URGENT: MEDICAL DEVICE CORRECTION

SOLTIVE Laser Fibers

Product Name	Model Number	Serial/Lot Number(s)	UDI-DI
SOLTIVE Pro SuperPulsed Laser System	TFL-SLS	All Serial Numbers	00821925044135
SOLTIVE Premium SuperPulsed Laser System	TFL-PLS		00821925044111
TFL Premium Laser Unit	TFL-CPLU		00821925044586
TFL Standard Laser Unit	TFL-CSLU		00821925044593
150 Micron TFL Ball Tip Single Use Fiber	TFL-FBX150BS	All Lot Numbers	00821925043916 - 5 Pack 00821925043923 – 1 Piece
200 Micron TFL Ball Tip Single Use Fiber	TFL-FBX200BS		00821925043978 – 5 Pack 00821925043985 – 1 Piece
150 Micron TFL Single Use Fiber, 5/Box	TFL-FBX150S		00821925043879 – 5 Pack 00821925043886 – 1 Piece
200 Micron TFL Single Use Fiber, 5/Box	TFL-FBX200S		00821925043930 – 5 Pack 00821925043947 – 1 Piece
365 Micron TFL Single Use Fiber, 5/Box	TFL-FBX365S		00821925043992 – 5 Pack 00821925044005 – 1 Piece
550 Micron TFL Single Use Fiber, 5/Box	TFL-FBX550S		00821925044036 – 5 Pack 00821925044043 – 1 Piece
940 Micron TFL Single Use Fiber, 5/Box	TFL-FBX940S		00821925044074 – 5 Pack 00821925044081 – 1 Piece

Date: 6-MAY-2025

Attention: Operating Room Director, Surgical Department Chief, Risk Management

Dear Healthcare Provider:

Olympus is writing to inform you of a Field Corrective Action pertaining to the Olympus SOLTIVE SuperPulsed Laser System ("SOLTIVE Laser"), models Pro TFL-SLS and Premium TFL-PLS, and the SOLTIVE Laser Single Use Fibers (Reference model numbers listed above). The SOLTIVE Laser is intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in urology, lithotripsy, gastroenterological surgery and gynecological surgery. SOLTIVE Laser Single Use Fibers are delivery devices that transmit laser energy from the laser console to the treatment site through the fiber tip. The SOLTIVE Laser Fibers are only indicated for use with the SOLTIVE Laser Systems.

Reason for Action:

Olympus investigated complaints received for unexpected **smoke, sparks, flare, burning of a device or equipment, unsteady flames, steady flames and burns to a clinician or supporting staff** occurring while using the SOLTIVE Laser Systems and SOLTIVE Laser Fibers.

Since the SOLTIVE Laser's launch in 2019, Olympus has identified one-hundred and seventy-five (175) reportable malfunctions and two (2) serious injuries, including breakage of a fiber that resulted in a burn to the hand of the user and a single-use fiber that caught on fire causing a procedural delay. There is no evidence that material within the operating room progressed to a fire in any of the reported incidents.

The preliminary results of the investigation indicate that a fiber break, at the strain relief or along the length of the fiber (Image 1 below), is the cause of, or contributes to, these incidents. Olympus is continuing to investigate the issue and will take appropriate actions regarding the investigation findings.

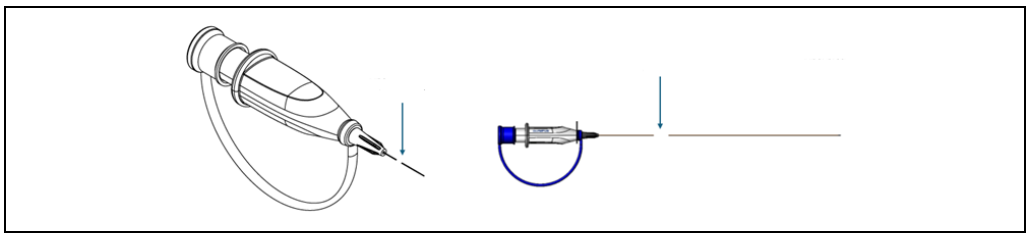

Image 1: Fiber fracture near strain relief (left), and fiber fracture along the length of the fiber (right).

