



URGENT FIELD SAFETY NOTICE - SINGAPORE

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

Issue Date: 30 August 2019
X Original Notice ___ Revised Notice Revision No.: Rev. 1

Reference/REF No: See Appendix A: Product List

FSCA Ref.: 2019-006MA

Type of Action: Customer Notification

FSCA Helpdesk Email: cindy.tan@convatec.com

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	<p>The Natura™ Accordion Convex Wafer is used in conjunction with a Natura Ostomy Pouch to form a two-piece Ostomy system, they have matching couplings which allow the pouch and Skin Barrier to snap together. The wafer is a Skin Barrier and is based on the existing Natura Accordion Cut-to-Fit flange which is designed to aid comfortable application by reducing the pressure required to connect the pouch to Skin Barrier flange. The convexity is designed to also help address issues ostomates experience with irregular and difficult-to-manage stomas. The product is supplied non-sterile.</p> <p>SurFit™/ Combihesive™ Wafers: System 92 Secure Moldable Convex Durahesive™ Wafer is a tan trilaminate (alternating layers of adhesive and polyethylene) Durahesive adhesive mass that is mounted to a convex disc. A flange is attached to the convex disc. A white, square non-woven collar is attached between outer edges of the flange and the disc. A clear polystyrene release shield covers the adhesive and tape border.</p> <p>System 92 Secure Durahesive Wafer with Convex is a flanged convex disc which is mounted to trilaminate (alternating layers of adhesive and polyethylene) Durahesive adhesive. A white square non-woven collar is attached between the edges of the flange and the disc.</p>

	Wafers are intended to be used in conjunction with Natura and Natura+ ostomy pouches to manage stomal output.
--	--

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 Appendix A.</p> <p>All customers may refer to Appendix A to verify if their product is included in the scope of this Field Safety Notice.</p> <p>Upon request, a custom scope listing based on your receipts will be provided. Please contact your ConvaTec Customer Service 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>
---	--

DISTRIBUTOR ACTIONS

1	Verify if you have affected product in your inventory and identify which of your customers have received potentially affected product using Appendix A: Product List showing affected Product Codes/REF No. and LOT Numbers.
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 Appendix A: 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. 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 Appendix A: 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 Appendix A: 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. 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 Appendix A: 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. 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

FSCA Help Desk - SINGAPORE:

ConvaTec Singapore Customer Service

Tel: +65 6245 9838 / [REDACTED]

Email: [REDACTED]

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>
---	--

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>	30 August 2019	<u>Signature</u> [REDACTED]

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



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, 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	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 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):	

FSCA Help Desk - SINGAPORE:

ConvaTec Singapore Customer Service

Tel: +65 6245 9838 / [REDACTED]

Email: [REDACTED]



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, 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	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):	

FSCA Help Desk - SINGAPORE:

ConvaTec Singapore Customer Service

Tel: +65 6245 9838 / [REDACTED]

[REDACTED]



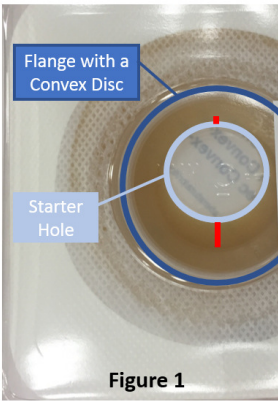
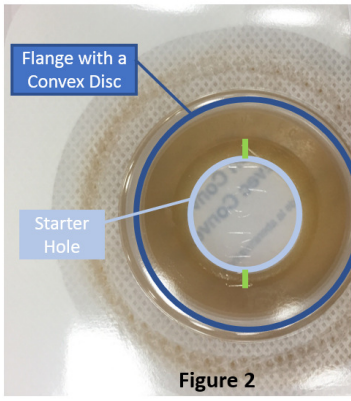
List of Attachments

Attachment 1: Photographic Examples of Labelling and Affected Product

Attachment 2: Ostomy Product User Letter

Appendix A: Product List showing affected Product Codes/REF No. and LOT Numbers

Attachment 1: Photographic Examples of Labelling and Affected Product

For the AFFECTED product	
<p>...the shipper and market unit labeling will include the product code and lot number.</p> <p>See example photos to the right.</p> <p>Product Code (REF/SKU)</p> <p>Lot Number</p>	 
<p>... the physical product will present as a skin barrier with a starter hole (stoma hole), as shown to the right.</p>	<div> <p>Off Center Starter Hole (Stoma Hole) This product may be out of specification</p>  <p>Figure 1</p> </div> <div> <p>Centered Starter Hole (Stoma Hole) This product should be within specification</p>  <p>Figure 2</p> </div> <div> <p>The starter hole should be "centered" in relation to the flange.</p> <p>The red lines in the photo on the left should be more equal.</p> <p>The green lines in the photo on the right are more equal.</p> </div>

