July 27, 2023

URGENT MEDICAL CORRECTIVE ACTION

OLYMPUS TJF-Q190V DUODENOSCOPE
All Serial Numbers
UDI-DI - 04953170405563

ATTENTION: Endoscopy Department, Infection Control and Reprocessing Units

Dear Health Care Professional:

Olympus is writing to inform you of a voluntary corrective action of all TJF-Q190V duodenoscopes ("TJF-Q190V"). The TJF-Q190V 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 and inquiries from the FDA regarding these reports. Olympus is reminding users to closely follow reprocessing instructions, including periodic inspections by Olympus Service, and informing users about an updated manual intended to improve comprehension of existing steps. Olympus is reminding users that using a damaged or contaminated endoscope can present an infection risk to patients.

Updated Reprocessing Manual

Olympus has updated the existing TJF-Q190V Reprocessing Manual with a **new Reprocessing Manual, and TJF duodenoscopes shipped after June 2022 include this new Reprocessing Manual**. The steps included in the new Reprocessing Manual remain unchanged from the previous Reprocessing Manual, 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 Manual was developed in collaboration with independent Human Factors experts.

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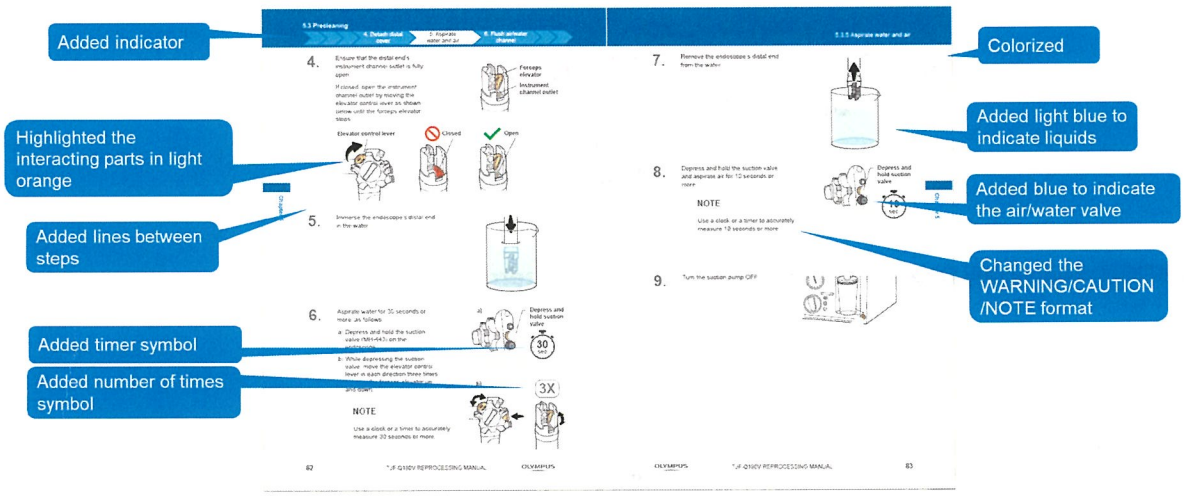
Examples of the visual improvements



The new Reprocessing Manual is available on our customer web portal. Download a copy of the new Reprocessing Manual by visiting our OlympusConnect customer website at https://www.OlympusConnect.com. New users will need to register. Once registered select the Product Support button on the left navigation bar, select the [Reprocessing Manuals] button, locate the TJF-Q190V Manuals and select the [Download] button.

Paper copies of the new Reprocessing Manual and new wall charts are available and can be mailed to your facility. Please request a paper copy of the new Reprocessing Manual and/or wall chart in the comments section of the recall web portal.

Required TJF Inspection

The TJF-Q190V Operation Manual requires maintenance of the forceps elevator mechanism to be performed by Olympus service personnel once a year or after 100 reprocessing cycles, whichever occurs sooner. 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 consider incorporating voluntary routine microbiologic surveillance of endoscopes as part of their quality improvement / quality assurance efforts. For customers who wish to conduct sampling and culturing of their endoscopes, Olympus currently suggests utilizing the FDA/CDC/ASM protocol titled *Duodenoscope Surveillance Sampling & Culturing: Reducing the Risks of Infection.* This comprehensive document is readily accessible to the public on the FDA website, without any associated costs.

It is important to note that, as of the time of this correspondence, there is no national requirement or mandate for the implementation of sampling and culturing procedures for endoscopes, regardless of their

model or type. For further information, we advise consulting the aforementioned FDA/CDC/ASM document and adhering to the best practice guidelines followed by your facility.

Olympus requests you to report any patient injuries, including infections or persistent microbial colonization associated with any Olympus endoscope. Call our Technical Assistance Center (TAC) at 1-800-848-9024, option 1, to report complaints.

Olympus will dispatch a specialist to any healthcare facility reporting an infection complaint or reprocessing problems to train customers on reprocessing instructions and assist in facility adherence to the TJF reprocessing instructions.

Action Steps:
Our records indicate your facility has purchased one or more TJF-Q190V duodenoscope(s). **Olympus requests you take the following action:**

1. Inspect your inventory of duodenoscopes and identify any TJF-Q190V models.
2. Download the new TJF-Q190V Reprocessing Manual. Ensure all reprocessing personnel are completely knowledgeable and thoroughly trained on the reprocessing instructions in the new Reprocessing Manual. Meticulous cleaning of the TJF-Q190V forceps elevator recesses and attention to following all reprocessing instructions is required.
3. Complete the enclosed response form and return it to our recall partner, Sedgwick, via Email olympus7521@sedgwick.com or Fax 888-208-4588. For any questions about the acknowledgment form, please call the Sedgwick team at 866-912-9552.
    - Requests for a paper copy of the new Reprocessing Manual and/or the wall chart can be made on the response form.
4. If you may have further distributed the TJF-Q190V, please identify your customers, notify them at once of this field corrective action, and appropriately document your notification process. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

The U.S. Food and Drug Administration is aware of this action. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact Ashley Mitch directly at (484)-553-1029 or at Ashley.Mitch@Olympus.com for any additional information or support concerning this matter.

Sincerely,

Cynthia Ow

Cynthia Ow
Field Corrective Action Lead, Americas