Therefore, we want to call attention to the direction provided in the Instructions for Use for proper fiber handling to prevent damage and for detection of fiber damage:

Fiber Handling:
As per the SOLTIVE Laser Fibers Instructions for Use, please use caution when handling the fiber. As instructed, remove the fiber carefully from its packaging. Remove the protective cap (DO NOT hold the rubber strain relief or the fiber).

Detecting Laser Fiber Damage:
The SOLTIVE Laser System has an Aiming Beam that can be used to ensure the laser fiber is free from damage.

- This function enables the user to check the connected fiber safely by evaluating the shape of the laser beam directly at the output of the fiber and the integrity of the surgical fiber. If the aiming beam is not present at the distal end of the surgical fiber, its intensity is reduced or looks diffused, this may be an indication of malfunction or damage to the system.
- **Warning:** Do not deliver the treatment beam without checking the integrity of the aiming beam, in the event that the optical fiber is damaged. Accidental laser exposure or fires may occur if a damaged fiber is used during a procedure.

The following supplemental guidance details the steps to detect fiber damage:

Aiming Beam Test During Device Preparation:

- During the "Device Preparation" steps identified in the Instructions for Use, The SOLTIVE Laser System requires the user to conduct a laser fiber inspection (Fiber Verification) when a new fiber is connected to the system.
    1) When inserting the fiber connector to the fiber coupler on the laser system, the aiming beam will turn on and a "Fiber Verification" screen appears (Image 2 below).

2) Visually inspect the strain relief and all portions of the fiber external to the scope for fiber damage (i.e., fiber break). If green light from the aiming beam appears at any portion other than the distal tip, such as along the fiber's length or inside the strain relief connector, the fiber has been damaged. Replace with a new fiber and repeat the Fiber Verification. Please note, there may still be a faint green light visible at the fiber tip even if the fiber is damaged. Examples of the aiming beam with damaged fibers are shown in Images 5-8 below.
3) If the fiber does not emit green light inside the strain relief connector or along the entire length of the fiber, select "OK" on the Fiber Verification screen and resume procedure per Instructions for Use.

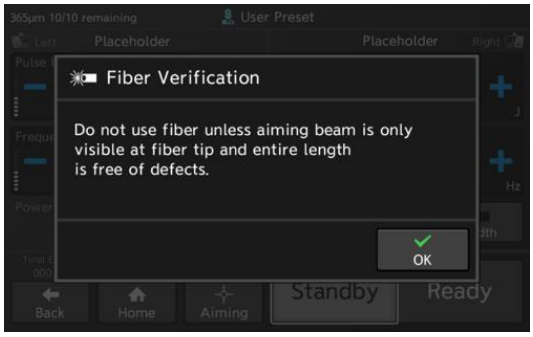

Image 2: Fiber Verification screen

Aiming Beam Test During Procedure:

- At any time during the procedure, if it is suspected that the fiber has been subjected to possible damage (e.g., stepped on, pulled, left lying in a vulnerable position, kinked, tightly coiled, pinched, etc.), **DO NOT PROCEED** and conduct a "Fiber Damage Test" per the steps below:

4) Ensure laser system is in standby mode by pressing the STANDBY button on the screen.
5) Ensure aiming beam is active; IF NOT, press the Aiming Beam button on the screen and activate the aiming beam. The default setting of the aiming beam is 3. Users have the ability to increase the aiming beam intensity to 10 to aid with visual inspection.
6) Visually inspect the strain relief and all portions of the fiber external to the scope for fiber damage (i.e., fiber break). If green light from the aiming beam appears at any portion other than the distal tip, such as along the fiber's length or inside the strain relief connector, the fiber has been damaged. Replace with a new fiber and perform Fiber Verification. Please note, there may still be a faint green light visible at the fiber tip even if the fiber is damaged. Examples of the aiming beam with damaged fibers are shown in Images 5-8 below.
7) If the fiber does not emit green light inside the strain relief connector or along the external inspected portions of the fiber, set the aiming beam to your preferred intensity settings and resume procedure per Instructions for Use.

