

**URGENT: MEDICAL DEVICE CORRECTION****OLYMPUS SOLTIVE™ SuperPulsed Laser System**

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

Date: 27-FEB-2026

Attention: Operating Room, Urology Department, Risk Management

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 through our recall web portal:
  - a. Go to <https://olympusamerica.com/recall>
  - b. Enter the recall number: "0494"
  - c. Complete the form as instructed.
3. Olympus representatives will begin contacting customers to coordinate on-site repairs of affected unit(s) at a mutually convenient time. 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.

Olympus requests you to report any complaints, including failure of the system to start up or operate, smoke, or a burning smell, to our Technical Assistance Center (TAC) at 1- 800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly by phone at (647) 999-3203 or by e-mail [Cynthia.Ow@Olympus.com](mailto:Cynthia.Ow@Olympus.com).

Sincerely,

*Cynthia Ow*

Cynthia Ow  
Field Corrective Actions Lead, Americas

**URGENT: MEDICAL DEVICE CORRECTION**  
OLYMPUS SOLTIVE™ SuperPulsed Laser System  
Attachment – Affected Serial Numbers

**TFL PREMIUM LASER SYSTEM - TFL-PLS**

Serial Number	Serial Number	Serial Number	Serial Number	Serial Number
MDUF190072	MDUF220061	MDUF220167	MDUF220259	MDUF220366
MDUF210204	MDUF220063	MDUF220169	MDUF220262	MDUF220367
MDUF220008	MDUF220066	MDUF220171	MDUF220267	MDUF220371
MDUF220010	MDUF220073	MDUF220173	MDUF220273	MDUF220382
MDUF220017	MDUF220085	MDUF220174	MDUF220278	MDUF220384
MDUF220018	MDUF220096	MDUF220175	MDUF220281	MDUF220391
MDUF220021	MDUF220097	MDUF220176	MDUF220286	MDUF220394
MDUF220022	MDUF220100	MDUF220178	MDUF220287	MDUF220402
MDUF220024	MDUF220104	MDUF220182	MDUF220289	MDUF220406
MDUF220026	MDUF220109	MDUF220184	MDUF220293	MDUF220407
MDUF220027	MDUF220111	MDUF220186	MDUF220294	MDUF220429
MDUF220028	MDUF220113	MDUF220187	MDUF220298	MDUF220432
MDUF220029	MDUF220114	MDUF220189	MDUF220302	MDUF220435
MDUF220033	MDUF220116	MDUF220190	MDUF220304	MDUF220436
MDUF220034	MDUF220117	MDUF220191	MDUF220307	MDUF220437
MDUF220035	MDUF220118	MDUF220194	MDUF220310	MDUF220438
MDUF220036	MDUF220120	MDUF220201	MDUF220315	MDUF220439
MDUF220038	MDUF220123	MDUF220203	MDUF220322	MDUF220440
MDUF220042	MDUF220126	MDUF220206	MDUF220324	MDUF220444
MDUF220044	MDUF220127	MDUF220208	MDUF220327	MDUF220447
MDUF220045	MDUF220128	MDUF220209	MDUF220329	MDUF220448
MDUF220048	MDUF220130	MDUF220210	MDUF220332	MDUF220449
MDUF220049	MDUF220133	MDUF220211	MDUF220334	MDUF220450
MDUF220050	MDUF220135	MDUF220216	MDUF220335	MDUF220451
MDUF220051	MDUF220138	MDUF220229	MDUF220336	MDUF220453
MDUF220052	MDUF220141	MDUF220240	MDUF220338	MDUF220454
MDUF220053	MDUF220144	MDUF220242	MDUF220342	MDUF220455
MDUF220054	MDUF220146	MDUF220243	MDUF220345	MDUF220458
MDUF220055	MDUF220158	MDUF220245	MDUF220346	MDUF220464
MDUF220056	MDUF220159	MDUF220249	MDUF220349	MDUF220465
MDUF220057	MDUF220161	MDUF220253	MDUF220350	MDUF220468
MDUF220058	MDUF220162	MDUF220254	MDUF220360	MDUF220473
MDUF220060	MDUF220165	MDUF220258	MDUF220364	MDUF220476

