



Reference: 2019-002M

18-Apr-2019

FIELD SAFETY NOTICE

REVISED OPERATION MANUAL FOR VARIOUS OLYMPUS ENDOSCOPE MODELS

Dear Sir/Madam,

OLYMPUS is implementing a Field Safety Corrective Action for the devices listed below. The endoscopes are intended for use in endoscopy and endoscopic surgery within the duodenum.

Model Name	Model Number
Evis Lucera Duodenovideoscope	JF-260V
Evis Lucera Duodenovideoscope	TJF-260V
Evis Exera Duodenovideoscope	TJF-160VR
Affected Serial Number(s)	
All serial range	

Olympus has received customer complaints on the JF-260V and TJF-260V endoscopes about fraying elevator wires. To date, a total of 11 cases have occurred in the world, resulting in injury inside of the patient's body, and one case where the finger of a hospital staff member was injured by a frayed elevator wire with respect to the JF-260V / TJF-260V models.

In addition, Olympus received complaints about fraying elevator wires of the TJF-160VR, but these complaints have not resulted in any known adverse events.

In an effort to mitigate potential risk to patient and staff health, Olympus is undertaking this action to notify users about these complaints and the need for careful inspection of the endoscope prior to use in accordance with the instructions provided below.

OLYMPUS SINGAPORE PTE LTD

Business Regn No. 198900566E

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www.olympus.com.sg

Action(s) to be taken by end user

Our records indicate that you have purchased the affected product(s) and we requests you to take the following action(s):

1. Please inspect the affected products prior to patient use as per the enclosed Instructions for Safe Use. The Operation Manual contains the same inspection instructions in Chapter 3.2, Inspection of the Endoscope. There are added pictures and additional instructions on the enclosed Instructions for Safe Use to assist in performing this inspection.
2. Indicate on the enclosed Response Form that you have received this notification.
3. Email the completed Response Form to the Regulatory Affairs Department at mes-ra.osp@olympus-ap.com, or you may return the completed form to your local Olympus representative.

OLYMPUS regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. If you have any questions or concerns, please do not hesitate to contact us for additional information.

Contact information

Olympus Singapore Pte. Ltd.

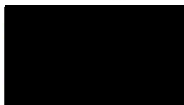
Regulatory Affairs Department

Email : mes-ra.osp@olympus-ap.com

Tel : (+65) 6833 4214

Fax : (+65) 6834 2438

Sincerely,



Loh E Thei

Division Manager

Medical Systems Business Division

Olympus Singapore Pte. Ltd.

Cc: Chairman Medical Board and relevant Head of Departments

Instructions for safe use

This instruction includes special care points for safe usage excerpted from the Instruction Manual of Olympus TJF TYPE 160VR duodenovideoscope. They points are particularly important and should be noted when using Olympus TJF TYPE 160VR duodenovideoscope. Before using the scopes, read the "Instruction 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 repair.

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

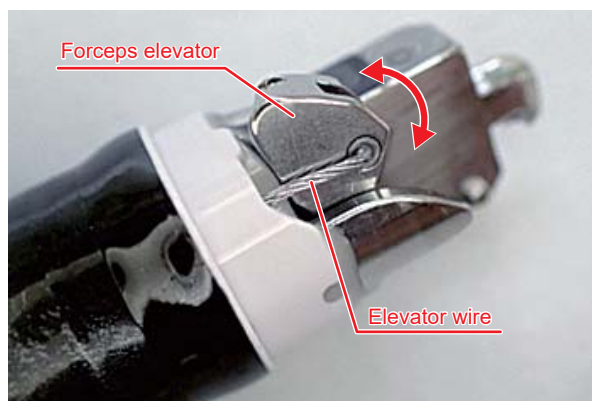
- If the elevator wire at the distal end is either damage broken, frayed or bent, the equipment may not function properly but and may also compromise patient operator or other medical personnel safety resulting in more severe equipment damage.
- When attaching the distal cover, make sure to confirm that 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.

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”.

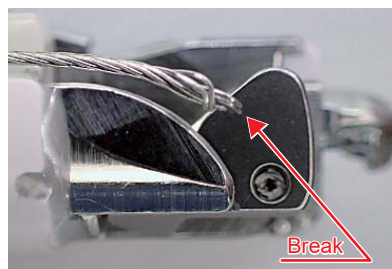
■ “raise ⇔ lower”



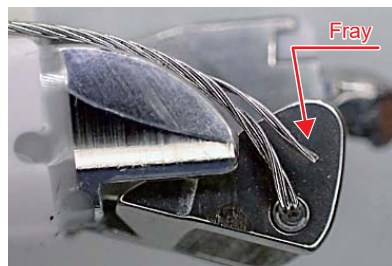
OK



Not OK



Not OK



Not OK



If any irregularity is observed during the inspection described in Chapter 3 of the Instruction Manual, “Preparation and Inspection”, do not use the endoscope and solve the problem as described in Section 5.1, “Troubleshooting guide”. If the problem still cannot be resolved, send the endoscope to Olympus for repair as described in Section 5.3, “Returning the endoscope for repair”. Also, should any abnormality be observed while using the endoscope, stop using it immediately and withdraw the endoscope from the patient as described Section 5.2, “Withdrawal of the endoscope with an abnormality”.

Manufactured by

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Instructions for safe use

This instruction includes special care points for safe usage excerpted from the Instruction Manual of Olympus JF TYPE 260V / TJF TYPE 260V duodenovideoscope. They points are particularly important and should be noted when using Olympus JF TYPE 260V / TJF TYPE 260V duodenovideoscope. Before using the scopes, read the "Instruction 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 repair.

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CAUTION

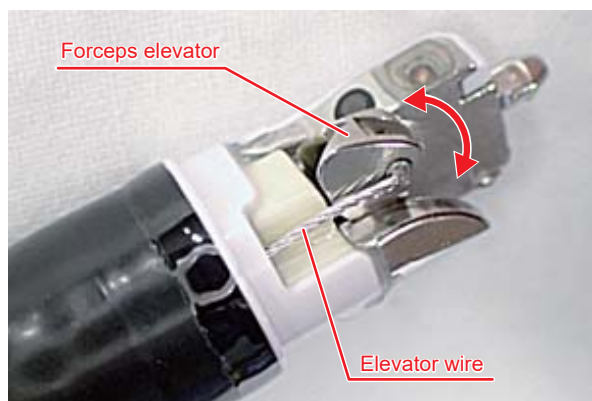
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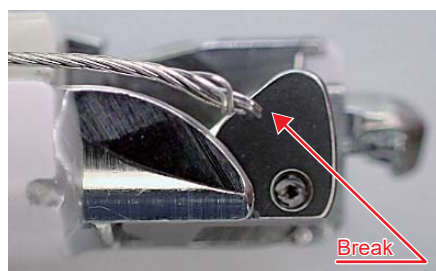
■ “raise ↔ lower”



OK



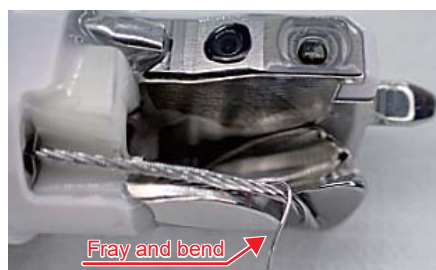
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