FUJIFILM
medwlQlrk

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

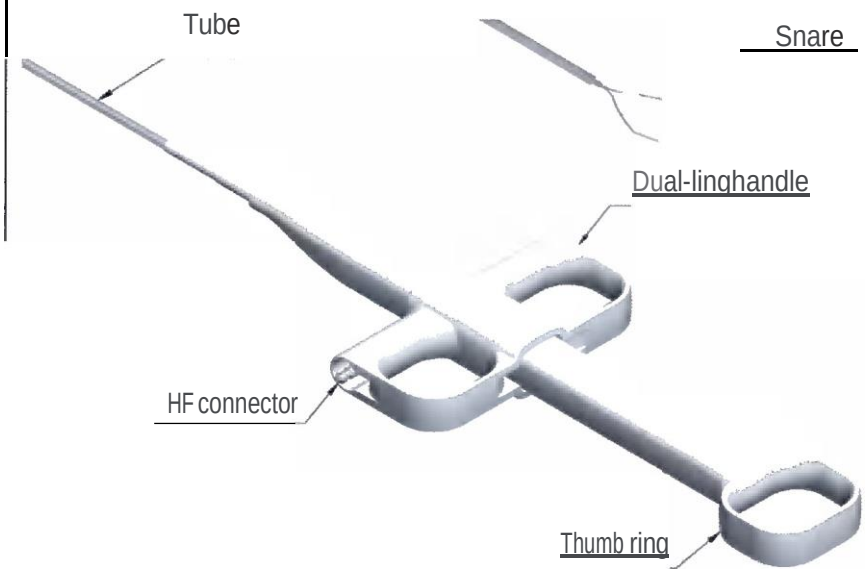
Date: 24.08.2022

Field Safety Notice
CrossSnare

Dear customer

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

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. Prima clinical ur ose of device s * CrossSnares are commonly used in hospitals or medica! practices to remove or ablate pol s.
1	4. Device Model/Catalo ue/ art number s * 502308 and 502309
1	5. Affected serial or lot number ran e 22252483 22252574 and 22252721

2 Reason for Field Safety Corrective Action FSCA *

1. Description of the product problem*

2	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	2. Hazard givina rise to the FSCA*
	As long as the limit values are exceeded the products might pose a small potential threat to the health of users or oatients (headache nausea or vertiao).
2	3. Probabilitv of problem arising
	There is a very small chance that above-mentioned symptoms might occur if the products are aoolied in a clinical procedure. During storage no harm is present.
2	4. Predicted risk to oatient/users
	Headache nausea or vertigo miaht occur.

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the Use** D Identify Device D Quarantine Device ☐ Return Device D Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other 181 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 fellows:	
	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. Goeds 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 paçie 1 of this FSNJ	
	a. Companv 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	...
		...

	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 maintainawareness on this noticeand resulting action for an appropriate period to ensure effectivenessof the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Comoetent Authoritv if aoorooriate as this orovides important feedback.*

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