Date: November 18, 2021
Olympus reference: QIL 154-015

URGENT FIELD SAFETY NOTICE

RE: INSPECTION CHECKLIST FOR EVIS EXERA II DUODENOVIDEOSCOPE OLYMPUS TJF-Q180V

Attention: Endoscopy Department, Risk Management and Reprocessing Units

	Model Name	Affected Serial Numbers
EVIS EXERA II DUODENOVIDEOSCOPE OLYMPUS TJF-Q180V	**TJF-Q180V**	**All**

Dear Healthcare Professional,

Olympus is writing to inform you of supplemental material for inspection of the Olympus Duodenoscope model TJF-Q180V ("TJF-Q180V"). The TJF-Q180V has been designed to be used with an Olympus video system and other ancillary equipment for endoscopy and endoscopic surgery within the duodenum.

Olympus introduced an annual TJF-Q180V inspection program whereby users are asked to return the TJF-Q180Vs in their possession for inspection. Olympus has reviewed the data obtained via this program and has observed deterioration of the TJF-Q180V's distal end adhesive. The probability of damage to or deterioration of the TJF-Q180V increases with the number of procedures performed and/or the increase in the total operating hours and/or reprocessing chemical damage. Continued use of a TJF-Q180V with adhesive deterioration or other damages may pose a risk of endoscope contamination due to ineffective reprocessing or fluid invasion. A contaminated endoscope can present an infection risk to patients.

The instructions for use (IFU) that accompany each TJF-Q180V Duodenoscope distributed by Olympus instruct the persons in charge of medical equipment maintenance in each hospital to inspect the device periodically in addition to the inspection required before each patient procedure. In an effort to aid and assist our customers in conducting TJF-Q180V inspections, Olympus has developed an illustrated checklist (enclosed) to supplement the Operation and Reprocessing Manuals. The checklist contains reference photos showing TJF-Q180V deteriorations and damages to aid users in identifying when an endoscope requires repair prior to clinical use.

Olympus requests you to report any patient injuries, including infections or persistent microbial colonization associated with any Olympus endoscope. Please contact your local Olympus representative to report complaints.

Please note that this corrective action does not apply to the TJF-Q190V/Q290V/Q170V duodenoscope models. The TJF-Q190V/Q290V/Q170V models have a different distal end structure and use a removable distal end cover.

Actions to be taken by the end user:

Our records indicate that your facility has purchased one or more of the affected TJF-Q180V duodenoscopes. Therefore, **Olympus requires you to take the following actions:**

1. Inspect your inventory for the referenced devices and identify any device with the model number specified above. Please check all areas of the hospital to determine if any of these devices remain in inventory.
2. Carefully read the content of this Field Safety Notice as well as the attached Checklist. This Checklist should be used, in combination with the TJF-Q180V Operation and Reprocessing Manuals when conducting inspections of the TJF-Q180V. Ensure all personnel are completely made aware and knowledgeable on the new Checklist.
   For your reference, the sections of the TJF-Q180V Operation and Reprocessing Manuals which contain the inspection checks are detailed below.
   3.2 Inspection of the endoscope: Operation manual (RC2609)
   3.6 Inspection of endoscopic system: Operation manual (RC2609)
   5.3 Leakage testing of the endoscope: Reprocessing manual (RC2603)
3. Send the completed Reply Form back to your Olympus representative ([xxx]) latest by [XXXX] regardless of whether you have any affected inventory at your facility.
4. If you have further distributed the products listed, identify your customers, forward them this Field Safety Notice, appropriately document your notification process and let us know the end-customer feedbacks accordingly.

Your National Competent Authority has been informed of this Field Safety Notice.

Olympus regrets any inconveniences caused by this Field Safety Notice and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at [phone number] or at [e-mail address] for any additional information concerning this Checklist.

Sincerely,

REPLY FORM – QIL 154-015

OLYMPUS URGENT FIELD SAFETY NOTICE INSPECTION CHECKLIST FOR EVIS EXERA II DUODENOVIDEOSCOPE OLYMPUS TJF-Q180V	
[Name & Address of Hospital/Medical Facility]	
[Dept/Attn]	
[**Date]**	
Model name	**Quantity of TJF-Q180V IFU hard copies required**
TJF-Q180V	

Dear Sirs or Madams,

I herewith confirm the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity to follow the TJF-Q180V Inspection Checklist carefully.

Name (Signature) _____

Name (Print) _____

Position _____

Please scan / email your completed paper form response to XXXX latest by XXXX.