Date: 16.09.2026

**Olympus Reference: FY25-089-F-1 Removal of SOLTIVE™ Fiber Products**

# URGENT FIELD SAFETY NOTICE

**RE: SOLTIVE™ Laser Fiber Products** (See Appendix 1 – Affected Products List)
**Attention:** Operating Room / Surgery and Risk Management Departments

Dear Healthcare Professional:

Olympus is initiating a Medical Device Recall / Product Removal for the SOLTIVE SuperPulsed laser fiber products listed in the Appendix 1 of this letter. New versions of these devices are being introduced that use a new material for the strain relief component (see Figure 1). These products along with either the SOLTIVE Pro or SOLTIVE Premium laser generator consoles and their accessories (footswitch, interlock connector, etc.) make up the SOLTIVE laser system, which 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.

## Reason for Action:

Olympus identified and is implementing an alternate material for the strain relief component that will more immediately self-extinguish if it were to ignite. Olympus is requesting users transition to products incorporating the new strain relief material and return all existing unopened and unexpired SOLTIVE laser fiber products.

**Note 1**: Olympus is committed to transitioning users from the existing SOLTIVE laser fiber devices to units incorporating the new device material as quickly as possible. Until you receive the new version, existing devices may continue to be used safely when used in strict accordance with the safety information presented in the IFU and in the supplemental information provided, either within the previous letter (see 'Background') or in the 'SOLTIVE Laser Fiber Aiming Beam Quick Reference' guide provided with all product distributed since that letter was sent.

**Note 2**: Due to the nature of laser fibers, the safety information in the IFU and the Aiming Beam Quick Reference guide must continue to be followed with the new version of the product as the core material of all laser fibers remain susceptible to fracture (see 'Background') even with these changes to the strain relief component.

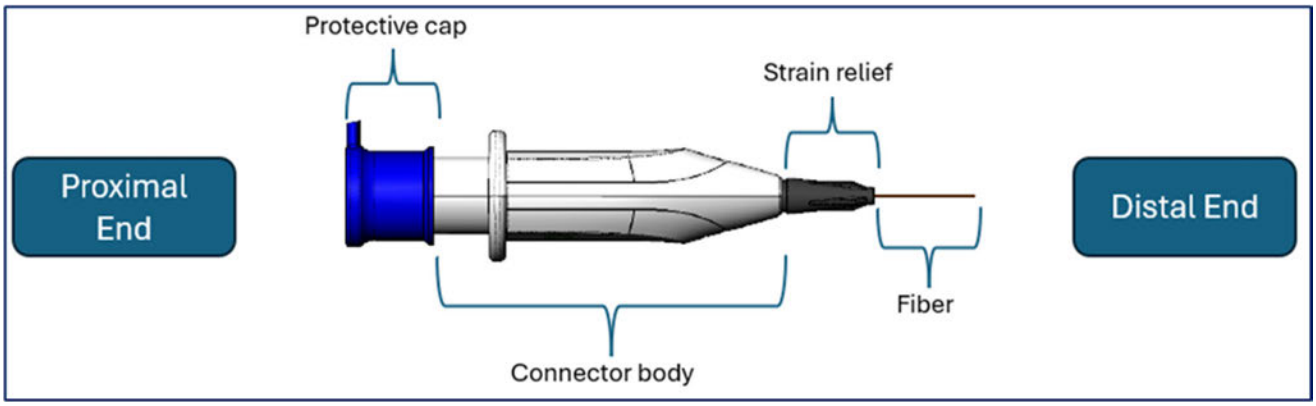


**Figure 1. Image showing the components of a SOLTIVE laser fiber device.**

Further updates to the product labeling are being developed and will be communicated to users separately.

**Background:**

In 2025, Olympus identified an increased number of complaints reporting thermal events associated with the use of SOLTIVE laser fiber devices. A known risk associated with these devices is that a break in the core material within the fiber can cause a dispersion of the laser energy at that location which can lead to accidental laser exposure to the patient or operating room personnel or thermal damage to or ignition of adjacent equipment or materials. In some of the reported instances in which the breakage occurred within or near the strain relief, the strain relief component itself ignited and did not immediately self-extinguish.

A previous letter sent in May 2025 informed consignees of 175 malfunctions and two serious injuries that were reported associated with this issue globally, reminded users of the relevant safety information contained in the IFU, and provided supplemental guidance to help identify laser fiber devices with a broken core and prevent their use with the treatment beam, which could cause these types of thermal events. SOLTIVE laser fiber products distributed since the 2025 letter have included a 'SOLTIVE Laser Fiber Aiming Beam Quick Reference' guide which provides comparable information on identifying laser fiber devices with a broken core.

