Reference: 2025-011M

30 December 2025

URGENT - FIELD SAFETY NOTICE

To all users of **Olympus** Shockpulse Lithotripsy System

Product Name	Model Number	Serial Numbers
ShockPulse-SE Lithotripsy System – Reusable Probes	SPL-SR	CG5043, CG5061, CG5045, CG5031, CG5041, CG5042, CG5059, CG6097, CG7002

Re: Olympus to Repair the Miswiring.

Attention: Operating Room, Urology, Risk Management

Dear Healthcare Provider:

Olympus is writing to inform you of a Field Corrective Action pertaining to the ShockPulse-SE Lithotripsy Systems (SPL-S or SPL-SR), 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.

OIympus 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 of the affected units.
Therefore, Olympus require you to take the following actions:

1. Examine your inventory and identify any affected devices with the serial number(s) listed in the Table.
2. Olympus representative will contact you to make arrangement to return your device. 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 and return the 'Response Form' to us.
4. If you have further distributed this product, identify them and forward this notification.

Olympus requests that you report any complaints related to the Shockpulse device and adverse events experienced with the use of this product to Olympus.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact us.

Contact for enquiries.
Regulatory Affairs and Quality Assurance Department
Email : mes-ra.oml@olympus.com
Tel : (603) 7650 8990
Fax : (603) 7650 8999

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

Hideki Nagai
Hideki Nagai (Dec 30, 2025 12:55:12 GMT+8)

Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd

Response Form

Please send the complete and signed Response Form to Regulatory Affairs and Quality Assurance Department at:

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs & Quality Assurance
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.:_____
Date : _____
Ref : 2025-011M

URGENT - FIELD SAFETY NOTICE

Re: Olympus to Repair the Miswiring.

I acknowledge receipt of the Field Safety Notice ("FSN") referenced above. I confirm that I have further communicated to any affected departments.

Check the applicable boxes below:

☐ I DO NOT have affected product remaining. Product has been condemned or discarded.

☐ I DO have the affected product, which I will adhere to this FSN letter.

Additional Customer Requests:

(Indicate if you have any additional requests to support this action)

Name: _____

Designation: _____

……..…… ……..…….....

Signature & Company Stamp Date

2025-011M FSN Customer Letter (1)

Final Audit Report 2025-12-30

Created:	2025-12-30 (Korean Standard Time)
By:	Rohaya Binti Asib (rohaya.asib@olympus.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAeV7zdoXKcgmxcYiLrNN89QD2LJEzkztt

"2025-011M FSN Customer Letter (1)" History

Document created by Rohaya Binti Asib (rohaya.asib@olympus.com)
2025-12-30 - 12:28:39 PM GMT+9- IP address: 136.226.234.96

Document emailed to Hideki Nagai (hideki.nagai@olympus.com) for signature
2025-12-30 - 12:29:40 PM GMT+9

Email viewed by Hideki Nagai (hideki.nagai@olympus.com)
2025-12-30 - 1:54:06 PM GMT+9- IP address: 104.47.51.126

Document e-signed by Hideki Nagai (hideki.nagai@olympus.com)
Signature Date: 2025-12-30 - 1:55:12 PM GMT+9 - Time Source: server- IP address: 136.226.234.96

Agreement completed.
2025-12-30 - 1:55:12 PM GMT+9