

## URGENT FIELD SAFETY NOTICE

**RE:** EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1TH190

**Attention:** Endoscopy Department, Risk Management Department

Material ID	Model	Serial Numbers
N4505850	GIF-1TH190	All
N4505840	GIF-1TH190	All

Dear Health Care Provider,

Olympus has become aware of a matter that requires your attention. This Urgent Field Safety Notice pertains to the EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1TH190 (GIF-1TH190).

Our records indicate that your facility has purchased one or more of the GIF-1TH190.

This endoscope is intended for use in endoscopic diagnosis and treatment within the upper digestive tract (including the esophagus, stomach, and duodenum).

The GIF-1TH190 Reprocessing Manual has mandatory instructions for cleaning and disinfection with an optional final Ethylene Oxide Gas (EOG) sterilization.

As a result of testing, Olympus discovered EOG sterilization failures in which the GIF-1TH190 failed to achieve sterilization following the GIF-1TH190's Reprocessing Manual. As a result of the subsequent investigation, Olympus determined that changes are required to the endoscope's channel drying steps prior to EOG sterilization in order to ensure effective endoscope sterilization. Accordingly, Olympus has updated the instructions for the endoscope channel's drying process and validated that the new, updated channel drying steps will result in GIF-1TH190 endoscope EOG sterilization. The revised instructions "Dry the endoscope" in Chapter 5.7 of the GIF-1TH190 Reprocessing Manual are provided in the attached Addendum.

### **Risk to Health, if EOG is performed**

In the current drying procedure for the channels prior to EOG sterilization, the endoscope may not be adequately sterilized.

The risk to patient health is patient infection, in case the channels drying procedure from the Olympus IFU is used prior to EOG sterilization.

### **Action steps to be taken by the end user:**

**Olympus requests you to take the following actions:**

1. Carefully read the content of this Urgent Field Safety Notice (FSN) as well as the attached "Addendum." The Addendum provides the new, revised channel drying steps.
2. Ensure all reprocessing personnel are completely knowledgeable and thoroughly aware of the contents.

3. Inspect your inventory for the referenced device. Please check all areas of the hospital to determine if any of these devices remain in inventory.
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. 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 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 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-20- FY24-OMSC-20-GIF-1TH190

<b>OLYMPUS URGENT FIELD SAFETY NOTICE EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1TH190</b>
<b>[Name &amp; Address of Hospital/Medical Facility]</b>
<b>[Dept/Attn]</b>
<b>[Date]</b>

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.