

URGENT FIELD SAFETY NOTICE

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 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.

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.
- c) Ensure you train your personnel on the updated operation and reprocessing instructions.

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- 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.
- 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