Rev 1: September 2018
FSN Ref: 2021-002 FSCA Ref: 2021-002

Date: 07-05-2021

Urgent Field Safety Notice
Connecting Tubes (Sterile)

For Attention of*:Skamex Spolka z ograniczona, odpowiedzialnoscia spolka jawna, Pilsudskiego 145D, str, Lodz, 92-301

Contact details of local representative (name, e-mail, telephone, address etc.)*
Regional ConvaTec Customer Service Contact Tel: + 41 (0) 52 630 54 01 Fax: +41 (0) 52 63 54 99 Email: ccc.customerservice@convatec.com

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Urgent Field Safety Notice (FSN)
Connecting Tubes (Sterile)

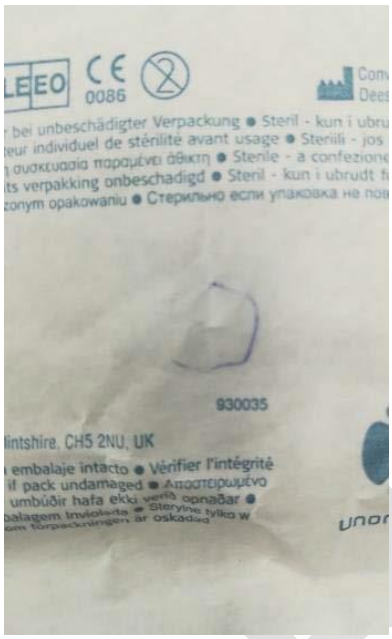
1. **Information on Affected Devices***	
	Device Type(s)*
	Connecting tubes are intended to connect two existing devices or as an extension between an existing device and a vacuum source. Connecting tubes are supplied sterile and are intended for transient use in surgical departments, theatres, intensive care, postoperative recovery and acute care facilities. The device is intended to be used by healthcare professionals, who have been properly trained in the use of the devices.
	1. Commercial name(s)
	Connecting Tubes (Sterile) (Connecting Tube / Funnel CH30/300cm)
	2. Unique Device Identifier(s) (UDI-DI)
	N/A
	3. Primary clinical purpose of device(s)*
	Connecting tubes are used to connect two existing devices or as an extension between an existing device and a vacuum source. They are intended for transient use transient use in surgical departments, theatres, intensive care, postoperative recovery and acute care facilities.
	4. Device Model/Catalogue/part number(s)*
	Not applicable
	5. Software version
	Not applicable
	6. Affected serial or lot number range
	Product code 419344, REF 16064184 and LOT 327948

2 Reason for Field Safety Corrective Action (FSCA)*

1. Description of the product problem*

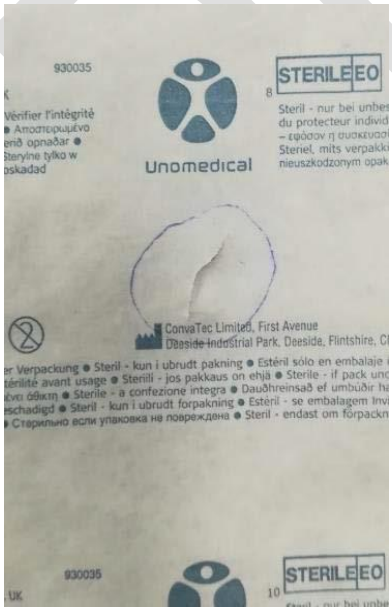
ConvaTec are voluntarily initiating a market action for the above-stated product as during representative testing the following 3 test failures were observed:
Two samples failed bubble leak testing – One due to a visible hole in the gas paper (picture 1) and one due to a poor seal between the gas paper and film (picture 2).
One sample failed visual inspection due to a small hole visible to the naked eye (picture 3).
These failures indicate a failure of the sterile barrier packaging materials resulting in a sterile product becoming non-sterile. Using a non-sterile device on a patient may potentially expose the patient to infectious agents.
This Field Safety Notice relates to Lot 327948 of Product Code 419344 only (REF 16064184)

