

**Urgent Field Safety Notice - Recall of the specific product Percutaneous dilator set with Item Number RBC008 and LOT Number 8606049**

For the Attention of:

[Redacted]  
 [Redacted]  
 [Redacted]  
 [Redacted]  
 [Redacted]  
 [Redacted]

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FSN\_PCN Dilator\_20220729

Coloplast REF: FSCA\_PCN Dilator\_20220729

[Redacted]  
 Regulatory Affairs Manager

Dir. +49 406698073 [Redacted]  
 deobuz@coloplast.com

**5. August 2022**

1. Information on Affected Devices*	
1.	<p>1. Device Type(s)*</p> <p>The FSN concerns the dilator with working sheath in the Percutaneous dilator set REF. RBC008. This set contains Percutaneous nephrostomy dilator Ch/Fr 6 and dilator with working sheath Ch/Fr 8</p> <p>Figure 1: Dilator with working sheath Ch/Fr 8</p> 
1.	<p>2. Commercial name(s)</p> <p>Percutaneous dilator set</p>
1.	<p>3. Unique Device Identifier(s) (UDI-DI)</p> <p>57089326358518H</p>
1.	<p>4. Primary clinical purpose of device(s)*</p> <p>Dilator for tract preparation or splittable working sheath to protect the parenchyma</p>
1.	<p>5. Device Model/Catalogue/part number(s)*</p> <p>RBC008</p>
1.	<p>6. Affected serial or LOT number range</p> <p>Lot 8606049: manufacturing date: 2022-01-20 / expiry date: 2027-01-20</p>

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	<p>1. Description of the product problem*</p> <p>20 pieces from a single lot of percutaneous dilator, with a design change that has not been approved according to procedures, have been released in French and German market. Although there is no new or increased risk, Coloplast has voluntarily elected to remove the product as it has not completed internal requirements for release.</p>
2.	<p>2. Hazard giving rise to the FSCA*</p> <p>No new or increased risk for the patient.</p>

Sitz der Gesellschaft:  
 Hamburg  
 Amtsgericht Hamburg  
 HRB 65501  
 Geschäftsführer:  
 Henning Reichardt

Danske Bank A/S:  
 BIC: DABADKKK  
 IBAN:  
 DK95 3000 4511 1119 00

Zertifiziert nach  
 DS/EN ISO 13485:2016

<b>3. Type of Action to mitigate the risk*</b>	
3.	<p><b>1. Action To Be Taken by the User*</b></p> <p> <input checked="" type="checkbox"/> Identify Device              <input type="checkbox"/> Quarantine Device              <input checked="" type="checkbox"/> Return Device              <input type="checkbox"/> Destroy Device         </p> <p> <input type="checkbox"/> On-site device modification/inspection         </p> <p> <input type="checkbox"/> Follow patient management recommendations         </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)         </p> <p> <input type="checkbox"/> Other                      <input type="checkbox"/> None         </p> <p>Provide further details of the action(s) identified.</p>
3.	<p><b>2. Is customer Reply Required? *</b> (If yes, form attached specifying deadline for return)</p> <p style="text-align: right;">Yes</p>

<b>4. General Information*</b>					
4.	<p><b>1. FSN Type*</b></p> <p style="text-align: right;">New</p>				
4.	<p><b>2. Further advice or information already expected in follow-up FSN? *</b></p> <p style="text-align: right;">No</p>				
4.	<p><b>3. Manufacturer information</b> (For contact details of local representative refer to page 1 of this FSN)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">a. Company Name</td> <td>Coloplast A/S</td> </tr> <tr> <td>b. Address</td> <td>Holtedam 13050 Humlebæk Denmark</td> </tr> </table>	a. Company Name	Coloplast A/S	b. Address	Holtedam 13050 Humlebæk Denmark
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b. Address	Holtedam 13050 Humlebæk Denmark				
4.	<p><b>4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *</b></p>				
4.	<p><b>5. List of attachments/appendices:</b></p> <p style="text-align: right;"><b>Customer Reply Form</b></p>				
4.	<p><b>6. Name/Signature</b></p> <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 200px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div>				

<b>Transmission of this Field Safety Notice</b>	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</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>

Note: Fields indicated by \* are considered necessary for all FSNs. Others are optional.