Date: XX.XX.XXXX

**Olympus reference: QIL FY26-EMEA-09-FY26-010 ShockPulse Lithotripsy Transducer**

# URGENT FIELD SAFETY NOTICE

**RE: ShockPulse Lithotripsy Transducer**

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

| Material ID | Model Number | Material Description | Serial Number(s) | UDI-DI |
|---|---|---|---|---|
| EGSPL-T | SPL-T | ShockPulse SE Transducer | All | 00821925043831 |
| EGSPL-SR | SPL-SR | ShockPulse SE Lithotriptor | | 00821925043824 |

Dear Healthcare Professional/Provider:

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-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.

**Actions Required:**

Our records indicate that your facility has purchased one or more of the affected products. Therefore, Olympus requires 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. 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.

Your competent authority is aware of the actions described in this letter. Olympus requests that you report any complaints, including device failure, to [local facility complaint reporting contact]. Adverse events experienced with the use of this product may also be reported to your local competent authority.

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

## REPLY FORM: QIL FY26-EMEA-09-FY26-010 ShockPulse Lithotripsy Transducer

| | |
|---|---|
| **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. |
| *Name* | *Signature* | *Date (YYYY-MM-DD)* |

Please send the completed form to *XXX* by date *XXX*.