

Date: 27 July 2021

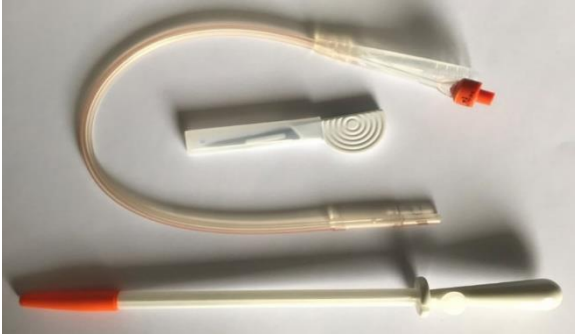

Urgent Field Safety Notice – Recall of specific Item and lot numbers
AJ9216 lot 7928434
Supraflow[®] supra-pubic drainage set

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
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This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages
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Urgent Field Safety Notice (FSN)
Supraflow® supra-pubic drainage set
Risk addressed by FSN

1. Information on Affected Devices*	
1.	<p>1. Device Type(s)*</p> <p>This FSN concerns the Supraflow® supra-pubic drainage set REF. AJ9216, a set containing a silicone Foley Catheter Ch/Fr16, a splittable trocar size 16 (Ch/Fr20/24) and a scalpel.</p> <p>Figure 1: Supraflow® supra-pubic drainage set REF. AJ9216</p>  <p>Figure 2: Comparison of both trocars included Supraflow® supra-pubic drainage set REF. AJ9216 (Ch/Fr16) and AJ9212 (Ch/Fr12)</p> 
1.	<p>2. Commercial name(s)</p> <p>Supraflow® supra-pubic drainage set</p>
1.	<p>3. Primary clinical purpose of device(s)*</p> <p>The Supraflow® supra-pubic drainage sets are intended for suprapubic drainage of urine from the bladder.</p>
1.	<p>4. Device Model/Catalogue/part number(s)*</p> <p>AJ9216</p>
1.	<p>5. Affected lot number range</p> <p>Lot 7928434: manufacturing date: 2021-03-18 / expiry date: 2026-03-17</p>

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	<p>1. Description of the product problem*</p> <p>Following discrepancies between packaging labels and contents due to inversion of two trocar batches from different size, Coloplast initiates a voluntary recall.</p>
2.	<p>2. Hazard giving rise to the FSCA*</p> <p>A difference in size of trocar - size 12 (Ch/Fr16/20) instead of size 16 (Ch/Fr20/24) included in the Supraflow® supra-pubic drainage set REF. AJ9216 - was identified and reported by 2 customers. The inconsistency of sizes between the trocar and the catheter makes the device unusable. No clinical consequence has been reported within these complaints.</p> <p>Visible information is available for the operator such as color-coded trocar protective cap and valve, number of Charrière compatible on trocar handle. However, failure to identify the issue may lead to a significant prolonged procedure for change of trocar if a correct suprapubic drainage set is available, or interruption / reschedule of the surgery if no correct suprapubic drainage set is available.</p>
2.	<p>3. Background on Issue</p> <p>No clinical consequence was reported by the complaining hospitals. A review of the complaints database was carried out on references AJ9216 and AJ9212 and no similar case has been reported since CE marking until these current cases.</p>

3. Type of Action to mitigate the risk*	
3.	<p>1. Action To Be Taken by the User*</p> <p><input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Return Device</p> <p>The customers affected by this recall are kindly advised to return any unused product covered by the list above to the address mentioned below:</p> <p style="text-align: center;">Distribution Center of Coloplast Champlan Recall Supraflow trocar Service Retour 2 bis route du Chemin Blanc ZAC du Clotais 91160 CHAMPLAN France</p>
3.	<p>2. By when should the action be completed?</p> <p>September 30 2021</p>
3.	<p>3. Is customer Reply Required? *</p> <p>(If yes, form attached specifying deadline for return)</p> <p>Yes</p>

4. General Information*					
4.	<p>1. FSN Type*</p> <p>New</p>				
4.	<p>2. Further advice or information already expected in follow-up FSN? *</p> <p>No</p>				
4.	<p>3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)</p> <table border="1" style="width: 100%;"> <tr> <td>a. Company Name</td> <td>Coloplast A/S</td> </tr> <tr> <td>b. Address</td> <td>Holtedam 1 3050 Humlebæk Denmark</td> </tr> </table>	a. Company Name	Coloplast A/S	b. Address	Holtedam 1 3050 Humlebæk Denmark
a. Company Name	Coloplast A/S				
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4.	<p>4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *</p> <p>Yes</p>				
4.	<p>5. List of attachments/appendices:</p> <p>Customer Reply Form</p>				

4.	6. Name/Signature	Tina Gotschalk Senior Vigilance Specialist

Transmission of this Field Safety Notice	
	<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.