



February 5, 2024

MEDICAL DEVICE SAFETY REMINDER

OLYMPUS Soltive™ SuperPulsed Laser System

Models: Pro (TFL-SLS) and Premium (TFL-PLS)

Serial Numbers: All serial numbers

UDI-DI: TFL-SLS – 00821925044135; TFL-PLS - 00821925044111

Attention: Operating Room Director

Dear Healthcare Provider:

As part of Olympus' post market surveillance of Soltive Laser use, including a review of customer complaints and adverse events, we have become aware that some clinicians are defaulting to the preset laser values for all clinical procedures when that is not consistent with the Instructions for Use. 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 reminds users that preset treatment parameters may not be appropriate for all patients and are guidelines only. Olympus is sending this reminder after reviewing twenty-seven (27) complaints reported between 2021 to 2023 related to ureteral stone procedures that described serious injuries.

The desired clinical outcome may be achieved at lower laser settings than the preset laser values depending on patient specifics and the anatomical location of treatment. While the preset laser values may be appropriate and applicable for clinical procedures, our Instructions for Use recommend physicians to start with low laser settings and increase them progressively to achieve the desired effect on the targeted tissue. The Soltive Laser Instructions for Use instructs users to consider starting clinical treatment with low laser settings and gradually increase laser power output to achieve the therapeutic effect. The IFU statement from page 15 is included below, and the Preset Treatment Parameters are detailed on page 49.

“Preset laser settings are guidelines only; always start with low settings and then increase them progressively to achieve the desired effect on targeted tissue. Olympus does not make recommendations regarding the practice of medicine.”

Users can create and set their own laser preset values. The Soltive Laser Instructions for Use contains directions on page 36 on how users can create and save individual preset values. An Olympus representative can assist you in setting up laser preset values at your facility. Please contact our Olympus Technical Assistance Center (TAC) at 1-800-848-9024 (option 1) if you

would like an Olympus representative to conduct an on-site review of how to set up and save individual laser preset values.

Risk To Health

The use of laser energy that is too high may result in injury to the patient. Injuries include but are not limited to: possible renal impairment or tissue injury (blanching of tissue, bleeding, mucosal abrasion, perforation, and/or stenosis/stricture). Individual treatment should be based on clinical training, clinical observation of laser-tissue interaction, and appropriate clinical endpoints.

Action Steps:

1. Ensure all personnel, including clinical staff, are completely knowledgeable and thoroughly aware of the contents of this letter and the Instructions for Use.
2. 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 "0441"
 - c. Complete the form.
3. If you have distributed these devices outside your facility, please provide a copy of this letter to those facilities immediately.

Olympus requests you to report any complaints, including any injuries associated with the Soltive Laser, 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 in addressing this situation. If you require additional information, please do not hesitate to contact me directly at (647) 999-3203 or at Cynthia.Ow@Olympus.com

Sincerely,

Cynthia Ow

Cynthia Ow

Field Corrective Action Regional Lead, Americas