Reference: 2025-009M

17 December 2025

URGENT - FIELD SAFETY NOTICE

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

Product Name	Model Number	Serial Numbers
ShockPulse Lithotripsy Transducer	SPL-T	All
ShockPulse-SE Lithotripsy System – Reusable Probes	SPL-SR	All

Re: Olympus to Provide Supplemental Guidance.

Attention: Operating Room, Urology, Risk Management

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

Background:
Olympus recently informed you through a Field Safety Notice, dated 14 October 2025, of complaints received for the ShockPulse Lithotripsy Transducer either failing to start up, or the transducer starting up briefly and then stopping, 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 indicated that the transducer may fail in the field before reaching its expected 100 reprocessing cycles.

Reason for Update:
Olympus' investigation has additionally identified instances of the ShockPulse Generator remaining in a blinking phase waiting to recognize the transducer. Assessment of complaints has determined that damage to the transducer plug and/or to the generator receptacle may cause the ShockPulse Transducer to not startup, the ShockPulse Generator to display an error light, and of the ShockPulse Generator to not recognize the transducer.

Since June 2021, Olympus has received reports of six (6) serious injuries for prolonged procedures resulting from the ShockPulse device not working or working inconsistently.

Due to the potential for these issues to impact the functionality of the ShockPulse Transducer, it is increasingly important that a back-up transducer and probe are sterilized and available prior to beginning a procedure.

Olympus continues to investigate these issues and potential mitigations. Olympus will communicate the outcome to customers in subsequent communication. In the interim, the following supplemental guidance has been developed to assist users in preventing and identifying damage to the ShockPulse Transducer.

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

Supplemental Guidance:

<table>
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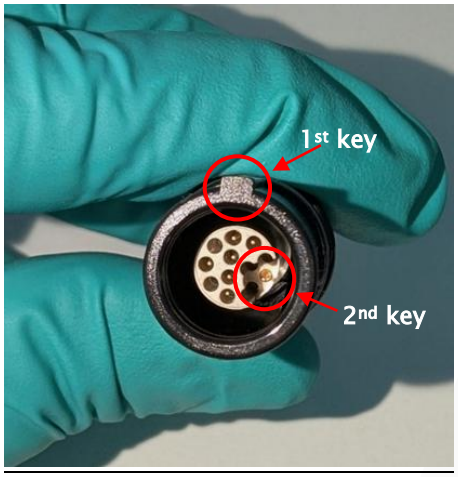
<td> 
</td>
<td><u>Transducer Plug Configuration:</u>
• 7 pins
• Double-keyed
○ 1st key (“key way”): Square feature on top
○ 2nd key: Round recessed pin on bottom right
<u>Inspection Criteria:</u>
• Correct orientation of keying features (as shown in picture)
• No lint, debris, or moisture present
• Pins are straight (not bent)
• No cracks or physical damage</td>
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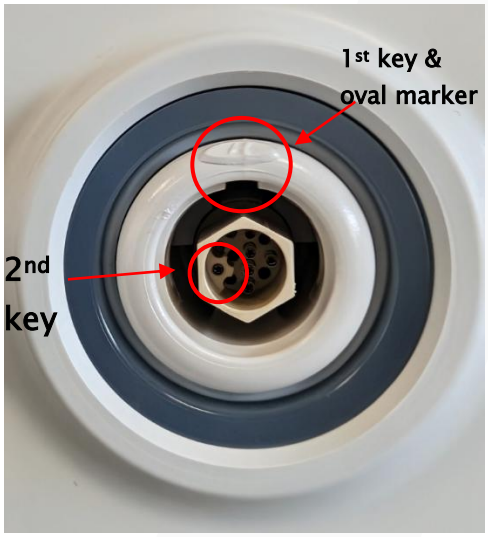
<td> 
</td>
<td><u>Generator Transducer receptacle Configuration:</u>
• 7 pin terminals
• Double keyed:
○ 1st key (“key way slot”): Square feature centered at top. The white oval marker on the outer ring indicates the location of the square.
○ 2nd key: Round pedestal terminal on bottom left.
<u>Inspection Criteria:</u>
• Correct orientation of keying features (as shown in picture)
• No lint, debris, or moisture present
• Pin terminals are round (not bent)
• No cracks or physical damage</td>
</tr>
</table>

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Steps to plug the Transducer into the Generator (per the "Assembling the Unit" section of the ShockPulse-SE Lithotripsy System (SPL-S, SPL-SR) IFU):

Connect the transducer to generator by aligning key way of the transducer connector with the key way slot on the transducer receptacle on the front panel. Push straight in. CAUTION: Do not twist or turn the plug.

