September 12, 2024

URGENT: MEDICAL DEVICE CORRECTION

OLYMPUS Soltive™ SuperPulsed Laser System
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-CPLU	TFL Premium Laser Unit	00821925044586
TFL-CSLU	TFL Standard Laser Unit	00821925044593

Attention: Operating Room Director, Risk Management

Dear Healthcare Professional/ 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. 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 received a complaint regarding the Soltive Laser System preset laser settings. The term "Bladder Stone" was incorrectly translated in both Spanish and Portuguese to "Kidney Stone" (Cálculo renal) on the systems' Graphical User Interface (GUI). As a result of the incorrect Spanish and Portuguese translation from "Bladder Stone" to "Kidney Stone" on the GUI, there is a potential to deliver an incorrect or unintended amount of energy to the patient's anatomy. This issue is specific to the preset laser settings and does not affect users who are not utilizing the preset option. Olympus has not received any additional complaints related to this issue.

Olympus reminds users to verify that the settings for the intended procedure are indicated on the Treatment Screen in Standby Mode before transitioning to Ready Mode. Reference illustration below of the settings displayed in the Treatment Screen for user verification prior to energy delivery. Additionally, the Soltive Laser Instructions for Use instructs users to start clinical treatment with low laser settings and gradually increase laser power output to achieve the desired therapeutic effect.

Standby Mode

Ready Mode

OLYMPUS CORPORATION OF THE AMERICAS
3500 CORPORATE PARKWAY, CENTER VALLEY, PA 18034
TELEPHONE (484) 896-5000

Olympus will be issuing a software update to correct the translation error in the coming months and will contact you at that time to coordinate the update for your unit(s). The Instructions for Use for the Soltive Laser is being carefully assessed for any corrections or improvements required.

Risk to Health:

Use of the Bladder Stone preset setting/energy, rather than the Kidney Stone preset setting/energy, in the treatment of a kidney stone may result in kidney injury (e.g. bleeding, tissue injury, perforation, and possible renal impairment). All preset laser settings should be verified as appropriate and adjusted for intended anatomy prior to activation of the laser emission by the treating physician. Individual treatment should be based on clinical training, clinical observation of laser-tissue interaction, and appropriate clinical endpoints.

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 notification.
2. Please check all areas of your facility to determine if you have the devices specified above.
3. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this notification and the Soltive Laser System Instructions for Use.
4. If you have further distributed this product, identify your customers, and forward them this notification.
5. 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: "**0452**"
    c. Complete the form as instructed.

Olympus requests that you report any complaints, including translation errors on the Soltive Laser System GUI or Instructions for Use, or any associated injuries to the Olympus Technical Assistance Center (TAC) at 1-800-848-9024 (option 1). 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 at Cynthia.Ow@Olympus.com or by phone at (647) 999-3203.

Sincerely,

Cynthia Ow

Cynthia Ow
Field Corrective Action Regional Lead, Americas