

URGENT FIELD SAFETY NOTICE

Recall of Single Use Distal Cover MAJ-2315

Used with: EVIS EXERA III Duodenovideoscope TJF-Q190V, EVIS LUCERA Elite Duodenovideoscope TJF-Q290V, Duodenovideoscope TJF-Q170V

Attention: Endoscopy Department, Risk Management

Material ID	Material Description	UDI	Lot Number
N5786100	MAJ-2315 Single Use Distal Cover	04953170403019	Lower than H2530

Dear Health Care Provider:

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



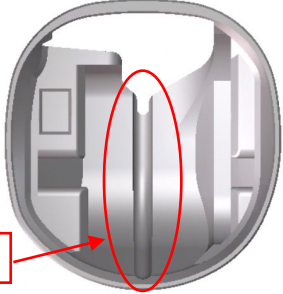

The Single Use Distal Cover has been designed to be attached to Olympus duodenovideoscopes to cover the distal end of the insertion tube and around the forceps elevator. The duodenovideoscopes TJF-Q190V/TJF-Q290V /TJF-Q170V are intended to be used with an Olympus video system center, light source, documentation 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 cause mucosal injury, become cracked and/or detach from the endoscope during use. Consequences of a detached or cracked cover could include the risk of aspiration, inhalation, tissue damage or bleeding, or obstruction that will require urgent removal, and/or burns from an uncovered distal end. Medical management should be appropriate for the clinical circumstance.

Olympus redesigned the distal cover and has observed a decrease in the referenced complaints. Olympus is initiating a medical device recall for distal covers with the original design (see the following table for a comparison). The recall does not impact the new distal cover design.

As required in the Instruction for Use, it is important to ensure that the newly designed distal cover is attached correctly, and checked carefully, before conducting a procedure. As a reminder, we are including with this letter, below, the section from the MAJ-2315 "Instruction for Use" regarding proper attachment.

	Original Design	New Design
Lot number	Lower than H2530	H2530 or higher
Overview		
Tear off line design change (Back view)		

Instructions for Use:

Correct application and inspection of the distal cover before the procedure is critical. In addition, inspection of the distal end after the procedure is also important.

As a reminder, the MAJ-2315 Instructions for Use contains the following instructions (page 5 and 6):

WARNING

Should any irregularity be observed when inspecting the distal cover, do not use it. A distal cover with irregularity could not serve the endoscope properly and/or could fall off during the examination. Using the endoscope without the distal cover could cause patient injury and this could result in thermal injury when the endoscope is used with high-frequency EndoTherapy accessories. In addition, if the distal cover falls off in the oral cavity, it may cause aspiration or respiratory distress if not promptly identified and removed.

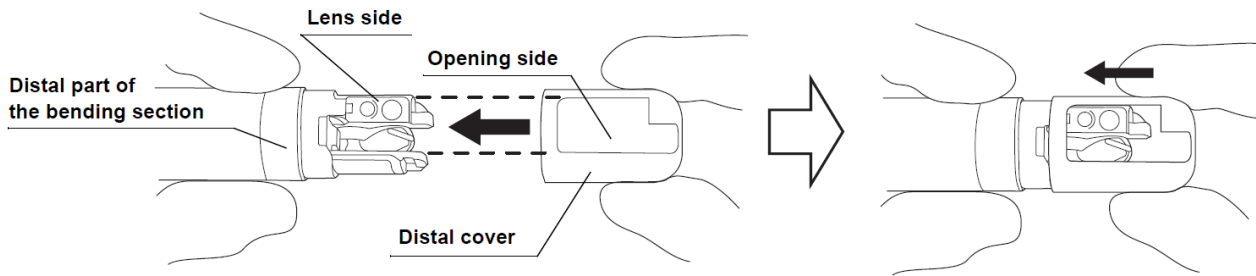
- Never use the endoscope unless the distal cover is properly attached to the distal end. If the distal cover is not attached properly, it may slip off or fall off the distal end during the examination. This could result in thermal injury when the endoscope is used with high-frequency EndoTherapy accessories. Also, continuing the examination with the distal cover off may cause patient injury by the uncovered distal end of the endoscope. In addition, if the distal cover falls off in the oral cavity, it may cause aspiration or respiratory distress if not promptly identified and removed.