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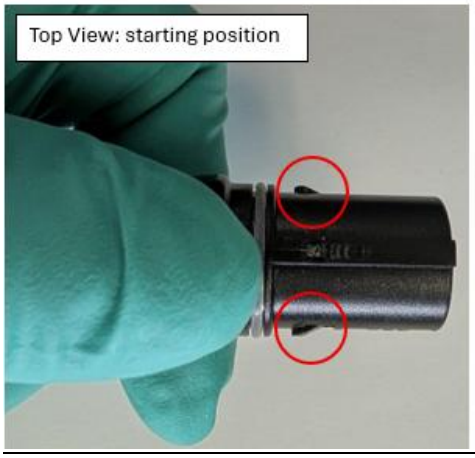

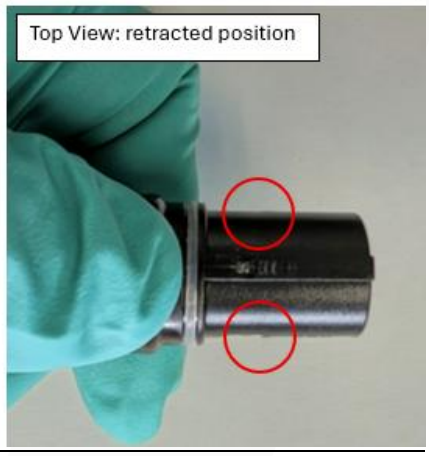

Steps to remove the Transducer from the Generator:

Position Your Hand:

- Place your thumb on the top finger groove of the transducer plug.
- Place your index finger on the bottom groove of the plug.
- Support the proximal end of the plug with the palm of your hand.

Grip the Outer Sleeve:

- Squeeze the outer plug sleeve between your thumb and index finger ("1" in picture).

Pull Toward You:

- While maintaining the grip, pull the outer sleeve toward you to release the locking mechanism ("2" in picture).

Remove the Plug:

Once unlocked, gently remove the plug from the generator.

CAUTION: Do not twist or turn the plug.

As a reminder, the following Cautions listed in the "Warnings and Cautions" section of the ShockPulse-SE Lithotripsy System (SPL-SR) Instructions for Use should be followed:

CAUTION: A back-up transducer and probe should be sterilized and available prior to beginning a procedure.

CAUTION: Do not twist or turn the transducer or footswitch plugs when connecting them to the generator; equipment damage may result.

If damage to the transducer plug, including the pins, is identified, cease use of the damaged transducer and utilize the back-up transducer. Contact Olympus to initiate the return of your damaged device for complaint investigation.

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If damage to the generator transducer receptacle, including the pin terminals, is identified, cease use of the generator. Contact Olympus to initiate return of your generator for repair.

Risk to Health:
Potential patient risks that may occur in the event of a transducer loss of power, intermittent functionality, decreased performance, and/or a damaged transducer plug or generator receptacle 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.

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

1. Carefully read the content of this notification. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this notification, including new Supplemental Guidance.
2. Add a copy of this letter with the Supplemental Guidance to your existing Instruction for Use. You may continue to use the device according to this letter and 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 them and forward 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 failure of the ShockPulse transducer to function 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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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 : 2025-009M

URGENT - FIELD SAFETY NOTICE

Re: Olympus to Provide Supplemental Guidance.

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

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2025-009M FSN Customer Letter

Final Audit Report 2025-12-16

Created:	2025-12-16 (Korean Standard Time)
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