

Reference: 2025-004M

10 October 2025

## URGENT - FIELD SAFETY NOTICE

To all users of **Olympus Duodenoscopes**

Product Name	Model Number	Serial Numbers
Evis Exera III Duodenovideoscope	TJF-Q190V	All

### Re: Olympus to Provide Online Training Materials on Reprocessing for TJF Duodenoscopes

Attention: **Endoscopy Department, Infection Control, Reprocessing Units**

Dear Health Care Professional:

Olympus is writing to inform you of a Field Corrective Action pertaining to the TJF-Q190V 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.

#### **Risk to Health:**

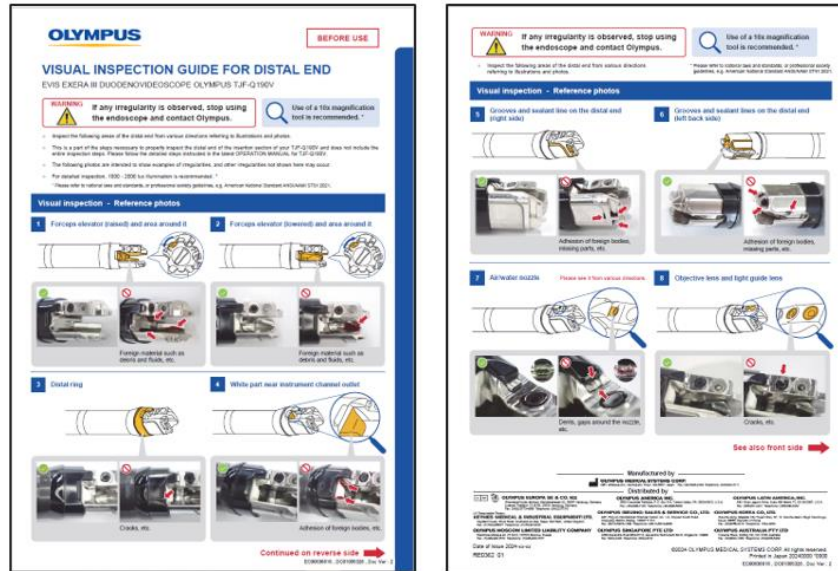
The potential risk related to improper and/or incomplete reprocessing of Olympus duodenoscopes includes exposure to a contaminated device which may result in patient infection. The severity of infection would depend on overall patient health and/or risk factors (e.g. immunocompromised patients) which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

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.

## 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.\*<sup>1</sup>
- For detailed inspection, 1000 - 2000 lux illumination is recommended.\*<sup>1</sup>

\*<sup>1</sup> 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 conducted 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 [Home page - Olympus Continuum Professional Education](#)
  - 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:
    - i. Introduction to Duodenoscope Reprocessing updated training module
    - ii. Updated Operation Manual (Operation IFU)
    - iii. Reprocessing Manual (Reprocessing IFU)
    - iv. Visual Inspection Guide
    - v. 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 and return the ‘Response Form’ to us.
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 our Field Service Engineer (FSE) team.
6. Olympus recommends that you receive on-site TJF duodenoscope reprocessing training at your facility. Please contact FSE team to schedule your on-site training.
7. If you have further distributed this product, identify your customers, and forward them this notification.

Olympus requests that you report any complaints, including infections and adverse events experienced with the use of this product to Olympus.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact us.

Contact for enquiries.

Regulatory Affairs and Quality Assurance Department

Email : [mes-ra.oml@olympus.com](mailto:mes-ra.oml@olympus.com)

Tel : (603) 7650 8990

Fax : (603) 7650 8999

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

*Hideki Nagai*

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Hideki Nagai  
Managing Director  
Olympus (Malaysia) Sdn. Bhd

## Response Form

Please send the complete and signed Response Form to Regulatory Affairs and Quality Assurance Department at:

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs & Quality Assurance  
Fax/Email : (603) 7650 8999 / [mes-ra.oml@olympus.com](mailto:mes-ra.oml@olympus.com)  
From : \_\_\_\_\_ [Facility Name] Contact no.: \_\_\_\_\_  
Date : \_\_\_\_\_  
Ref : 2025-004M

### **URGENT - FIELD SAFETY NOTICE**

#### **Re: Olympus to Provide Online Training Materials on Reprocessing for TJF Duodenoscopes**

I acknowledge receipt of the Field Safety Notice (“FSN”) referenced above. I confirm that I have further communicated to any affected departments.

Check the applicable boxes below:

- I DO NOT have affected product remaining. Product has been condemned or discarded.
- I DO have the affected product, which I will adhere to this FSN letter.

#### **Additional Customer Requests:**

*(Indicate if you have any additional requests to support this action)*

Name: \_\_\_\_\_

Designation: \_\_\_\_\_

.....  
Signature & Company Stamp

.....  
Date






# 2025-004M FSN Customer Letter

Final Audit Report

2025-10-10

Created:	2025-10-10 (Australian Western Standard Time)
By:	Seo Ching Yeoh (seoching.yeoh@olympus.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAakoA258burr2IVu9GRZ1iNcY-Hne2mEdn

## "2025-004M FSN Customer Letter" History

-  Document created by Seo Ching Yeoh (seoching.yeoh@olympus.com)  
2025-10-10 - 1:16:56 PM GMT+8- IP address: 167.103.62.109
-  Document emailed to Hideki Nagai (hideki.nagai@olympus.com) for signature  
2025-10-10 - 1:17:23 PM GMT+8
-  Email viewed by Hideki Nagai (hideki.nagai@olympus.com)  
2025-10-10 - 4:47:25 PM GMT+8- IP address: 104.47.51.126
-  Document e-signed by Hideki Nagai (hideki.nagai@olympus.com)  
Signature Date: 2025-10-10 - 4:52:51 PM GMT+8 - Time Source: server- IP address: 136.226.234.98
-  Agreement completed.  
2025-10-10 - 4:52:51 PM GMT+8