

URGENT: MEDICAL DEVICE CORRECTION**ShockPulse Lithotripsy System**

Product Name	Model Number	Serial Numbers	UDI DI
ShockPulse Lithotripsy Generator	SPL-G	Refer to Attachment	00821925044203
ShockPulse-SE Lithotripsy System – Single-Use Probes	SPL-S	Refer to Attachment	00821925044197

Date: 08-JAN-2026

Attention: Urology, Operating Room, Risk Management

Dear Healthcare Provider:

Olympus is writing to inform you of a Medical Device Correction pertaining to the ShockPulse-SE Lithotripsy Systems (SPL-S), which include the ShockPulse Lithotripsy Generator (SPL-G). The ShockPulse-SE Lithotripsy System is intended to be used for fragmentation of urinary tract calculi in the kidney, ureter, and bladder.

Reason for Action:

Olympus discovered through an internal investigation that specific serial numbers of ShockPulse generators may have a mis-wired component. This condition does not impact the intended functionality of the device; however, the miswiring may introduce additional electrical noise on the power supply output. The presence of noise on the ultrasonic input circuit is not compliant with applicable electromagnetic compatibility (EMC) standards and may adversely affect the overall reliability of the system.

Risk to Health:

In the unlikely event that the ShockPulse Lithotripsy generator's output becomes reduced, inconsistent, or ceases entirely, there is a potential for procedural delays while troubleshooting or replacing the generator. If a replacement unit is not immediately available, the procedure may need to be canceled and rescheduled.

Olympus has not received any complaints or reports of serious injury associated with this matter.

Actions Required:

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

1. Examine your inventory and identify any affected devices with the serial number(s) listed in the Attachment.
2. Please contact Customer Service at 1-800-848-9024, option 2, to obtain a Return Material Authorization. Olympus will arrange for the return of your device to our Repair Center. Olympus will repair the affected part at no charge and return the device back to you.
3. 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: "0485"
 - c. Complete the form as instructed.

5. If you have further distributed the affected products, please forward this notification to other users who may have them.

Olympus requests you to report any complaints related to the ShockPulse device 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 by phone at (647) 999-3203 or by email at Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
Sr. Manager
Field Corrective Action, Americas

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ShockPulse Lithotripsy System

Attachment – Affected Serial Numbers (US Distribution)

ShockPulse System Model Number	ShockPulse Generator Model Number	Serial Number
SPL-S	SPL-G	DG0137
SPL-S	SPL-G	CG5084
SPL-S	SPL-G	CG5097
SPL-S	SPL-G	CG5022
SPL-S	SPL-G	CG5023
SPL-S	SPL-G	CG5025
SPL-S	SPL-G	CG5021
SPL-S	SPL-G	CG7007
SPL-S	SPL-G	CG7009
SPL-S	SPL-G	CG7010
SPL-S	SPL-G	CG7008
SPL-S	SPL-G	CG7006
SPL-S	SPL-G	CG7005
SPL-S	SPL-G	CG6087
SPL-S	SPL-G	CG6085