Date: January XX, 2023
Olympus Reference: QIL FY24-EMEA-33-FY24-OSTA-17 Soltive Pouch Seal

URGENT FIELD SAFETY NOTICE

RE: recall of SOLTIVE Laser Fibers, Model TFL-FBX200BS, lot KR262848
Attention: XX Department, Risk Management Department

Material ID	Description	Lot Number	GTIN
EGTFL-FBX200BS	SOLTIVE 200µ BT SU Fiber, 5/Bx	KR262848	00821925043978

Dear Healthcare Professional:

Olympus is writing to inform you of the potential for a breached sterile pouch seal on the 200 Micron TFL Ball Tip Single-Use SOLTIVE Laser Fiber. SOLTIVE Laser Fibers are delivery devices that transmit laser energy from the laser console to the treatment site through the fiber tip. The Fibers are sterile packed, single-use fibers with a laser connector. SOLTIVE Laser Fibers are compatible for use with SOLTIVE Laser System.

Olympus has received one (1) complaint regarding a breach of the TFL-FBX200BS Laser Fiber pouch seal. Initial investigation shows this to be an isolated event. However, while Olympus continues with ongoing investigation activities, Olympus is requesting that customers return this model and lot. No patient injuries were reported with this sterile barrier breach.

Risk to Health

A breached sterile pouch seal on the 200 Micron TFL Ball Tip Single-Use SOLTIVE Laser Fiber can lead to the potential harms of minor procedure delays when noticed prior to use or patient infections if the breached seal is not noticed prior to use in a patient.

The Product Specifications section of the IFU states that fibers should not be used if the packaging has been damaged.

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 and lot 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/lot.
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.

Olympus requests you to report any complaints, including sterile package damage, to **[Regional Complaint Intake Contact]**. **[Region to include as applicable]** Adverse events experienced with the use of this product may also be reported to **[Regional to revise to local competent authority]** by **[competent authority contacts]**.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly at **[Regional contact]**.

Sincerely,
[SIGNATORY]
[Contact Name]

REPLY FORM – QIL FY24-EMEA-33-FY24-OSTA-17 Soltive Pouch Seal

OLYMPUS URGENT FIELD SAFETY NOTICE
SOLTIVE Laser Fibers, Model TFL-FBX200BS, lot KR262848

[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.