

Date: Nov XX, 2023

Olympus reference: QIL FY24-EMEA-29-FY24-EMEA-14 White Tape

## URGENT FIELD SAFETY NOTICE

### Product Return to Olympus Repair Center for additional Inspection

Product Name	Model/Catalog Number	Serial/Lot Number(s)	UDI PI

Attention: *Endoscopy Department, Operating Room, Urology, Gynecology, Pulmonology, Risk Management*

Dear Healthcare Professional/Provider:

Olympus is writing you to inform you of an issue that happened during the last repair of your product that requires urgent inspection of your endoscope.

#### **Reason for Action:**

Olympus recently received complaints indicating that the insertion tube of a repaired endoscope was wrapped with white tape.

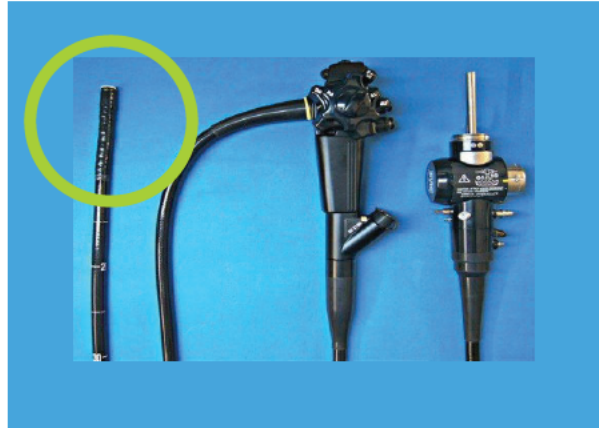
**Wrong – White Tape**



This white tape is used during the repair process to protect sensitive parts of the endoscope from damage, (scratches and dents). It is to be removed during final

inspection prior to being returned to the customer for patient use. The endoscope is not intended to be used on a patient with this white service tape attached.

Correct – no tape



### **Risk to Health:**

If not removed, the white tape could potentially damage the mucosal tissue and lead to bleeding. Additionally the tape could fall off during examination, fall into the patient's digestive tract and potentially be retained. If the tape slips off during insertion into the oral cavity it may cause aspiration, respiratory distress, and asphyxia. Reprocessing of an endoscope with the white tape attached might lead to insufficient disinfection with the potential for risk of contamination and subsequent patient infections.

You may have detected the white tape in the meantime and removed it. In an abundance of caution, Olympus recommends the return of your product for an additional inspection to ensure that your endoscope is meeting our repair and inspection specifications and standards.

### **Actions Required:**

1. Carefully read the content of this Field Safety Notice.
2. Inspect your inventory to identify the device(s) **XXXXXXX** with serial number(s) **XXXXXXX**.
3. If you find the product wrapped with white tape at the distal end or had found and already removed it, segregate the device and cease usage with immediate effect.
3. Contact your Olympus customer service representative by **[Regional contact]**. Olympus will issue a Return Material Authorization to return any affected product at no charge.



4. If you have further distributed this product, identify your customers, and forward them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.
4. Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative **XXXXXXX** latest by **DD MM YYYY**.

Your National Competent Authority has been informed of this Field Safety Notice. Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation.

If you require additional information, please do not hesitate to contact me at [phone number] or [e-mail address].

Sincerely,



**REPLY FORM** – (Reply Form may be optional depending on the regional needs)

<b>Facility Name</b>	
<b>Facility Address</b>	
<b>Contact Name</b>	
<b>Additional Customer Requests</b> (Indicate if you have any additional requests to support this action)	

Insert description of the product names and model numbers of the affected products

<b>Catalog #</b>	<b>Serial / Lot #</b>	<b>Date Shipped</b>	<b>Qty Shipped to your facility</b>	<b>Qty remaining in Stock</b>

I acknowledge receipt of this notification. I confirm that I have further communicated this notification to any affected departments.

<b>Completed By:</b>		
		Click or tap to enter a date.
<i>Name</i>	<i>Signature</i>	<i>Date (YYYY-MM-DD)</i>

Please send the completed form to XXX by date XXX.