



URGENT FIELD SAFETY NOTICE
END USERS

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 Dressing



Report any adverse events involving this product to the ConvaTec Customer Care Line.

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PRODUCT IDENTIFICATION

Product Identification Procedure:

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

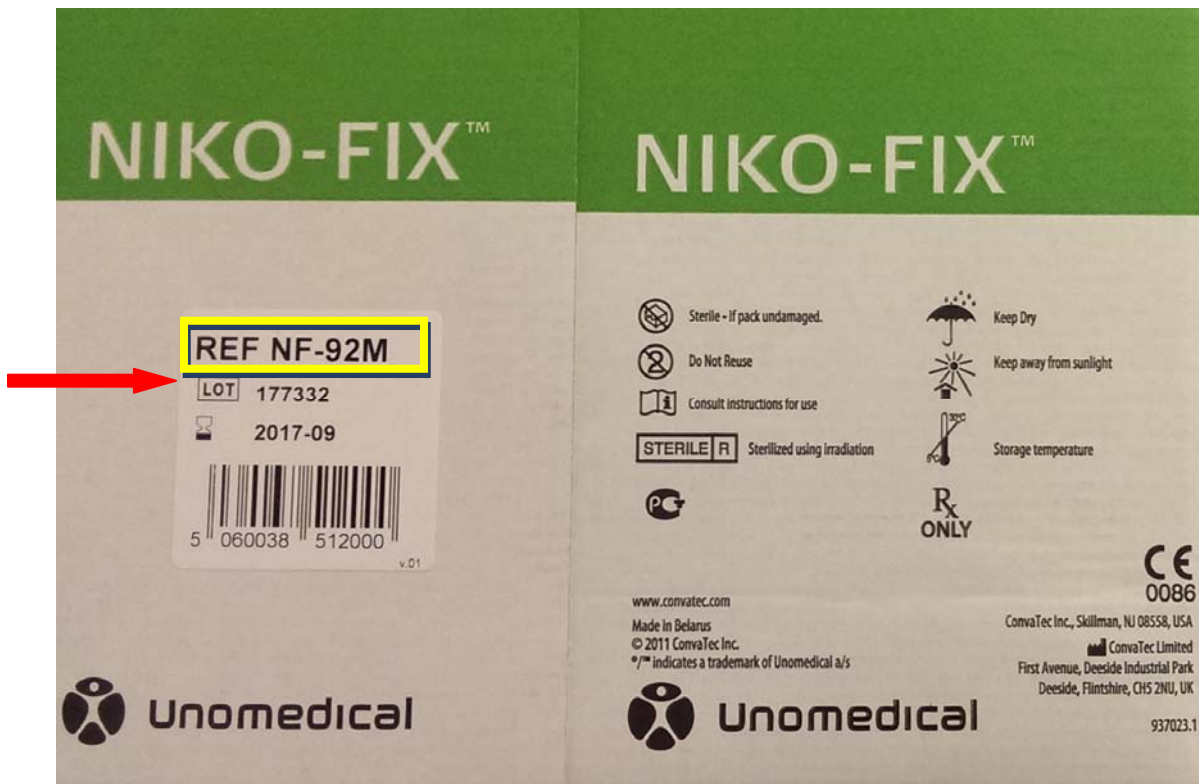
The reference number can be found on the device label which is located on both the primary packaging as well as the shipping carton.

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 box 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 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 your distributor as soon as possible.
4. Return all affected products to your distributor for credit or replacement by the 30 January 2015.
5. Please mark all returned product clearly with: "2014 –02 Niko-Fix™ Securement Device from Your Name Here"

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:



RECALL RESPONSE FORM
URGENT FIELD SAFETY NOTICE
PLEASE COMPLETE AND FAX COMPLETED FORM TO

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

CONSIGNEE ACCOUNT No	CONSIGNEE NAME: (PRINT NAME)	CONSIGNEE ADDRESS:	CONSIGNEE PHONE

The following Lots of Niko-Fix™ Securement device(s) have been distributed to your facility:

REF:	DEVICE:	LOT No:	QUANTITY:

COMPLETE Check the appropriate as applicable:

_____ 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:

FORM Completed and Returned From:

 NAME (CAPITAL LETTERS) AND
 POSITION

 SIGNATURE

 DATE

 ADDRESS



Contact Person (PRINT NAME) _____

Contact Telephone Number _____