

URGENT FIELD SAFETY NOTICE

RE: Single Use Distal Cover MAJ-2315

Used with: EVIS EXERA III Duodenovideoscope TJF-Q190V, EVIS LUCERA Elite

Attention: Endoscopy Department, Risk Management Department

| Material ID | Material Description | Lot Number | UDI |
|-------------|----------------------------------|------------|----------------|
| N6192000 | MAJ-2315 Single Use Distal Cover | All | 04953170441271 |

Dear Health Care Provider:

Olympus has become aware of an issue that requires your attention. This letter pertains to all lot numbers of the Single Use Distal Cover, model MAJ-2315.

The Single Use Distal Cover has been designed to be attached to Olympus duodenovideoscopes to cover the distal end of the insertion tube and around the forceps elevator. The duodenovideoscopes TJF-Q190V/TJF-Q290V /TJF-Q170V are intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories and other ancillary equipment for endoscopy and endoscopic surgery.

Reason for this letter:

Olympus has become aware that the Single Use Distal Cover MAJ-2315 may unexpectedly detach from the duodenoscope during use. Olympus received 79 complaints of the MAJ-2315 distal cover falling off within or outside patients. This included 30 events considered to be Serious Injury, which involved foreign body retrieval and/or additional treatment. Consequences of a detached cover could include the risk of mucosal injury, tissue damage, bleeding, perforation, or obstruction due to retained distal cover in the gastrointestinal tract that would require urgent medical intervention for removal, and/or burns from the use an uncovered duodenoscope distal end. Detachment of a distal cover in the oral cavity may result in aspiration, airway obstruction, or respiratory distress and would require immediate medical intervention for removal. Appropriate medical intervention/management should be based on the clinical circumstance.

Olympus is reinforcing the instructions for MAJ-2315 distal cover attachment and user verification of distal cover attachment. This Field Safety Notice instructs you on the correct method for MAJ-2315 distal cover attachment. You will be contacted by an Olympus representative to schedule on-site, in-service training at your user facility on MAJ-2315 distal cover attachment and verification of cover attachment to the duodenoscope's distal end.

As required in the Instruction for Use, it is important to ensure that the distal cover is attached correctly, and checked carefully, before conducting a procedure. As a reminder, we are including with this letter the below illustrations on how to correctly attach the MAJ-2315 distal cover and confirm distal cover attachment.

Additionally, as a reminder, do not apply anti-fogging products, such as olive oil or products containing petroleum based substances to the MAJ-2315 distal cover or the endoscope. These products may

cause cracks in the MAJ-2315 distal cover, which could contribute to distal cover detachment, thermal injury from electric current leaks when performing high-frequency cauterization treatment, or mucosal injury from the sharp edges due to cracks on the distal cover.

Gently hold the distal part of the bending section of the endoscope and the distal cover. Align the opening side of the distal cover with the lens side of the distal end of the endoscope.

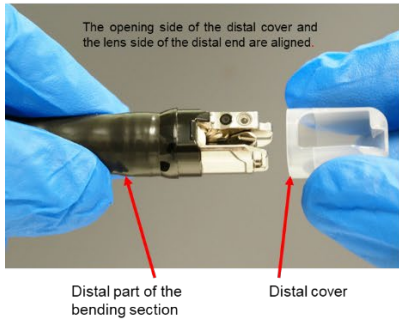


Figure 1: Alignment of distal cover and endoscope tip

Attach the distal cover by placing your finger onto the top center of the distal cover and pushing straight onto the distal end of the endoscope until the distal cover is over the hook of the distal ring. The distal cover is attached correctly when the distal cover completely covers the distal ring, and the hook is completely visible.

