Date: November XX, 2019
Olympus reference: QIL 152-006

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 theTJF-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 & DUODENOFIBERSCOPES
[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

OLYMPUS®

CE 0197

Instructions for safe use

Name	Model
EVIS EXERA DUODENOVIDEOSCOPE	TJF-160R
EVIS DUODENOVIDEOSCOPE	TJF-140R, JF-140R, TJF-240, JF-240
OES DUODENOFIBERSCOPE	JF-1T40
DUODENOFIBERSCOPE	JF-TE3

The section below provides instructions and additional inspection points that need to be followed in connection with the forceps elevator wire of the endoscope described in “Inspection of the endoscope” of Chapter 3, “Preparation and inspection” in the Operation Manual.
Other parts of the instructions in Chapter 3, “Preparation and Inspection” are not changed. Refer to the Operation Manual of each specific endoscope including the case when any irregularity is suspected. Before using the endoscopes, read this instructions and the Operation Manual and the Reprocessing Manual carefully and follow the instructions. If an abnormality is detected before or during usage, or the equipment is malfunctioning, do not use the equipment and contact Olympus to request a repair.
No new repair parts and no repairs or service are available for some of the affected endoscope models listed above. Contact Olympus to discuss the options for an endoscope upgrade.

Cautions

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.

CAUTION

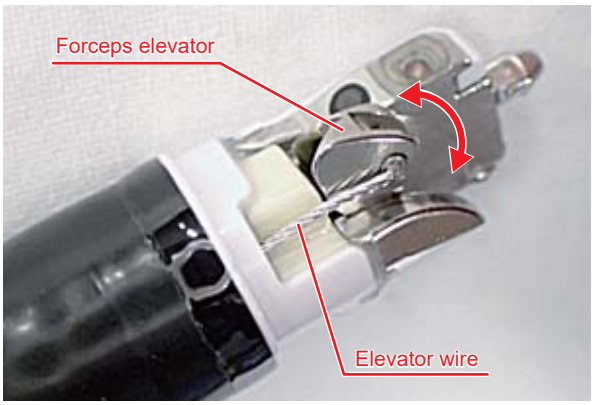
- If the elevator wire at the distal end is either damage broken, frayed or bent, the equipment may not function properly but and may also compromise patient operator or other medical personnel safety resulting in more severe equipment damage.
- When attaching the distal cover, make sure to confirm that 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.
- Using a stiff brush or excessive force when brushing may scratch the distal end and result in water leakage; cause the elevator wire to come off the distal end, bend or kink the elevator wire so that the forceps elevator will no longer work.

Inspection of the elevator wire at the distal end

The qualified user should inspect the elevator wire at the distal end according to the following procedure.

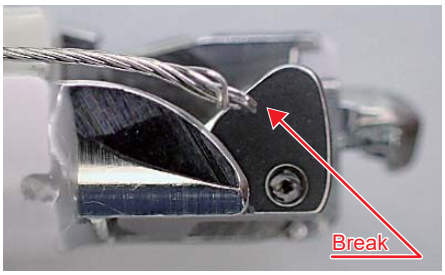
Visually confirm that the elevator wire at the distal end is not broken, frayed or bent, when moving the elevator control lever to make the forceps elevator “raise ↔ lower”.

■ “raise ↔ lower”



OK

Not OK



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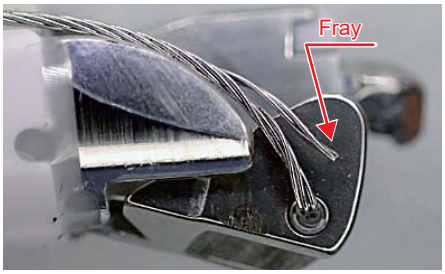

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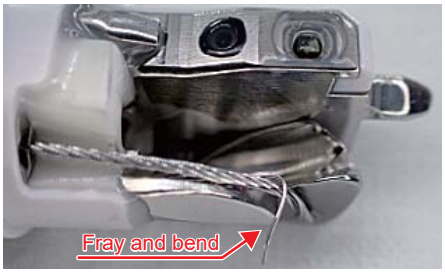

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Printed in Japan 2019XXXX *0000