Picture 1



Picture 2

Picture 3



2. Hazard giving rise to the FSCA*
The hazard identified is microbial/viral contamination. This poses a potential risk to the patient and user of exposure to infectious agents.
3. Probability of problem arising
Bubble leak testing/ visual inspection results indicate a high risk of probability of occurrence.
4. Predicted risk to patient/users
The anticipated risk to patients is assessed as high based on bubble leak test/ visual inspection data.
5. Further information to help characterise the problem
N/A
6. Background on Issue
During 2X sterilization, two failures were observed during bubble leak testing for the Connecting Tubes. **NOTE:** 2X Sterilization is not a standard process conducted by ConvaTec. The products referenced were shipped before Validation of the 2X Sterilization Process had been conducted. Several potential root causes were identified including ineffective training of operators, unsuitable packaging materials and shipment of product prior to completion of validation of the 2X sterilization process. Preventative actions include additional training of operators, packaging configuration updates and qualification of a new sterilization cycle (with acceptable Journey hazard testing bubble leak testing).

3. Type of Action to mitigate the risk*

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 complete activities detailed in Attachment 1 of this document

2. By when should the action be completed?	As soon as possible
3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes within 30 days

4. Action Being Taken by the Manufacturer

☒ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☐ Other ☐ None

This issue affects only one batch of this product (Product Code 419344, REF 16064184 LOT 327948). All affected product has been dispatched to customers therefore no product removal is required at ConvaTec. Product removal and destruction is requested as detailed within this FSN

	5. By when should the action be completed?	N/A – no further action to be taken by the manufacturer	
	6. Is the FSN required to be communicated to the patient /lay user?		No

	4. General Information*	
	1. FSN Type*	New
	2. For updated FSN, reference number and date of previous FSN	N/A
	3. For Updated FSN, key new information as follows:	
	N/A	
	4. Further advice or information already expected in follow-up FSN? *	No
	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
	6. Anticipated timescale for follow-up FSN	N/A
	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Convatec Limited
	b. Address	First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU
	c. Website address	www.Convatec.com
	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
	9. List of attachments/appendices:	Attachment 1: Distributor, Retailer and Customer Actions
	10. Name/Signature	Karen Howes (Senior Regulatory Affairs Manager)
		DocuSigned by: howes Signer Name: howes Signing Reason: I approve this document Signing Time: May 26, 2021 | 4:27:56 PM BST E558040F0FCE4D7A8C41C944E53BBCC1

	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..*

ATTACHMENT 1
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 return it to the address on the response form. **Return the attached Corrective Action Response Form even if no affected product is in inventory.**
3	You will be reimbursed for the product. 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.***
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 of the affected LOT.
2	Perform a count of affected product currently in inventory. Dispose of all affected product. Complete the enclosed Corrective Action Response Form and return it to the address on the response form. **Return the attached Corrective Action Response Form even if no affected product is in inventory. It is important that you send a copy of the Corrective Action Response Form to your distributor in order to receive reimbursement for the returned product.**

END USERS (HOSPITALS SERVICES OTHERS):

1	Immediately stop use and quarantine all the affected LOT.
2	Perform a count of affected product currently in inventory. Dispose of all affected product. Complete the enclosed Corrective Action Response Form and return it to the address on the response form. **Return the attached Corrective Action Response Form even if no affected product is in inventory. It is important that you send a copy of the Corrective Action Response Form to your distributor in order to receive reimbursement for the returned 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.

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: Connecting Tubes (Sterile)

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 identified customers that received or may have received this device	
☐	I have attached customer list	Add details to Table 2
☐	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

Table 2. Customer List: Please provide details of affected Connecting Tubes (Sterile) product that were distributed to your customers.

Customer Name	Product Code / REF No.	SAP Code	LOT No.	Quantity

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

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, **:** Connecting Tubes (Sterile) have been distributed to your facility:

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
☐	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):	