Date: December XX, 2023
Olympus Reference: QIL FY24-EMEA-32-FY24-OSTA-12

URGENT FIELD SAFETY NOTICE

RE: SOLTIVE Laser System, Single-use Laser Fibers
Attention: Urology Department, Risk Management Department

Material ID	Description	Lot/Serial Numbers	GTIN
EGTFL-FBX150S	SOLTIVE 150µ SU Fiber ,5/Bx	All	00821925043916
EGTFL-FBX200S	SOLTIVE 200µ SU Fiber, 5/Bx	All	00821925043930
EGTFL-FBX365S	SOLTIVE 365µ SU Fiber, 5/Bx	All	00821925043992
EGTFL-FBX550S	SOLTIVE 550µ SU Fiber, 5/Bx	All	00821925044036
EGTFL-FBX940S	SOLTIVE 940µ SU Fiber, 5/Bx	All	00821925044074
EGTFL-FBX150BS	SOLTIVE 150µ BT SU Fiber, 5/Bx	All	00821925043879
EGTFL-FBX200BS	SOLTIVE 200µ BT SU Fiber, 5/Bx	All	00821925043978

Dear Healthcare Professional:

Olympus (Gyrus ACMI, Inc.) is writing to inform you of errors identified in the SOLTIVE Single-use Laser Fiber Instructions for Use. The SOLTIVE Laser System is intended for use in 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. SOLTIVE Laser Fibers are delivery devices that transmit laser energy from the laser console to the treatment site through the fiber tip.

Olympus conducted an internal review of the SOLTIVE Single-use Fibers and identified inconsistencies in the IFU. Olympus is providing you with the attached labeling addendum, which identifies the errors in the current instructions and the corrections that will be implemented in the IFU. The corrections are summarized as follows:

1. **Cleaning the Fiber Tip:** Instructions have been updated to remove hydrogen peroxide because it was not validated, as follows: Prior to cleaning the tip, the laser must be placed in the STANDBY mode. During the treatment the laser fiber can be cleaned with a sterile pad immersed in ~~hydrogen peroxide or~~ sterile water.

2. **Fiber Cleaving and Stripping Instructions:** Instructions have been clarified and replaced with the following:
   1. Reference Table 3 to select the appropriate fiber stripper for the fiber size.

   2. Strip the fiber so this action results in approximately 20 mm of exposed fiber per the fiber stripper Instructions for Use.

   3. Holding the fiber cleaver, per the fiber cleaver Instructions for Use, score the fiber so the final exposed glass tip is 3-5mm, as recommended for each fiber size in Table 3.

4. Confirm proper stripping cleaving of the fiber by checking the aiming beam as described in Figure 1A.

5. Repeat the cleaving procedure from step 2 until a satisfactory aiming beam pattern is achieved.

3. Accessories: Table 3 has been corrected to reflect 200 µm core diameter instead of 240 µm.

Fiberoptic Stripper Selection			
Outer Diameter (µm)	**Core Diameter (µm)**	**Stripper Size**	**Desired Strip Length (mm)**
370 – 430	**200**	0.012	~3

Risk to Health:

The Instructions for Use currently instructs the user that the SOLTIVE Single-use Laser Fiber is cleaved first and then stripped, leaving 20 mm of exposed fiber. This presents the potential for the fiber to break during use. The potential harms related to a broken fiber include burns, procedure delays, prolonged surgery and foreign body in patient.

Olympus has received 92 complaints for fiber breakage. However, Olympus has reviewed and determined the complaints were not directly related to these issues in the Instruction for Use.

Action steps to be taken by the end user:

Olympus requests you to take the following actions:

1. **Carefully read** the content of this Field Safety Notice as well as the attached "Addendum".
2. **Ensure all personnel, including clinical staff, are completely knowledgeable** and thoroughly aware of the contents. The Addendum identifies the errors in the current IFU and provides the corrected instructions.
3. **Inspect your inventory and identify** any products of the models subject to this action. Please check all areas of the hospital to determine if any of these devices remain in inventory. Add a copy of the enclosed addendum with your remaining inventory. You may continue to use the products, but this should be done in accordance with the attached labeling addendum.
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-32-FY24-OSTA-12 Soltive Single-use Laser Fibers

OLYMPUS URGENT FIELD SAFETY NOTICE **SOLTIVE Laser System, Single-use Laser Fibers**
[Name & Address of Hospital/Medical Facility]
[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.