URGENT FIELD SAFETY NOTICE
DISTRIBUTORS

Commercial name: Suction Catheters and Gastro-enteral Tubes (see Attachment 1 for commercial name and full details)

Issue Date: 19.07.2018

REF No: See Attachment 1

FSCA ID: *2018-005/A*

Type of action: Recall / Product Disposal

Please note that this action only applies to specific product codes and does not affect all product codes of Suction Catheters and Gastro-enteral Tubes.

Description of the problem:

ConvaTec has voluntarily initiated a recall of specific product codes of Suction Catheters and Gastro-enteral Tubes.

Internal assessment of this product's packaging integrity has confirmed that these devices are not meeting our expectations or those of our customers. Transportation testing conducted on the product packaging failed confirming the potential for a breach in the sterile barrier. Using a non-sterile device on patient may expose the patient to infectious agents increasing the patient risk of developing infection. ConvaTec has not received any reports of incidents related to the packaging seal issue.

Suction Catheters are intended for oro-nasopharyngeal and tracheobronchial suctioning of the upper and lower airways to remove excessive secretion in patients who are unable to clear these secretions themselves. Suction catheters are sterile, single patient and single procedure use devices that are intended for indirect connection to an active medical device.

Duodenal Tubes are single-use devices which may be inserted through the nose or mouth via the esophagus into the stomach or duodenum, to assist in the drainage of gastric contents, decompression of the stomach or duodenum, obtaining a specimen of gastric contents, administration of medication or fluids, and enteral feeding.

Stomach tubes are single-use devices which may be inserted through the nose or mouth via the esophagus into the stomach, to assist in the drainage of gastric contents, decompression of the stomach, obtaining a specimen of gastric contents, administration of medication or fluids, and enteral feeding.

Only the identified product part codes within this notice may have a potential to breach in the sterile barrier packaging.

For this reason and to address any potential risk of harm, all of the affected products should **not be used**.

Product Identification Procedure:
The only way to identify affected product is by comparing product code and manufactured date to the recalled product list (see Attachment 1). There is no other discernable difference between affected and unaffected product.

See Attachment 2 for example package labeling that highlights the location of the product code and manufactured date on the device labels. These are located on the primary packaging and the shipping carton. The product code (reference number) is preceded by the word 'REF' and the manufactured date is preceded by  and is in YYYY-MM-DD format

Advice on action to be taken by distributor.

Our records show that you have taken delivery of affected product. Please follow the steps below:

1. Please examine the enclosed questionnaires. Immediately stop distributing and quarantine all affected products.

2. Please forward copies of the 'Field Safety Notice END USERS' to your customers, asking them to return the affected products to you along with a completed 'Recall Response Form for END USERS'.

3. When the completed Response Form(s) have been returned to you, please complete the 'Recall Response Form for DISTRIBUTORS' and contact the dedicated recall centre (see page 3) for further instructions on how to dispose of affected product and to arrange credit. Products will not be automatically replaced - new orders will need to be raised.

4. Please also return the completed 'Recall Response Form for DISTRIBUTORS', and all 'Recall Response Form for END USERS' to your 'Recall centre' via Fax/ E-mail.
   PLEASE PROVIDE A COMPLETED RESPONSE AS SOON AS POSSIBLE.

Continue to report any adverse events involving this product to the ConvaTec Customer Care Line (see Regional contact list for details).

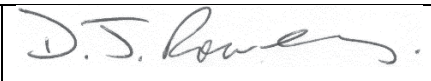
Transmission of this Field Safety Notice:
This notice should be sent to all others who have received the affected devices within your organization or to any organization where the affected devices have been transferred.

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

If you have any questions relating to this recall, please contact the recall centre. For other support please contact your distributor or local ConvaTec representative (see contact list for details).

The relevant National Authorities have been advised about this Field Safety Corrective Action.

