Rev 1: September 2018

FSN Ref: 2021-012

FSCA Ref: 2021-012

Date:

Urgent Field Safety Notice
Natura™ Accordion Flange Convex Cut-to Fit wafer

For Attention of*: All affected consignees (CS to edit)

Contact details of local representative
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

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Urgent Field Safety Notice (FSN)
Natura™ Convex Cut-to-Fit Accordion Flange

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	System 4 Secure Accordion Wafers are used in conjunction with System 4 Secure Accordion Ostomy Pouch to form a two-piece Ostomy system. They have matching couplings which allow the pouch and Skin Barrier to snap together
1.	2. Commercial name(s)
	Natura™ Convex Cut-to Fit Accordion Flange
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	System 4 Secure Accordion Wafers are used in conjunction with System 4 Secure Accordion Ostomy Pouch, to form a two-piece Ostomy system, they have matching couplings which allow the pouch and Skin Barrier to snap together. The intended use for the products is wafers for the management of stoma output in conjunction with pouches.
1.	5. Affected serial or lot number range
	2 affected lots – REF 421635 LOT 1F00229 and REF 421633 LOT 1F01439

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	There is potential for the primary pack of the wafer to include an incorrect size of the accordion product such that the wafer coupling will not match the corresponding ostomy pouch coupling.
2.	2. Hazard giving rise to the FSCA*
	The following hazards have been identified are: 1. The primary pack of the wafer includes an incorrect size of the accordion product 2. The wafer will not match the corresponding ostomy pouch and customer cannot use the product 3. The product received by the user is different from the one marketed in the packaging

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***
	☒ Identify Device ☒ Quarantine Device ☐ Return Device ☒ Destroy Device
	☐ On-site device modification/inspection
	☐ Follow patient management recommendations
	☐ Take note of amendment/reinforcement of Instructions For Use (IFU)
	☐ Other ☐ None
	Please see Attachment 1 for action to be taken

3.	2. By when should the action be completed?	As soon as possible.
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer reply required? * (If yes, form attached specifying deadline for return)	Yes within 30 days
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Product that has been shipped will be destroyed. Product that has remained within ConvaTec at distribution centres will be reworked.	
3	6. By when should the action be completed?	31 October 2022
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	N/A	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	ConvaTec Limited
	b. Address	Site of manufacture: ConvaTec Haina, Carretera Sánchez Km. 18.5, PIISA Industrial Park, Haina, San Cristóbal, Dominican Republic Legal manufacturer – ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU
	c. Website address	https://www.convatec.co.uk
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	

4.	5. List of attachments/appendices:	Attachment 1: Distributor and customer actions Attachment 2: Example of Product packaging
4.	6. Name/Signature	Courtney Smith Regulatory Affairs Director, Ostomy Care and Critical Care DocuSigned by: Courtney Smith Signer Name: Courtney Smith Signing Reason: I have reviewed this document Signing Time: May 26, 2022 | 3:30:09 PM BST 18C584397FF34C80A5D3283D05D64343 Lars Bresler Vice President Quality, Infusion Care (Authorised Representative) DocuSigned by: Lars Bresler Signer Name: Lars Bresler Signing Reason: I approve this document Signing Time: May 25, 2022 | 1:33:24 PM BST F068ABB11F444F85B7B5CD6FC27FD1C2

	Transmission of this Field Safety Notice
	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) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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.*

Version number	Version history	Date of approval
01	Original	2nd March 2022
02	Section 1 updated to include REF number Section 2 – Reason for FSCA (Description of Product problem) updated to state that there is potential for the primary pack to contain the incorrect product as it has been confirmed that not all packs are affected by this issue. However, all distributed product from lot 1F00229 and 1F01439 is to be destroyed to ensure that all potentially affected product is removed from the market.	See Name/signature approval date

ATTACHMENT 1

DISTRIBUTOR ACTIONS:

1	Immediately stop distributing and quarantine all of the affected LOT(s).
2	Perform a count of affected product currently in inventory. Dispose of all affected product. **Complete the Certificate of Destruction and the Corrective Action Response Form**. **Return the attached Corrective Action Response Form even if no affected product is in inventory.**
3	Submit the Corrective Action Response Form and Certificate of Destruction to Customer Services for reimbursement for the destroyed product. The Certificate of Destruction must be completed and submitted to obtain credit. Please ensure your account number is correctly identified on the attached Corrective Action Response Form.
4	If you have distributed this product to other wholesalers, then forward this letter to them and ask that they follow these Distributor Actions and return the attached Corrective Action Response Form to the address listed on the form.
5	Send a copy of this market action package to all other consignees: Retailers, if applicable, hospitals and end users. ***It is extremely important to identify the responsible individual, who is in charge of corrective action activities, at hospital locations. This will make the field action process more effective and eliminate confusion and duplicated effort.***

RETAILER ACTIONS:

1	Immediately stop distributing and quarantine all of the affected LOT(s).
2	Perform a count of affected product currently in inventory. Dispose of all affected product. **Complete the Certificate of Destruction and the Corrective Action Response Form**. **Return the attached Corrective Action Response Form even if no affected product is in inventory.**
3	Submit the Corrective Action Response Form and Certificate of Destruction to your distributor for reimbursement for the destroyed product. The Certificate of Destruction must be completed and submitted to obtain credit. Please ensure your account number is correctly identified on the attached Corrective Action Response Form.
4	If you have distributed this product to customers, then where possible forward this letter to them and ask that they follow the Customer Actions. If this is not possible post page one of this Field Safety Notice in a conspicuous location in your store.

