



February XX, 2021

Olympus reference: **QIL 153-016**

URGENT FIELD SAFETY NOTICE

RE: HANDLING AND USE OF DUODENOVideoscopes TJF-Q170V/TJF-Q190V/TJF-Q290V AND SINGLE-USE DISTAL COVER MAJ-2315

Attention: Endoscopy Department, Risk Management Department

	Model Name	Serial number
OLYMPUS DUODENOVideoscope	TJF-Q170V	All
OLYMPUS EVIS EXERA III DUODENOVideoscope	TJF-Q190V	All
EVIS LUCERA ELITE DUODENOVideoscope	TJF-Q290V	All
SINGLE USE DISTAL COVER	MAJ-2315	All

Dear Healthcare Professional:

Olympus Medical Systems Corporation (“Olympus”) has become aware of a matter that requires your attention. This Field Safety Notice pertains to the above-referenced Olympus endoscope models and the single-use distal cover: DUODENOVideoscope TJF-Q170V/TJF-Q190V/TJF-Q290V and DISTAL COVER MAJ-2315.

Olympus has identified an increase in the number of complaints from customers reporting that mucosal tissue was found within the single-use distal cover, MAJ-2315, after withdrawing TJF-Q190V/TJF-Q290V duodenoscopes from patients. In the reported complaints, the user facilities have reported mucosal injuries in the esophagus, stomach and duodenum.

While Olympus is continuing to fully investigate these incidents, the following use conditions and observations have been reported by healthcare professionals:

- One facility reported that injury occurred during withdrawal of the duodenoscope while suctioning, and the facility believes that using suction while withdrawing the scope may have caused or contributed to the injury.
- Another facility reported a crack at the tear off line of the distal cover that may have caused or contributed to the reported esophageal injury.
- One injury was reported during treatment for a patient having stricture in the digestive tract.

Although most of the injuries reported did not necessitate additional treatment, two cases did require medical intervention: Proton Pump Inhibitor (PPI) medication in one case and clipping in the other case.

Olympus is thoroughly investigating the root cause or causes of these reported events. However, in the interest of transparency and in support of your continuing safe use of the newest Olympus duodenoscope models, Olympus is sending this letter to provide the following information that we believe may reduce the potential occurrence of similar incidents.

Instructions for Use and User Considerations

Olympus is asking all customers currently using the devices listed above to carefully consider and follow, where appropriate, the following information and recommendations during procedures. As a reminder, the Instructions for Use for the TJF-Q190V, TJF-Q290V, TJF-Q170V models and the MAJ-2315 contain the following instructions:

TJF-Q170V (RC5083 02) 3.5 Attaching accessories to the endoscope

TJF-Q190V (RC6454 02) 3.5 Attaching accessories to the endoscope

TJF-Q290V (RC5078 03) 3.5 Attaching accessories to the endoscope

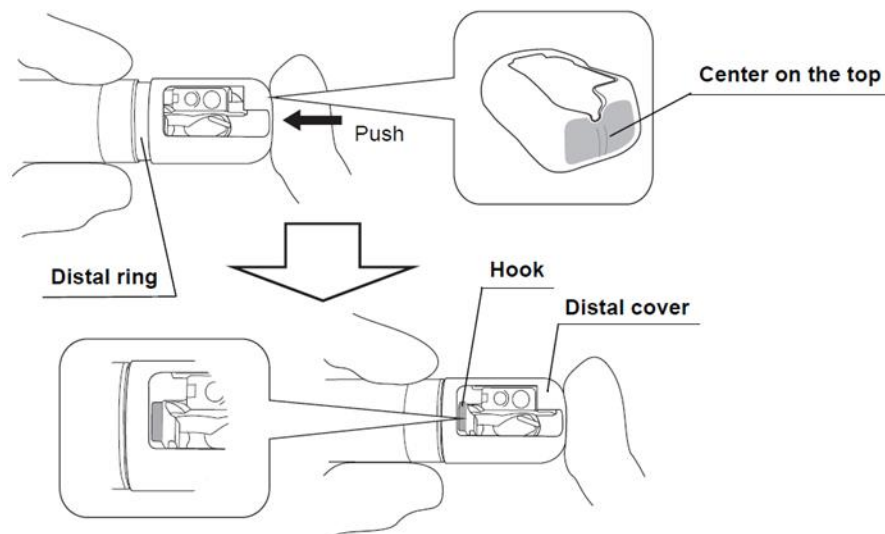
MAJ-2315 (RC4852 06) 7.3 Attaching the distal cover