Authorisation:

Name Duncan Rowley	Title Director, Regulatory Affairs and Quality Assurance, EMEA	Address ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, CH5 2NU, U.K.	
Date	19.07.2018	Signature	

Recall Centre: Dedicated help desk for this Field Safety Corrective Action:
Tel: 1-800-851-379
Fax: +44-207 6601 568
Email: convatecproductrecall@stericycle.com

'Regional contact' for other support:

Belgium / Estonia / France / Germany / Israel / Netherlands / Switzerland / Ireland
Tel: + 41 (0) 52 630 54 01
Fax: +41 (0) 52 630 54 99
Email: ccc.customerservice@convatec.com

Denmark
Tel: +45 4816 7030
Fax: +45 8025 3413
Email: customerservicenordic@convatec.com

Finland
Tel: +358 (0) 20 7659 630
Email: mail.fi@convatec.com

Italy
Tel: 800500190
Email: clienti.convatec@convatec.com

Norway
Tel: +47 22686095
Fax: + 47 80019602
Email: customerservicenordic@convatec.com

Sweden
Tel: +46 (0)42 332010
Fax: +46 200887486
Email: customerservicenordic@convatec.com

United Kingdom
Tel: +44 (0) 1244 832206
Fax: 0800 279 9004
Email: unomedical-uk.customerservice@convatec.com

Czech Republic, Iceland, Poland, Slovakia, Spain,
Tel: + 41 (0) 52 630 54 01
Fax: +41 (0) 52 630 54 99
Email: ccc.customerservice@convatec.com

ConvaTec

RECALL RESPONSE FORM for DISTRIBUTORS

URGENT FIELD SAFETY NOTICE

PLEASE COMPLETE AND RETURN by Fax/Email

Consignee of the device:

Consignee Account No:	10311757
Consignee Name:	ArcRoyal Ltd
Consignee Address:	Virginia Road, 0, Co. Meath, Ireland

The following Suction Catheter and Gastro-enteral products, have been distributed to your facility:

Invoice #	Sales Order #	Product Code / REF No.	SAP Code	LOT No.	Quantity Delivered (pieces)
3032007264	124749DK	05125181	1307385	486328	200
3032008287	135096DK+135097DK+13	05125181	1307385	153243	100
3032008373	135095DK1	05125181	1307385	150102	100
3032008643	141602DK+141603DK	05125181	1307385	166410	100
3032009338	154172	05125181	1307385	166410	100
3032009547	159844	05125181	1307385	166410	100
3032009722	165283	05125181	1307385	166410	100
3032009981	171832	05125181	1307385	210388	100
3036567485	185415	05125181	1307385	234742	100
3032010235	179728	05125181	1307385	239357	100
3036692661	194440	05125181	1307385	7E01490	100
3036848456	204149	05125181	1307385	7L03378	100

Please answer each of the following.

1. **Have You Distributed the Product Further?** **NO** ☐ **YES*** ☐
   If YES, have you notified down to your customer?** **NO ☐ **YES** ☐
   ***If NO explain why not:**

2. ☐ **We have NO affected product.**
3. ☐ **We have the following affected product:**

Record quantity (pieces) for each LOT to be disposed:

LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand

Please provide details of affected Suction Catheter, Duodenal Tube and Stomach Tube products that were distributed to your customers:

Customer Name	Product Code / REF No.	SAP Code	LOT No.	Quantity (pieces)

FORM Completed and Returned From:

Name (CAPITAL LETTERS):	
Position:	
Company Name:	
Address:	
Phone No:	
Signature:	
Date (dd/mmm/yyyy):	

