Date: XX.XX.XXXX

Olympus reference: QIL FY26-EMEA-25-FY26-049 Soltive Power Supply Failure

URGENT FIELD SAFETY NOTICE

RE: OLYMPUS SOLTIVE™ SuperPulsed Laser System

Attention: *Operating Room, Urology Department, Risk Management*

Material ID	Model Number	Material description	Serial Numbers	UDI DI
EGTFL-SLS	TFL-SLS	SOLTIVE Pro SuperPulsed Laser System	See Attachment	00821925044135
EGTFL-PLS	TFL-PLS	SOLTIVE Premium SuperPulsed Laser System		00821925044111
EGTFL-CPLU	TFL-CPLU	TFL Premium Laser Unit		00821925044586
EGTFL-CSLU	TFL-CSLU	TFL Standard Laser Unit		00821925044593

Dear Healthcare Provider:

Olympus is writing to inform you of a Medical Device Corrective Action pertaining to specific Olympus SOLTIVE SuperPulsed Laser System ("SOLTIVE Laser") products, models Pro (TFL-SLS) and Premium (TFL-PLS). SOLTIVE Laser products are 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 has received ninety-eight (98) complaints describing an abrupt loss of power and functionality of the SOLTIVE SuperPulsed Laser System, or an inability to power on the unit. The investigation determined that a potential defect in the 24V power supply module in some SOLTIVE Laser units may cause the system to become inoperable. In some cases smoke or a burning smell may also occur. By design, the issue causing any smoke or burning smell that is detected would be contained within the internal laser console enclosure and would be self-extinguishing.

Of the ninety-eight (98) complaints reported, two (2) were classified as "serious injuries" due to the need to reschedule the procedure after a power failure resulted in the SOLTIVE system becoming inoperable; however, there is no evidence of any patient injury within these two (2) reported incidents. Twenty-four (24) of the complaints, involving a burning smell or smoke and/or a power failure without any patient or user injury, were reported as malfunctions.

Action:

To correct this issue, Olympus will replace the 24V power supply module of the affected SOLTIVE Laser units. You may continue using your SOLTIVE Laser until the service is completed.

Risk to Health:

Potential patient risks associated with a loss of power or functionality of the Soltive Laser System include delays in initiating a procedure, extended procedure times, or the need to reschedule the procedure altogether.

If the issue is identified during device preparation, it may delay the start of the procedure. If the issue occurs during use, it can prolong the procedure. In such cases, the user may elect to replace the device or complete the procedure utilizing alternative systems and/or standard surgical instrumentation. If no backup device or alternative system is available, the physician may need to reschedule the procedure for a later date.

Actions Required:

Our records indicate that your facility has received one or more affected SOLTIVE Laser units. Olympus requests you to take the following actions:

1. Examine your inventory and identify any of the affected devices listed in the attachment.
2. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply Form that you have received and understood this notification by filling out and returning the completed enclosed Reply Form back to your local Olympus representative *XXX latest by XXX.*
3. Starting from April 2026, Olympus representatives will begin contacting customers to coordinate the service of affected unit(s). In the meantime, you may continue using your SOLTIVE Laser until the service is completed.
    a. Olympus will replace the 24V power supply module at no charge to you.
    Note: Any issues beyond the replacement of the 24V module in this corrective action will follow the standard SOLTIVE Laser repair process and your service contract, if applicable.
4. If you have further distributed the affected products, please forward this notice to other users who may be impacted.

[If applicable:] [competent authority] is aware of the actions described in this letter.
Olympus requests that you report any complaints, including failure of the system to start up or operate, smoke, or a burning smell, to *[local facility complaint reporting contact]. [If applicable:]* Adverse events experienced with the use of this product may also be reported *[local competent authority]* by *[method].*

Olympus fully appreciates your prompt cooperation in addressing this situation. 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

Attachment – Affected Serial Numbers

Material description	Material ID	Serial Numbers
SOLTIVE Pro SuperPulsed Laser System	EGTFL-SLS	MDUF220358, MDUF230017, MDUF230072, MDUF230076 MDUF230213, MDUF230241, MDUF230240, MDUF230362
SOLTIVE Premium SuperPulsed Laser System	EGTFL-PLS	MDUF200324, MDUF210030, MDUF220002, MDUF220015, MDUF220005, MDUF220009, MDUF220014, MDUF220011, MDUF220012, MDUF220079, MDUF220078, MDUF220062 MDUF220090, MDUF220093, MDUF220081, MDUF220088 MDUF220092, MDUF220065, MDUF220082, MDUF220086, MDUF220087, MDUF220067, MDUF220091, MDUF220080, MDUF220106, MDUF220115, MDUF220140, MDUF220145, MDUF220137, MDUF220110, MDUF220152, MDUF220149, MDUF220154, MDUF220153, MDUF220147, MDUF220150, MDUF220151, MDUF220226, MDUF220170, MDUF220166, MDUF220180, MDUF220183, MDUF220204, MDUF220179, MDUF220193, MDUF220199, MDUF220217, MDUF220230, MDUF220232, MDUF220233, MDUF220234, MDUF220219, MDUF220223, MDUF220225, MDUF220185, MDUF220192, MDUF220213, MDUF220164, MDUF220156, MDUF220235, MDUF220280, MDUF220266, MDUF220308, MDUF220297, MDUF220341, MDUF220312, MDUF220337, MDUF220379, MDUF220380, MDUF220377, MDUF220442, MDUF220482, MDUF220441, MDUF220466, MDUF220456, MDUF220511, MDUF220517, MDUF220519, MDUF220508, MDUF220543, MDUF220524, MDUF220530, MDUF220546, MDUF220559, MDUF220551, MDUF220537, MDUF220545, MDUF220550, MDUF220557, MDUF220573, MDUF220578, MDUF230003, MDUF230037, MDUF230040, MDUF230088, MDUF230091, MDUF230097, MDUF230021, MDUF230036, MDUF230049, MDUF220541, MDUF220296, MDUF230202, MDUF230204, MDUF230216, MDUF230229, MDUF230246, MDUF230260, MDUF230264, MDUF230253, MDUF230301, MDUF230293, MDUF230302, MDUF230309, MDUF230316, MDUF230349, MDUF230288, MDUF230311, MDUF230347, MDUF230330, MDUF230359, MDUF230383, MDUF230376, MDUF230387, MDUF230396, MDUF230423, MDUF230424, MDUF230427, MDUF230404, MDUF230410, MDUF230222, MDUF230234, MDUF230261, MDUF230267, MDUF230268, MDUF230280, MDUF230226, MDUF230184, MDUF230200, MDUF230259, MDUF230262, MDUF230250, MDUF220252, MDUF220295, MDUF220320, MDUF220231, MDUF220285, MDUF220288,

Material description	Material ID	Serial Numbers
		MDUF220303, MDUF220306, MDUF220323, MDUF220328, MDUF220326, MDUF220331, MDUF220339, MDUF220340, MDUF220344, MDUF220368, MDUF230163, MDUF230167, MDUF230428, MDUF230400, MDUF240006, MDUF230388, MDUF240004, MDUF240005, MDUF240024, MDUF240025, MDUF240028, MDUF240018, MDUF230389

REPLY FORM: QIL FY26-EMEA-25-FY26-049 Soltive Power Supply Failure

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests (Indicate if you have any additional requests to support this action)	

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*