URGENT FIELD SAFETY NOTICE
END USERS

Commercial name: Suction Tube 3M Double Wrap Sterile

ISSUE DATE: 26 Jun 2015

REF Number: 530.25.300

Lot Numbers: 813740R001, 813740R002, 813740R003, 813740R004, 813740R005, 813740R006, 813740R007, 814137R005, 814137R006, 814137R007

FSCA ID: 2015-02

Type of action: Recall – Return of Product to Manufacturer

An internal assessment of product complaints has confirmed that these devices are not meeting our expectations or those of our customers. Customers should stop using products with the listed lot numbers.

Description of the problem:

An internal assessment of product complaints has confirmed that these devices are not meeting our expectations or those of our customers. Specifically, the connector part for application to the suction devices in these LOTs, has failed to meet its required reliability.

Suction Tubes are intended to connect a suction device, such as a suction catheter or suction handle, to a vacuum unit. Suction Tubes are equipped with multi-purpose connectors that are designed to fit many suction devices and outlets.

The connector parts of the specified LOTs have a higher probability to crack, once applied to suction devices outlets.

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

Identification Procedure:

The affected devices can be identified by the product reference number.

The reference number can be found on the device label, which is located on both the primary packaging as well as the shipping carton.

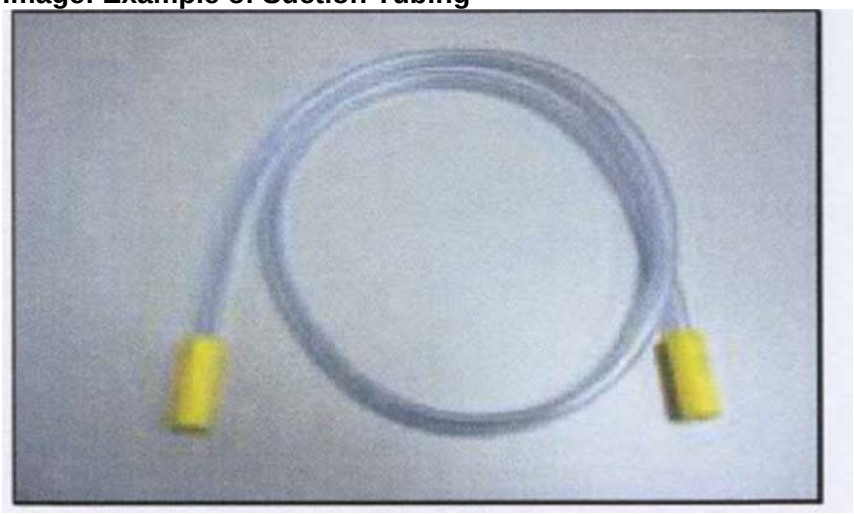
The reference number, or product code, is demarcated in this notice with a Green box in ***LABEL 1***. The reference number is preceded by the word 'REF.'

The LOT number, or product code, is demarcated in this notice with a Red box in ***LABEL 1***. The reference number is preceded by the Symbol ' LOT ,

LABEL 1:

Sterile Suction tubing labelling example:

Image: Example of Suction Tubing



Advice on action to be taken by user.

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

1. Please stop the use of all affected devices as defined in this document.
2. Ensure that all of the affected devices in stock are quarantined.
3. Check stock and complete the enclosed questionnaire, which should be forwarded to the Regional contact person for this FSCA as soon as possible.
4. Return all affected products to ConvaTec Limited for credit or replacement.
5. Please mark all returned product clearly with: "2015-02 Suction Tubes from *Your Name Here*"

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

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

Regional contact person (and EC Rep) for this Field Safety Corrective Action:

Mark Cresswell
Regulatory Affairs Manager
ConvaTec Limited
First Avenue
Deeside Industrial Park
Deeside, Flintshire, CH5 2NU
United Kingdom
T: +44 (0) 1244 584265
E: mark.cresswell@convatec.com

RECALL RESPONSE FORM

URGENT FIELD SAFETY NOTICE

PLEASE COMPLETE AND RETURN

The following Consignee received the following Suction Tubes:

CONSIGNEE ACCOUNT No	CONSIGNEE NAME:	CONSIGNEE ADDRESS:	CONSIGNEE PHONE
10309924 / 10311571	Mölnlycke Health Care Klinipro, sro	Na Novém Poli c.p. 381/1 Karvina - Stare Mestro Czech Republic	+420 597 017 111

The following Lots of Suction Tubes have been distributed to your facility:

REF:	DEVICE:	LOT No:	QUANTITY:
530.25.300	Suction Tube 3M	813740R001	3000
		813740R002	2000
		813740R003	3000
		813740R004	2750
		813740R005	3000
		813740R006	3000
		813740R007	2000
		814137R005	475
		814137R006	525
		814137R007	125

COMPLETE Check the appropriate as applicable:

_____ No lots of affected Suction Tubes are in my possession.

_____ Yes the following lots of affected Suction Tubes are in my possession. The quantity of each lot number is recorded in the following table.

REF:	DEVICE:	LOT No:	QUANTITY to be returned:

FORM Completed and Returned From:

_____ _____ _____

NAME (CAPITAL LETTERS) AND POSITION SIGNATURE DATE

_____

ADDRESS

Contact Telephone Number _____