Olympus Reference: FY26-067-F Correction of Mislabeled POWERSEAL
Date: 18.08.2026

URGENT FIELD SAFETY NOTICE

RE: OLYMPUS POWERSEAL
Attention: Endoscopy Department, Operating Room, Risk Management

Material ID	Model	Description	UDI	Lot Number
EGPS-0523CJDA	PS-523CJDA	POWERSEAL 5 MM (in diameter) 23 CM (long) Curved Jaw Sealer & Divider, Double Action	00821925044531	FR490902

Dear Healthcare Professional /Provider:

Olympus is writing to inform you of a Field Safety Notice related to the POWERSEAL 5-mm diameter x 23-cm long Curved Jaw, Double Action Sealer & Divider. These products are intended for use in laparoscopic/minimally invasive or open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics are desired. POWERSEAL devices can be used on vessels (arteries, veins, pulmonary arteries, pulmonary veins) up to and including 7 mm, lymphatics, and tissue bundles.

Reason for Action:

Olympus determined that the affected lot listed above may contain a labelling discrepancy. Specifically, affected units were packaged in an outer shelf box printed for a 37-cm device (see Figure 1) versus an outer shelf box printed for a 23-cm device. However, other labelling on the outer shelf box, as well as the device and product cord label correctly identify the product as the 23-cm device. The discrepancy between the printed box and the attached labelling may result in customer confusion.

All devices contained within Lot FR490902 are the correct 23-cm length. This issue is limited to the outer shelf box and does not affect the device, its performance, quality, or safety. The correct length of 23 cm is shown in the innermost packaging.
There were 2 complaints related to this issue, and no serious injuries were reported.
If you have the affected lot number, please refer to the “Actions Required” section.

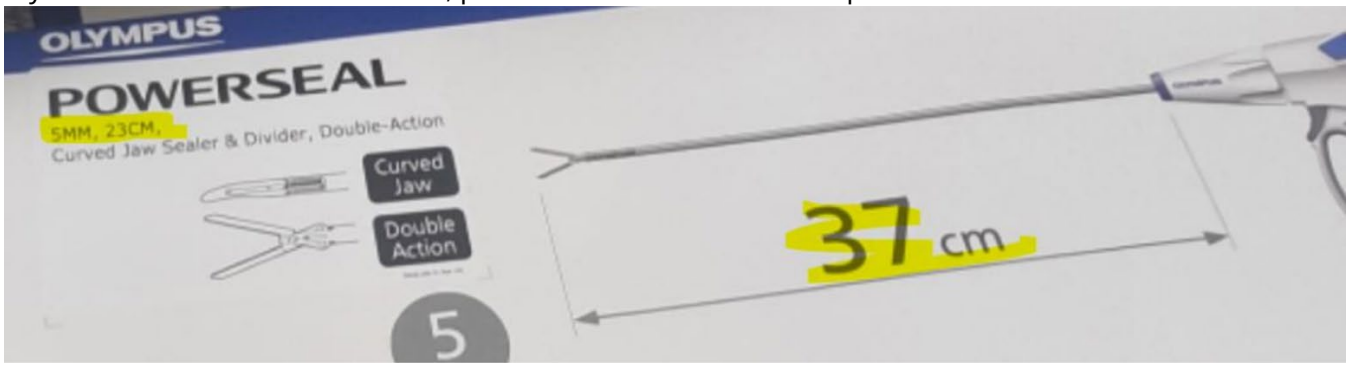

Figure 1. Detailed view of the discrepancy between sticker label (upper left, 23cm) and the incorrect printed label (indicating 37 cm) on the outer shelf box.

Figure 2: Image of product label device in the inner packaging showing the lot numbers and correct device length of 23cm

Risk to Health:

Potential patient risks associated with the packaging/labeling discrepancy include a delay in initiating treatment or prolongation of the procedure. If identified during procedural set-up, the clinician may need to replace the device before use, resulting in a delay to the start of the procedure. If identified during the procedure, the clinician may need to obtain the correct device or an alternative device, which could prolong the procedure.

This discrepancy can also be identified before patient involvement during initial receipt of product and/or during inventory checks. In these situations, the affected product can be removed from use without impacting patient care. In these cases, there are no health consequences or impact to a patient.

Actions to be taken by the end user:

Our records indicate that your facility has purchased one or more of the products from the affected Lot (FR490902). Therefore, Olympus requires you to take the following actions:

1. Carefully read the contents of this letter.

2. Review your inventory for affected lot numbers. If you have the affected lot number, please discard the outer box and attach this letter to the inner device packaging.

3. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this notification. This is not a product removal action. You may continue to use the device as per this letter and the instructions for use.

4. Check the sterile packaging and device label before use to ensure you are using the correct length for your procedure.
5. If you have further distributed this product, identify your customers, and forward them this notification.
6. 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.

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

Olympus requests that you report complaints, including any injuries during use of the Powerseal, 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]
We appreciate your cooperation in addressing this matter. Our goal is always to ensure patient safety while minimizing disruption to patient care. If you require additional information or have any concerns, please do not hesitate to contact me at [phone number] or [e-mail address].
Sincerely,

REPLY FORM FY26-067-F Correction of Mislabeled POWERSEAL

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests (Indicate if you have any additional requests to support this action)	

Insert description of the product names, lot numbers and quantity of the affected products remaining in your facility

Catalogue Number	**Lot Number**	**Quantity**

I acknowledge receipt of this notification. I confirm that I have communicated further 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 XX.XX.XXXX*