

URGENT FIELD SAFETY NOTICE

RE: OLYMPUS DUODENOSCOES

Attention: Endoscopy Department, Infection Control, Reprocessing Units

Material ID	Model Number	Material Description	Serial Number(s)	UDI-DI
N5992960 N5992950 N5425051	TJF-Q190V	Evis Exera III Duodenovideoscope	All	04953170407314 04953170416040 04953170436260
N5993260 N5993250	TJF-Q290V	Evis Lucera Elite Duodenovideoscope	All	04953170405594 04953170436086
N6000360	TJF-Q170V	Duodenovideoscope	All	04953170408861

Dear Healthcare Professional:

Olympus is writing to inform you of a Field Corrective Action pertaining to the TJF-Q190V/TJF-Q290V/TJF-Q170V duodenoscopes ("TJF"). The TJF duodenoscope is a flexible gastrointestinal endoscope used in procedures such as endoscopic retrograde cholangio-pancreatography (ERCP).

Reason for Action:

Olympus's ongoing assessment of TJF duodenoscope reprocessing to address positive cultures and infections has identified updates to the reprocessing materials, detailed in the "Summary of Changes" section below, to minimize potential deviations in TJF duodenoscope reprocessing. Olympus is informing users of these changes and is reminding users to closely follow the operation and reprocessing instructions. Customers are required to acknowledge reviewing all such materials, which can be accessed through the link provided in the "Actions Required" section below.

From 2024 to present, Olympus has received 2 reports of death and 5 reports of serious injury from infection or positive culture potentially related to use of the TJF duodenoscope; these reports did not contain sufficient information for Olympus to determine if the TJF duodenoscope contributed to the transmission of an infection.

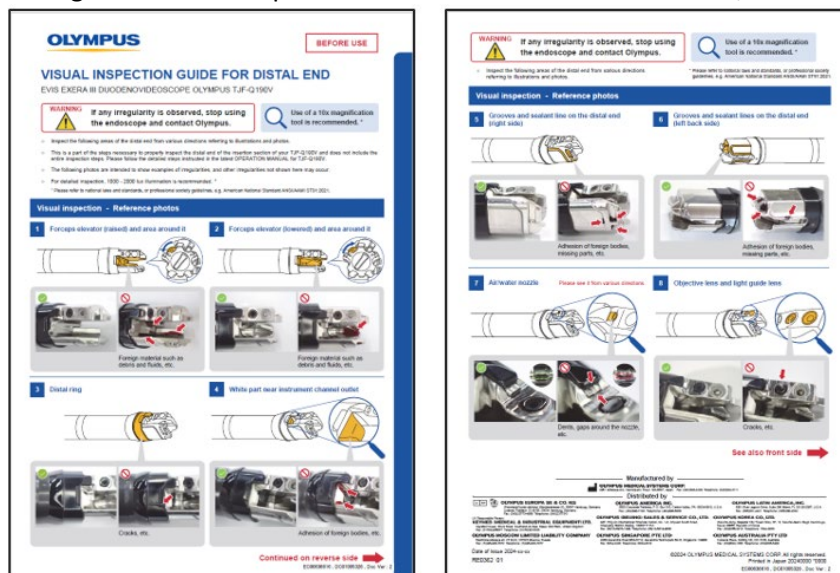
Risk to Health:

The potential risk related to improper and/or incomplete reprocessing of Olympus duodenoscopes includes exposure to a contaminated device which may result in patient infection. The severity of infection would depend on overall patient health and/or risk factors (e.g. immunocompromised patients) which may range from minor to life-threatening, and possibly death in extremely rare cases.

Summary of Changes:

- The "Introduction to Duodenoscope Reprocessing" training material has been updated to highlight the importance of precleaning as directed in the TJF Duodenoscope Reprocessing Instructions. This update can be found on slide 14 of the "Introduction to Duodenoscope Reprocessing" training material.
- Olympus created a Visual Inspection Guide to provide clear directions for inspecting the device for potential irregularities and damage. The guide recommends the use of 10X magnification tools for enhanced visual inspection of the endoscope (see Figure 1).

