FSN Ref: FSN_20240223_Ureteral dilator FSCA Ref: FSCA_20240223_Ureteral dilator

Date: 2024:03.20 Update 2024:07.08

# Field Safety Notice
# Ureteral dilator

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.)* |
| --- |
| This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages. |

# Field Safety Notice (FSN)
# Ureteral dilator
# Risk addressed by FSN

| 1. Information on Affected Devices* | |
|---|---|
| 1. | 1. Device Type(s)* |
| | Ureteral dilator is a sterile single use device intended to be used for dilation of the ureter during ureteroscopic procedure. The device is packaged in a double pouch packaging.  |
| 1. | 2. Commercial name(s)* |
| | Ureteral Dilator (Ch/Fr 12-14, length 48 cm) |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | Basic UDI-DI: 57089326358428G |
| 1. | 4. Primary clinical purpose of device(s)* |
| | Ureteral dilator is a sterile single use device intended to be used for dilation of the ureter during ureteroscopic procedure |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | RBD014 |
| 1. | 6. Affected serial or lot number range |
| | See appendix 1 |

| 2. Reason for Field Safety Corrective Action (FSCA)* | |
|---|---|
| 2. | 1. Description of the product problem* |
| | Possible sterility issue was detected in Coloplast's facility on some Ureteral dilator products. This issue on the Ureteral dilator packaging has been identified during testing plan. Defect is not easily visible by the users. |
| 2. | 2. Hazard giving rise to the FSCA* |
| | The main associated risk can possibly be urinary tract infection.<br><br>Coloplast initiates a voluntary recall on the Ureteral dilator impacted. |
| 2. | 3. Background on Issue |
| | This issue on the Ureteral dilator packaging has been identified during testing plan. |

| 3. Type of Action to mitigate the risk | |
|---|---|
| 3. | **1. Action To Be Taken by the User**<br><br>☒ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device<br><br>The customers affected by this recall are kindly advised to return any unused product covered by the list in appendix 1 to the address mentioned below:<br><br>**Distribution center of Coloplast Le Plessis Pate**<br>Att. Blaise Banzouzi<br>Obj: Recall Ureteral dialtor_202402<br>Service Retour<br>2 Rue Jacqueline Auriol,<br>91220 Le Plessis-Pâté.<br>France |

| | | |
|---|---|---|
| 3. | 2. By when should the action be completed? | September 30th, 2024 |
| 3. | 3. Is customer Reply Required?<br>(If yes, form attached specifying deadline for return) | Yes |
| **3.** | **4. Action Being Taken by the Manufacturer**<br><br>☒ Product Removal ☒ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☐ Other ☐ None | |

| **4. General Information*** | | |
|---|---|---|
| 4. | 1. FSN Type | Update |
| 4. | 2. Further advice or information already expected in follow-up FSN? | No |
| 4. | 3. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Coloplast A/S |
| | b. Address | Holtedam 13050 Humlebæk Denmark |
| 4. | 4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. | |
| 4. | 5. List of attachments/appendices: | Customer Reply Form |
| 4. | 6. Name/Signature | Stéphane Bouché<br>Senior Regulatory Affairs Manager |
| | |  |

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

## Appendix 1: list of affected lot number

| References impacted | Lot number impacted |
|---|---|
| RBD014 | 6885096, 6928493, 7036982, 7092593, 7148682, 7187751, 7275918, 7326750, 7362229, 7405815, 7424892, 7440816, 7459583, 7528743, 7575957, 7742150, 7806993, 7825256, 7874646, 7948615, 8050730, 8122897, 8174950, 8210399, 8313229, 8350283, 8359041, 8442175, 8519426, 8619976, 8700201, 8864944, 8946228, 8946264, 9122793, 9122794, 9168554, 9226390, 9246177, 9360599<br><br>Update July 2024: 9808520, 9808521 |