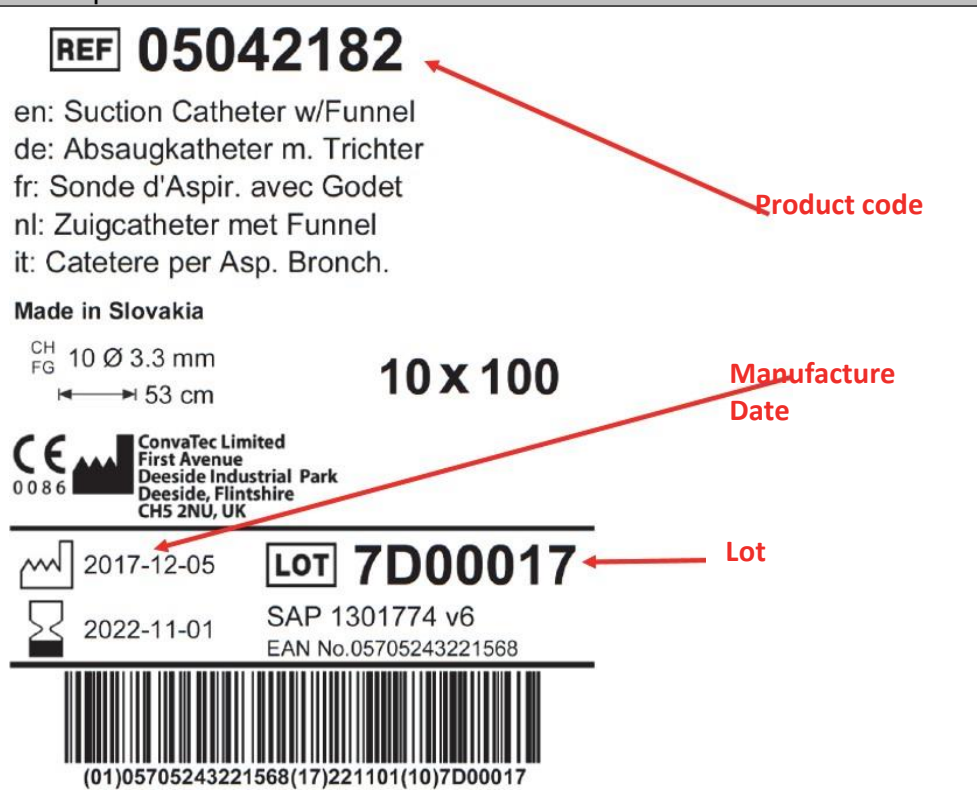
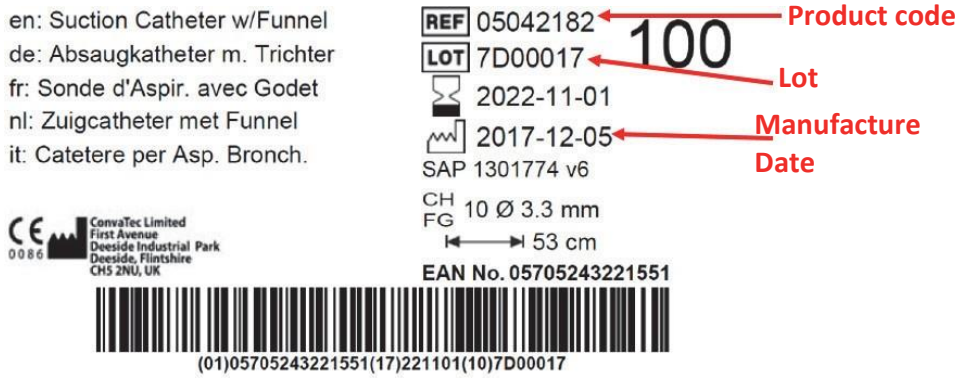
☐ As requested, I have also provided a copy of all 'Recall Response Forms for END USERS' returned from customers who received affected product (please tick to confirm).

Recall Centre: Dedicated help desk for this Field Safety Corrective Action:
Tel: 1-800-851-379
Fax: +44-207 6601 568
Email: convatecproductrecall@stericycle.com

Attachment 1: Product Affected: The following Codes with a manufactured date between 2013-07-01 and 2018-06-30.

Product Code / REF No.	SAP Code	Description
05042182	1301774	Suction Catheter / Funnel
05076181	1307451	Mülly Suction Catheter/Funnel
05079181	1307452	Mully Suction Catheter / Fingertip
05087182	1705177	Uno Suction Catheter Mully
05125181	1307385	Uno Suction Catheter /Ideal
05204023	1304087	Suction Catheter / Funnel
05308022	1303471	Ideal Suction Catheter / Funnel
06021183	1304885	Mully Suction Catheter / Fingertip
06023183	1304886	Mülly Suction Catheter/ Fingertip
07030181	1307405	Mülly Suction Catheter/Vacutip
07037182	1705178	Mülly Suction Catheter/Vacutip
07071022	1303480	Ideal Suction Catheter / SoftVac
07075022	1303484	Ideal Suction Catheter SoftVac
12003181	1307470	Uno Mully Metric
10007182	1705231	Duodenal Tube Levin /x-ray
10025022	1307360	Duodenal Tube Levin/introd.
10045022	1304034	Duodenal Tube Levin /x-ray
31011182	1302402	Feeding Tube / Purifeed

