Date: 16.06.2026

Olympus reference: FY26-051-F Missing Sterilization Validation Data and Invalid IFU Sterilization Cycles

URGENT MEDICAL DEVICE CORRECTION

RE: Ellik Evacuator Products
Attention: Operating Room/ Surgery and Risk Management Departments

Catalogue Number	Material Description	Lot Number(s)	UDI
EG194	Ellik Evacuator w/ bulb	BD	00821925002586
EG190A	Replacement glass body for an Ellik Evacuator	AD,CD	00821925003538

Dear Healthcare Professional:

This letter is to inform you that Olympus is initiating a product correction regarding the Ellik evacuator products listed in this letter. These products are distributed non-sterile with cleaning and sterilization instructions provided in the instructions for use (IFU). Some sterilization parameters included in the IFU may not consistently render the devices adequately sterile and therefore should no longer be used to sterilize the devices. Page 4 of this letter includes a sub-set of the sterilization parameters provided in the IFU which have been validated and are to be exclusively used to sterilize these devices going forward.
The Ellik (Figure 1) evacuator is used to irrigate the lower urinary tract and to removeand collect tissue following a transurethral resection procedure. These evacuators devices and their accessories
are intended for use with Gyrus ACMI® resection sheaths.

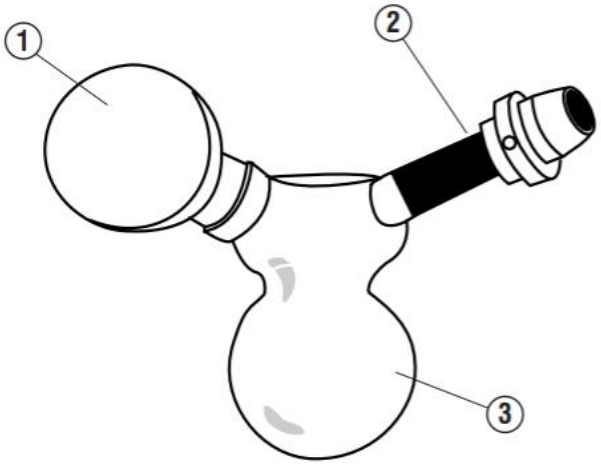

Figure 01: Ellik Evacuator Assembly for Elite Series Resectoscopes, REF 194

Ellik Evacuator, REF 194

The Ellik Evacuator and adapter accessories are compatible with Gyrus ACMI Elite and Elite 2 Resection Sheaths. Assembly of the Ellik Evacuator Components should be performed while immersed in a basin of water.

Figure Identifications (Figure 1)

1. Ellik Latex Bulb, REF 194-2
2. Cone with Male Connector and Tubing, Non-Locking, REF 191-NRS
3. Glass Body for Ellik Evacuator, REF 190A

Figure 1. Schematic of the Ellik Evacuator assembly.

Reason for Action:

This action is being taken because it has been determined that some of the sets of sterilization parameters provided in the IFU may not consistently render the devices adequately sterile.

Risk to Health:

If the affected Ellik evacuator devices are reprocessed using sterilization parameters that have not been validated to consistently achieve sterility, there is a potential risk that viable microorganisms may remain on the device prior to use. Use of a device that has not been adequately sterilized may increase the risk of infection, including localized or systemic infections, in patients undergoing transurethral resection procedures.

The likelihood and severity of infection may vary depending on factors such as the patient's health status, the nature of the procedure, and the level and type of microbial contamination, if present. To date, Olympus has not confirmed reports of serious adverse events directly attributable to this issue. However, continued use of unvalidated sterilization parameters could potentially increase the risk of infection to patients.

Actions Required:

Our records indicate that your facility has received one or more of the affected products. Olympus therefore requests that you take the following actions:

1. Examine your inventory for the model numbers / UDI numbers listed in the table on page 1 of this notice. If you have affected products in your inventory, replace any existing sterilization instructions for these products with those provided. Additionally, Olympus requests that you add these instructions to any existing copies of the IFU.
2. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply that you have received and understood this notification by filling out and returning the completed enclosed Reply Form back to your local Olympus representative at ra@olympus.co.uk latest by 11.07.2026.
3. If you have further distributed this product, identify your customers, and forward this notification to them.

Health Products Regulatory Authority (HPRA) is aware of the actions described in this letter.
Olympus requests that you report any complaints, to concerns@olympus.co.uk. Adverse events experienced with the use of this product may also be reported to the Health Products Regulatory Authority (HPRA) online.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly at jessica.valente@olympus.com or Olympus directly at 01702 616333 from Monday through Friday, or by email at ra@olympus.co.uk.

Sincerely,

Jessica Valente
Field Safety Corrective Actions Specialist

Instructions to Be Used (Exclusively) to Sterilize
Ellik Evacuator Products Going Forward

Sterilization of the Ellik Evacuator Devices (Replacing the table in Section 6 of the IFU)

All components of the Ellik Evacuator can be steam sterilized using the parameters shown in the table below. The Ellik Evacuator must be disassembled prior to sterilization.

Parameter	Option 1	Option 2	Option 3
Type of Cycle	Pre-Vacuum (Wrapped)	Pre-Vacuum (Wrapped)	Pre-Vacuum (Wrapped)
Temperature	132 °C (270 °F)	134 °C (273 °F)	135 °C (275 °F)
Exposure Time	4 minutes	3 minutes	3 minutes
Drying Time	30 minutes	30 minutes	30 minutes*

*Plus an additional 15 minutes of cool-down time on a wire rack outside the chamber.

REPLY FORM: FY26-051-F Missing Sterilization Validation Data and Invalid IFU Sterilization Cycles

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

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

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

Please send the completed form to ra@olympus.co.uk by 11.07.2026.