

## 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.

# OLYMPUS

---

- 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

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

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

## Instructions for safe use

This instruction includes special care points for safe usage excerpted from the Instruction Manual of Olympus TJF TYPE 160VR duodenovideoscope. These 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**

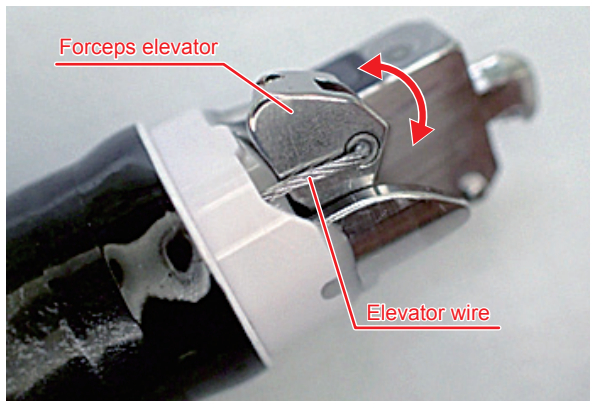
- If the elevator wire at the distal end is either damaged, broken, frayed or bent, the equipment may not function properly and may also compromise patient operator or other medical personnel safety resulting in more severe equipment damage.
- When attaching the distal cover, make sure to confirm that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

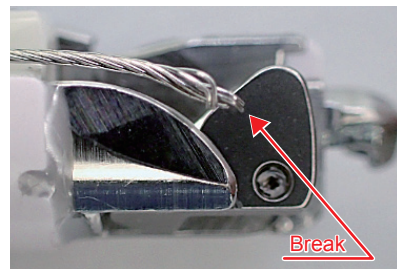
■ “raise ⇔ lower”



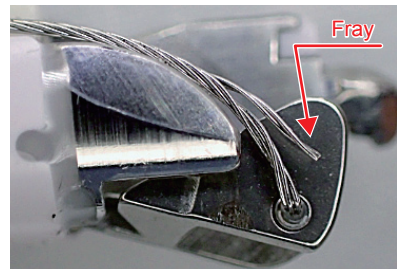
OK



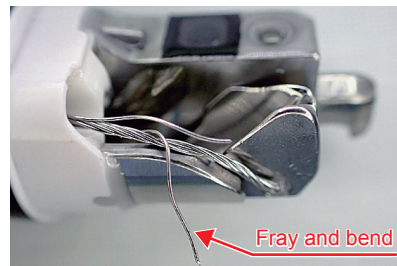
Not OK



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 in 5.2, “Withdrawal of the endoscope with an abnormality”.

Manufactured by  
MANUFACTURER

**OLYMPUS MEDICAL SYSTEMS CORP.**

2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan Fax: (042)646-2429 Telephone: (042)642-2111

Distributed by

AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

**OLYMPUS EUROPA SE & CO. KG**

(Premises/Goods delivery) Wendenstrasse 14-18, 20097 Hamburg, Germany  
(Letters) Postfach 10 49 08, 20034 Hamburg, Germany  
Fax: (040)23773-4656 Telephone: (040)23773-0

**KEYMED (MEDICAL & INDUSTRIAL EQUIPMENT) LTD.**

KeyMed House, Stock Road, Southend-on-Sea, Essex SS2 5QH, United Kingdom  
Fax: (01702)465677 Telephone: (01702)616333

**OLYMPUS MOSCOW LIMITED LIABILITY COMPANY**

Elektrozavodskaya str. 27 bld.8, 107023 Moscow, Russia  
Fax: (7)495-926-7072 Telephone: (7)495-926-7077

**OLYMPUS AMERICA INC.**

3500 Corporate Parkway, P.O. Box 610, Center Valley, PA 18034-0610, U.S.A.  
Fax: (484)896-7128 Telephone: (484)896-5000

**OLYMPUS LATIN AMERICA, INC.**

5301 Blue Lagoon Drive, Suite 290 Miami, FL 33126-2097, U.S.A.  
Fax: (305)261-4421 Telephone: (305)266-2332

**OLYMPUS (BEIJING) SALES & SERVICE CO., LTD.**

A8F, Ping An International Financial Center, No. 1-3, Xinyuan South Road,  
Chaoyang District, Beijing, 100027 P.R.C.  
Fax: (86)10-5976-1299 Telephone: (86)10-5819-9000

**OLYMPUS AUSTRALIA PTY LTD**

3 Acacia Place, Notting Hill, VIC 3168, Australia  
Fax: (03)9543-1350 Telephone: (03)9265-5400

**OLYMPUS SINGAPORE PTE LTD**

438B Alexandra Road #03-07/12, Alexandra Technopark Blk B, Singapore 119968  
Fax: 6834-2438 Telephone: 6834-0010

**OLYMPUS KOREA CO., LTD.**

2F-3F Majestar City Tower One, 12, Seocho-daero 38-gil, Seocho-gu, Seoul,  
06655, Korea  
Fax: (02)6255-3210 Telephone: 1544-3202