

URGENT FIELD SAFETY NOTICE

RE: OLYMPUS Soltive™ SuperPulsed Laser System.

Wireless Footswitch **Model TFL-AFSWL** for Soltive **Models Pro TFL-SLS and Premium TFL-PLS**

Attention: Operating Room Manager, Risk Management Department

| Material ID | Model Name | Material Description | Serial Numbers | UDI-DI |
|-------------|------------|--------------------------------|----------------|----------------|
| EGTFL-SLS | TFL-SLS | ThuliumFiber Laser SOLTIVE Pro | All | 00821925044135 |
| EGTFL-PLS | TFL-PLS | SOLTIVE PREMIUM LASER SYSTEM | All | 00821925044111 |
| EGTFL-AFSWL | TFL-AFSWL | SOLTIVE Footswitch - Wireless | All | 00821925044258 |

Dear Healthcare Professional:

Olympus is writing to inform you of a Field Corrective Action pertaining to the OLYMPUS Soltive Laser System ("Soltive Laser"), models Pro TFL-SLS and Premium TFL-PLS. Olympus has received complaints of the failure of the wireless footswitch to pair to and operate the Soltive Laser System. 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.

Reason for Action:

Olympus investigated complaints received where customers reported difficulties in pairing the wireless footswitch with the Soltive Laser, resulting in delays in surgical procedures or prolonged surgery. In an effort to mitigate any immediate and potential risk to patient health, Olympus is requiring Soltive Laser users to have an Olympus wired footswitch (part number TFL-AFSW) available for immediate use as a backup in the event a wireless footswitch does not pair with the Soltive Laser.

Risk to Health:

The potential immediate harms of the wireless footswitch not pairing are a delay in initiating scheduled surgical treatment/therapy or prolonged surgery due to the need to troubleshoot and/or replace the equipment due to an inability to pair the footswitch. The surgery may need to be rescheduled, in the event the wireless footswitch will not pair and no other equipment is available to complete the procedure.



Footswitch (wired or wireless)

TFL-AFSW (wired) and TFL-AFSWL (wireless)



If you do not have an Olympus wired footswitch, please contact Olympus as indicated in step 4 below. Olympus will provide a wired footswitch at no charge upon availability of inventory. In the interim, until you receive the wired footswitch, refer to the Soltive Laser System Instructions for Use, “Connecting the Wireless Footswitch” section for steps to pair the wireless footswitch to the Soltive Laser and to confirm the footswitch is functioning correctly. Follow these instructions to pair the footswitch prior to starting a procedure, or to re-pair the device during use should it disconnect.

Actions Required:

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

1. Carefully read the content of this notification.
2. Inspect your inventory and identify any devices with the model names specified above. Please check all areas of the hospital to determine if any of these devices remain in inventory.
3. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this notification and the Soltive Laser System Instructions for Use, including instructions related to connecting the wireless footswitch.
4. If you require a wired footswitch, contact Olympus customer care at [local facility customer care contact].
5. If you have further distributed this product, identify your customers, and forward them this notification.
6. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply Form that you have received and understood this notification by filling out and returning the completed enclosed Reply Form back to your local Olympus representative.

Olympus requests that you report any complaints, including failure of the wireless footswitch to pair with the Soltive Laser or any associated injuries, to [local facility complaint reporting contact]. Adverse events experienced with the use of this product may also be reported [local competent authority] by [method].

Olympus fully appreciates your prompt cooperation. 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



REPLY FORM: QIL FY25-EMEA-09-FY23-OSTA-13-Solitive Wireless Footswitch

| | |
|--|--|
| Facility Name | |
| Facility Address | |
| Contact Name | |
| Quantity of wired footswitches (part number EGTFLL-AFSW) required | |
| Additional Customer Requests (Indicate if you have any additional requests to support this action) | |

I acknowledge receipt of this notification. I confirm that I have communicated further to any affected departments.

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

Please send the completed form to **XXX** by **XX.XX.XXXX**