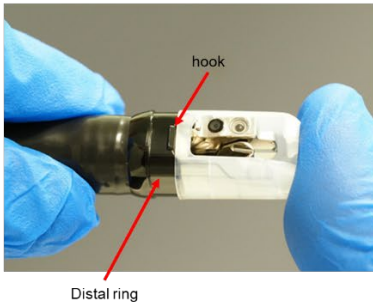


Figure 2: Attachment of distal cover to endoscope tip

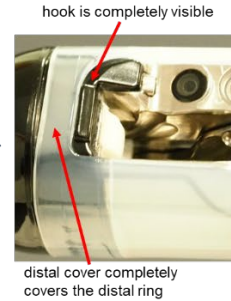


Figure 3: Verification of complete attachment

Hold the distal part of the bending section. Pull the distal cover gently to confirm that the distal cover does not slip and come off the end of the endoscope.

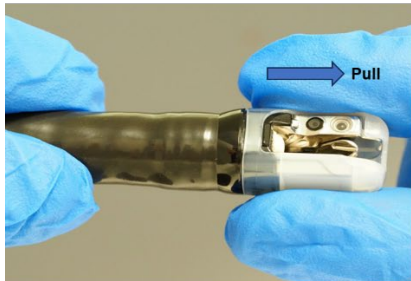


Figure 4: Confirmation of secure attachment - Pull

Confirm the distal cover completely covers the distal ring, and the hook is completely visible.



Twist the distal cover gently in both directions and confirm that the distal cover on the distal end of the endoscope does not slip and come off.

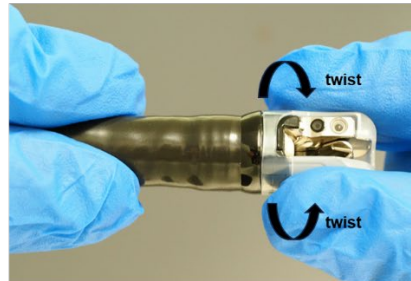


Figure 5: Confirmation of secure attachment - Twist

Confirm the distal cover is attached correctly:

- The distal cover completely covers the distal ring
- The hook is completely visible
- the distal cover is free of cracks or deformation



Figure 6: Confirmation of correct attachment



Information on MAJ-2315 distal cover attachment is also available in Quick Reference Guide under: https://www.olympus-europa.com/medical/en/Contact-and-Support/search_page.html?search_type=ifu&search_query=MAJ-2315

Action steps to be taken by the end user:

Our records indicate that you have purchased the MAJ-2315 Distal Covers. Olympus requires you to take the following action:

1. Carefully read the content of this Field Safety Notice.
2. Please ensure that all Olympus TJF duodenoscope users at your facility are knowledgeable on MAJ-2315 distal cover attachment and attachment verification to ensure the safe use of these devices.
3. Please ensure that the reference guide is distributed to all parties at your facility who will be involved in the process of attaching the MAJ-2315 distal cover.
4. Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative latest by **XX.XX.XXXX**.
5. Olympus representatives will be contacting you to schedule an upcoming on-site, in-service training at your user facility on MAJ-2315 distal cover attachment and attachment verification to ensure the safe use of these devices.
6. If you have distributed these devices outside your facility, please notify your customers of this matter immediately by forwarding them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.

Olympus requests that you report complaints, including mucosal injuries, distal cover detachment and/or cracks, and adverse events, to Olympus. Please report complaints to **[local facility complaint reporting contact]**. **[If applicable:]** Adverse events experienced with the use of this product may also be reported **[local competent authority]** by **[method]**.

Olympus regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact me directly at **[phone]** or at **[email]** for any additional information or support concerning this matter.

Sincerely,

Name

Title, Department/Region



REPLY FORM – QIL FY24-EMEA-28-FY24-OMSC-34-MAJ-2315

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|--|
| OLYMPUS URGENT FIELD SAFETY NOTICE Single Use Distal Cover MAJ-2315 |
| [Name & Address of Hospital/Medical Facility] |
| [Dept/Attn] |
| [Date] |

I herewith acknowledge 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 of following the instructions carefully.

Name (Signature) _____

Name (Print) _____

Position _____

Please send your completed paper form response to XXXXX <mailto:latest> by XXXX.