

Date: XX.XX.XXXX

Olympus Reference: FY27-901-F Single Use Distal Cover MAJ-2315 New Design

URGENT FIELD SAFETY NOTICE

RE: Single Use Distal Cover

Attention: Endoscopy Department, Risk Management

Affected Products:

Material	Model	Product Name	Lot Number(s)	UDI-DI
N6192000	MAJ-2315	Single Use Distal Cover	All (unexpired)	04953170441271

Dear Healthcare Professional/Provider:

Olympus is writing to inform you of Medical Device Removal pertaining to the Single Use Distal Cover, model MAJ-2315. The MAJ-2315 is a single use detachable cap designed to cover the exposed mechanical components at the distal end of the following Duodenoscope models TJF-Q190V, TJF-Q290V, and TJF-Q170V.

Reason for Action:

Olympus conducted an investigation into the Single Use Distal Covers after receiving complaints of the distal cover unexpectedly detaching from the duodenoscope during use. In the past 12 months, Olympus has received 96 complaints of the MAJ-2315 distal cover falling off within or outside patients. This included 36 events considered to be Serious Injury, which involved foreign body retrieval and/or additional treatment.

To address this issue, Olympus has developed a newly designed version of the Distal Cover (MAJ-2315), which contains a new attachment tool to help mitigate the risk of incorrect attachment of the distal cover to the scope.

All older versions of this product should be returned to Olympus and the newly designed version shall be used.

Risk to Health:

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.

Images showing the new design vs. the old design:



Fig.1 -Old Design Outer Packaging



Fig.2 and 3 - New Design Outer Packaging



Fig.4 - Old design internal packaging



Fig.5 - New design internal



Fig.6 - Old design Distal Cover

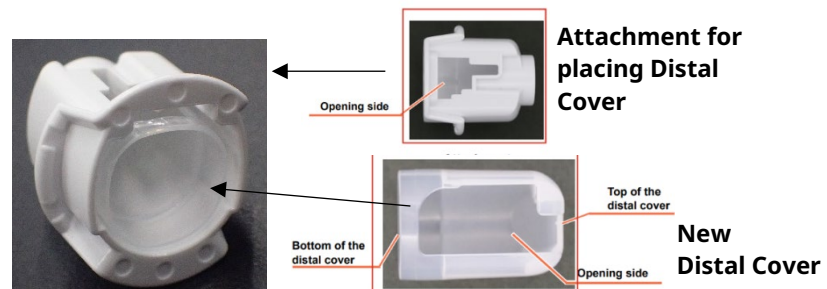
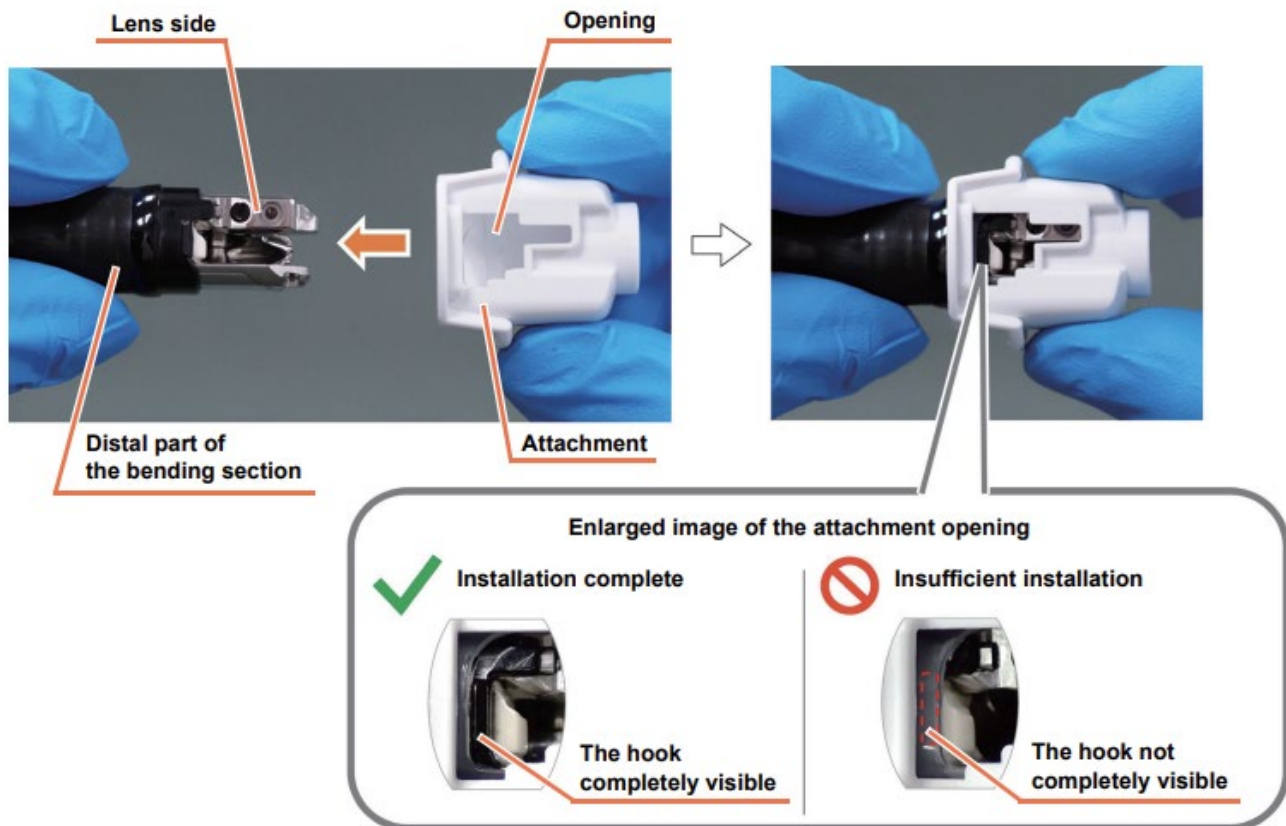


