

Date: **November XX, 2023**

Olympus Reference: QIL FY24-EMEA-13-FY24-OMSC-02

## URGENT FIELD SAFETY NOTICE

RE: OLYMPUS TJF-Q190V/Q290V/Q170V DUODENOSCOPE

- **New Reprocessing Manuals**
- **Required Duodenoscope Inspection**

Attention: Endoscopy Department, Infection Control and Reprocessing Units

| Material ID | Model     | Serial Numbers |
|-------------|-----------|----------------|
| N5992960    | TJF-Q190V | All            |
| N5992950    | TJF-Q190V | All            |
| N5425051    | TJF-Q190V | All            |
| N5993260    | TJF-Q290V | All            |
| N5993250    | TJF-Q290V | All            |
| N6000360    | TJF-Q170V | All            |

Dear Health Care Practitioner:

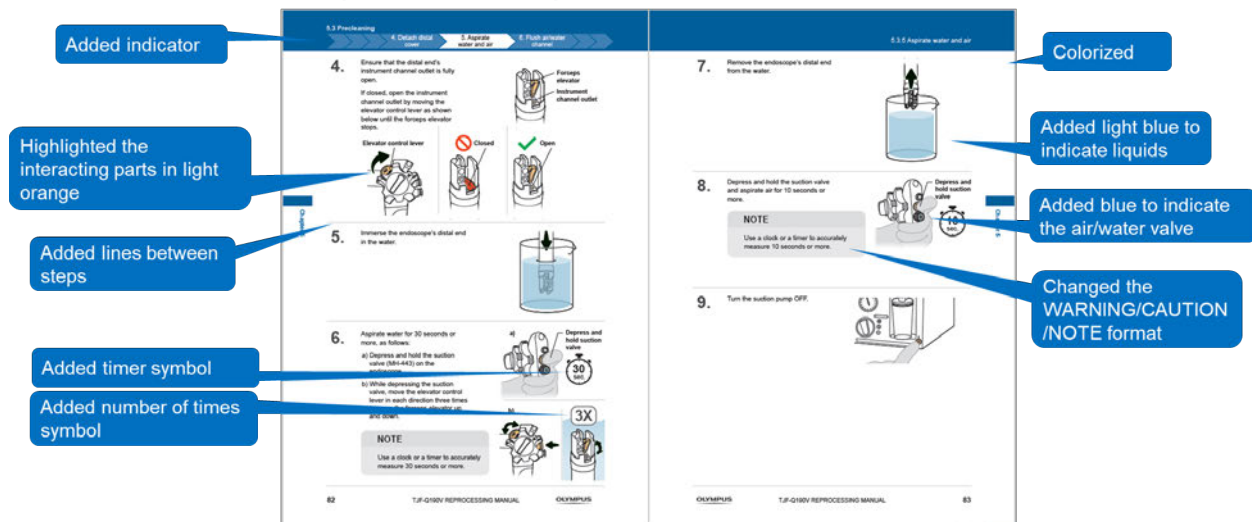
Olympus is writing to inform you of a voluntary corrective action of all TJF-Q190V/Q290V/Q170V duodenoscopes. The duodenoscope is a flexible gastrointestinal endoscope used in procedures such as endoscopic retrograde cholangiopancreatography (ERCP).

Olympus is initiating this action after becoming aware of recent reports of infections and positive cultures. Olympus is reminding users to closely follow reprocessing instructions, including periodic and annual inspections by Olympus Service, as well as regular microbiological checks and informing users about updated manuals intended to improve comprehension of existing reprocessing steps. Olympus is also reminding users that deviating from the reprocessing manual steps or use of a damaged or contaminated endoscope can present an infection risk to patients.

### **Updated Reprocessing Manuals**

Olympus has updated the existing TJF-Q190V/Q290V/Q170V Reprocessing Manuals with **new Reprocessing Manuals, and these models of duodenoscopes shipped from November 2023 include this new Reprocessing Manuals**. The steps included in the new Reprocessing Manuals remain unchanged from the previous Reprocessing Manuals, but the contents have been redesigned to contain easy-to-follow illustrations and the use of color visualizations designed for improved comprehension and provide clearer guidance. Additional enhancements include the use of timelines to help track the user's place along the process, as well as simplified text and other visualization techniques, designed to help improve the customer experience. This updated version of the Reprocessing Manuals was developed in collaboration with independent Human Factors experts.