**TFL PREMIUM LASER SYSTEM - TFL-PLS**

Serial Number	Serial Number	Serial Number	Serial Number	Serial Number
MDUF220483	MDUF230022	MDUF230109	MDUF230177	MDUF230263
MDUF220484	MDUF230023	MDUF230110	MDUF230179	MDUF230266
MDUF220485	MDUF230024	MDUF230112	MDUF230180	MDUF230269
MDUF220509	MDUF230028	MDUF230116	MDUF230181	MDUF230270
MDUF220513	MDUF230030	MDUF230117	MDUF230182	MDUF230273
MDUF220515	MDUF230031	MDUF230118	MDUF230185	MDUF230274
MDUF220516	MDUF230032	MDUF230119	MDUF230186	MDUF230275
MDUF220518	MDUF230034	MDUF230120	MDUF230189	MDUF230276
MDUF220521	MDUF230038	MDUF230122	MDUF230191	MDUF230277
MDUF220531	MDUF230039	MDUF230123	MDUF230192	MDUF230278
MDUF220532	MDUF230041	MDUF230125	MDUF230193	MDUF230281
MDUF220552	MDUF230045	MDUF230128	MDUF230194	MDUF230282
MDUF220554	MDUF230046	MDUF230130	MDUF230195	MDUF230284
MDUF220556	MDUF230048	MDUF230133	MDUF230198	MDUF230290
MDUF220563	MDUF230053	MDUF230134	MDUF230199	MDUF230292
MDUF220564	MDUF230056	MDUF230137	MDUF230207	MDUF230296
MDUF220565	MDUF230057	MDUF230139	MDUF230209	MDUF230298
MDUF220570	MDUF230060	MDUF230140	MDUF230210	MDUF230299
MDUF220571	MDUF230061	MDUF230141	MDUF230211	MDUF230304
MDUF220572	MDUF230065	MDUF230142	MDUF230215	MDUF230305
MDUF220574	MDUF230067	MDUF230143	MDUF230219	MDUF230306
MDUF220575	MDUF230069	MDUF230146	MDUF230221	MDUF230308
MDUF220576	MDUF230070	MDUF230148	MDUF230223	MDUF230317
MDUF220581	MDUF230079	MDUF230151	MDUF230227	MDUF230318
MDUF220582	MDUF230084	MDUF230152	MDUF230231	MDUF230319
MDUF220584	MDUF230085	MDUF230153	MDUF230232	MDUF230325
MDUF220588	MDUF230086	MDUF230154	MDUF230236	MDUF230326
MDUF230004	MDUF230092	MDUF230156	MDUF230242	MDUF230327
MDUF230005	MDUF230095	MDUF230157	MDUF230243	MDUF230328
MDUF230008	MDUF230096	MDUF230162	MDUF230245	MDUF230331
MDUF230010	MDUF230098	MDUF230165	MDUF230248	MDUF230333
MDUF230011	MDUF230101	MDUF230166	MDUF230251	MDUF230334
MDUF230012	MDUF230103	MDUF230168	MDUF230252	MDUF230335
MDUF230014	MDUF230104	MDUF230170	MDUF230255	MDUF230337
MDUF230015	MDUF230105	MDUF230171	MDUF230256	MDUF230338
MDUF230019	MDUF230106	MDUF230172	MDUF230257	MDUF230339
MDUF230020	MDUF230108	MDUF230174	MDUF230258	MDUF230341

**TFL PREMIUM LASER SYSTEM - TFL-PLS**

Serial Number	Serial Number	Serial Number	Serial Number	Serial Number
MDUF230342	MDUF230370	MDUF230394	MDUF230431	MDUF240015
MDUF230343	MDUF230371	MDUF230395	MDUF230432	MDUF240016
MDUF230344	MDUF230373	MDUF230398	MDUF230433	MDUF240017
MDUF230346	MDUF230375	MDUF230402	MDUF230434	MDUF240019
MDUF230350	MDUF230377	MDUF230406	MDUF230437	MDUF240020
MDUF230351	MDUF230379	MDUF230409	MDUF230438	MDUF240022
MDUF230353	MDUF230380	MDUF230411	MDUF240002	MDUF240026
MDUF230354	MDUF230382	MDUF230417	MDUF240007	MDUF240027
MDUF230355	MDUF230384	MDUF230418	MDUF240009	MDUF240030
MDUF230357	MDUF230385	MDUF230419	MDUF240010	MDUF240031
MDUF230360	MDUF230390	MDUF230420	MDUF240012	
MDUF230369	MDUF230392	MDUF230426	MDUF240013	

**TFL STANDARD LASER SYSTEM - TFL-SLS**

Serial Number	Serial Number
MDUF190114	MDUF220492
MDUF220353	MDUF220494
MDUF220354	MDUF220497
MDUF220359	MDUF220498
MDUF220414	MDUF220500
MDUF220415	MDUF220501
MDUF220418	MDUF220505
MDUF220419	MDUF220506
MDUF220420	MDUF230074
MDUF220421	MDUF230075
MDUF220423	MDUF230144
MDUF220424	MDUF230239
MDUF220425	MDUF230320
MDUF220426	MDUF230363
MDUF220427	MDUF230364
MDUF220428	MDUF230413