

URGENT FIELD SAFETY NOTICE

NEW INSTRUCTIONS FOR SAFE USE FOR SEVERAL OLYMPUS DUODENOVideoscopes & DUODENOFIBERScopes

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

	Model Name	Serial numbers affected
OLYMPUS EVIS EXERA DUODENOVideoscope	TJF-160R	All
OLYMPUS EVIS DUODENOVideoscope	TJF-140R, JF-140R, TJF-240, JF-240	All
OLYMPUS OES DUODENOFIBERScope	JF-1T40	All
OLYMPUS DUODENOFIBERScope	JF-TE3	All

Dear Health Care Practitioner:

Olympus has become aware of an issue that requires your attention. This Field Safety Notice relates to the above-referenced OLYMPUS Duodenovideoscopes and Duodenofiberscopes.

Our records indicate that your facility has purchased one or more of these models. These endoscopes are intended for use in endoscopy and endoscopic surgery within the duodenum.

Olympus has received complaints about fraying elevator wires of Olympus Duodenovideoscope JF-260V, TJF-260V and TJF-160VR. Additionally, Olympus is aware of adverse event complaints on the JF-260V and TJF-260V Duodenovideoscopes. To date, with respect to the JF-260V / TJF-260V models, a total of 12 adverse events have occurred worldwide. Of these 12, 6 resulted in an injury inside a patient's body and 6 adverse event where the finger of a hospital staff member was injured by a frayed elevator wire. The risk level has been evaluated as within acceptable based upon the severity level of harm and the occurrence rate. Olympus has already issued a Field Safety Notice on the JF-260V and TJF-260V in March 2019 (Olympus reference QIL 151-011) as well as on the TJF-160VR in May 2019 (Olympus reference QIL 152-001) in order to enhance the inspection for the frayed wire prior to use.

The products listed in the table above have a detachable distal end cover and an opened forceps elevator wire at the distal end design similar to JF-260V, the TJF-260V and the TJF-160VR. No complaints and reportable events have been reported on the injury related to the frayed forceps elevator wire associated with the devices affected by this FSCA since 2004. Although the subjected products have already been discontinued, there is a possibility that injury may occur by frayed elevator wire in the future when using the affected models.



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 the Instructions for Safe Use. 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 models and attach the provided **Instructions for Safe Use** to your existing inventory.
- b) Implement the Instructions for Safe Use in your facility and conduct the described forceps elevator wire 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 Instructions for Safe Use.
- d) Complete the attached Field Safety Notice Reply Form and inform all relevant departments about the Instructions for Safe Use procedures.
- e) Send the completed reply form back to your Olympus representative (xxx) latest by XXXX.
- g) If you have further distributed this product, identify your customers, forward them this FSN including the Instructions for Safe Use, 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 such as other compatible endoscope accessories 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 152-006

OLYMPUS URGENT FIELD SAFETY NOTICE NEW INSTRUCTIONS FOR SAFE USE FOR SEVERAL OLYMPUS DUODENOVideosCOPE & DUODENOFIBERSCOPIES					
[Name & Address of Hospital/Medical Facility]					
[Dept/Attn]					
[Date]					
OLYMPUS Endoscopes affected Models (Should you require additional copies of these Instructions for Safe Use, please indicate in the table below the total quantity required for each model.)					
	JF-160R		TJF-140R		JF-140R
	TJF-240		JF-240		JF-1T40
	JF-TE3				

I herewith acknowledge the receipt of your Field Safety Notice as well the Instruction for Safe Use for each affected model of scope we have at our facility.

Further I confirm that I have transferred the content of the attached FSN and the Instructions for Safe Use to all affected departments on which this action has an impact. I understand the necessity of inspection of the Duodenovideoscopes and the Duodenofiberscopes prior and after every use.

Name (Signature) _____

Name (Print) _____

Position _____

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