

URGENT FIELD SAFETY NOTICE

RE: OLYMPUS Soltive™ SuperPulsed Laser System
Attention: Operation Room Director

Material ID	Material Description	Serial Number	UDI
EGTFL-SLS	SOLTIVE PRO Thulium Fiber Laser System	All	00821925044135
EGTFL-PLS	SOLTIVE PREMIUM Thulium Fiber Laser System	All	00821925044111

Dear Health Care 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 indicate in the reply form 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 to be taken by the end user:

Olympus requires you to take the following action:

1. Carefully read the content of this Field Safety Notice.
2. Ensure all personnel, including clinical staff, are completely knowledgeable and thoroughly aware of the contents of this letter and the Instructions for Use.
3. Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative latest by **XX.XX.XXXX**.
4. If you have distributed these devices outside your facility, please notify your customers of this matter immediately by forwarding them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.

Olympus requests you to report any complaints, including any injuries associated with the Soltive Laser, to **[Regional Complaint Intake Contact]**. **[Region to include as applicable]** Adverse events experienced with the use of this product may also be reported to **[Regional to revise to local competent authority]** by **[competent authority contacts]**.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly at **[Regional contact]**.

Sincerely,

[SIGNATORY]

[Contact Name]



REPLY FORM – QIL FY24-EMEA-36-FY24-OSTA-06-Soltive Laser System

OLYMPUS URGENT FIELD SAFETY NOTICE OLYMPUS Soltive™ SuperPulsed Laser System
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[Date]

I herewith acknowledge the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity of following the instructions carefully.

Name (Signature) _____

Name (Print) _____

Position _____

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

YES

NO

Please send your completed paper form response to XXXXX <mailto:>latest by XXXX.