Updated July 16, 2024, to add Laser Unit Part Numbers (TFL-CPLU, TFL-CSLU)

June 28, 2024

URGENT: MEDICAL DEVICE CORRECTION

OLYMPUS Soltive™ SuperPulsed Laser System Wireless Footswitch

Serial Numbers: All serial numbers

Model	Name	UDI
TFL-SLS	SOLTIVE Pro SuperPulsed Laser System	00821925044135
TFL-PLS	SOLTIVE Premium SuperPulsed Laser System	00821925044111
TFL-AFSWL	Wireless Footswitch	00821925044258
TFL-CPLU	TFL Premium Laser Unit	00821925044586
TFL-CSLU	TFL Standard Laser Unit	00821925044593

Attention: Urology Department

Dear HealthCare Provider:

Olympus America Inc. (“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.

Olympus investigated complaints where customers reported difficulties in pairing the wireless footswitch with the Soltive Laser, resulting in delays to 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.

Risks 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) TFL-AFSWL (wireless)

If you do not have an Olympus wired footswitch, please inform 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. Olympus requests that you acknowledge receipt of this letter. **Access the Olympus recall portal to indicate that you have received this notification.**
    a. Go to https://olympusamerica.com/recall
    b. Enter the recall number "0448"
    c. Complete the form as instructed and include your account ID number.
    d. Indicate in the comments if your facility does not have a wired footswitch. Olympus Customer Service will contact you to make arrangements for a wired footswitch.
5. If you have further distributed this product, identify your customers, and forward them this notification.

Olympus requests that you report any complaints, including failure of the wireless footswitch pairing with the Soltive Laser System, or any associated injuries to the 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 from Monday through Friday or by e-mail Cynthia.Ow@olympus.com.

Sincerely,

Cynthia Ow
Cynthia Ow
FCA Regional Lead, Americas