Date: 04.08.2022

Field Safety Notice
CrossSnare

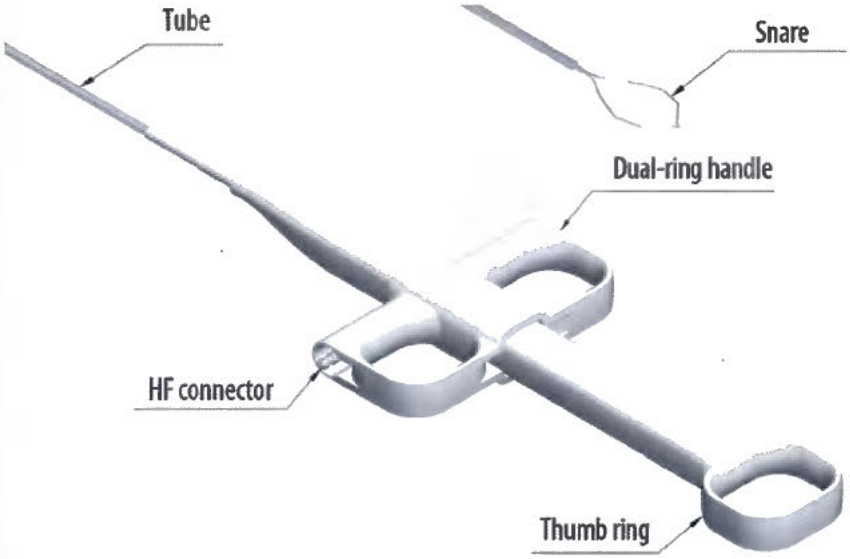
Dear customer

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.

Company Name/Logo

Rev 1: September 2018
FSN Ref: FSN_CAPA-2022-031 FSCA Ref: FSCA_CAPA-2022-031

Field Safety Notice (FSN)
CrossSnare
Elevated EO residuals

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	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. 
1.	2. Commercial name(s)
	POL1-X 1-10-23-220-OL and POL1-X 1-15-23-220-OL
1.	3. Primary clinical purpose of device(s)*
	CrossSnares are commonly used in hospitals or medical practices to remove or ablate polyps.
1.	4. Device Model/Catalogue/part number(s)*
	502308 and 502309
1.	5. Affected serial or lot number range
	22252483, 22252574 and 22252721

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	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.
	2. Hazard giving rise to the FSCA*

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.	3. Probability of problem arising
	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.	4. Predicted risk to patient/users
	Headache, nausea or vertigo might occur.

	3. Type of Action to mitigate the risk*		
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☒ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.		
3.	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.	
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)		Yes

	4. General Information*	
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:	
	Additional information will be given on the safety of use of the affected products.	
4.	4. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**FUJIFILM medwork GmbH**
	b. Address	**Medworkring 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	[redacted]

	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) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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.*

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

FUJIFILM
medwork

Rev 1: September 2018
FSN Ref: FSN_CAPA-2022-031_en_final FSCA Ref: FSCA_CAPA-2022-031

Date: 24.08.2022

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.

FUJIFILM
medwork

Rev 1: September 2018
FSN Ref: FSN_CAPA-2022-031_en_final FSCA Ref: FSCA_CAPA-2022-031

Field Safety Notice (FSN)
CrossSnare
Elevated EO residuals

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	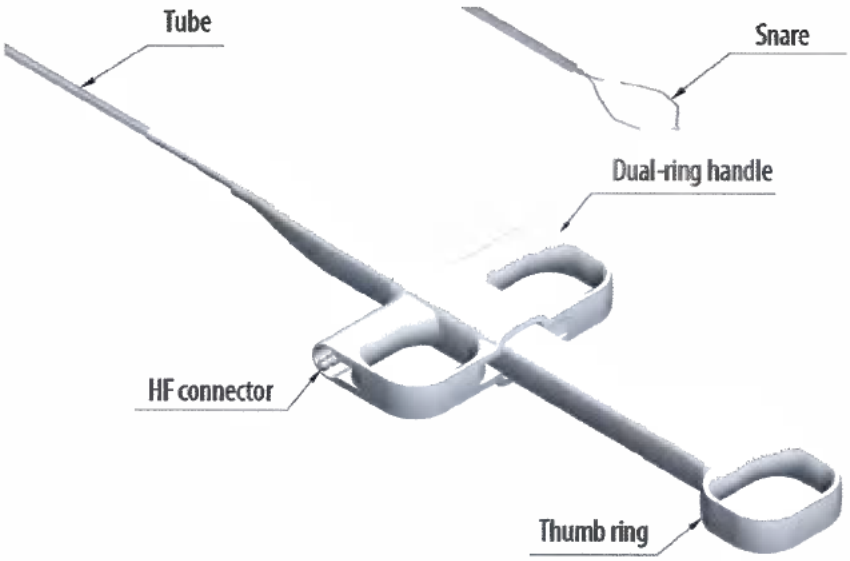
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3.	**1. Action To Be Taken by the User***
	☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device
	☐ On-site device modification/inspection
	☐ Follow patient management recommendations
	☐ Take note of amendment/reinforcement of Instructions For Use (IFU)
	☐ Other ☒ None

	4. General Information*	
4.	1. FSN Type*	Update
4.	2. For updated FSN, reference number and date of previous FSN	FSN_CAPA-2022-031 dated 04.08.2022
4	3. For Updated FSN, key new information as follows:	
	The repetition of the residual gas determination on the product POL1-X1-15-23-220-OL, LOT 22252794 after 21 days of storage after completion of the post-conditioning phase of sterilisation (TQL 21) resulted in a significantly reduced value of 0.88 mg EO per product. The permitted limit of 4 mg per product according to DIN EN ISO 10993-7 is thus complied with. Goods of the affected products POL1-X1-15-23-220-OL and POL1-X1-10-23-220-OL that have been stored for 21 days can be released for sale and use.	
4.	4. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**FUJIFILM medwork GmbH**
	b. Address	**Medworkring 1, 91315 Höchstadt**
	c. Website address	**www.medwork.com**
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