Reference: 2025-005M

14 October 2025

URGENT - FIELD SAFETY NOTICE

To all users of **Olympus ShockPulse Lithotripsy Transducer**

Product Name	Model/Catalog Number	Serial Number(s)
ShockPulse Lithotripsy Transducer	SPL-T	All

Re: Olympus to Reinforce the IFU.

Attention: **Operating Room Manager, Urology, Risk Management**

Dear Health Care Professional:

Olympus is writing to inform you of a Field Safety Notice relating to the ShockPulse Lithotripsy Transducer (SPL-T). The ShockPulse Lithotripsy Transducer is part of the ShockPulse-SE Lithotripsy System (SPL-S or SPL-SR) which is intended for fragmentation of urinary tract calculi in the kidney, ureter, and bladder.

Reason for Action:
Olympus received customer feedback that the ShockPulse Lithotripsy Transducer may either fail to start up, or the transducer may start briefly and then stop, accompanied by an error light on the generator. In addition, the body of the transducer handpiece may gradually increase in temperature during clinical use. The investigation has shown that the transducer may fail in the field before reaching its expected 100 reprocessing cycles.

While Olympus continues its investigation into this issue, users are reminded of the importance of **ensuring that a back-up transducer and probe are sterilized and available prior to beginning a procedure** (refer to the Cautions section in the IFU), to ensure continuity of care.

Olympus received one reported serious injury which occurred intraoperatively during use due to inconsistent transducer energy delivery. The user completed the procedure with the same device, resulting in a 45-minute procedural delay. There is no evidence of additional patient harm in this reported incident.

Risk to Health:
Potential patient risks that may occur in the event of a transducer loss of power, intermittent functionality, or decreased performance include delays in starting a procedure prolonged procedures, or a requirement to reschedule procedures. Additionally, the user may experience a temporary thermal sensation if the temperature of the transducer handpiece increases due to the malfunction. This sensation is generally transient; however, it may be noticeable during handling and in extremely rare cases may result in redness, pain, or swelling that does not require medical treatment.

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
Unit T2-L05-1, PJ33, No. 3, Jalan Professor Khoo Kay Kim, Section 13, 46200 Petaling Jaya, Selangor, Malaysia
Tel: (603) 7650 8990 Fax: (603) 7650 8999

Actions Required:
Our records indicate that your facility has purchased one or more of the affected products. **Therefore, Olympus requests you to take the following actions:**

1. Carefully read the content of this Field Safety Notice.
2. Ensure all personnel are completely knowledgeable on the content of this notification. This is not a product removal action. You may continue to use the device according to the instruction for use, which cautions users to **ensure that a back-up transducer and probe are sterilized and available prior to beginning a procedure**.
3. If you have further distributed this product, identify your customers and forward them this notification.
4. Olympus requests that you acknowledge receipt of this letter and return the 'Response Form' to us.

Olympus requests that you report any complaints, including device failure 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
Managing Director
Olympus (Malaysia) Sdn. Bhd

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Tel: (603) 7650 8990 Fax: (603) 7650 8999

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 : 2025-005M

URGENT - FIELD SAFETY NOTICE

Re: Olympus to Reinforce the IFU.

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

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
Unit T2-L05-1, PJ33, No. 3, Jalan Professor Khoo Kay Kim, Section 13, 46200 Petaling Jaya, Selangor, Malaysia
Tel: (603) 7650 8990 Fax: (603) 7650 8999

2025-005M FSN Customer Letter

Final Audit Report 2025-10-14

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