Fig.7 - New design Distal Cover and white attachment used for placing the distal cover on to the scope.

Excerpt from the IFU showing the correct attachment of the new distal cover:

Refer to the IFU for detailed instructions on attaching the distal cover and removing the attachment tool.

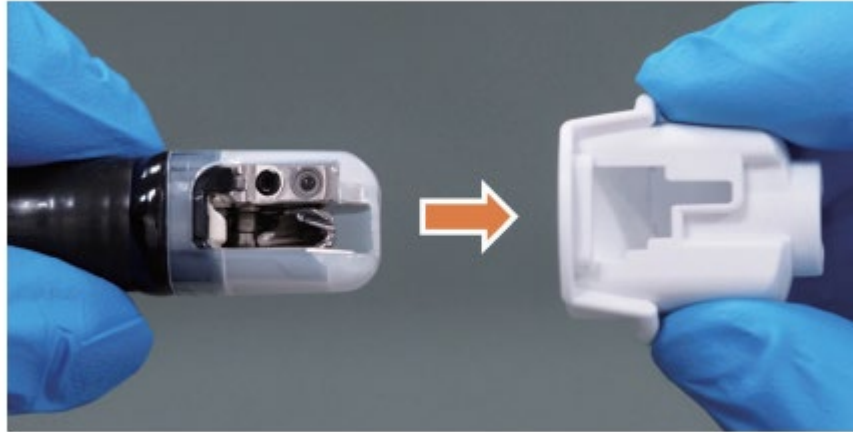
3. Gently hold the distal part of the bending section and the attachment with your other hand. Align the opening of the attachment with the lens side of the distal end of the endoscope and push the attachment through the opening of the attachment until the hook is completely visible



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. Hold and pull the attachment away from the endoscope to remove from the distal end of



the endoscope.

Note: If the attachment is not pressed in enough, the distal cover will not be attached to the distal end of the endoscope and will remain filled inside the attachment. If the distal cover cannot be attached smoothly, replace it with a new one.

Actions Required:

Our records indicate that your facility has received one or more units of the previous design. Olympus requests you to take the following actions:

1. Examine your inventory for the previous design of the Single Use Distal Covers, model MAJ-2315 (see Fig.1-6 above).
2. **All older versions of this product should be returned to Olympus and the newly designed version shall be used.**
3. **Transition to the newly designed version as soon as possible by placing an order through [Local Customer Service Contact].**
4. Once you have received the new design of the MAJ-2315, stop using the old design and set aside for return.
5. If you have affected products in your inventory, please contact Olympus with regard to return of affected products. Olympus will issue a credit to your facility upon return of your affected product.
6. Olympus requests that you acknowledge receipt of this letter [local facility method/contact].
7. Please forward this notice to other users who may have the affected products if you have further distributed it.

[If applicable:] [competent authority] is aware of the actions described in this letter.



Olympus requests that you report any 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 fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact *[me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX]*.

Sincerely,

Name

Olympus title



REPLY FORM – FY27-901-F Single Use Distal Cover MAJ-2315 New Design

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests (Indicate if you have any additional requests to support this action)	

Insert Catalogue Number, Lot Number and Quantity of the affected products remaining in your facility .

Catalogue Number	Lot Number	Quantity

I acknowledge receipt of this notification. I confirm that I have further communicated to any affected departments.

Completed By:		
		Click or tap to enter a date.
<i>Name</i>	<i>Signature</i>	<i>Date (YYYY-MM-DD)</i>

Please send the completed form to XXX by date XXX.