CAUTION

Do not apply anti-fogging products, olive oil, or products containing petroleum-based substances (e.g., Vaseline®) to the distal cover or the endoscope. These products may cause cracks in the distal cover. If a distal cover with cracks is used, it may cause patient injury such as:

- Thermal injury from electric current leaks when performing high-frequency cauterization treatment.
- Damage or cuts to the mucosal membrane from sharp edges due to the cracks on the distal cover.

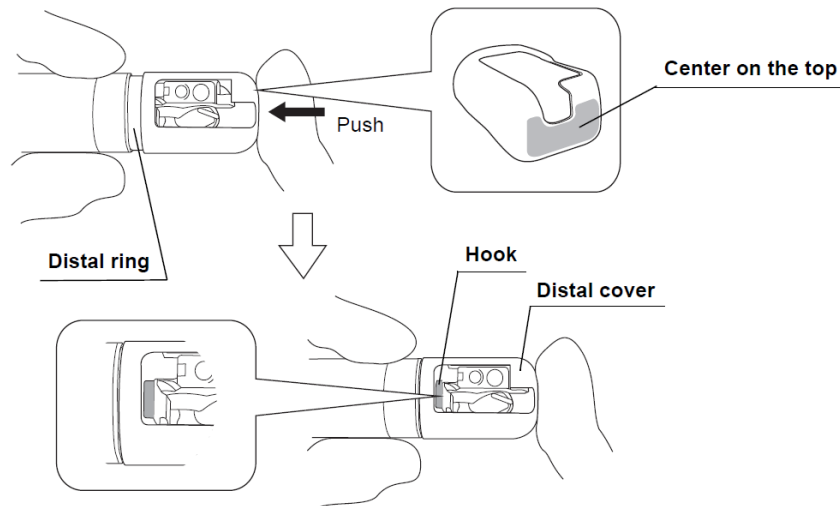
- 3 Gently hold the distal part of the bending section and the distal cover. Align the opening side of the distal cover with the lens side of the distal end of the endoscope.



CAUTION

When attaching the distal cover, gently hold the bending section as close to the distal end as possible. Forcefully grasping other parts of the bending section can damage the mechanism of the bending section or deform its covering. It may also become impossible to straighten the bending section during an examination.

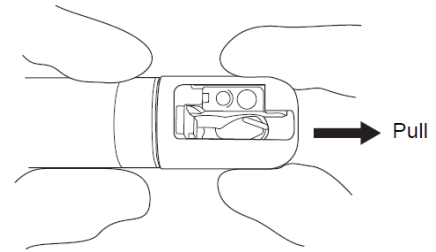
- 4 Put your finger onto the center on the top of the distal cover and push the top of the distal cover straight onto the distal end of the endoscope until the hook of the distal ring is completely visible within the opening of the distal cover.



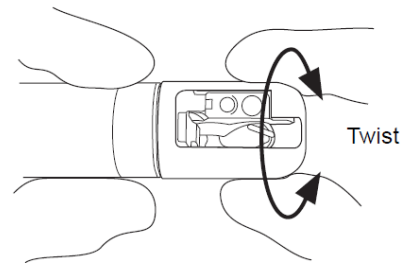
WARNING

Detach the distal cover from the distal end of the endoscope when the distal cover cannot be attached to the endoscope smoothly or any incorrect attaching procedure is noticed. Refer to Section 9.5, "Detach the distal cover" for detaching the distal cover. With a new distal cover, repeat Step 1 through 4. If the distal cover is not attached properly, it may slip off or fall off the distal end during the examination. This could result in thermal injury when the endoscope is used with high-frequency EndoTherapy accessories. Also, continuing the examination with the distal cover off may cause patient injury by the uncovered distal end of the endoscope. In addition, if the distal cover falls off in the oral cavity, it may cause aspiration or respiratory distress if not promptly identified and removed.

