December 4, 2023

URGENT: MEDICAL DEVICE REMOVAL

Name: Soltive SuperPulsed Laser System – Fiber Strippers and Cleavers
Model: Fiber Stripper: TFL-AFS150, TFL-AFS200, TFL-AFS365, TFL-AFS550, TFL-AFS940
Fiber Cleaver: TFL-AFC

Lot Number: All units sold prior to 2023

Attention: Urology Department, Gynecology Department, Risk Management

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)

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TELEPHONE (484) 896-5000

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.

Actions 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. **Examine your inventory and quarantine** any devices with the lot number specified above.

2. Please contact Olympus customer service representative at 1-800-848-9024, option 2, with the quantity and model of affected devices. Olympus will issue a Return Material Authorization to return any affected product at no charge. Olympus will issue a credit to your facility upon return of affected product.

3. **Access the Olympus recall portal to indicate that you have received this notification.**
   a. Go to https://olympusamerica.com/recall.
   b. Enter the recall number **"0435"**
   c. Complete the form as instructed.

4. If you have distributed these devices outside your facility, please provide a copy of this letter to those facilities immediately.

The U.S. Food and Drug Administration is aware of the actions described in this letter.

Olympus requests you to report any complaints, including product labeling issues, to our Technical Assistance Center (TAC) at 1- 800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly by phone at (647) 999-3203 or by e-mail at Cynthia.Ow@olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
FCA Regional Lead, Americas