Attachment 2: Example Package Labeling

For the Affected product	
The **shipper** label	
The **market unit** label	

URGENT FIELD SAFETY NOTICE
END USERS

Commercial name: Suction Catheters and Gastro-enteral Tubes (see Attachment 1 for commercial name and full details)

Issue Date: 19.07.2018

REF No: See Attachment 1

FSCA ID: 2018-005/A

Type of action: Recall / Product Disposal

Please note that this action only applies to specific product codes and does not affect all product codes of Suction Catheters and Gastro-enteral Tubes.

Description of the problem:

ConvaTec has voluntarily initiated a recall of specific product codes of Suction Catheters and Gastro-enteral Tubes.

Internal assessment of this product's packaging integrity has confirmed that these devices are not meeting our expectations or those of our customers. Transportation testing conducted on the product packaging failed confirming the potential for a breach in the sterile barrier. Using a non-sterile device on patient may expose the patient to infectious agents increasing the patient risk of developing infection. ConvaTec has not received any reports of incidents related to the packaging seal issue.

Suction Catheters are intended for oro-nasopharyngeal and tracheobronchial suctioning of the upper and lower airways to remove excessive secretion in patients who are unable to clear these secretions themselves. Suction catheters are sterile, single patient and single procedure use devices that are intended for indirect connection to an active medical device.

Duodenal Tubes are single-use devices which may be inserted through the nose or mouth via the esophagus into the stomach or duodenum, to assist in the drainage of gastric contents, decompression of the stomach or duodenum, obtaining a specimen of gastric contents, administration of medication or fluids, and enteral feeding.

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Only the identified product part codes within this notice may have a potential to breach in the sterile barrier packaging.

For this reason and to address any potential risk of harm, all of the affected products should **not be used**.

Product Identification Procedure:
The only way to identify affected product is by comparing product code and manufactured date to the recalled product list (see Attachment 1). There is no other discernable difference between affected and unaffected product.

See Attachment 2 for example package labeling that highlights the location of the product code and manufactured date on the device labels. These are located on the primary packaging and the shipping carton. The product code (reference number) is preceded by the word 'REF' and the manufactured date is preceded by  and is in YYYY-MM-DD format

Advice on action to be taken by the end user.

Our records show that you have taken delivery of affected product. Please follow the steps below:

1. Please stop the use of all affected devices as defined in this document.
2. Check stock and ensure that all affected devices that you have in stock are quarantined.
3. Complete the enclosed 'Recall Response Form for END USERS' which should be forwarded to your distributor **as soon as possible**.
4. Contact your distributor to arrange return of affected products, if applicable, and to arrange credit. New orders will need to be raised.

PLEASE PROVIDE A COMPLETED RESPONSE AS SOON AS POSSIBLE.

Continue to report any adverse events involving this product to the ConvaTec Customer Care Line (see Regional contact list for details).

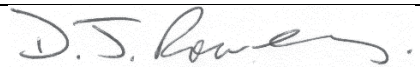
Transmission of this Field Safety Notice:
This notice should be sent to all others who have received the affected devices within your organization or to any organization where the affected devices have been transferred.

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

If you have any questions relating to this recall, please contact the recall centre. For other support please contact your distributor or local ConvaTec representative. See contact list for details.

The relevant National Authorities have been advised about this Field Safety Corrective Action.

