FSN Ref: TW1527576
FSCA Ref: TW1527576

Date:

Urgent Field Safety Notice
Suction Catheters

For Attention of*:

Contact details of local representative
Regional ConvaTec Customer Service Contact Tel:

FSN Ref: TW1527576
FSCA Ref: TW1527576

Urgent Field Safety Notice (FSN)
Suction Catheters

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Suction Catheters are medical devices made of plastic, flexible tubes for use in the respiratory tract to suction tracheobronchial secretions (mucus, saliva). Each suction catheter consists of the flexible catheter of various lengths and various types of tips and a distal end which can be a funnel connector of a FingerTip, VacuTip or Y-connector which all enable vacuum control. The connectors are usually colour coded to help determining the size of the suction catheter. The machine ends of suction catheters are indirectly attached to a suction waste collection jar via suction tubing before connecting to an active vacuum source. Some of the devices have a metric marking printed on the catheter to indicate suction depth
1.	2. Commercial name(s)
	Suction Catheters (Suction Catheters with Vacutip including Y-connector, Suction Catheters with Funnel)
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	Suction Catheters are intended for Oro-, nasopharyngeal and tracheobronchial suction of the upper and lower airways to remove excessive secretions from a patient's airway. It is an invasive device with respect to body orifices and is not to be connected directly to an active medical device, it is connected via suction tubing.
1.	5. Affected serial or lot number range
	See Attachment one

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Following an internal investigation to determine whether or not the flow test on the machine was working properly, it was identified that the test was not working properly. The version of the PLC program was incorrect. It had been updated in April 2021, but identified to contain some errors, which could mark defective products as 'OK' at the conclusion of the test. This issue affects suction catheters sizes CH04-CH07.

2.	2. Hazard giving rise to the FSCA*
	There were 2 complaints received which refer to an issue with suction, but with no claim with harm. Likelihood of occurrence of any harms is High for affected Suction Catheters because blocked/clogged tube can lead to Infection and Respiratory Distress. Secondary effect will be prolongation of treatment. Although no real harm was caused by blocked catheter, the internal investigation identified eight units with some level of blockage, out of 15,900 pieces that were tested.

	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	
3.	2. By when should the action be completed?	As Soon As Possible
3.	3. Particular considerations for: 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	
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?	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?	

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	Unomedical
	b. Address	Site of Manufacture: Priemyselný park 3 071 01 Michalovce, Slovakia Legal manufacturer – Convatec Limited, First Avenue, Deeside Industrial Parl, 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 – List of Batches affected by this FSCA. Attachment 2 – Response form
4.	6. Name/signature	DocuSigned by: Lars Bresler Signer Name: Lars Bresler Signing Reason: I approve this document Signing Time: Mar 22, 2022 | 11:57:40 AM GMT F068ABB11F444F85B7B5CD6FC27FD1C2 Lars Bressler Vice President Quality, Infusion Care (Authorised Representative)
		DocuSigned by: Karen Howes Signer Name: Karen Howes Signing Reason: I approve this document Signing Time: Mar 22, 2022 | 1:24:20 PM GMT E558040F0FCE4D7A8C41C944E53BBCC1 Karen Howes Senior Regulatory Affairs Manager