Examples of Aiming Beam test with NO damage to fibers (Images 3 and 4 below):

Image 3: Fiber with no damage

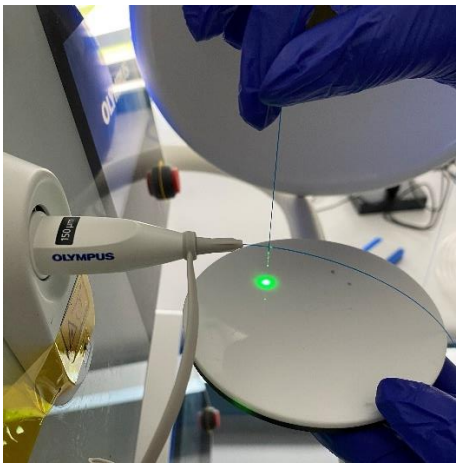

Image 4: Good Aiming Beam at Default Setting (3)

Examples of Aiming Beam test with damaged fibers (Images 5, 6, 7 and 8 below):

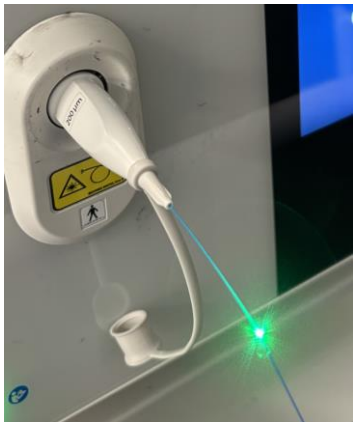

Image 5: Damaged fiber along fiber length

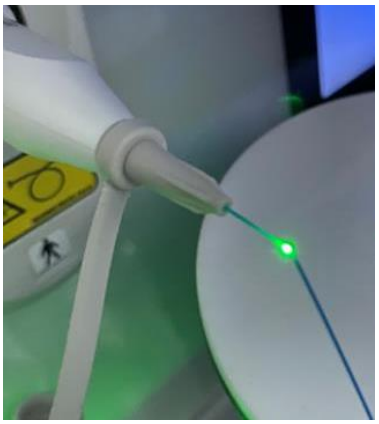

Image 6: Damaged fiber along fiber length

Image 7: Damaged fiber within the strain relief

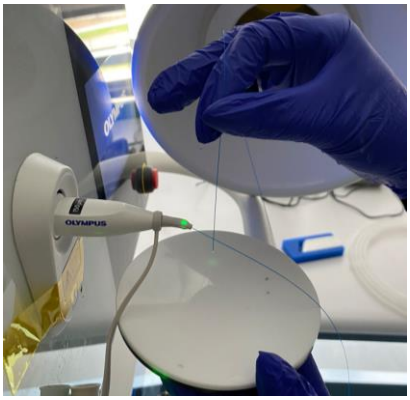

Image 8: Broken Aiming Beam at Default Setting (3)

If at any time damage is suspected, and the aiming beam test is not conducted, replace the fiber before proceeding with the procedure.

Additionally, Olympus reminds users to carefully follow the SOLTIVE Laser Single Use Fibers Instructions for Use and the SOLTIVE Laser System Instructions for Use, which provide critical Warnings, Safety Considerations, and Cautions regarding fiber handling and fire prevention. The relevant sections of the Instructions for Use are included in Appendix 1 of this letter.

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.

Additional Guidelines & Resources for Safe Laser Use

- Guidelines and standards related to laser safety, such as those published in the updated 2021 *Guidelines for Perioperative Practice*, by AORN (Association of periOperative Registered Nurses), should be followed. Perioperative team members should be well-informed about fire prevention and risk management plans, which should include specific actions to take in the event of a fire. AORN guidelines for fire prevention include the following:
    - Place the laser in stand-by mode or turn the laser off when laser transmission is not required.
    - Standard of practice/care is to keep a basin of saline or water on the sterile field in case of a fire.
    - During the procedure, moist materials (i.e., towels, sponges) are used to protect exposed tissues around the surgical site, and the user keeps them moist throughout the procedure.
    - Use water-soluble lubricants near the surgical field only.
    - Place the working end of the laser fiber in a holster-type device before and between uses.
    - Facilities should have a developed Laser Safety program in place which includes, but is not limited to education, competency and laser certification for all personnel in laser usage and potential laser hazards along with established usage criteria, safety controls, and authorized procedures for all healthcare personnel.

