



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.	<p>1 Action To Be Taken by the User</p> <ul style="list-style-type: none"> <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 <p>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.</p>		
3.	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">2 By when should the action be completed?</td> <td>Without delay (identification & inspection of devices), continuous inspection before use according to instructions for use</td> </tr> </table>	2 By when should the action be completed?	Without delay (identification & inspection of devices), continuous inspection before use according to instructions for use
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3.	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%;">3 Is customer Reply Required?</td> <td style="text-align: center;">Yes</td> </tr> </table>	3 Is customer Reply Required?	Yes
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3.	<p>4 Vom Hersteller zu ergreifende Maßnahmen</p> <ul style="list-style-type: none"> <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 <p>Replacement delivery for damaged products.</p>		
3.	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">5 By when should the action be completed?</td> <td>Without delay after notification of defective products by means of the reply form</td> </tr> </table>	5 By when should the action be completed?	Without delay after notification of defective products by means of the reply form
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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	<div style="background-color: #cccccc; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: #cccccc; width: 40px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: #cccccc; width: 120px; height: 15px; margin-bottom: 5px;"></div>

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>