Date: XX.XX.XXXX

Olympus reference: QIL FY25-EMEA-30-FY24-OSTA-06-1 Soltive Laser System

URGENT FIELD SAFETY NOTICE

RE: OLYMPUS Soltive™ SuperPulsed Laser System

Attention: Operating Room Director, Risk Management

Material ID	Model	Name	Serial Number	UDI
EGTFL-SLS	TFL-SLS	SOLTIVE Pro SuperPulsed Laser System	All	00821925044135
EGTFL-PLS	TFL-PLS	SOLTIVE Premium SuperPulsed Laser System	All	00821925044111

Attention: *Operating Room Director, Risk Management*

Dear Healthcare Provider:

Olympus is writing to inform you of an upcoming software update 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.

Olympus will contact you to schedule time for an Olympus Field Representative to visit your facility and install the software update. The following summarizes the changes to your SOLTIVE Laser System(s) software:

- **Procedure Presets Treatment Parameters Update:** Olympus is implementing an update to the SOLTIVE Laser software to adjust the treatment parameters of Procedure Presets for Lithotripsy and Manual Mode. The attached Addendum to the SOLTIVE Laser System Instructions for Use details the new treatment parameters of the Procedure Presets to be implemented through the upcoming software update. As per the instructions below, Olympus will be updating the software version on your SOLTIVE Laser unit on-site at your facility to reflect the updated treatment parameters described in the attached Addendum.

  Additional information regarding the use of the SOLTIVE Laser Procedure Presets Treatment Parameters is included in the attached communication titled "**Urgent Field Safety Notice QIL FY24-EMEA-36-FY24-OSTA-06-Soltive Laser System**", which reminds SOLTIVE users that the Procedure Presets are guidelines only. The Instructions for Use recommend physicians to start with low laser settings and increase them progressively to achieve the desired effect on the targeted tissue.

  As a reminder, the SOLTIVE Laser System provides preset laser settings options for lithotripsy, soft tissue, and BPH Procedures (Procedure Preset). However, individual treatment should be based on clinical training, clinical observation of laser-tissue interaction, and appropriate clinical endpoints. 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. Please note that users can create and save their own unique treatment parameters as Individual Presets.

- **Spanish and Portuguese GUI Translation Correction:** Olympus is implementing the correction for a separate Field Action pertaining to a Spanish and Portuguese translation error in the SOLTIVE Laser System preset treatment parameters. The term "Bladder Stone" was incorrectly translated in both Spanish and Portuguese to "Kidney Stone" (Cálculo renal) on the systems' Graphical User Interface (GUI). Additional information regarding this Field Action is detailed in the attached communication titled "**Urgent Field Safety Notice QIL FY25-EMEA-12-FY25-008 Soltive GUI**", *which Olympus issued to you in September 2024*. The translation error will be corrected through this software update.

Actions Required:

Our records indicate that your facility has purchased one or more of the affected products. Olympus will contact you to schedule time for an Olympus Field Representative to visit your facility and install the software update. You may continue using your SOLTIVE Laser System until the software update is installed.

Additionally, 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. Olympus's record of the completed software update on your SOLTIVE system(s) will serve as the acknowledgment of this field corrective action for your facility.
5. If you have further distributed this product, identify your customers, and forward them this notification.
6. Following the installation of the software update on your SOLTIVE system(s), ensure all personnel are thoroughly trained on the attached IFU Addendum corresponding with this update. The updated version of the full IFU can be located electronically at *[insert local repository for eIFUs]*. If you would like to receive a physical copy of the updated IFU, please contact *[insert local resource].*

Olympus requests that you report any complaints related to the SOLTIVE Laser System or any associated injuries to *[local facility complaint reporting contact].* Adverse events experienced with the use of this product may also be reported *[local competent authority]* by *[method].*

Olympus fully appreciates your prompt cooperation. If you require additional information, please do not hesitate to contact *[me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX].*

Sincerely,

Name Olympus title

REPLY FORM: QIL FY25-EMEA-30-FY24-OSTA-06-1 Soltive Laser System

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests	

I acknowledge receipt of this notification. I confirm that I have communicated further to any affected departments.

Completed By:		
		Click or tap to enter a date.
Name	*Signature*	*Date (YYYY-MM-DD)*

Please send the completed form to *XXX* by *XX.XX.XXXX*