



Date: July XX, 2021
Olympus reference: QIL 154-006

URGENT FIELD SAFETY NOTICE

RE: SOFTWARE UPGRADE AND UPDATED INSTRUCTIONS FOR USE FOR OLYMPUS SOLTIVE™
SUPERPULSED LASER SYSTEM PRO EGTFL-SLS AND PREMIUM EGTFL-PLS

Attention: Operating Room Director

	Model Name	Serial number
OLYMPUS Soltive™ SuperPulsed Laser System	Pro EGTFL-SLS	All
OLYMPUS Soltive™ SuperPulsed Laser System	Premium EGTFL-PLS	All

Dear HealthCare Professional,

Olympus America Inc. (“Olympus”) has recently received complaints of patient injury associated with the OLYMPUS Soltive Laser System (“Soltive Laser”), models Pro (EG)TFL-SLS and Premium (EG)TFL-PLS, when used in dusting and fragmentation of ureteral stones. 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.

The complaint investigations revealed a user likely exceeded the 20W standard presets for stone dusting and fragmentation when treating impacted stones in the ureter and ureteropelvic junction. A combination of using laser power settings exceeding the cooling power of irrigation fluid, with ureters and kidneys that were already under stress due to stone impaction, were likely contributing factors to ureteral thermal injury in three patients. It is also possible that the ureteral thermal injury contributed to the kidney failure observed at post-operative follow-up in two of these three patients.

To mitigate the risk for thermal injury events, users should exercise the same level of caution and lower power settings for ureter and ureteropelvic junction procedures with Soltive laser applications as they do when using other laser units, such as Holmium YAG lasers. This may be especially important for patients presenting with impacted ureteral stones. Additionally, irrigation flow is important even at lower power settings to cool the tissue site during laser emission.

To mitigate and prevent thermal injury events, Olympus is issuing a software upgrade for the Soltive Laser to version 2.1. Software version 2.1 includes a new Ureteral Stone Preset of 8W under the Lithotripsy treatment mode. Olympus is currently updating the Soltive Laser Instructions for Use (“IFU”) to reflect these software changes which also includes a pop-up alert reminding user to consider the potential clinical consequences of selecting settings greater than 20W in sensitive anatomy like the ureter. Enclosed with this Field Safety Notice you can find an Addendum to the IFU containing a summary of the new updated IFU sections.




Olympus will contact your facility as soon as possible to schedule a software upgrade for your Soltive Laser.

Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more of the affected Soltive™ SuperPulsed Laser Systems. Therefore, Olympus requires you to take the following actions:

1. Carefully read the content of this Field Safety Notice as well as the attached Addendum “PN0024336_AA Soltive Laser Software Revisions”. This Addendum contains the summary of the new updated IFU sections.
2. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this FSN and the referenced Addendum and attach the Addendum to the existing IFU of the mentioned devices.
3. An Olympus representative will reach out to you within the next 9 months (maximum) to arrange a mutually convenient time to have your Soltive Laser(s) updated.
4. Please note on the enclosed FSN Reply Form the serial number available in your facility and that you have received, understood, and followed this information. Kindly also indicate the quantity of required IFU hard copies per Model on the Reply Form.

Note: Please note that Olympus is currently still adopting the affected IFUs and will update the local translations afterwards. Once the IFUs have been updated the most current language version will be available on the following Olympus webpage:
www.olympus-europa.com.

When opening the webpage select ‘Medical Systems’, select ‘Contact & Support’, click on the magnifying symbol (), select ‘Instruction Manual’ and search for the relevant model (e.g. ‘TFL’).

5. Send the completed Reply Form back to your Olympus representative ([xxx]) latest by [XXXX] regardless of whether you have any affected inventory at your facility.
6. If you have further distributed the products listed, identify your customers, forward them this Field Safety Notice including the Addendum “PN0024336_AA Soltive Laser Software Revisions”, appropriately document your notification process and let us know the end-customer feedbacks accordingly.

Your National Competent Authority has been informed of this Field Safety Notice.

Olympus regrets any inconveniences caused by this Field safety Corrective Action fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at [phone number] or at [e-mail address] for any additional information concerning this matter.

Sincerely,



REPLY FORM – QIL 154-006

URGENT FIELD SAFETY NOTICE		
RE: SOFTWARE UPGRADE AND UPDATED INSTRUCTIONS FOR USE FOR OLYMPUS SOLTIVE™ SUPERPULSED LASER SYSTEM PRO EGTFL-SLS AND PREMIUM EGTFL-PLS		
[Name & Address of Hospital/Medical Facility]		
[Dept/Attn]		
[Date]		
Model name	Quantity of replacement IFUs required	Serial numbers available in your facility
OLYMPUS Soltive™ SuperPulsed Laser System Pro EGTFL-SLS		
OLYMPUS Soltive™ SuperPulsed Laser System Premium EGTFL-PLS		

Dear Sirs or Madams,

I herewith confirm the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN and Addendum to all affected departments on which this action has an impact and attached the referenced Addendum to the existing IFUs. I understand the necessity of following the updated IFU carefully.

Name (Signature) _____

Name (Print) _____

Position _____

Please scan / email your completed paper form response to XXXX latest by XXXX.