**Risk to Health:**

Harms associated with accidental laser exposure or fires may lead to patient or user pain or burns. Burns as a result of operating room fires could potentially pose critical or life-threatening risks if they occur in the presence of oxygen, other flammable gases/substances, or combustible fabrics. Additionally, reports have indicated that this issue has caused delays or cancellations of procedures to acquire replacement devices.

**Actions Required:**

Our records indicate that your facility has received one or more of the affected products. Olympus therefore requests that you take the following actions:

1. Examine the carton labels of all SOLTIVE laser fiber products in your inventory for the model numbers, UDI-DI numbers, and manufacturing dates indicated in the Appendix 1 of this letter. If you have the affected versions of these products in your inventory, transition to the new versions of the products as soon as possible by placing an order through Customer Service or using your usual ordering process. The new versions of these products will have a manufacturing date after that indicated in the Appendix 1 of this letter.

   **Note**: Different catalog numbers have different manufacturing dates indicated.

2. Until you receive the new versions of these products, you can continue using the affected versions while strictly following the safety information presented in the IFU and in the Aiming Beam Quick Reference guide.
3. Once you have received the new versions of these product, stop using the affected versions and set them aside for return.
4. If you have affected products in your inventory, please contact Olympus with regard to return of affected products. Olympus will issue a credit to your facility upon return of your affected product.
5. Olympus requests that you acknowledge receipt of this letter [local facility method/contact]. **Note**: This request applies even if you no longer have any affected product in your inventory.
6. If you have further distributed them, forward this letter to other users who may have affected products.

*[If applicable:] [competent authority] 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 fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact *[me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX].*

*Sincerely,*
*Name*
*Olympus title*

## Appendix 1 - Affected Products List

| Material ID | Model Number | Product Name | UDI-DI | Manufactured On or Before [YYYY-MM-DD] |
|---|---|---|---|---|
| EGTFL-FBX150BS | TFL-FBX150BS | SOLTIVE 150µ BT SU Fiber, 5/Bx | 00821925043916 - 5 Pack<br>00821925043923 – 1 Piece | 2026-04-29 |
| EGTFL-FBX200BS | TFL-FBX200BS | SOLTIVE 200µ BT SU Fiber, 5/Bx | 00821925043978 – 5 Pack<br>00821925043985 – 1 Piece | 2026-06-03 |
| EGTFL-FBX150S | TFL-FBX150S | SOLTIVE 150µ SU Fiber ,5/Bx | 00821925043879 – 5 Pack<br>00821925043886 – 1 Piece | 2026-06-29 |
| EGTFL-FBX200S | TFL-FBX200S | SOLTIVE 200µ SU Fiber, 5/Bx | 00821925043930 – 5 Pack<br>00821925043947 – 1 Piece | 2026-06-29 |
| EGTFL-FBX365S | TFL-FBX365S | SOLTIVE 365µ SU Fiber, 5/Bx | 00821925043992 – 5 Pack<br>00821925044005 – 1 Piece | 2026-06-03 |
| EGTFL-FBX550S | TFL-FBX550S | SOLTIVE 550µ SU Fiber, 5/Bx | 00821925044036 – 5 Pack<br>00821925044043 – 1 Piece | 2026-06-29 |
| EGTFL-FBX940S | TFL-FBX940S | SOLTIVE 940µ SU Fiber, 5/Bx | 00821925044074 – 5 Pack<br>00821925044081 – 1 Piece | 2026-06-29 |
| EGTFL-FBX150R | TFL-FBX150R | SOLTIVE 150µ RU Fiber, 5/Box | 00821925043893 – 5 Pack<br>00821925043909 – 1 Piece | 2026-07-15 |
| EGTFL-FBX200R | TFL-FBX200R | SOLTIVE 200µ RU Fiber, 5/Box | 00821925043954 – 5 Pack<br>00821925043961 – 1 Piece | 2026-07-15 |
| EGTFL-FBX365R | TFL-FBX365R | SOLTIVE 365µ RU Fiber, 5/Box | 00821925044012 – 5 Pack<br>00821925044029 – 1 Piece | 2026-07-15 |
| EGTFL-FBX550R | TFL-FBX550R | SOLTIVE 550µ RU Fiber, 5/Box | 00821925044050 – 5 Pack<br>00821925044067 – 1 Piece | 2026-07-15 |
| EGTFL-FBX940R | TFL-FBX940R | SOLTIVE 940µ RU Fiber, 5/Box | 00821925044098 – 5 Pack<br>00821925044104 – 1 Piece | 2026-03-09 |

