XXXXX, 2019
Olympus reference: QIL 152-001

URGENT FIELD SAFETY NOTICE – Follow up

NEW OPERATING AND REPROCESSING INSTRUCTIONS FOR THE OLYMPUS TJF-160VR DUODENOVIDEOSCOPE

Attention: Operating Room Manager, Risk Management Department and Reprocessing Units

	Model Name	**Serial number**
OLYMPUS Duodenovideoscope	TJF-160VR	all

Dear Health Care Practitioner,

Olympus has become aware of a matter that requires your attention. This follow-up Field Safety Notice is distributed to include and summarize all the changes that were made to the updated operation and reprocessing manuals. This Field Safety Notice pertains to the above-referenced Olympus endoscope model and our records indicate that your facility has purchased one or more of this model. This endoscope is intended for use in endoscopic diagnosis and treatment within the duodenum.

Olympus has received complaints about fraying elevator wires of the TJF-160VR, but these complaints have not resulted in any known adverse events. However, Olympus is aware of adverse events on the JF-260V / TJF-260V duodenovideoscopes which have a similar structure to the TJF-160VR duodenovideoscope. To date, with respect to the JF-260V / TJF-260V models, a total of 11 adverse events occurred worldwide. 10 out of them resulting in injury inside a patient's body and one adverse event where the finger of a hospital staff member was injured by a frayed elevator wire.
From the severity level of harm and the occurrence rate, the risk level to be evaluated is within acceptable. In an effort to maximize patient safety and mitigate any potential risk to patient health, Olympus is notifying users of these complaints and the need for careful inspection prior to use in accordance with in the updated operation/reprocessing manuals. Olympus has added pictures and additional instructions in the enclosed Instructions for Safe Use to assist in performing this inspection.

Please note the key differences in the updated operation/reprocessing manuals:
Operation Manual:
In Chapter 3 "*Preparation and Inspection*" the following was updated:

- On page 17 (English version) the below caution was added

CAUTION

The elevator wire at the distal end is any damage (broken, frayed, or bent), not only the equipment does not function properly but also the broken elevator wire may compromise patient, operator, or other medical personnel safety.

- In section "*Inspection of the forceps elevator mechanism*" the part "*Inspection for smooth operation*" was updated as follows:

1. While observing the forceps elevator at the distal end of the endoscope, slowly move the elevator control lever all the way in the "◀U" direction. Confirm that the lever can be operated smoothly and that the forceps elevator is raised smoothly. Hold the elevator control lever and confirm that the forceps elevator remains stationary while pushed from behind. Visually confirm that the portion of the elevator wire extending from the distal end of the endoscope is not broken, frayed, or bent (see Figure 3.5). If any damage (broken, frayed, or bent portion) is observed on the elevator wire as shown in Figure 3.5, do not use the endoscope.

2. While observing the forceps elevator at the distal end of the endoscope, slowly move the elevator control lever all the way in the opposite direction of the "◀U" direction. Confirm that the lever can be operated smoothly and that the forceps elevator is lowered smoothly. Visually confirm that the portion of the elevator wire extending from the distal end of the endoscope is not broken, frayed, or bent (see Figure 3.5). If any damage (broken, frayed, or bent portion) is observed on the elevator wire as shown in Figure 3.5, do not use the endoscope.

