

URGENT FIELD SAFETY NOTICE

RE: Reprocessing manual update for ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-190-10-3D

Attention: Endoscopy Department, Risk Management

Product name	Model name	Serial number	Material Number
ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE	LTF-190-10-3D	All	N4501730
ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE	LTF-190-10-3D	All	N4501750

Dear Healthcare Practitioner,

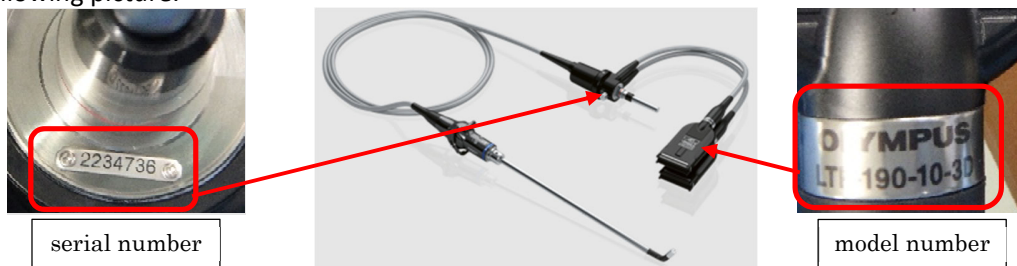
Olympus is writing to inform you of a revised, corrected reprocessing manual for the LTF-190-10-3D DEFLECTABLE VIDEOSCOPE ("LTF-190-10-3D"). The LTF-190-10-3D is used with other supporting equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs.

Olympus identified the wrong glutaraldehyde (GA) concentration in the reprocessing manual. The reprocessing manual incorrectly stated 2-35% GA concentration. The corrected GA concentration is 2-3.5% GA concentration. Olympus is providing in this letter an Addendum which corrects the disinfectant concentration of GA in the reprocessing manuals. Please review the enclosed Addendum for detail.

Action steps to be taken by the end user:


Our records indicate that your facility has purchased one or more of the affected LTF-190-10-3D. Therefore, Olympus requires you to take following actions:

1. Inspect your inventory for the referenced devices and identify any device with the LTF-190-10-3D model name. Please check all areas of the hospital to determine if any of these devices remain in inventory. The model number can be found on the device as illustrated in the following picture.



2. Carefully read this Field Safety Notice as well as the attached "Addendum". Disinfectant concentration of glutaraldehyde (GA) was corrected.
(Correct GA concentration: 2 – 3.5 %, Incorrect GA concentration: 2 – 35 %)



3. Ensure all personnel are completely knowledgeable on this labeling change.
4. If your facility require the latest version of the LTF-190-10-3D reprocessing manual, please indicate this in the reply form.
Alternatively, the new version of the LTF-190-10-3D Reprocessing manual can be found on the Olympus webpage www.olympus-europa.com under Medical Systems → Products & Solutions →  → Instruction Manual and search for “LTF-190-10-3D” model name.
5. Send the completed Reply Form back to your Olympus representative **XXXXX** latest by **XX.XX.XXXX** regardless of whether you have any affected inventory at your facility.
6. If you have further distributed the listed products, identify your customers, forward them this Field Safety Notice, appropriately document your notification process and let us know the end-customer feedbacks accordingly.

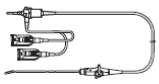

Olympus regrets any inconveniences caused by this Field Safety Notice and fully appreciates your prompt cooperation in addressing this situation. In case of any questions or concerns, please do not hesitate to contact Olympus directly at **[phone number]** or at **[e-mail address]**.

Sincerely,

Addendum to the Reprocessing Manual of the LTF-190-10-3D

Revised "List of compatible methods validated in terms of microbiological efficacy and material durability" in the Section 3.1

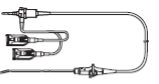

Before revised (RC0881 ver.9 -P.13)

	For sterilization	Ethylene oxide gas sterilization (gas mixture 20% ethylene oxide gas/80% CO ₂)				
		Ethylene oxide gas sterilization (100% ethylene oxide gas)				
	For disinfection	2 – 35% glutaraldehyde				
	For cleaning	Detergent solution				
		Ultrasonic cleaning				
Endoscope						
Sterilization cap (MAJ-1538)						

compatible
 not compatible

Table 3.1

After revised (RC0881 ver.10 -P.13)

	For sterilization	Ethylene oxide gas sterilization (gas mixture 20% ethylene oxide gas/80% CO ₂)				
		Ethylene oxide gas sterilization (100% ethylene oxide gas)				
	For disinfection	2 – 3.5% glutaraldehyde				
	For cleaning	Detergent solution				
		Ultrasonic cleaning				
Endoscope						
Sterilization cap (MAJ-1538)						

compatible
 not compatible

Table 3.1



REPLY FORM – QIL FY23-EMEA-09

URGENT FIELD SAFETY NOTICE Model name: LTF-190-10-3D
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[Inventory information (Serial Number(s) of LTF-190-10-3D)]
[Quantity of LTF-190-10-3D Reprocessing Manual hard copies or electronic pdf documents required]
[Date]

Dear Sirs or Madams,

I herewith confirm 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 to follow the steps.

Name (Signature) _____

Name (Print) _____

Position _____

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