URGENT FIELD SAFETY NOTICE
DISTRIBUTORS

Commercial name: Niko-Fix™ Securement Device

ISSUE DATE: **4 November 2014**
REF No: **NF-92M**

LOT No: **159427, 159428, 159439, 162484, 170512, 170513, 171653, 173971.**

FSCA ID: 2014-02

Type of action: **Recall – Return of Product to Manufacturer**

Customers should be aware the listed Lots of Niko-Fix™ Securement Device are NOT sterile. Customers should stop using products with the listed lot numbers.

Description of the problem:
ConvaTec has become aware that certain lots of Niko-Fix™ Securement devices did not undergo their sterilization procedure. While the package is labeled as sterile the product has **NOT** been sterilized and therefore is **NOT** sterile.

The listed lot numbers are **NOT** sterile and customers should immediately discontinue using the affected lots of Niko-Fix™ securement devices.

REF Number: NF-92M

Lot Numbers: 159427, 159428, 159439, 162484, 170512, 170513, 171653, 173971.

Advice on action to be taken by user.

In the event a product from the affected lot numbers has been used, please immediately remove and replace with an alternative securement device. Please observe the area for signs and symptoms of infection e.g erythema, oedema, pain or discharge and treat appropriately. Every effort should be made to follow up on patients no longer under the care of a health care provider.

Image of Niko-Fix™ Securement Device

Report any adverse events involving this ConvaTec Customer Care Line:

Austria, Switzerland, Netherlands, Poland
Tel: + 41 (0) 526305401
Fax: +41 (0) 52 630 54 99
ccc.customerservice@convatec.com

Denmark
Tel: +45 48167030
Fax: +45 44411993
Questions.nordics@convatec.com

Finland
Tel: +358 (0) 20 7659 630
Fax: +358 (0) 20 7659 633
mail.fi@convatec.com

Great Britain
Tel: +44 (0) 1244 832206
Fax: +44 (0) 1244 832207
unomedical-uk.customerservices@convatec.co.uk

Italy
Tel +39 (0) 6 89 78 99 59
Emiliano.decarli@convatec.com

PRODUCT IDENTIFICATION

Product 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 Yellow box in **LABEL 1**. The reference number is preceded by the word 'REF.'

The LOT number is demarcated in this notice with a Red arrow in **LABEL 1.** The lot number is preceded by the word 'LOT'

LABEL 1

Niko-Fix™ - Carton example.

Instructions on action to be taken by the user:

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

1. Please examine both the enclosed questionnaires and immediately put all products you may have on hold.
2. Please forward copies of the Field Safety Notice END USERS and "Recall Questionnaire for end users" to your customers, asking them to return the affected products to you.
3. When the products and completed "Recall Questionnaire for end users" have been returned to you, please contact ConvaTec to arrange for the stock to be uplifted and returned for credit. Please place new purchase orders for replacement stock.
4. Please mark all returned product clearly with: "2014 -02 Niko-Fix™ Sterile Securement Device from *Your Name Here*"
5. Please also return completed "Recall Questionnaire for Distributor" and all "Recall Questionnaires for End Users" to us via Fax/ E-mail.

Transmission of this Field Safety Notice:
This notice should be sent to all others who have received the affected Niko-Fix™ Securement products 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.

Contact reference person relating to this letter: *(distributor to complete)*

Name:
Position:
Address:

Tel:
Fax:
E-mail:

Regional contact person for this Field Safety Corrective Action:

Austria, Switzerland, Netherlands, Poland
Tel: + 41 (0) 526305401
Fax: +41 (0) 52 630 54 99
ccc.customerservice@convatec.com

Denmark
Tel: +45 4816 7030
Fax: +45 44411993
Questions.nordics@convatec.com

Finland
Tel: +358 (0) 20 7659 630
Fax: +358 (0) 20 7659 633
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Great Britain
Tel: +44 (0) 124 483 2206
Fax: +44 (0) 1244 832207
unomedical-uk.customerservices@convatec.co.uk

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Tel +39 (0) 06 89 78 99 59
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RECALL RESPONSE FORM

URGENT FIELD SAFETY NOTICE

PLEASE COMPLETE AND FAX COMPETED FORM TO

The following Consignee received the following Niko-Fix™ Securement device:

Name: _____

Address: _____

The following Lots of NIKO-FIX Securement device(s) have been distributed to your facility:

Invoice #	Sales Order #	REF	Lot No	Number Delivered

The consignee confirms (please, tick off all that apply):

_____ No lots of affected Niko-Fix™ devices are in my possession.

_____ Yes the following lots of affected Niko-Fix™ devices are in my possession. The quantity of each lot number is recorded in the table below.

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

_____ Niko-Fix devices have been further distributed to the following customers:

NAME:	ADDRESS:	QUANTITY:

_____ I as the distributor will contact the above listed customers to ensure that they are following the instructions submitted to them.

_____ I request ConvaTec to contact the following customers. Please provide information for each customer below.

Contact Person (PRINT NAME) _____

Contact Telephone Number _____

FORM Completed and Returned From:

_____	_____	_____
NAME (CAPITAL LETTERS) AND POSITION	SIGNATURE	DATE

_____

ADDRESS