FSN Ref: 2021-011
FSCA Ref: 2021-011

Date:

Urgent Field Safety Notice
Urostomy Pouches (Various Products- See Appendix 1)

For Attention of*: All affected consignees

Contact details of local representative

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The products which are the subject of this Field Safety Notice are specific batches of certain two-piece urostomy systems and urostomy pouches with fold over taps (see Appendix 1 for product information).
1.	2. Commercial name(s)
	See Appendix 1
1.	3. Primary clinical purpose of device(s)*
	The products are intended for the management of stomal output.
1.	4. Affected serial or lot number range
	See Appendix 1

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Customer complaints of leakage / cracked tap have been reported.
2.	2. Hazard giving rise to the FSCA*
	There is potential for leakage of effluent from affected devices.

FSN Ref: 2021-011
FSCA Ref: 2021-011

	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 Affected product to be disposed of by customer
3.	2. By when should the action be completed? — Within 30 days of receipt of Field Safety Notice
3.	3. Particular considerations for: N/A 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 of receipt of Field Safety Notice
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None
3	6. By when should the action be completed? — As soon as possible
3.	7. Is the FSN required to be communicated to the patient / lay user? — Yes
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?
	No

	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)	

FSN Ref: 2021-011
FSCA Ref: 2021-011

	a. Company Name	ConvaTec Limited
	b. Address	Site of manufacture: Priemyselný park 3, 071 01 Michalovce, Slovakia. Legal manufacturer - 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.	Yes
4.	5. List of attachments/appendices:	Appendix 1: List of Affected Products Appendix 2: Distributor, Retailer and Customer Actions
4.	6. Name/Signature	Justin Lovelace Regulatory Affairs Manager DocuSigned by: Justin Lovelace Signer Name: Justin Lovelace Signing Reason: I approve this document Signing Time: Jan 27, 2022 | 8:02:13 PM GMT 5C8AE9E875CF433B9C9EBF9DE4538C48
		Lars Bressler VP Quality, Infusion Care & Authorised Representative DocuSigned by: Lars Bresler Signer Name: Lars Bresler Signing Reason: I approve this document Signing Time: Jan 24, 2022 | 11:40:03 AM GMT 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.*

FSN Ref: 2021-011
FSCA Ref: 2021-011

Appendix 1: List of Affected Products

Reference Number	Lot Number	Product Description
413116	1G00060	C/HESIVE2SPCH URO FUT STD CLR38MM1X30FR Combihesive 2S
402551	1G00293	C/HESIVE2SPCH URO FUT STD CLR57MM1X10EEU Combihesive 2S
402550	1G00607	C/HESIVE2SPCH URO FUT STD CLR45MM1X10EEU Combihesive 2S
402552	1G01511	C/HESIVE2SPCH URO FUT STD CLR70MM1X10EEU Combihesive 2S
401537	1G02646	NATURA PCH URO FUT STD CLR 70MM1X10NL/GB Combihesive Natura
401535	1G02647	NATURA PCH URO FUT STD CLR 45MM1X10NL/GB Combihesive Natura
402549	1H00256	C/HESIVE2SPCH URO FUT STD CLR38MM1X10EEU Combihesive 2S
401535	1H00484	NATURA PCH URO FUT STD CLR 45MM (1X10)DE Combihesive Natura

FSN Ref: 2021-011
FSCA Ref: 2021-011

Appendix 2

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.

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.

FSN Ref: 2021-011
FSCA Ref: 2021-011

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 orders have been distributed to your facility: C/HESIVE2SPCH URO FUT STD CLR38MM1X30FR / C/HESIVE2SPCH URO FUT STD CLR57MM1X10EEU / C/HESIVE2SPCH URO FUT STD CLR45MM1X10EEU / C/HESIVE2SPCH URO FUT STD CLR70MM1X10EEU / NATURA PCH URO FUT STD CLR 70MM1X10NL/GB / NATURA PCH URO FUT STD CLR 45MM1X10NL/GB / C/HESIVE2SPCH URO FUT STD CLR38MM1X10EEU / NATURA PCH URO FUT STD CLR 45MM (1X10)DE (Customer Services to edit as required)

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:
☐	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

FSN Ref: 2021-011
FSCA Ref: 2021-011

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

FSN Ref: 2021-011
FSCA Ref: 2021-011

FIELD SAFETY NOTICE RETAILER CORRECTIVE ACTION RESPONSE FORM

PLEASE COMPLETE AND RETURN by Email

Consignee of the device:

Consignee Account No:	
Consignee Name:	
Consignee Address:	

The following orders have been distributed to your facility: C/HESIVE2SPCH URO FUT STD CLR38MM1X30FR / C/HESIVE2SPCH URO FUT STD CLR57MM1X10EEU / C/HESIVE2SPCH URO FUT STD CLR45MM1X10EEU / C/HESIVE2SPCH URO FUT STD CLR70MM1X10EEU / NATURA PCH URO FUT STD CLR 70MM1X10NL/GB / NATURA PCH URO FUT STD CLR 45MM1X10NL/GB / C/HESIVE2SPCH URO FUT STD CLR38MM1X10EEU / NATURA PCH URO FUT STD CLR 45MM (1X10)DE(Customer Services to edit as required)

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:
☐	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

FSN Ref: 2021-011
FSCA Ref: 2021-011

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

FSN Ref: 2021-011
FSCA Ref: 2021-011

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 orders have been delivered to you: C/HESIVE2SPCH URO FUT STD CLR38MM1X30FR / C/HESIVE2SPCH URO FUT STD CLR57MM1X10EEU / C/HESIVE2SPCH URO FUT STD CLR45MM1X10EEU / C/HESIVE2SPCH URO FUT STD CLR70MM1X10EEU / NATURA PCH URO FUT STD CLR 70MM1X10NL/GB / NATURA PCH URO FUT STD CLR 45MM1X10NL/GB / C/HESIVE2SPCH URO FUT STD CLR38MM1X10EEU / NATURA PCH URO FUT STD CLR 45MM (1X10)DE (Customer Services to edit)

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

Customer action undertaken		
☐	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

FSN Ref: 2021-011
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FORM Completed and Returned From:	
Name (CAPITAL LETTERS):	
Position:	
Company Name:	
Address:	
Phone No:	
Signature:	
Date (dd/mmm/yyyy):	