FUJIFILM medwork

Field Safety Notice

Polypectomy snare – POL1-X1-10-23-220-OL

December 2023

Attn: Representative for Medical Safety, Quality Management, Purchasing, Endoscopy

Dear Sir or Madam,

FUJIFILM medwork GmbH, as the manufacturer of Polypektomy snares (POL1-X1-Series) hereby informs of a field safety corrective action regarding the above mentioned product.

In some cases, at specific lots of article POL-X1-10-23-220-OL (Polypektomy snares) the components were connected incorrectly during production, as the rope was not fully inserted into the pipe section during the joining process. For affected products, there is a possibility of reduced retention force of the press connection between the pull rope and the snare head. This could lead to the snare falling off.

Our records indicate that your institution has received products from the affected lots which can be affected. All other lots are not impacted and can be used.

Scope of Problem

The issue affects all below listed lots of article POL1-X1-10-23-220-OL:

Affected Lots
22354743, shelf life 22.08.2028
22354744, shelf life 22.08.2028
22354745, shelf life 16.08.2028
22354746, shelf life 20.08.2028
22354747, shelf life 24.08.2028
22354748, shelf life 16.08.2028

Impact and Associated Risk

At current time, we have received different customer complaints relating to this defect – fallen off snare head / snare head detaches during use.
In none of the cases were adverse consequences for the patient or user reported.

The error has already been considered in our risk analysis and explicitly identifies the error that has occurred as a hazard. The damage "Foreign body in GI tract" is rated as low severity.

According to FUJIFILM medwork GmbH's risk policy, the risk with this combination of severity of damage and probability of occurrence is still within the acceptable range. However, as a future increased probability of occurrence

cannot be excluded, FUJIFILM medwork GmbH has decided to issue a Field Safety Notice as a precautionary action and to remove the affected products from the market.

If products of the lots mentioned have already been used, there is no risk for the patient and no further actions are necessary.

Actions Requested

FUJIFILM medwork requests that you take the following steps:

- Please share this information with others in your organisation, as appropriate.
- Please do not use any further products from the affected lots with immediate effect.
- Identify all devices from the affected lots in your stock and destroy them.
- Complete attached customer reply form and return it via email to safety_officer_feg@fujifilm.com or via fax to +49 2102 5364 -98756.
- Contact your local FUJIFILM representative with any questions related to this issue.
- Please keep this information at least until the corrective action has been completed.

Sharing the information described herein:

Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this "Field Safety Notice".
If you have passed the products on to third parties, please forward a copy of this information to them or inform your local FUJIFILM Representative.

Reporting and Customer Assistance

The appropriate Regulatory Agencies have been notified of this action. Adverse events or quality problems experienced with the use of this product may be reported directly to FUJIFILM medwork as well as to the national competent authority.

Should you have questions about this issue, please contact your local FUJIFILM Representative.

FUJIFILM medwork is committed to providing the highest quality products and support. Thank you for your assistance in this matter, and we sincerely apologize for any inconvenience this action may cause you.

Sincerely,

i.V. C. Schröder
PRRC, Division Manager Technology
FUJIFILM medwork GmbH