Actions Required:

Our records indicate that your facility has purchased one or more of the affected products. Therefore, Olympus requires you to take the following actions:

1. Carefully read the content of this letter, including Appendix 1 detailing the relevant Instructions for Use sections.
2. Ensure all surgeons and personnel are completely knowledgeable and thoroughly trained on the content of this letter, the instructions provided for detecting fiber damage, Appendix 1, and the SOLTIVE Laser System and Fibers Instructions for Use. Include a copy of this letter with the Instructions for Use. You may continue to use the device as per this letter and the Instructions for Use.

3. Olympus requests that you acknowledge receipt of this letter through our recall web portal:
   a. Go to https://olympusamerica.com/recall
   b. Enter the recall number: "0470"
   c. Complete the form as instructed.
4. If you have further distributed this product, identify and forward them this letter.

Olympus requests you to report any complaints, including fiber damage/breaks, smoke, sparks, flare, burning of a device or equipment, unsteady flames, steady flames and burns to a clinician or supporting staff occurring while using the SOLTIVE Laser Systems and SOLTIVE Laser Fibers. **Olympus requests that you send the involved fiber(s) to Olympus for complaint investigation purposes.** Please report complaints 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. If you require additional information, please do not hesitate to contact me directly by phone at (647) 999-3203 or by e-mail Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
Field Corrective Actions Lead, Americas

Appendix 1

The SOLTIVE Laser Single Use Fibers Instructions for Use provides the following Warnings, Safety Considerations, and Cautions regarding fiber handling:

Warnings

- Do not use a defective or damaged laser fiber. The fiber may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked, or tightly coiled.
- Do not activate the laser beam until it is positioned on the target in a liquid medium.
- Do not clamp the fiber with a hemostat or other instruments.
- Failure of the structural integrity of the device or the failure of the device may lead to treatment room personnel or patient injury, and/or fire in the treatment room.
- If the fiber tip is visibly damaged or requires excessive amounts of energy to affect coagulation or vaporization, discontinue use and replace with a new fiber for optimum results. Alternately, strip and cleave the fiber as outlined in Fiber Cleaving and Stripping Instructions.

Safety Considerations

- Observe the detailed safety information in the Instructions for Use of the respective SOLTIVE laser device and the instructions for protection against laser radiation, ensuring that all treatment room personnel wear appropriate protective eyewear during the procedure. Please follow Laser Safety Protocols as defined by your institution. Damaged or improper use of the laser fiber in an incorrect manner may lead to:
  - Severe eye or tissue injury
  - Fire in the treatment area
  - Unintended exposure to the patient or medical staff to laser radiation

Cautions

- [When inserting the fiber connector to the fiber coupler on the laser system] Be careful to not use too much force, as this can damage the fiber or laser system connector.

Device Handling

- Do not bend or coil the Soltive Laser Fibers beyond the recommended minimum bend radius (Reference table below); doing so may result in light leakage or fiber breakage that could cause personal injury if the laser is fired.
- Care must be taken to avoid exceeding the minimum bend radius of fibers. Always check the laser aiming beam at the tip of the fiber before delivering high energies or damage to the endoscope may result.

Minimal Bend Radius of Fiber					
Core diameter (µm)	150	200	365	550	940
Minimal Bend Radius (mm)	≥ 7	≥ 7	≥ 29	≥ 58	≥ 73

The SOLTIVE Laser System Instructions for Use provides the following Warnings for prevention of fires or explosions. Additional information related to fire hazards can be found in the Hazards and Protections section of the SOLTIVE Laser System IFU.

- A UL-approved fire extinguisher and water should be readily available.
- Keep a bottle of sterile saline and a fire extinguisher in the same room where a laser procedure is being performed.

Warnings

- Solvents such as glues or flammable solutions used to clean or disinfect need to be allowed to evaporate, before using the laser.
- This device should not be used in the presence of flammable or explosive materials such as volatile anesthetics, alcohol, specific surgical preparation solutions and any other flammable substances.
- A risk of fire and or explosion exists when the laser output is used in the presence of flammable materials, solutions or gases or in an oxygen enriched environment.
- Do not deliver the treatment beam without checking the integrity of the aiming beam, in the event that the optical fiber is damaged. Accidental laser exposure or fires may occur if a damaged fiber is used during a procedure.