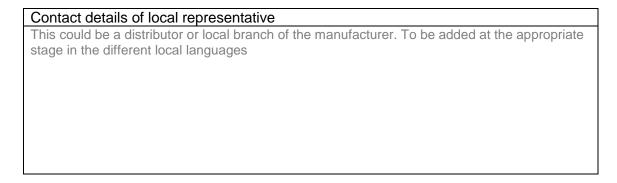
FSN Ref: 2021-012 FSCA Ref: 2021-012



Date:

<u>Urgent Field Safety Notice</u> <u>Natura™ Accordion Flange Convex Cut-to Fit wafer</u>

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



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<u>Urgent Field Safety Notice (FSN)</u> 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	Commercial name(s)
	Natura™ Convex Cut-to Fit Accordion Flange
1	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 – 1F00229 and 1F01439

	2 Reason for Field Safety Corrective Action (FSCA)*						
2	Description of the product problem*						
	The primary pack of the wafer includes 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 □ Quar	antine Device	☐ Return Device	□ Destroy Device □		
			<i>I</i> :				
		☐ On-site device modification	n/inspection				
		☐ Follow patient managemen	nt recommendations				
		☐ Follow patient management recommendations					
		☐ Take note of amendment/reinforcement of Instructions For Use (IFU)					
		☐ Other ☐ None	Э				
		Please see Attachment 1 for action to be taken					
3.	2			as possible.			
ა.	2.	By when should the	A3 3001	i as possible.			
		action be completed?					



3.	3.	Particular considerations for: Choose an item.					
		Is follow-up of patients or r No	eview of patients' previous resu	Its recommended?			
3.	4.	Is customer reply required	? *	Yes within 30 days			
	(If	yes, form attached specifyir	ng deadline for return)				
3.	5.	Action Being Taken by	the Manufacturer				
		,					
		☐ Software upgrade	☑ On-site device modification/inspe ☐ IFU or labelling change	ection			
	☐ Other ☐ None						
		Product that has been shipped w distribution centres will be rewor	vill be destroyed. Product that has remaked.	ained within ConvaTec at			
3	6.	By when should the action be completed?	Rework to be performed in acco	rdance with timelines defined in			
3.	7.	Is the FSN required to be of /lay user?	communicated to the patient	No			
3	8.	If yes, has manufacturer p	rovided additional information su	uitable for the patient/lay			
		user in a patient/lay or non	-professional user information le	etter/sheet?			
		N/A					

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	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	
	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.	The Competent (Regulatory) Authoromounication to customers.	ority of your country has been informed about this
4.	5. List of attachments/appendices:	Attachment 1: Distributor and customer actions Attachment 2: Example of Product packaging
4.	6. Name/Signature	Justin Lovelace
	J. T.	Regulatory Affairs Manager Judin (Malac) Signer Name: Justin Lovelace Signing Reason: I approve this document Signing Time: Mar 2, 2022 1:55:02 PM GMT Lafes Brassley 3B9C9EBF9DE4538C48 Vice President Quality, Infusion Care (Authoristed Representative) Lars Brosler Signing Reason: I approve this document Signing Time: Mar 2, 2022 11:32:39 AM GMT

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.*

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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:

	THE BRITISH OF THE STATE OF THE				
1	Immediately stop distributing and quarantine all of the affected LOT(s).				
	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	infinediatery 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.

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• 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.



FIELD SAFETY NOTICE DISTRIBUTOR CORRECTIVE ACTION RESPONSE FORM

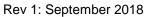
PLEASE COMPLETE AND RETURN by Email

Consigne	e of the d	evice:					
Consignee Account No:							
Consignee Name:							
Consign	nee Addr	ess:					
The follo		lucts have been	distrib	outed to your facility -	Natura Accordion I	Flange Convex C	Cut-to
Invo	ice#	Sales Orde	r#	Product Code / REF No.	SAP Code	LOT No.	Quantity Delivered
Distribu	utors (Tic	k all that apply	y and ;	give details, where a	pplicable)		
	I confirmation Notice.	m the receipt, th	e read	ing and understanding	of the Field Safety		
	I have c	hecked my stoc	k, quarantined and disposed of affected inventory			Add details to Table	, 1
	I have a	ttached the Cert	ificate	of Destruction			
I have identified custom device				•			
			ntified customers of this Field Safety Notice			Date sent:	
	I have r	eceived confirm	ation o	of reply from all ident	ified customers	Attach responses	
	Neither	I nor any of my	custo	mers 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 .	Table 1. Quarantined Inventory: Record quantity for each LOT disposed of.						
LOT No. Units on Hand							

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



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FIELD SAFETY NOTICE CUSTOMER CORRECTIVE ACTION RESPONSE FORM

PLEASE COMPLETE AND RETURN by Email

Consignee of	f the de	evice:					
Consignee Account No:							
Consignee Name:							
Consignee .	Addre	ess:					
The following Fit wafer):	g prod	ucts have been o	distrib	uted to your facility (Natura Accordion F	Flange Convex C	Cut-to
Invoice	#	Sales Order	·#	Product Code / REF No.	SAP Code	LOT No.	Quantity Delivered
Customer a	action	undertaken on	beha	lf of Healthcare Org	anisation (Tick all tha	at apply)	
		n receipt of the land its content.	Field S	Safety Notice and that	I read and		
I performed all actions requested by the			ted by the FSN.				
		rmation and req		actions have been bro	ught to the attention		
					of affected inventory	Add details to Table	2 1
□ I1	have at	tached the Certi	ficate	of Destruction			
□ No	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.	Table 1. Quarantined Inventory: Record quantity for each LOT disposed of.						
LOT No.	LOT No. Units on Hand						

FSN Ref: 2021-012 FSCA Ref: 2021-012



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.