Figure 1: Visual Inspection Guide for distal end: Front side/Back side



- The Operation Manual has been updated as set forth below to include a Warning relating to visual inspection of the endoscope distal end, as well as the recommendation for use of 10X magnification tools for enhanced visual inspection of the endoscope (see Figure 2).

Figure 2: Operation Manual: Section “3.3 Inspection of the endoscope”

WARNING

Inspect the distal end with reference to the attached “VISUAL INSPECTION GUIDE FOR DISTAL END”. If any irregularity is observed, stop using the endoscope and contact Olympus. The irregularity may pose an infection control risk.

NOTE

- To inspect the distal end, use of a 10x magnification tool is recommended.*¹
- For detailed inspection, 1000 - 2000 lux illumination is recommended.*¹

*¹ Please refer to national laws and standards, or professional society guidelines, e.g. American National Standard ANSI/AAMI ST91:2021.

Olympus is requiring customers to review the online updated “Introduction to Duodenoscope Reprocessing” training material, Visual Inspection Guide, and Operation Manual. You are also required to review the existing Reprocessing Manual and On-Track Reprocessing In-Service/Customer Competency form. Please see “Actions Required” steps 2-3 below to access these materials.

In addition to the required online training mentioned above, Olympus is recommending that customers receive on-site TJF duodenoscope reprocessing training at their facility. This training is offered for all new customers and is available by request to all existing customers. To request on-site training, please see “Actions Required” step 6 below.

Actions Required:

Our records indicate that your facility has purchased one or more of the affected products. Therefore, Olympus requires you to take the following actions:

1. Carefully read the content of this notification.
2. Access the Olympus education portal and complete the required training course.
 - a. Go to this **link**:
[TJF Training - Europe - Olympus Continuum Professional Education](#) or scan the **QR-Code**

 - b. Log in with your existing account or create a new account.
 - c. Complete the TJF Training and Labeling course, which requires you to download and review the following materials:
 - 1) Introduction to Duodenoscope Reprocessing updated training module
 - 2) Updated Operation Manual (Operation IFU)
 - 3) Reprocessing Manual (Reprocessing IFU)
 - 4) Visual Inspection Guide
 - 5) OnTrack Reprocessing In-Service/Customer Competency form
 - d. Acknowledge that you have read and understood all these materials.
 - e. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply Form that you have received and understood this notification by filling out and returning the completed enclosed Reply Form back to your local Olympus representative **XXX** latest by **XXX**.
3. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this notification and the full extent of the TJF duodenoscope reprocessing steps as detailed in the reprocessing training materials. All applicable personnel should review these materials either via the downloaded documents or by accessing the education portal themselves.
4. Keep a copy of this notification with your current Operation Manual. Olympus requests that you replace any existing copies of the Operation Manual with the updated Operation Manual and include a copy of the Visual Inspection Guide, obtained through the link above in Step 2.
5. If you would like to receive a physical copy of some or all of the above-mentioned reprocessing materials from Olympus, please contact [\[Regions to revise to reflect their resources\]](#).
6. Olympus recommends that you receive on-site TJF duodenoscope reprocessing training at your facility. Contact [\[local contact for coordinating training\]](#) to schedule your on-site training.
7. If you have further distributed this product, identify your customers, and forward them this notification.

[\[If applicable:\] \[competent authority\]](#) is aware of the actions described in this letter.

Olympus requests that you report any complaints, including infections, to [\[local facility complaint reporting contact\]](#). [\[If applicable:\]](#) Adverse events experienced with the use of this product may also be reported [\[local competent authority\]](#) by [\[method\]](#).

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact [\[me directly at XXXX@olympus.com/ Olympus directly at \(XXX\) XXX-XXXX from Monday through Friday or by e-mail at XXX\]](#).

Sincerely,

[Name](#)

[Olympus title](#)

REPLY FORM – QIL FY26-EMEA-07-FY26-902-F TJF Reprocessing

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests (Indicate if you have any additional requests to support this action, e.g. require hard copies of the training)	

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

Completed By:		
		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](#).