

FSN Ref: FSN-2023-001

FSCA Ref: FSCA-2023-001

Date: 12.07.2023

Urgent Field Safety Notice **CBC NUCOS**

For Attention of: Medical personnel performing venipuncture

Contact details of manufacturer
Kimetec GmbH Caroline Ihle Gerlinger Str. 36-38 71254 Ditzingen Germany Telephone: + 49 (0)7156 / 17602 - 200 Fax: + 49 (0)7156 / 17602 - 500 E-mail: quality@kimetec.de

Urgent Field Safety Notice

CBC NUCOS

Damage to the tourniquet ribbon

1. Information on Affected Devices	
1. 1 Device type	Tourniquet, reusable
1. 2 Commercial name	CBC NUCOS
1. 3 Unique Device Identifier (UDI-DI)	14250373654154
1. 4 Intended use	Medical device to stop venous blood flow so that it is easier to locate and puncture a vein.
1. 5 Catalogue number	500580
1. 6 Affected lot numbers	40848/202204 41090/202205

2. Reason for Field Safety Corrective Action (FSCA)	
2. 1 Description of the product problem	Due to sharp-edged structures inside the vein tourniquet buckle of the affected production batches, friction can cause damage to the ribbon (small holes, cracks). In case of further use of already damaged vein tourniquets, the belt may completely tear in the worst case.
2. 2 Hazard giving rise to the FSCA	If the ribbon is torn, the product can no longer be used for its intended purpose. In addition, if the tourniquet breaks while under tension, the user or patient might be injured by flying parts.
2. 3 Background on issue	Kimetec GmbH has received a report of an incident in which a CBC NUCOS tourniquet ruptured during use, resulting in a minor injury to the user.

3. Type of Action to mitigate the risk		
3.	1 Action To Be Taken by the User <input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Devices <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input checked="" type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None As described in the instructions for use, always check the product for external damage and proper working, prior to each use. For this visual inspection, pull the tourniquet apart slightly to be able to detect even small holes or cracks that are not visible in the relaxed state. If damaged, the CBC NUCOS tourniquet must not be used any further.	
3.	2 By when should the action be completed?	Without delay (identification & inspection of devices), continuous inspection before use according to instructions for use
3.	3 Is customer Reply Required?	Yes
3.	4 Vom Hersteller zu ergreifende Maßnahmen <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input checked="" type="checkbox"/> Other <input type="checkbox"/> None Replacement delivery for damaged products.	
3.	5 By when should the action be completed?	Without delay after notification of defective products by means of the reply form

4. General information		
4. 1	FSN Type	Initial Field Safety Notice
4. 2	Further advice or information already expected in follow-up FSN?	No
4. 3	Manufacturer information	
	a. Company Name	Kimetec GmbH
	b. Address	Gerlinger Str. 36-38 71254 Ditzingen Deutschland
	c. Website address	www.kimetec.de
4. 4	The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4. 5	List of attachments	Reply form
4. 6	Name/Signature	Caroline Ihle CEO Kimetec GmbH

Transmission of this Field Safety Notice	
	<p>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.</p> <p>Please transfer this notice to other organisations on which this action has an impact (as appropriate).</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.</p>

Field Safety Notice Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN-2023-001
FSN Date	2023-07-12
Product/ Device name	CBC NUCOS
Product Code(s)	500580
Batch/Serial Number (s)	40848/202204 41090/202205

2. Distributor/Importer Details	
Company Name*	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	info@kimetec.de
Postal Address	Kimetec GmbH Gerlinger Str. 36-38 71254 Ditzingen Germany
Customer Helpline	+ 49 [0] 71 56 / 1 76 02 - 200
Fax	+ 49 [0] 71 56 / 1 76 02 - 500
Deadline for returning the Distributor/Importer reply form	2023-09-30

4. Distributors/Importers (Tick all that apply)		
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
<input type="checkbox"/>	I have checked my stock and quarantined inventory.	Distributor/Importer to enter quantity and date
<input type="checkbox"/>	I have identified customers that received or may have received this device.	
<input type="checkbox"/>	I have attached customer list.	
<input type="checkbox"/>	I have informed the identified customers of this FSN.	Date of communication:
<input type="checkbox"/>	I have received confirmation of reply from all identified customers.	
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form)
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form)
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory.	
Print Name*		
Signature*		
Date *		

Mandatory fields are marked with *

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.

Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN-2023-001
FSN Date	2023-07-12
Product/ Device name	CBC NUCOS
Product Code(s)	500580
Batch/Serial Number (s)	40848/202204 41090/202205

2. Customer Details	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
<input type="checkbox"/>	*I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A

<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		N/A	Comments:	
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
<input type="checkbox"/>	Other Action (Define):			
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A		
<input type="checkbox"/>	I have a query, please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query		
Print Name*				
Signature*				
Date*				

Mandatory fields are marked with *

4. Return acknowledgement to sender	
Email	info@kimetec.de
Postal Address	Kimetec GmbH Gerlinger Str. 36-38 71254 Ditzingen Germany
Customer Helpline	+ 49 [0] 71 56 / 1 76 02 - 200
Fax	+ 49 [0] 71 56 / 1 76 02 - 500
Deadline for returning the customer reply form	2023-09-30

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.