CUSTOMER ACTIONS:

1	Immediately stop using any of the affected products.
2	Perform a count of affected product. Dispose of all affected product. **Complete the Certificate of Destruction and Corrective Action Response Form and return to your retailer / distributor to obtain reimbursement for the affected product. Return the Corrective Action Response Form even if you no longer have product.**

Transmission of this Field Safety Notice:

- 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)
- Please transfer this notice to other organisations on which this action has an impact. (as appropriate)
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- 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.

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

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FIELD SAFETY NOTICE DISTRIBUTOR CORRECTIVE ACTION RESPONSE FORM

PLEASE COMPLETE AND RETURN by Email

Consignee of the device:

Consignee Account No:	
Consignee Name:	
Consignee Address:	

The following products have been distributed to your facility -Natura Accordion Flange Convex Cut-to Fit wafer

:

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

Distributors (Tick all that apply and give details, where applicable)		
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	
☐	I have checked my stock, quarantined and disposed of affected inventory	Add details to Table 1
☐	I have attached the Certificate of Destruction	
☐	I have identified customers that received or may have received this device	
☐	I have informed the identified customers of this Field Safety Notice	Date sent:
☐	I have received confirmation of reply from all identified customers	Attach responses
☐	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 for each LOT disposed of.*

LOT No.	Units on Hand

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

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FSN Ref: 2021-012

FSCA Ref: 2021-012

FIELD SAFETY NOTICE CUSTOMER CORRECTIVE ACTION RESPONSE FORM

PLEASE COMPLETE AND RETURN by Email

Consignee of the device:

Consignee Account No:	
Consignee Name:	
Consignee Address:	

The following products have been distributed to your facility (Natura Accordion Flange Convex Cut-to Fit wafer):

:

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

Customer action undertaken on behalf of Healthcare Organisation (Tick all that apply)		
☐	I confirm receipt of the Field Safety Notice and that I read and understand its content.	
☐	I performed all actions requested by the FSN.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	I have checked my stock, quarantined and disposed of affected inventory	Add details to Table 1
☐	I have attached the Certificate of Destruction	
☐	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.

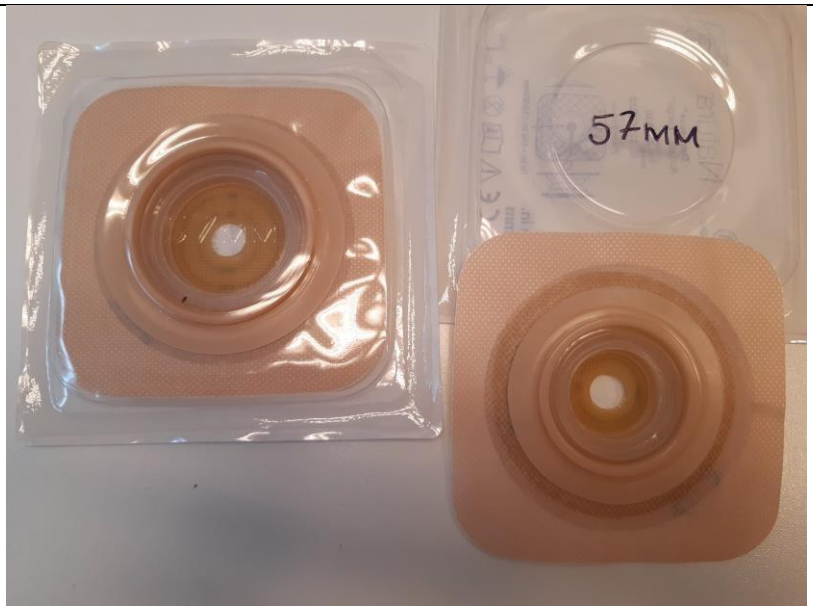
Table 1. Quarantined Inventory: *Record quantity for each LOT disposed of.*

LOT No.	Units on Hand

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

ATTACHMENT 2 – Representative product label
Please note this image is an example to show the position of the Product Code and Lot Number. The Product Codes and Lot Numbers of the affected batches can be found in the FSN above.

Carton (market unit) Front  Back  	Front and back of the market unit. The Ref number is at the top right of the front panel The lot number is in the middle of the back panel
Product	An example of the product

 57MM	

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