ATTACHMENT ONE

Affected Product LOTs Sizes CH04-CH07

ICC #	SAP # or REF#	Lot#	Date of Mfg.	Expiry Date	Market Unit Qty.	Devices Qty.
419604	1307464	1D02021	14.04.2021	03.2026	100	2000
505294	1307383	1D02023	14.04.2021	03.2026	100	2000
419604	1307464	1D02022	14.04.2021	03.2026	100	8000
510283	1726890	1D02019	14.04.2021	03.2026	75	54000
419716	1307386	1D02024	14.04.2021	03.2026	100	2000
510325	1726953	1D02020	14.04.2021	03.2026	75	2250
510325	1726953	1D04561	29.04.2021	03.2026	75	900
419716	1307386	1D04560	29.04.2021	03.2026	100	2000
419716	1300087	1E01093	07.05.2021	04.2026	100	3000
505294	1307383	1E01094	07.05.2021	04.2026	100	2000
419604	1307464	1E01092	07.05.2021	04.2026	100	4000
419716	1307386	1F00856	07.06.2021	05.2026	100	2000
510325	1726953	1F00543	03.06.2021	05.2026	75	4500
505129	1308056	1F00544	03.06.2021	05.2026	100	2000
419604	1308551	1F00545	03.06.2021	05.2026	100	9000
510283	1726890	1E04200	27.05.2021	04.2026	75	74250
419604	1307464	1F00546	03.06.2021	05.2026	100	7000
505294	1307383	1F02780	17.06.2021	05.2026	100	2000
510335	1726973	1F02781	17.06.2021	05.2026	75	1350
505636	1308211	1F02779	17.06.2021	05.2026	100	2000
501431	1308213	1F04518	29.06.2021	05.2026	100	2000
419114	1266299	1F04519	29.06.2021	05.2026	100	4000
505294	1307383	1G01727	12.07.2021	06.2026	100	2000
419604	1307464	1G01295	08.07.2021	06.2026	100	11000
510325	1726953	1G01729	12.07.2021	06.2026	75	4500
419716	1300087	1G01728	12.07.2021	06.2026	100	2000
501431	1304996	1H00318	03.08.2021	07.2026	100	2000
510335	1726973	1H01164	06.08.2021	07.2026	75	1350
419716	1307386	1H01232	06.08.2021	07.2026	100	2000
419716	1300087	1H01233	06.08.2021	07.2026	100	2000
510283	1726890	1H03454	24.08.2021	07.2026	75	27000
419114	1266299	1J01054	07.09.2021	08.2026	100	2000
510283	1726889	1J01053	07.09.2021	08.2026	75	6750
419716	1300087	1J01827	10.09.2021	08.2026	100	7000
510335	1726973	1J01980	13.09.2021	08.2026	75	1350

419113	1266298	1D03857	27.04.2021	03.2026	100	2000
510347	1726987	1E02938	20.05.2021	04.2026	75	1350
510282	1726887	1E04585	31.05.2021	04.2026	75	9000
510347	1726988	1F04516	29.06.2021	05.2026	75	9000
505236	1307382	1H00316	03.08.2021	07.2026	100	2000
510282	1726888	1G02534	15.07.2021	06.2026	75	4950
510282	1726887	1G02535	15.07.2021	06.2026	75	9000
510282	1726885	1H02123	12.08.2021	07.2026	75	9000
510347	1726987	1H03134	20.08.2021	07.2026	75	1350
510347	1726988	1J01052	07.09.2021	08.2026	75	9000
419113	1266298	1J02838	17.09.2021	08.2026	100	2000

FSN Ref: TW1527576
FSCA Ref: TW1527576

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.*

convaTec

ATTACHMENT 2

DISTRIBUTOR ACTIONS:

1	Immediately stop distributing and quarantine all of the affected LOT.
2	Perform a count of affected product currently in inventory. Dispose of all affected product. Complete the enclosed the Corrective Action Response Form and Certificate of Destruction Form.
3	Return the Corrective Action Response Form and Certificate of Destruction to Customer Services for reimbursement for the destroyed product. Please ensure your account number is correctly identified on the attached Corrective Action Response Form. **Return the attached Corrective Action Response Form even if no affected product is in inventory.**
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.***
6	Send a complete list of all consignees to the ***ConvaTec*** Coordinator. This information is required to allow ***ConvaTec*** to perform corrective action effectiveness checks.

RETAILER ACTIONS:

1	Immediately stop distributing and quarantine all affected LOTs.
2	Perform a count of affected product currently in inventory. Dispose of all affected product. Complete the enclosed the Corrective Action Response Form and Certificate of Destruction Form
3	Return the Corrective Action Response Form and Certificate of Destruction to your Distributor for reimbursement for the destroyed product. Please ensure your account number is correctly identified on the attached Corrective Action Response Form. **Return the attached Corrective Action Response Form even if no affected product is in inventory.**
4	Post page one of this Field Safety Corrective Action notice in a conspicuous location in your store.

END USERS (HOSPITALS SERVICES OTHERS):

1	Immediately stop distributing and quarantine all of the affected LOT.
2	Perform a count of affected product currently in inventory. Dispose of all affected product. Complete the enclosed the Corrective Action Response Form and Certificate of Destruction Form
3	Return the Corrective Action Response Form and Certificate of Destruction to your Distributor/ retailer for reimbursement for the destroyed product. Please ensure your account number is correctly identified on the attached Corrective Action Response Form. **Return the attached Corrective Action Response Form even if no affected product is in inventory.**

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.

Rev 1: September 2018
FSN Ref: 2021-010
FSCA Ref: 2021-010

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 -
:

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

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

Rev 1: September 2018
FSN Ref: 2021-010
FSCA Ref: 2021-010

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 :RA to add product description

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):	