Attachment 2
Ostomy Product User Letter

Urgent
Medical Device Field Safety Notice

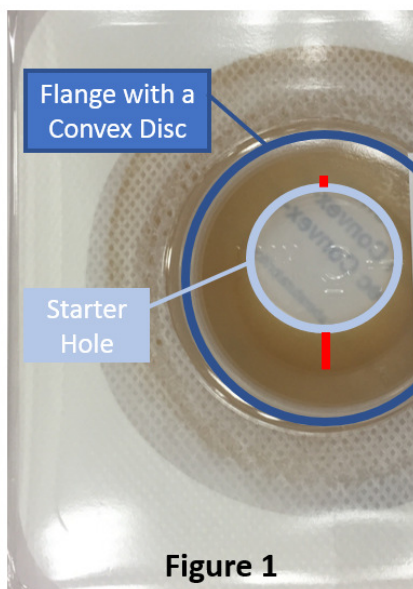
Dear Ostomy Product User,

We are writing to notify you of a visually-detectable problem affecting convex two-piece skin barriers manufactured from February 2017 to September 2018, specifically where the starter hole (stoma hole) is off-center. (For a list of affected product, see Appendix A of this letter.) The risk of injury is low and is contained to specific lots manufactured over a specific timeframe in the past. Not all product or boxes belonging to the specific lots have this problem. However, since this risk can be visually-detected, we are taking precautionary measures to notify you of this matter so that you can thoroughly check your product to see if it:

- a) was manufactured during this period and
- b) is visually off-center.

Our records indicate you may be in receipt of this product. Example images are provided below:

Off Center Starter Hole (Stoma Hole)
This product may be out of specification

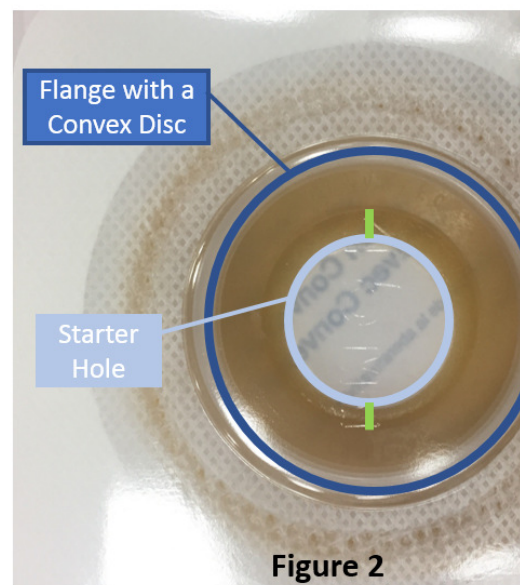


The starter hole should be "centered" in relation to the flange.

The **red** lines in the photo on the left should be more equal.

The **green** lines in the photo on the right are more equal.

Centered Starter Hole (Stoma Hole)
This product should be within specification





We are sending this communication to make you aware of the issue and outlining the steps you can take if you identify off-center product at point of use.

- Please examine your inventory. If you have received product that resembles **Figure 1 on the left**, isolate the affected product and contact the ConvaTec Customer Service Team at one of the numbers below to arrange for return and replacement of the affected product.

FSCA Help Desk - SINGAPORE:
ConvaTec Singapore Customer Service
Tel: +65 6245 9838 / [REDACTED]
Email: [REDACTED]

- If you have received product that resembles **Figure 2 on the right**, no additional action is needed.
- If you are unsure, please contact the ConvaTec Customer Service Team for assistance.

The ConvaTec Customer Service Teams are a group of highly trained product specialists and nurses to help you get the care and information you need throughout your journey as an ostomate.

ConvaTec strives to provide the highest quality products and services to every customer. Our goal is to manufacture products that offer comfort, confidence and security. We want to reassure you that we have addressed the issue on the manufacturing line and corrected product has been distributed into the market.

If you have any further questions or concerns about this notice, please contact the ConvaTec Customer Service Team.

FSCA Help Desk - SINGAPORE:
ConvaTec Singapore Customer Service
Tel: +65 6245 9838 / [REDACTED]
Email: [REDACTED]

Thank you for being a valued ostomy product user. ConvaTec is passionate about improving people's lives and we put people at the center of everything we do.

Sincerely,

David Pudwill
Senior Director, Ostomy Franchise Regulatory Affairs and Quality Assurance
ConvaTec

APPENDIX A
LIST OF PRODUCTS AFFECTED
BY PRODUCT NAME, PRODUCT CODE & LOT NUMBER

Product Name	Product Code	Lot Number
SUR-FIT Natura Durahesive Moldable Convex Skin Barrier with flange, Small, 13-22mm	404592	7C05401
		7M03044
		8A00115
		8A03532
		8A04652
		8A06020
		8C00510
SUR-FIT Natura Durahesive Moldable Convex Skin Barrier with flange, Medium, 22-33mm	404593	7G02078
		7J01301
		7K04909
		7M01936
		8A00074
		8B00644
		8C01171
SUR-FIT Natura Durahesive Moldable Convex Skin Barrier with flange, Large, 33-45mm	404594	8C02729
		7E04176
		7F05062
		7H04920
		7J02079
		7L04700
		7L05271
		7M01995
		8D00463
		8D02814
		8D03557
		8E00637
		8E01067

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 ConvaTec Singapore Customer Service.