Quick Reference Guide (RC5911) "How to use the single use distal cover"

CAUTION

Never use a single use distal cover with cracks or pinholes. Replace it with a new one. If a single use distal cover with cracks or pinholes is used, it could fall off during the examination and/or, it may cause thermal injury due to electric current leaks from cracks or pinholes when high-frequency cauterization treatment is performed. Also, using the single use distal cover with cracks may cause patient injury due to sharp edges.

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.



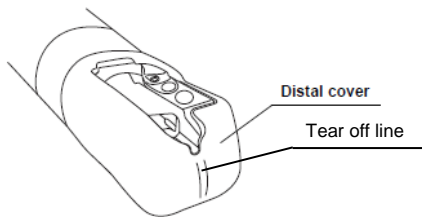
CAUTION

Push the center on the top of the single use distal cover. Otherwise, it may cause the break of the portion on the single use distal cover such as the tear off line.

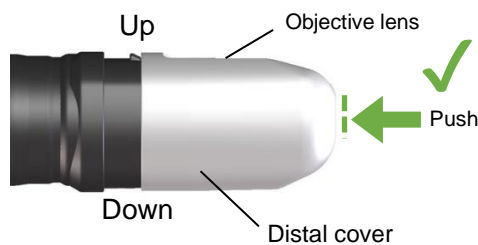
NOTE

If finding irregularities on the single use distal cover or incorrect attaching the single use distal cover in the steps from 3 through 8, detach the single use distal cover from the distal end of the endoscope and replace it with a new one. Refer to “■ Detaching the single use distal cover” on page 50. With a new single use distal cover, repeat Step 1 through 8. (Refer to the instruction manual for the steps.)

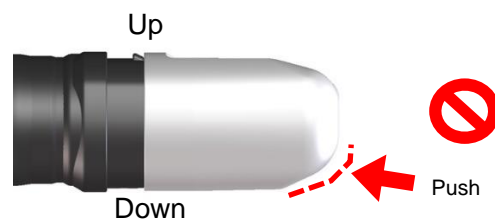
- Attachment and Inspection of Distal Cover: During transport and storage, make sure that the single use distal cover is not compressed or squeezed, as this may result in damage to the distal cover before it is attached to the duodenoscope. Please follow the directions in the Instructions for Use to prevent cracks or deformation of the distal cover when attaching to a duodenoscope, attaching it gently and without excessive force. For example, a distal cover attached by inappropriately placing the fingers around the cover or pushing from an angled direction may cause a crack or deformation in the distal cover (see figure below titled “<Side view of the distal cover>”). After attaching the distal cover, confirm that the tear off line and other parts of the distal cover are free of cracks or deformation. When a damaged distal cover is attached to the duodenoscope and the damage is not detected during final inspection before usage, there is a risk the distal cover may not function correctly.



< Side view of the distal cover >



Correct: Put finger onto the center on the top of the distal cover, and push the top of the distal cover straight



Incorrect: Put finger **around** the center on the top of the distal cover, and/or push the top of the distal cover **at an angle**

- Use of Suction Upon Withdrawal: Olympus has received reports of mucosal tissue being found by users who used the suction function while physically removing the duodenoscope from patients. This phenomenon may be mitigated by suctioning intermittently during withdrawal, using the suction function when the duodenoscope is stationary and stopping the suction function while the duodenoscope is in motion.
- Post-Procedure: Please inspect the distal cover post-procedure. If mucosal tissue is found within the distal cover or trapped in the forceps elevator after withdrawal of the duodenoscope, please consider endoscopic visualization of the upper GI tract to assess for potential injury requiring medical intervention.

With respect to ERCP procedures performed with the TJF-Q170V/TJF-Q190V/TJF-Q290V duodenoscopes on patients having stricture in the digestive tract, please pay particular attention to these Instructions for Use and user considerations.

Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more of the affected TJF-Q170V/TJF-Q190V/TJF-Q290V duodenoscopes. Therefore, Olympus requires you to take the following actions:

1. Carefully read the content of this Field Safety Notice as well as the attached *Quick Reference Guide "How to use the single use distal cover"*. This *Quick Reference Guide* contains the instructions on how to attach the single-use distal cover properly.
2. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this FSN and the referenced Instructions for Use.
Note: The most current language versions of the Instructions for Use and the *Quick Reference Guide* are available on the following Olympus webpage: <http://www.olympus-europa.com>
When opening the webpage select 'Medical Systems', select 'Contact & Support', click on the magnifying symbol (🔍), select 'Instruction Manual' and search for the relevant model (e.g. 'TJF-Q190V').
3. If you have further distributed this product, identify your customers, forward them this Field Safety Notice including the attached *Quick Reference Guide*, appropriately document your notification process and let us know the end-customer feedbacks accordingly.
4. Indicate on the Reply Form that you have received and understood this Field Safety Notice including the attached *Quick Reference Guide* by filling in the completed enclosed Reply Form back latest by XXXX. Kindly also indicate the quantity of required Instructions for Use and/or *Quick Reference Guide* hard copies per Model on the Reply Form.

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

Olympus will continue to monitor and investigate any reported complaints or adverse events relating to this phenomenon. However, until further notice, please pay attention to this new information during procedures performed with these devices.

We fully appreciate your prompt cooperation in addressing this situation and working with us to ensure your patients are treated only with safe and effective Olympus products that you have come to rely upon. If you require additional information or on-site support, please do not hesitate to contact Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX.



Sincerely,

Attachments:

Quick Reference Guide (RC5911) "How to use the single use distal cover"



REPLY FORM – QIL 153-016

OLYMPUS URGENT FIELD SAFETY NOTICE HANDLING AND USE OF DUODENOVideoscopes TJF-Q170V/TJF-Q190V/TJF-Q290V AND SINGLE-USE DISTAL COVER MAJ-2315		
[Name & Address of Hospital/Medical Facility]		
[Dept/Attn]		
[Date]		
Additional Instructions for Use and/or Quick Reference Guide request Should you require hard copies of the mentioned Instructions for Use, please indicate in the table below behind each model the total quantity required. Your local Olympus organization will then arrange to send you the hard copies accordingly.		
Model name	Quantity of Instructions for Use required	Quantity of Quick Reference Guides required
TJF-Q170V		
TJF-Q190V		
TJF-Q290V		

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 TJF-Q170V/TJF-Q190V/TJF-Q290V Instructions for Use carefully.

Name (Signature) _____

Name (Print) _____

Position _____

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

Quick Reference Guide (RC5911) “How to use the single use distal cover”

OLYMPUS

How to use the single use distal cover MAJ-2315 for EVIS EXERA III Duodenovideoscope TJF-Q190V



WARNING This quick reference guide is a summary of the steps necessary to properly use your MAJ-2315. Follow the detailed steps instructed in the latest **OPERATION/PROCESSING MANUAL** for T.J.F-Q190V.
CAUTION Do not apply anti-fogging products, olive oil, or products containing peroxide-based substances (e.g. Xeriflin®) to the distal cover and the endoscope. These products may cause cracks of the distal cover. If a distal cover with cracks is used, it may cause thermal injury due to electric current leaks when high-frequency cauterization treatment is performed.

Attaching the distal cover

1. 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.
2. 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.
3. Hold the distal part of the bending section. Pull the distal cover gently to confirm that it does not slip and come off.
4. 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.
5. Confirm that the distal cover is free of cracks or deformation.
6. Confirm that there is no adhesion of foreign materials between the distal end of the endoscope and the distal cover.
7. Confirm that the single use distal cover is not seen on the endoscopic view.

Detaching the distal cover

1. Hold the gripper of the distal cover and tear the top of the distal cover along the tear off line.
2. Keeping the gripper apart from the distal end, rotate the distal cover in the direction of the arrow as shown above with the gripper to detach the distal cover.
3. If the distal cover cannot be detached, pull the gripper toward the direction of the arrow as shown above and completely tear the distal cover from the distal end.
4. After using the distal cover, dispose of it in an appropriate manner.

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