

## **Safety instruction in the field**

### **AXS\_TOME Papillotom**

May 2025

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

Dear Ladies and Gentlemen,

FUJIFILM medwork GmbH, as the manufacturer of the AXS\_TOME Papillotomes (article number PAP1-X8-30-35-260-OL), hereby informs about a safety corrective measure in the field with regard to the above mentioned product.

According to our records, your facility has received products from the affected batches.

In batch LOT 22550951, LOT 22450710, LOT 22455696

of the article, the 260 cm long guidewire for use in short wire technology is preloaded in the guidewire connection for long-wire technology. As a result, the use of short-wire technology for instrument change is not immediately possible as planned and the intervention can be delayed.

All other products of the AXS\_TOME series or batches are not affected and can be used.

#### **Health risk**

There is no risk to patient and user. Due to the fault, the guidewire must be removed from the guidewire lumen and reinserted at the short wire guidewire connection. This can prolong the intervention for a short time.

The hazard in the combination of the severity of the damage and the probability of occurrence was assessed as part of the risk management of FUJIFILM medwork GmbH, and is within the acceptable range that does not require a recall of the affected products. However, in order to minimize delays in the intervention for the individual patient despite the low probability of occurrence, FUJIFILM medwork GmbH has decided to publish a safety instruction in the field as a precautionary measure and to withdraw the affected products from the market.

#### **Required measures**

- 1) By the user when defects are detected

Before use:

Carefully pull the guidewire out of the mentioned proximal guidewire connector for long wire technology. Then insert it into the somewhat more distal, red-marked guidewire connection for short wire technology and thus preload the papillotome correctly.

During use:

Bring the tip of the papillotome into a stable position in front of the papilla or in the bile duct. Remove the guidewire completely from the mentioned proximal guidewire connector for long-wire technology. Then insert it into the distal guidewire connection marked in red and push it towards the distal tip until it exits the instrument.

## 2) Returning the defective products

FUJIFILM medwork asks you to take the following steps:

- Please do not use any further products from the affected batches from now on.
- Identify all the products in your inventory from the affected batches and keep them in a secure location until they are returned.
- Fill out the attached customer response form, sign it and send it
  - by e-mail to [vigilance\\_hceu@fujifilm.com](mailto:vigilance_hceu@fujifilm.com)
- If you have products to return, please pack them in a suitable shipping box. After receiving the customer response form, FUJIFILM will contact you to arrange the return.
- Please keep this information at least until the measures are completed.

### **Share the information described here:**

Please ensure in your organization that all users of the above products and other products informing persons are made aware of this urgent safety information.

If you have given the products to a third party, please forward a copy of this information or inform your local FUJIFILM representative.

### **Reporting and customer support**

The competent supervisory authorities have been informed of this measure. Adverse events or Quality issues associated with the use of this product may be reported directly to FUJIFILM medwork and to the competent national authority.

If you have any questions about this topic, please contact your local FUJIFILM representative.

Maximum quality and service is our claim. Therefore, we very much regret the inconvenience caused, apologize for our mistake and thank you for your support in implementing this measure.

Best regards,

I.V. V Schmitt  
PRRC, Head of Market  
FUJIFILM medwork GmbH