May XX, 2022
Olympus reference: QIL FY23-EMEA-04

URGENT FIELD SAFETY NOTICE

RECALL OF 150 MICRON SOLTIVE SUPERPULSED LASER FIBERS

Attention: **Endoscopy Department, Risk Management**

Material Order Number	Model	Model Description	Serial / Lot Number
EGTFL-FBX150BS	TFL-FBX150BS	SOLTIVE 150µ BT SU Fiber, 5/Bx	KR149856

Dear Healthcare Professional:

Olympus has become aware of an issue that requires your urgent attention. This letter pertains to the Soltive Superpulsed Laser Fiber Product referenced above.

The SOLTIVE SuperPulsed 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. The SOLTIVE SuperPulsed Laser Fibers ("Laser Fibers") transmit laser energy from the laser console to the treatment site through the fiber tip.

Reason for this Action:

Olympus has received a limited number of complaints that the Laser Fiber size on the immediate pouch label did not match the product's size. These complaints were identified by users during preparation for use. Olympus investigations confirmed that the model and size of Laser Fiber may be mismatched between the product's carton (box of 5), immediate pouch packaging and/or the device (see table below).

Lot	Model		
	Carton Label (box of 5)	Pouch Label (each unit)	Device included in the package
KR149856	TFL-FBX150BS	TFL-FBX200S (incorrect)	TFL-FBX150BS

Laser Fibers are available in different diameters and the maximum energy output is constrained to the device size. The choice of fiber diameter is determined by the user based on the needs of the intended surgical procedure. Prior to use, users must register the Laser Fiber's RFID with the laser system which displays the size and model. The handle on each Laser Fiber is color coded and lists the diameter size.

How to recognize this issue or device failure:

Prior to use, Olympus is reminding customers to verify that the size of fiber labeled on the device handle is the size chosen for the procedure. If the scanned RFID does not match the size on the product pouch and/or the carton you should not use that Laser Fiber and you should obtain another Laser Fiber where there is a complete match among the product, the pouch label and the carton box.

Please report mismatched product and packaging label as a complaint to Olympus.

Risk to Health:

This product labeling discrepancy may result in prolonged surgical procedure as a smaller fiber core diameter results in less energy delivery, and/or delay of treatment while the desired replacement laser fiber size is secured.

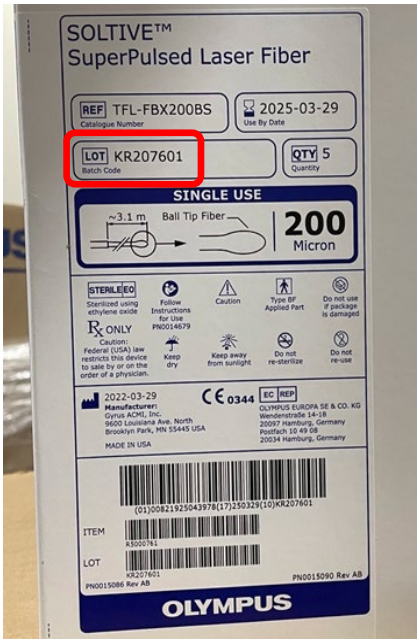
Olympus has not received any reports of serious injury associated with this matter.

Action steps to be taken by the end user:

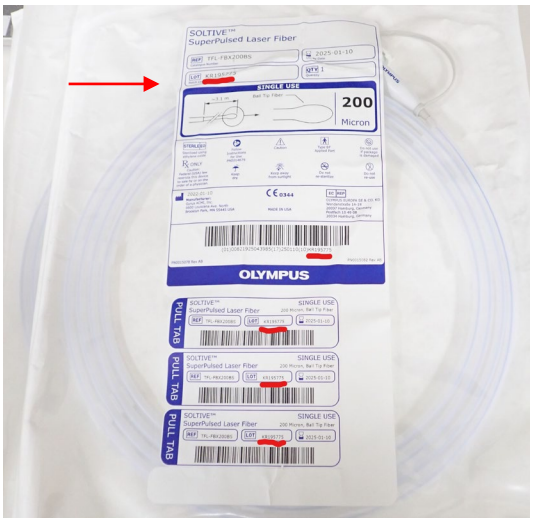
Olympus is requesting that you identify and return any product with the affected lot number.

Our records indicate that your facility has purchased one or more products with the affected lot number. Olympus requires you to take the following action:

1. Carefully read the content of this Field Safety Notice.
2. Immediately assess any product you have in stock and review the carton and pouch labels for the affected lot number provided in this communication. **Cease use and quarantine any affected product.** The images below show the location of the lot number on both the carton and pouch labels.



Location of Lot Number on Carton Label



Location of Lot Number on Pouch Label

3. Ensure all personnel are completely knowledgeable on the content of this FSN.
4. If you have further distributed this product, identify your customers and forward them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedbacks accordingly.

5. Indicate on the Reply Form the product's material name, lot number and quantity, which still remain at your facility.
6. Indicate on the Reply Form that you have received and understood this Field Safety Notice.
7. Olympus requests that you acknowledge receipt of this letter by [region to enter method of collecting acknowledgements] latest by XXXX**.**
8. Olympus will contact you to arrange return of the products and arrange for a credit note to your facility for any returned products.

Your National Competent Authority has been informed of this Field Safety Notice.

Olympus requests you to report any patient injuries and adverse events relating to the use of this product to Olympus and [region to enter relevant health authority]. Please report complaints to [region to enter local contact for complaint reporting].

Olympus regrets any inconvenience from this corrective action and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at [Number] or at [e-mail] for any additional information or support concerning this matter.

Sincerely,

[Name]
[Region or Entity]

REPLY FORM – QIL FY23-EMEA-04

OLYMPUS URGENT FIELD SAFETY NOTICE **REMOVAL OF TFL-FBX150BS Lot KR149856**		
[Name & Address of Hospital/Medical Facility]		
[Dept/Attn]		
[**Date]**		
Material number	**Serial/Lot Numbers**	**Total quantities still available on stock** (If no stock is available, please insert 0)

Dear Sirs or Madams,

I herewith confirm 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 to follow the steps.

Name (Signature) _____

Name (Print) _____

Position _____