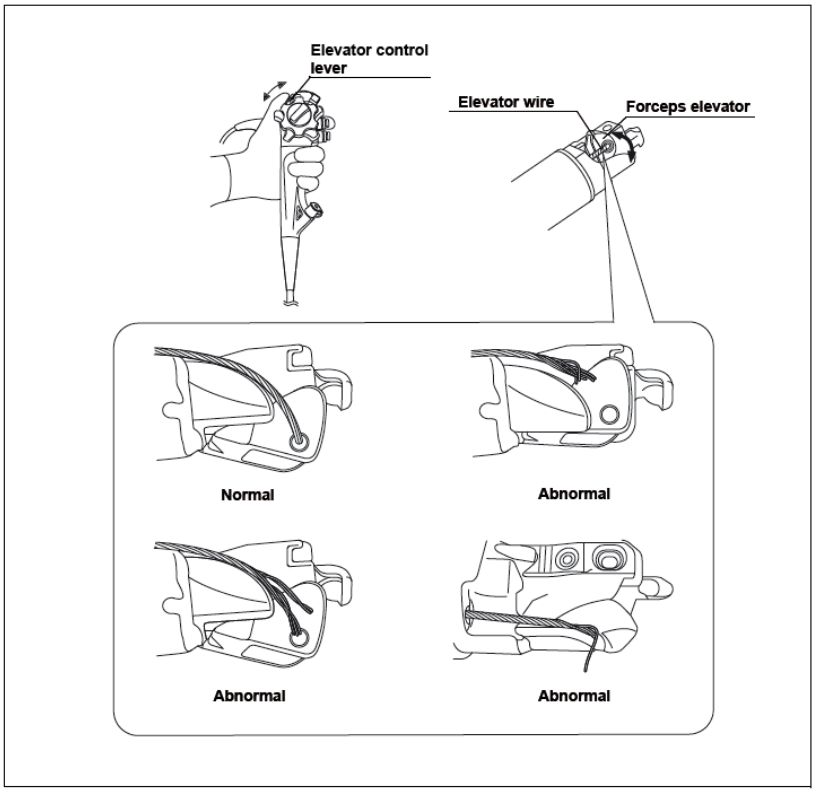

Figure 3.5

- In the section "*3.4 Attaching accessories to the endoscope*", part "*Attaching the distal cover*" the following caution was added:

CAUTION

- When attaching the distal cover, gently hold the bending section as close to the distal end as possible. Forcefully grasping other parts of the bending section can damage the mechanism of the bending section or deform its covering.
- When attaching the distal cover, make sure to confirm that the portion of the elevator wire at the distal end is not broken, frayed, or bent. Otherwise, the broken elevator wire may cause injury. Also, if the broken elevator wire is deformed, it may compromise patient, operator, or other medical personnel safety.

Reprocessing Manual:

- In Chapter 1 "*General Policy*", section "*1.6 Precautions when the elevator wire is damaged (broken, frayed, or bent)*" the following was added:

If the elevator wire is damaged (broken, frayed, or bent), pay attention to the following contents, carefully perform the cleaning and disinfection or sterilization and return it to Olympus for repair.

WARNING

The elevator wire at the distal end is damaged (broken, frayed, or bent), the damaged elevator wire may cause injury or pose an infection control risk when detaching of the distal cover or cleaning the endoscope. In this case, carefully detach the distal cover and perform cleaning.

Advice on actions to be taken by the user:

Olympus requires you to take the following immediate actions:

a) Inspect your inventory of operation and reprocessing manuals for the referenced Olympus model and discard the existing ones.
b) Implement the updated operation and reprocessing instructions in your facility and conduct the described inspection prior to every use. Olympus has added pictures and additional instructions on the enclosed Instructions for Safe Use to assist in performing this inspection. Please keep this Instruction for safe use together with the updated operation and reprocessing manuals.
c) Ensure you train your personnel on the updated operation and reprocessing instructions.
d) Complete the attached Field Safety Notice Reply Form, identifying the number of replacement Instructions for use manuals required and informed all relevant departments about the updated operation and reprocessing procedures. **Please do complete the attached Reply Form even if you have already returned the initial Reply Form to your local Olympus representative.**
e) Send the completed reply form back to your Olympus representative (xxx)
f) On receipt of your complete Field Safety Notice Reply Form, Olympus will arrange to send you the required amount of replacement manuals specified in your completed form.
g) If you have further distributed this product, identify your customers, forward them this FSN including the attachments, and appropriately document your notification process.

Your National Competent Authority has been informed of this Field Safety Notice.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you require additional information or on-site support, please do not hesitate to contact Olympus directly at (XXX) XXX-XXXX from Monday till Friday or by e-mail at XXX.

Sincerely,

REPLY FORM – QIL 152-001

OLYMPUS URGENT FIELD SAFETY NOTICE NEW OPERATING AND REPROCESSING INSTRUCTIONS FOR THE OLYMPUS TJF-160VR DUODENOVIDEOSCOPE	
[Name & Address of Hospital/Medical Facility]	
[Dept/Attn]	
[**Date]**	
OLYMPUS Endoscopes affected Models (Should you require additional copies of these replacement manuals, please indicate in the table above the total quantity required for each model.)	
	TJF-160VR

I herewith acknowledge the receipt of your Field Safety Notice as well as one hard copy version of operation, reprocessing manual and Instruction for Safe Use for each affected model of scope we have at our facility.
Further I confirm that I have discarded any existing inventory of operation and reprocessing manuals for the above referenced Olympus endoscope, trained the responsible personnel and transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity of inspection of the duodenovideoscopes prior to every use.

Name (Signature) _____

Name (Print) _____

Position _____

Please fax this completed reply form to Olympus at [contact number] latest by XXXX