Date: XX.XX.XXXX
Olympus reference: QIL FY24-EMEA-39-FY24-OSTA-13-Soltive Power Cords

# 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 HealthCare Provider:

Olympus (Gyrus ACMI, Inc.) is writing to inform you of a field correction for the Soltive SuperPulsed Laser System to ensure that an appropriate power cord is installed with the laser system. 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 is conducting this field corrective action after learning internally that we may have supplied non-compliant power cords for use with the Soltive Laser. To address this situation, an Olympus representative will conduct an inspection of your Soltive Laser power cord and replace any non-compliant power cords at no charge to you. To continue using your Soltive Laser System until an Olympus representative performs the power cord inspection, we ask that your Biomedical Department, or other qualified personnel, confirm that the installed power cord meets the specifications detailed below. If you confirm your power cord does not meet the specifications, you are unable to confirm, or you have questions regarding the specifications, quarantine your Soltive Laser System and contact Olympus **[Regional contact]** to receive additional guidance and/or to schedule an immediate on-site inspection as indicated in step 4 on the next page of this letter.

- C19 Female Connector (locking mechanism is not a requirement)
- Plug, specific to country requirements
- Cable, approximately 15’ in length, meeting the following specifications:

| Component/ Part No. | Manufacturer/Trademark | Type No./model No./ | Technical data | Standard No./, Edition | Mark(s) & Certificates of conformity[1)] |
|---|---|---|---|---|---|
| Power Cord, Straight Connector (International) | Quail Electronics, Inc. (Interchangeable) | 8504.180AL (Interchangeable) | 1.5mmCu²x3, H05VV-F, 16A, 250V, IEC60320 connector | EN 50525-2-11 IEC 60320 | VDE, TUV |

**Risk To Health**:

Olympus has received a total of five (5) complaints where the use of a power cord could have potentially contributed to the event. One (1) of these complaints, in which the procedure was cancelled, was reported as a serious injury and one (1) of these complaints was reported as a malfunction.
If the power cord used for the Soltive Laser device is non-compliant it may affect the performance of the device. Potential harms that may be associated with the use of a non-compatible power cord include burns or electrical shock to the user, or prolonged surgeries/cancellation of procedures.

## Action steps to be taken by the end user:

Olympus has determined based upon our installation records that your facility may be in possession of an affected Soltive Laser System. Olympus requires that you take the following actions:

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.
3. Confirm that the installed power cord meets the specifications detailed in this letter via your Biomedical Department or other appropriate personnel. You may continue using your Soltive Laser System after confirming the specifications of the power cord.
4. If you have questions regarding the specifications of the power cord, are unable to confirm the specifications, or if you identify that the cord does not meet the specifications, quarantine your Soltive Laser System and contact Olympus **[Regional contact]** to receive additional guidance and/or to schedule an immediate on-site inspection.
5. Olympus Service will reach out to you to schedule an on-site service to inspect the power cord. If the power cord is found to be non-compliant, it will be replaced at no cost to you.
6. 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.
7. 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-39-FY24-OSTA-13-Soltive Power Cords**

| **OLYMPUS URGENT FIELD SAFETY NOTICE**<br>**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 _____

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