

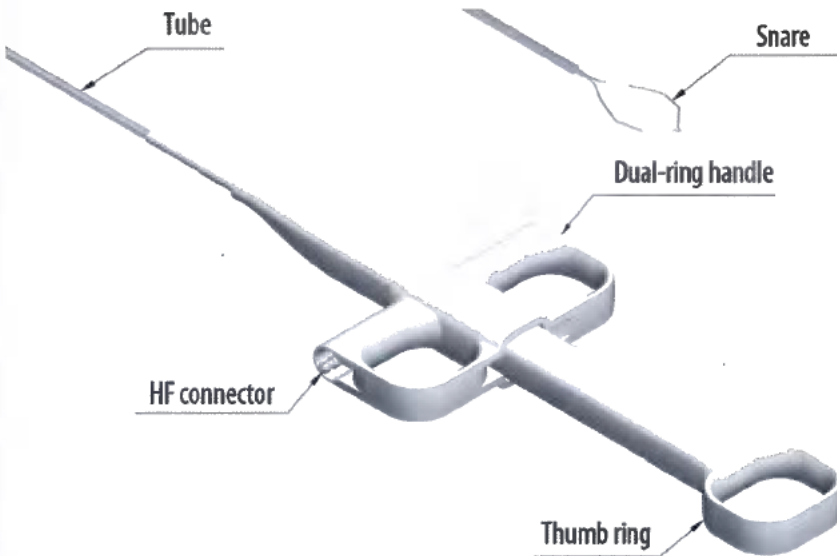
**Date:** 04.08.2022

**Field Safety Notice**  
**CrossSnare**

Dear customer

FUJIFILM medwork GmbH as manufacturer of the CrossSnare product, hereby notifies about the issue of a Field Safety Corrective Action relating to the aforementioned product.



**Field Safety Notice (FSN)**  
**CrossSnare**  
**Elevated EO residuals**

| <b>1. Information on Affected Devices*</b> |  |
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| 1  | <p><b>1. Device Type(s)*</b></p> <p>Polypectomy snares are used for representative sampling and the safe removal or ablation of parts of or even entire lesions. CrossSnare instruments are designed as a hybrid snare and can be used for both cold and hot ablation. They are equipped with a power connection on the handle to which a monopolar high-frequency surgical current source can be connected by means of an HF cable. CrossSnares are intended exclusively as single-use instruments.</p>  <p>Labels in diagram: Tube, Snare, Dual-ring handle, HF connector, Thumb ring</p> |
| 1  | <p><b>2. Commercial name(s)</b></p> <p>POL1-X 1-10-23-220-OL and POL1-X 1-15-23-220-OL</p>   |
| 1  | <p><b>3. Primary clinical purpose of device(s)*</b></p> <p>CrossSnares are commonly used in hospitals or medical practices to remove or ablate polyps.</p>   |
| 1  | <p><b>4. Device Model/Catalogue/part number(s)*</b></p> <p>502308 and 502309</p>   |
| 1  | <p><b>5. Affected serial or lot number range</b></p> <p>22252483, 22252574 and 22252721</p>  |

| <b>2 Reason for Field Safety Corrective Action (FSCA)*</b> |   |
|--|---|
| 2  | <p><b>1. Description of the product problem*</b></p> <p>DIN EN ISO 10993-7 defines values for EO and ECH residuals in EO sterilized products. Lab test results of POL1-X products showed elevated values for EO after the degassing period.</p> |
|  | <p><b>2. Hazard giving rise to the FSCA*</b></p>  |

|   |  |
|---|--|
| 2 | As long as the limit values are exceeded the products might pose a small potential threat to the health of users or patients (headache, nausea or vertigo).    |
| 2 | <b>3. Probability of problem arising</b>   |
| . | There is a very small chance that above-mentioned symptoms might occur if the products are applied in a clinical procedure. During storage no harm is present. |
| 2 | <b>4. Predicted risk to patient/users</b>  |
| . | Headache, nausea or vertigo might occur.   |

|  |   |  |   |
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| <b>3. Type of Action to mitigate the risk*</b>   |   |  |   |
| 3.   | <b>1. Action To Be Taken by the User*</b><br><br><input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device<br><br><input type="checkbox"/> On-site device modification/inspection<br><br><input type="checkbox"/> Follow patient management recommendations<br><br><input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)<br><br><input type="checkbox"/> Other <input type="checkbox"/> None<br><br>Provide further details of the action(s) identified. |  |   |
| 3.   | <table border="1" style="width: 100%;"> <tr> <td style="width: 40%; vertical-align: top;">2. By when should the action be completed?</td> <td style="vertical-align: top;">Identifying and quarantining the products should happen immediately after being notified in order to prevent their use.</td> </tr> </table>  | 2. By when should the action be completed?   | Identifying and quarantining the products should happen immediately after being notified in order to prevent their use. |
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| 3.   | <table border="1" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;">3. Is customer Reply Required? *<br/>(If yes, form attached specifying deadline for return)</td> <td style="text-align: center; vertical-align: top;">Yes</td> </tr> </table>   | 3. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return) | Yes   |
| 3. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return) | Yes   |  |   |

|    |  |   |
|----|--|---|
|    | <b>4. General Information*</b>   |   |
| 4. | 1. FSN Type*   | New   |
| 4. | 2. Further advice or information already expected in follow-up FSN? *  | Yes   |
| 4  | 3. If follow-up FSN expected, what is the further advice expected to relate to:<br>Additional information will be given on the safety of use of the affected products. |   |
| 4. | 4. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN)   |   |
|    | a. Company Name  | FUJIFILM medwork GmbH   |
|    | b. Address   | Medworking 1, 91315 Höchstadt   |
|    | c. Website address   | www.medwork.com   |
| 4. | 5. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *   |   |
| 4. | 6. Name/Signature  |   |
|    |  |  |

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|  | <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.