April 2, 2024

URGENT: MEDICAL DEVICE REMOVAL

Name: Powerseal Sealer & Divider
Model: PS-0544CJDA, PS-0537CJDA and PS-0523CJDA
Lot Numbers:

Model	UDI-DI	Lot Number
PS-0523CJDA	00821925044531	CA182554
PS-0537CJDA	00821925044555	CA182543
		CA182544
		CA182546
		CA182548
		CA191230
PS-0544CJDA	00821925044579	CA179370

Attention: Surgical Department, Risk Management

Dear Healthcare Professional:

Olympus (Gyrus ACMI, Inc.) is writing to inform you of a removal action for seven (7) lots of POWERSEAL Sealer & Divider bipolar electrosurgical devices ("POWERSEAL") distributed between November 2021 and August 2022. POWERSEAL is a bipolar electrosurgical device intended for use in laparoscopic/minimally invasive or open surgical procedures where ligation and division of vessels, tissue bundles and lymphatics is desired. It is intended to be used with the Olympus Electrosurgical Generator ESG-400 and ESG-410 only.

As part of Olympus' transformation initiatives and commitment to patient safety, a retrospective review identified a total of nine (9) POWERSEAL units determined to be out of specification which may have resulted in the device not performing as expected. These nine units were manufactured across the seven (7) lots identified above. Olympus has received one (1) complaint of malfunction associated with this issue for these lots. The root cause of the issue was identified and corrected in early 2022. However, as per our commitment to quality, we are initiating this product removal to ensure that none of the affected products remain in your inventory.

Risk to Health

Upon initial activation of the seal function, the POWERSEAL non-conformance results in an immediate *Incomplete Seal Cycle* tone with the accompanying message on the generator screen and no energy would be delivered to the device. Each subsequent activation of the seal function will result in the Incomplete Seal Cycle tone and accompanying message. The risk to health is a potential prolonged surgery resulting from the need to acquire another POWERSEAL device or alternative device to complete the procedure.

Actions to be taken by the end user:

Our records indicate that your facility has received one or more units from the affected lots identified above. While the likelihood that you received one of the 9 out of specification units is extremely low, and the likelihood that you still have units from the affected lots is also extremely low, **Olympus requests you to take the following actions:**

1. **Inspect your inventory and identify** any POWERSEAL products having the lot number identified above. Please check all areas of the hospital to determine if any of these devices remain in inventory. **Quarantine and cease use** of the affected model/lots.

2. **Please contact Customer Service** at **at 1-800-848-9024, option 2,** with the quantity, model and lot number of the affected device(s). Olympus will issue a Return Material Authorization to return any affected product at no charge. Olympus will issue a credit to your facility upon return of the affected product.

3. **Access the Olympus recall portal to indicate that you have received this notification.**

    a. Go to https://olympusamerica.com/recall
    b. Enter the recall number "0444".
    c. Complete the form as instructed and include your account ID number.

4. If you have distributed these devices outside your facility, please provide a copy of this letter to those facilities immediately.

Olympus requests you to report any complaints, including jaw breakage, to the Technical Assistance Center (TAC) at 1- 800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly by phone at (647) 999-3203 or by e-mail at Cynthia.Ow@olympus.com

Sincerely,

Cynthia Ow

Cynthia Ow
FCA Regional Lead, Americas