## Examples of the visual improvements



The new Reprocessing Manuals are available on Olympus webpage [www.olympus-europa.com](http://www.olympus-europa.com) under Medical Systems → Products & Solutions → 🔍 → Instruction Manual and search for relevant model name “TJF-Q190V”, “TJF-Q290V”, “TJF-Q170V”.

If your facility requires a hard copy of the latest version of the TJF-Q190V/Q290V/Q170V Reprocessing Manual, please indicate this in the reply form.

### Required Duodenoscope Inspection

The TJF-Q190V/Q290V/Q170V Operation Manuals require maintenance of the forceps elevator mechanism to be performed by Olympus service personnel once a year. This is not a new requirement and Olympus has been sending reminder letters on this preventative maintenance requirement to customers. The purpose of this inspection is to ensure your medical device is properly functioning, and it involves a critical inspection and maintenance of the distal end of the duodenoscope. We will increase the frequency of these reminder letters in an effort to ensure greater user compliance with this duodenoscope maintenance requirement.

### Microbiologic Surveillance

Additionally, Olympus encourages users to perform routine microbiologic surveillance of endoscopes where applicable locally as part of their quality improvement / quality assurance efforts. Olympus recommends endoscope sampling and culturing methods of the microbiologic surveillance program at your healthcare facility. Olympus requests you to report any patient injuries, including infections or persistent microbial colonization associated with any Olympus endoscope. **[Regions to revise to reflect their complaint intake departments].**

We recommend that the staff utilize the latest resources listed within this letter to familiarize themselves with the instructions for use which include how to properly reprocess the equipment.

Olympus is committed to ensuring access to trusted products, the benefits of partnerships that enhance patient safety, and education that empowers health care professionals to perform at



their very best. Please visit the Olympus IPC Website (<https://infectionprevention.olympus.com>) which provides information in the areas of infection control, reprocessing and microbiology, combining data-driven, practical advice and training with clinical and scientific information and research. If needed, please contact your local Olympus representative.

**Action steps to be taken by the end user:**

Our records indicate your facility has purchased one or more subject duodenoscope(s).

**Olympus requests you take the following action:**

1. Carefully read the content of this Field Safety Notice (FSN).
2. Inspect your inventory of duodenoscopes and identify all TJF-Q190V/Q290V/Q170V duodenoscopes.
3. Ensure all reprocessing personnel are completely knowledgeable and thoroughly trained on the reprocessing instructions in the new Reprocessing Manuals. Meticulous cleaning of the forceps elevator recesses and attention to following all reprocessing instructions are required.
4. Please indicate on the enclosed reply form that you have received this notification and taken the required actions by filling out and returning the completed enclosed Reply Form back to your local Olympus representative latest by **XX.XX.XXXX**.
5. If you have further distributed this product, identify your customers, forward them this Field Safety Notice, and appropriately document your notification process.

Olympus regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. If you have any questions or concerns, please do not hesitate to contact me directly at [phone number] or at [e-mail] **[Regions to revise to reflect their operations]**

Sincerely,  
**[SIGNATORY]**  
**[Contact Name]**



REPLY FORM – QIL FY24-EMEA-13-FY24-OMSC-02 for TJF-Q190V/290V/170V

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|---|
| <b>OLYMPUS URGENT FIELD SAFETY NOTICE</b><br><b>QIL FY24-EMEA-13-FY24-OMSC-02 for TJF-Q190V/290V/170V</b>     |
| <b>[Name &amp; Address of Hospital/Medical Facility]</b>  |
| <b>[Dept/Attn]</b>  |
| <b>[Quantity of TJF-Q190V/290V/170V Reprocessing Manual hard copies or electronic pdf documents required]</b> |
| <b>[Date]</b>   |

I herewith acknowledge the receipt of your Field Safety Notice.  
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity of following the instructions carefully.

Name (Signature) \_\_\_\_\_

Name (Print) \_\_\_\_\_

Position \_\_\_\_\_

Please send your completed paper form response to XXXXX <mailto:>latest by XXXX.