

URGENT: FIELD SAFETY NOTICE**RE:** ShockPulse Lithotripsy System**Attention:** Operating Room, Urology, Risk Management

Catalogue Number	Model Number	Product Name	Serial Numbers	UDI DI
EGSPL-G	SPL-G	ShockPulse Lithotripsy Generator	Refer to Attachment	00821925044203
EGSPL-SR	SPL-SR	ShockPulse-SE Lithotripsy System	Refer to Attachment	00821925043824

Dear Healthcare Provider:

Olympus is writing to inform you of a Field Corrective Action pertaining to the ShockPulse-SE Lithotripsy System SPL-SR, which includes 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. Olympus representative will reach out to you to arrange a mutually convenient time 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. 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*.
4. If you have further distributed the affected products, please forward this notification to other users who may have them.

[If applicable:] [competent authority] is aware of the actions described in this letter.

Olympus requests that you report any complaints related to the ShockPulse device 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

URGENT FIELD SAFETY NOTICE

Attachment – Affected Serial Numbers

ShockPulse System Model Number	ShockPulse Generator Model Number	Serial Numbers
SPL-SR	SPL-G	CG6037
SPL-SR	SPL-G	CG6061
SPL-SR	SPL-G	CG6071
SPL-SR	SPL-G	CG5040
SPL-SR	SPL-G	CG5037
SPL-SR	SPL-G	CG5039
SPL-SR	SPL-G	CG5028
SPL-SR	SPL-G	CG5033
SPL-SR	SPL-G	CG5032
SPL-SR	SPL-G	CG5030
SPL-SR	SPL-G	CG5036
SPL-SR	SPL-G	CG5034
SPL-SR	SPL-G	CG5027
SPL-SR	SPL-G	CG5062
SPL-SR	SPL-G	CG5066
SPL-SR	SPL-G	CG5065
SPL-SR	SPL-G	CG5060
SPL-SR	SPL-G	CG5057
SPL-SR	SPL-G	CG5055
SPL-SR	SPL-G	CG5056
SPL-SR	SPL-G	CG5050
SPL-SR	SPL-G	CG5051
SPL-SR	SPL-G	CG5052
SPL-SR	SPL-G	CG5053
SPL-SR	SPL-G	CG5054
SPL-SR	SPL-G	CG5049
SPL-SR	SPL-G	CG6096
SPL-SR	SPL-G	CG6094
SPL-SR	SPL-G	CG6088
SPL-SR	SPL-G	CG6070

REPLY FORM – QIL FY26-EMEA-18-FY23-OSTA-05-1 ShockPulse Mis-Wiring

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 further communicated to any affected departments.

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

Please send the completed form to XXX by date XXX.