Date: January XX, 2024
Olympus Reference: QIL FY24-EMEA-27-FY23-OSTA-09-Soltive Fiber Strippers & Cleavers

URGENT FIELD SAFETY NOTICE

RE: recall of Soltive Fiber Strippers and Cleavers
Attention: Urology Department, Gynecology Department, Risk Management

Material ID	Model Number	Description	Lot Number
EGTFL-AFS150	TFL-AFS150	SOLTIVE FIBER STRIPPER 150µm	All
EGTFL-AFS200	TFL-AFS200	SOLTIVE FIBER STRIPPER 200µm	All
EGTFL-AFS365	TFL-AFS365	SOLTIVE FIBER STRIPPER 365µm	All
EGTFL-AFS550	TFL-AFS550	SOLTIVE FIBER STRIPPER 550µm	All
EGTFL-AFS940	TFL-AFS940	SOLTIVE FIBER STRIPPER 940µm	All
EGTFL-AFC	TFL-AFC	SOLTIVE FIBER CLEAVER (5/BX)	All

Dear Healthcare Professional:

Olympus (Gyrus ACMI, Inc.) is writing to inform you about a removal action for the Soltive SuperPulse Laser System accessories, fiber strippers and cleavers.

The SOLTIVE Laser System are intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology, lithotripsy gastroenterological surgery and gynecological surgery. The fiber strippers and cleavers are used to refurbish the single-use tip of Soltive laser fibers in the event of fiber burn-back to optimize the aiming beam and laser output.

Olympus is taking this removal action after a review of reprocessing instructions for the fiber strippers and cleavers. Both the strippers and cleavers are provided non-sterile and labelled as reusable/autoclavable. Olympus does not have validated cleaning and sterilization instructions. Use of a non-sterile fiber stripper or cleaver on a sterile fiber poses a risk of contamination.

Figure 1: Fiber Strippers (Left) and Fiber Cleaver (Right)

Risk To Health

Olympus has not received any reported complaints involving patient injury or infection regarding the use of strippers or cleavers on laser fibers. However, improper reprocessing of the stripper and cleaver may potentially lead to contamination of single-use laser fibers with pathogens, which in turn may cause patient infection.

Action steps to be taken by the end user:

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

1. Carefully read the content of this Field Safety Notice.
2. **Inspect your inventory and identify** any products of the model subject to this action. Please check all areas of the hospital to determine if any of these devices remain in inventory. Quarantine and cease use of the affected model.
3. Contact your Olympus representative at [XXXXXXX] with regard to return and reimbursement procedure. Olympus will issue a credit to your facility upon return of affected product.
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.

The [local regulatory agency] 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 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-27-FY23-OSTA-09-Soltive Fiber Strippers & Cleavers

OLYMPUS URGENT FIELD SAFETY NOTICE
Soltive Fiber Strippers and Cleavers

[Name & Address of Hospital/Medical Facility]

[Inventory information]

Model	Lot Number	Quantity (single pieces)

[Dept/Attn]

[**Date]**

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.