTec Customer Support Team Phone: 30-210-6564740 E-Mail: Lila.Karipidi@convatec.com
Hungary	Stericycle Phone: 44 20 8089 3767 E-Mail: Convatec2p@stericycle.com	Please contact your local distributor
Iceland	Stericycle Phone: 44 20 8089 3767 E-Mail: Convatec2p@stericycle.com	Medor ehf Phone: 665 7011 E-Mail: signyf@medor.is
Ireland	Stericycle Phone: 44 20 8089 3767	Tracey Fairclough Phone: 07442188256

Country	Distributors, Retailers, Wholesalers should contact	End Users should contact
	E-Mail: Convatec2p@stericycle.com	E-Mail: tracey.fairclough@amcaregroup.co.uk
Israel	Stericycle Phone: 44 20 8089 3767 E-Mail: Convatec2p@stericycle.com	Please contact your local distributor
Italy	Stericycle Phone: 800-789926 E-Mail: Convatec2p@stericycle.com	ConvaTel Italia Phone: 800930930 E-Mail: convatel.italia@convatec.com
Luxembourg	Stericycle Phone: 44 20 8089 3767 E-Mail: Convatec2p@stericycle.com	Francoise Engelen Phone: 0032-476461740 E-Mail: info.convatec@convatec.com
Malta	Stericycle Phone: 44 20 8089 3767 E-Mail: Convatec2p@stericycle.com	Ian Pace Phone: +356-2133-4412 E-Mail: ian@ipl.com.mt
Netherlands	Stericycle Phone: 0800 0233049 E-Mail: Convatec2p@stericycle.com	CIC Woerden Phone: 0031-348436941 E-Mail: info.convatec@convatec.com
Norway	Stericycle Phone: 800 24 720 E-Mail: Convatec2p@stericycle.com	CIC Norway Phone: 800 30 995 E-Mail: convatec.kundeservice@convatec.com
Poland	Dział Pomocy ConvaTec Phone: 800120093 E-Mail: dzial.pomocy@convatec.com	Dział Pomocy ConvaTec Phone: 800120093 E-Mail: dzial.pomocy@convatec.com
Portugal	Customer Service Iberia Phone: 93 602 3700 E-Mail: CustomerServiceIberia@convatec.com	ConvaTel Phone: 800201678 E-Mail: convatel.pt@convatec.com
Romania	Stericycle Phone: 44 20 8089 3767 E-Mail: Convatec2p@stericycle.com	Please contact your local distributor
Slovakia	Stericycle Phone: 44 20 8089 3767 E-Mail: Convatec2p@stericycle.com	Zákaznícke centrum ConvaTec Nitra Slovakia Phone: +421 800 800 111 E-Mail: stomalinka@convatec.com
Slovenia	Stericycle Phone: 44 20 8089 3767 E-Mail: Convatec2p@stericycle.com	Please contact your local distributor
Spain	Customer Service Iberia Phone: 93 602 3700 E-Mail: CustomerServiceIberia@convatec.com	InfoTec Phone: 936023737 E-Mail: infotec@convatec.com
Sweden	Stericycle Phone: 020-10 93 35 E-Mail: Convatec2p@stericycle.com	Nordic Customer Service Phone: +46(0)42332010 E-Mail: customerservicenordic@convatec.com
Switzerland	Stericycle Phone: 0800-848035 E-Mail: Convatec2p@stericycle.com	ConvaTec Customer Service Phone: +41 800 55 11 10 E-Mail: convatec.switzerland@convatec.com

Country	Distributors, Retailers, Wholesalers should contact	End Users should contact
Turkey	Doğa Soysal, Fulya Tüzüner, or İrem Taspınar Phone: <ul style="list-style-type: none"> • +90 2164165200 • +90 3122198361 E-Mail: <ul style="list-style-type: none"> • doga.soyosal@convatec.com • fulya.tuzuner@convatec.com • irem.taspinar@convatec.com 	Doğa Soysal, Fulya Tüzüner, or İrem Taspınar Phone: <ul style="list-style-type: none"> • +90 2164165200 • +90 3122198361 E-Mail: <ul style="list-style-type: none"> • doga.soyosal@convatec.com • fulya.tuzuner@convatec.com • irem.taspinar@convatec.com
United Kingdom	Stericycle Phone: 0800 069 8202 E-Mail: Convatec2p@stericycle.com	Tracey Fairclough Phone: 07442188256 E-Mail: tracey.fairclough@amcaregroup.co.uk

**FIELD SAFETY NOTICE
DISTRIBUTOR RESPONSE FORM
PLEASE COMPLETE AND RETURN by Email**

Consignee of the device:

Consignee Account No:	
Consignee Name:	
Consignee Address:	

The following product, Convex Two-Piece Skin Barriers 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
<input type="checkbox"/>	I have identified customers that received or may have received this device
<input type="checkbox"/>	I have attached customer list
<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
<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 this action.



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 Convex Two-Piece Skin Barrier 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 Email**

Consignee of the device:

Consignee Account No:	
Consignee Name:	
Consignee Address:	

The following products, Convex Two-Piece Skin Barriers 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	
<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 this action.

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):	