Reference: 2021-003M

29th December 2021

URGENT - FIELD SAFETY NOTICE

To all users of Olympus Evis Exera II Duodenovideoscope TJF-Q180V

Re: Supplemental Material for Inspection of Olympus Evis Exera II Duodenovideoscope

Dear Customer,

Olympus is implementing a Field Corrective Action for the device listed below. The affected model and serial numbers are listed below.

Model Number	Model Description	Serial Number
TJF-Q180V	Evis Exera II Duodenovideoscope	All

Olympus Medical Systems Corporation ("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 reach out to any of our 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.

Action(s) to be taken by end user:

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

1. Please inspect your inventory of TJF-Q180V devices to identify any of the affected devices as reference above.
2. Please read through carefully the enclosed information including the checklist and share this notice to any healthcare professional from your organization as appropriate. The Checklist is used to supplement the TJF-Q180V Operation and Reprocessing Manuals when conducting inspections of the TJF-Q180V.
3. Complete and return the 'Response Form' to Olympus.

Olympus regrets any inconvenience caused 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 for enquiries
Regulatory Affairs Department
Email : mes-ra.oml@olympus.com
Tel : (603) 7886 9188
Fax : (603) 7887 2833

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

……
Yuji Sakaguchi
Managing Director
Olympus (Malaysia) Sdn. Bhd.

Response Form

Please send the complete and signed Response Form to Regulatory Affairs Department at:

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs
Fax/Email : (603) 7887 2833 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.:_____
Date : _____
Ref : 2021-003M

URGENT - FIELD SAFETY NOTICE

Re: Supplemental Material for Inspection of Olympus Evis Exera II Duodenovideoscope

I acknowledge receipt of the Field Safety Notice ("FSN") referenced above. I understand that I need to undertake the action(s) listed in the FSN.

Check the applicable boxes below:

☐ I DO NOT have affected devices remaining. All have been used or discarded.

☐ I DO have the affected devices, which I will adhere to the FSN.

Serial Number			

Name: _____

Designation: _____

....
Signature & Company Stamp Date