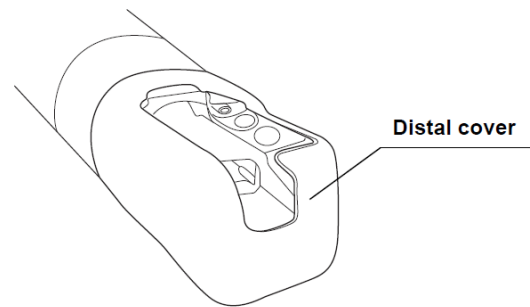
- 5** Hold the distal part of the bending section.
Pull the distal cover gently to confirm that the distal cover on the distal end of the endoscope does not slip and come off.



- 6** 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.



- 7** Confirm that the distal cover is free of cracks or deformation.



- 8** Confirm that there is no adhesion of foreign materials between the distal end of the endoscope and the distal cover.

NOTE

If finding irregularities on the distal cover or incorrect attaching the distal cover in the Steps from 3 through 8, detach the distal cover from the distal end of the endoscope and replace it with a new one. Refer to Section 9.5, "Detach the distal cover" for detaching the distal cover. With a new distal cover, repeat Step 1 through 8.

Olympus representatives are available to provide additional support and training. Please contact your local Olympus facility to further discuss.

Action steps to be taken by the end user:

Our records indicate that you have purchased or may use the MAJ-2315 Distal Covers with the original design. Olympus requires you to take the following action:

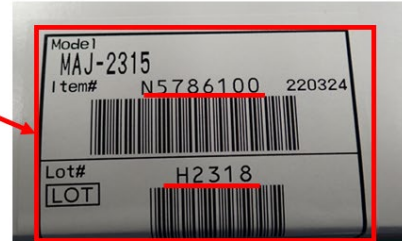
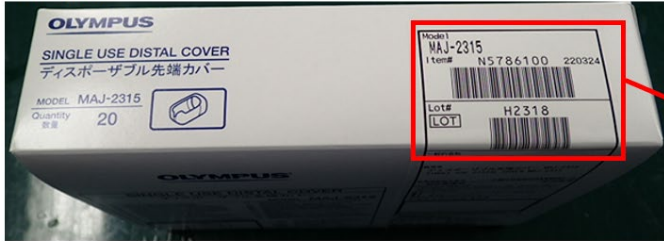
1. Carefully read the content of this Field Safety Notice.
2. Immediately locate and no longer use the MAJ-2315 with the original design. The original design can be identified by the item code (below) or by lot numbers less than H2530. The image below depicts the area where the lot number is identified. The lot number is on the Carton box and Pack.

Model: MAJ-2315

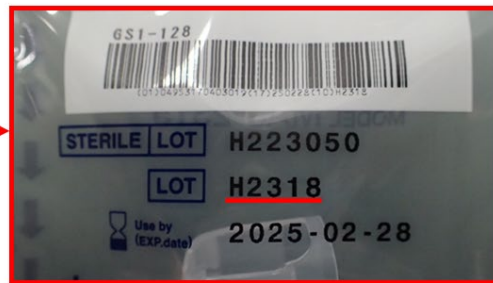
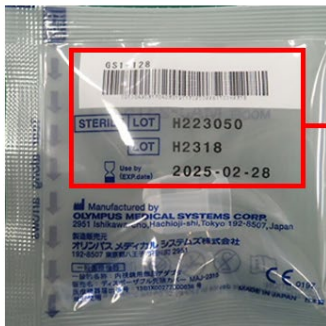
Item code: N5786100

Lot number: Lower than H2530

Carton box



Pack



3. Contact your Olympus representative at [XXXXXXXX]. Olympus will issue a Return Material Authorization to return any affected product at no charge to you. Olympus will issue a credit to your facility upon return of affected product.
4. 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.
5. 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 at [XXXXXXXX] latest by [XX.XX.XXXX].

Olympus requests that you report complaints, including mucosal injuries, distal cover detachment 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

