

URGENT FIELD SAFETY NOTICE**RE: DUODENOSCOPES: LABELLING UPDATE****Attention:** Endoscopy Department, Infection Control and 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 Health Care Professional:

We are writing to inform you about a correction to the reprocessing manual for the [TJF-Q190V/Q290V/Q170V] duodenoscope ("TJF"). The TJF duodenoscope is a flexible gastrointestinal endoscope used in procedures such as endoscopic retrograde cholangio-pancreatography (ERCP). This update is part of Olympus' ongoing commitment to patient safety and product quality.

Reason for Action:

Olympus is conducting this correction following recent post-market surveillance data suggesting a possible association of higher microbial contamination levels from TJF duodenoscopes when manual cleaning was delayed beyond one hour and a presoak was performed, compared to those TJF duodenoscopes where manual cleaning began within one hour after patient procedure. The current TJF reprocessing manual Section 5.9 "Presoak the endoscope" includes validated instructions to perform an extended detergent soak of the [TJF-Q190V/290V/170V] in cases where manual cleaning cannot begin within one hour and is delayed up to 24 hours after patient procedure. However, as a result of this post-market surveillance data and as a precautionary measure, Olympus no longer includes an option for delaying manual cleaning beyond one hour after patient procedure. The reprocessing manual for the [TJF-Q190V/290V/170V] is being updated to remove the "presoak the endoscope" step and will include instructions that require manual cleaning to begin within one hour after patient procedure for the TJF duodenoscope. Olympus' review of complaint data identified four reports of potential delayed cleaning. None of these complaints reviewed included a report of infection or serious injury.


Risk To Health:

If the manual cleaning process is delayed for more than one hour, there is a remote risk of infection due to potential dried debris that may not be removed, which could lead to a contaminated device. Infections can potentially have both immediate and long-range health consequences for all patients. Risk factors such as a compromised immune system or other underlying medical conditions (diabetes, cancer, undergoing/past

chemotherapy, patients on corticosteroid therapy, organ transplants, etc.) can further increase susceptibility to infection or infectious manifestations. This issue does not affect the functionality of these devices.


Summary of the reprocessing manual updates:

- 1) The warning “Perform manual cleaning within ONE hour” will be **added** to Section 5.5 “Manually clean the endoscope and accessories”, as shown below.

**WARNING**

Perform manual cleaning within ONE hour.

- Failure to do so may result in reduced effectiveness of endoscope reprocessing due to dried debris not being removed.
- Consult with your healthcare facility’s infection control committee if endoscope could not be reprocessed within one hour of patient procedure.



- 2) Section 5.9 “Presoak the endoscope” will be **removed** from the reprocessing manual.

The updated reprocessing instructions will require manual cleaning to begin within one hour after completing a patient procedure for the TJF duodenoscope. If manual cleaning of a [TJF-Q190V/290V/170V] is not initiated within one hour after a patient procedure, we recommend consulting with your internal Infection Prevention and Control committee. Your facilities should have protocols in place to address such situations or consider developing them if needed.

With this letter, Olympus reminds you to follow reprocessing instructions in the current reprocessing manual, in combination with the updated instructions provided in this letter. Olympus also reminds you to schedule periodic inspections with Olympus Service.

Actions Required:

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

1. Carefully read the content of this notification.
2. Ensure all reprocessing and endoscopy unit personnel are completely knowledgeable and thoroughly trained on the updated reprocessing instructions contained in this letter when using the TJF duodenoscope.
3. 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.
4. **If you** have further distributed the affected product, please identify your customers, and forward them this notification.

Your National Competent Authority is aware of the actions described in this letter.

Olympus requests that you report any complaints, to [local facility complaint reporting contact]. 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,

[SIGNATORY]

[Contact Name]



REPLY FORM

Olympus reference: QIL FY26-EMEA-01-FY25-073-Delayed Cleaning Elimination

Facility name	
Facility Address	
Contact Name	
Contact E-mail Address	
Contact Telephone Number	

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**.