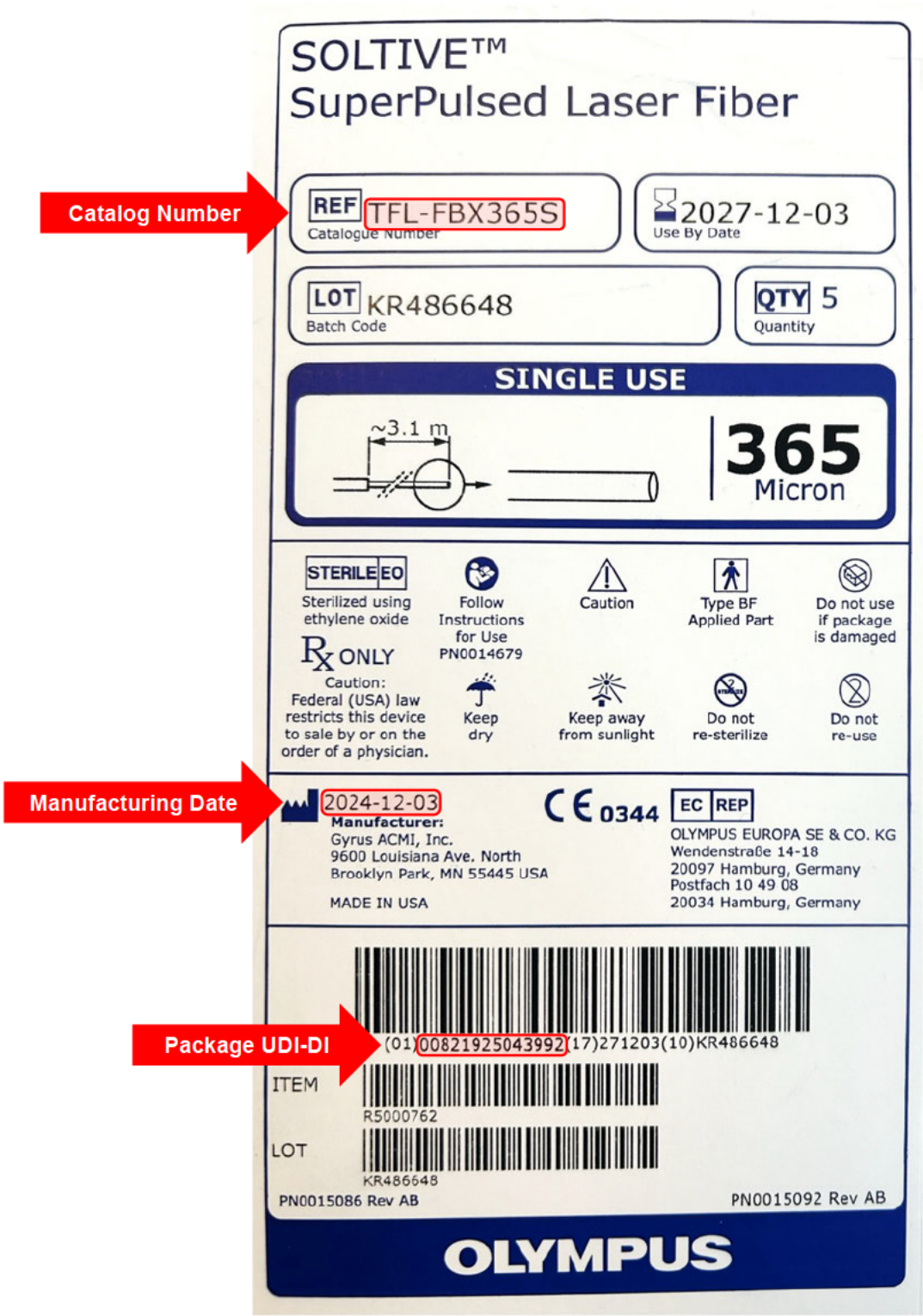


**Figure 2. Image showing an example of a carton label for a SOLTIVE SuperPulsed laser fiber product with the location of the identifying elements from the Appendix 1 indicated.**

OLYMPUS

# REPLY FORM – FY25-089-F-1 Removal of SOLTIVE™ Fiber Products

| | |
|---|---|
| **Facility Name** | |
| **Facility Address** | |
| **Contact Name** | |
| **Additional Customer Requests** (Indicate if you have any additional requests to support this action) | |

Insert Catalogue Number, Lot Number and Quantity of the affected products remaining in your facility .

| Catalogue Number | Lot Number | Quantity |
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I acknowledge receipt of this notification. I confirm that I have further communicated to any affected departments.

| **Completed By:** | | |
|---|---|---|
| | | Click or tap to enter a date. |
| *Name* | *Signature* | *Date (YYYY-MM-DD)* |

Please send the completed form to *XXX* by date *XXX*.