Authorisation:

Name Duncan Rowley	Title Director, Regulatory Affairs and Quality Assurance, EMEA	Address ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, CH5 2NU, U.K.	
Date	19.07.2018	Signature	

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Belgium / Estonia / France / Germany / Israel / Netherlands / Switzerland / Ireland
Tel: + 41 (0) 52 630 54 01
Fax: +41 (0) 52 630 54 99
Email: ccc.customerservice@convatec.com

Denmark
Tel: +45 4816 7030
Fax: +45 8025 3413
Email: customerservicenordic@convatec.com

Finland
Tel: +358 (0) 20 7659 630
Email: mail.fi@convatec.com

Italy
Tel: 800500190
Email: clienti.convatec@convatec.com

Norway
Tel: +47 22686095
Fax: + 47 80019602
Email: customerservicenordic@convatec.com

Sweden
Tel: +46 (0)42 332010
Fax: +46 200887486
Email: customerservicenordic@convatec.com

United Kingdom
Tel: +44 (0) 1244 832206
Fax: 0800 279 9004
Email: unomedical-uk.customerservice@convatec.com

Czech Republic, Iceland, Poland, Slovakia, Spain,
Tel: + 41 (0) 52 630 54 01
Fax: +41 (0) 52 630 54 99
Email: ccc.customerservice@convatec.com

ConvaTec

RECALL RESPONSE FORM for END USERS

URGENT FIELD SAFETY NOTICE

PLEASE COMPLETE AND RETURN by Fax/Email

Consignee of the device:

Consignee Name:	
Consignee Address:	

The following Suction Catheter and Gastro-enteral products, have been distributed to your facility:

Product Code / REF No.	SAP Code	LOT No.	Quantity Delivered (pieces)

Please answer each of the following.

1. ☐ **We have NO affected product.**
2. ☐ **We have the following affected product:**

Record quantity (pieces) for each LOT to be disposed:

LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand

FORM Completed and Returned From:

Name (CAPITAL LETTERS):	
Position:	
Company Name:	
Address:	
Phone No:	
Signature:	
Date (dd/mmm/yyyy):	

Recall Centre: Dedicated help desk for this Field Safety Corrective Action:
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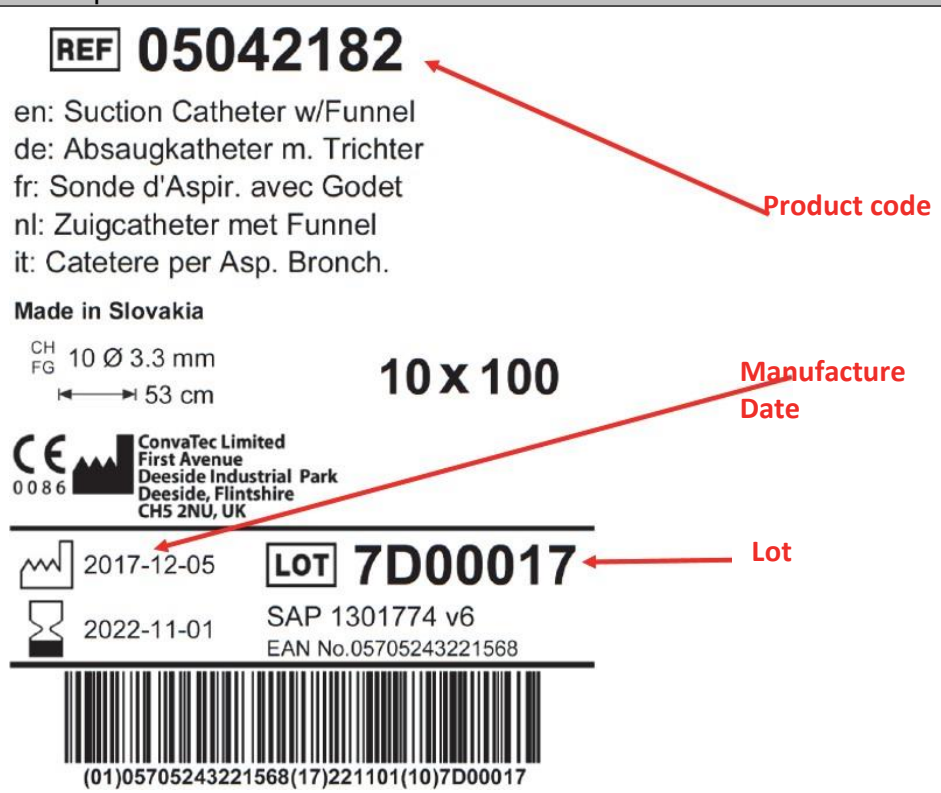
The **shipper** label	
The **market unit** label