September xx, 2021
Olympus reference: QIL 154-014

URGENT FIELD SAFETY NOTICE

RE: Return of a Medical Device to the supplier (Olympus)

Attention: Surgical Department

	Article Number	LOT number
Olympus Pneumoliner Containment Device for laparoscopic morcellation	**WA90500A**	**649135**

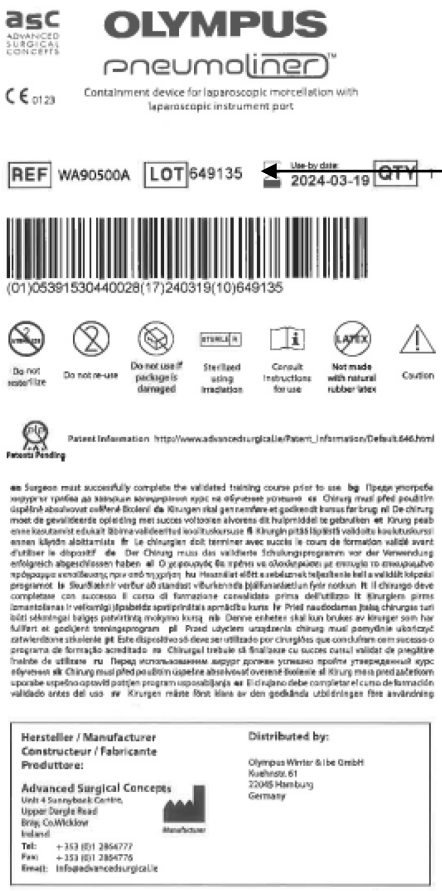
Dear Health Care Practitioner

Olympus was informed by Advanced Surgical Concepts (ASC), legal manufacturer of Pneumoliner (WA90500A), that ASC has become aware of an issue that requires your attention. Pneumoliner is a containment device for laparoscopic power morcellation with laparoscopic instrumentation. The Pneumoliner is intended for use as a multiple instrument port and tissue containment system during minimally invasive gynecologic laparoscopic surgery to enable the isolation and containment of tissue, considered benign, resected during single-port or multi-site laparoscopic surgery during power morcellation and removal.

The lot of Pneumoliner referenced above is non-conforming whereby the Pneumoliner Bag Distal Tab that exits the Introducer shaft is in the wrong orientation. Use of the affected product will lead to the situation, where the surgeon will deploy the Bag upside down, thus tissue encapsulation and bag closure can become more difficult. The risk is that the small bowel/viscera may become trapped in the bag at closure resulting in patient injury.

Please report to Olympus any adverse events associated with the use of this device that you are aware of or that you become aware of.

The lot number of the affected Pneumoliner is found on the shipper carton label, the unit box label and device label on the sterile Tyvek lid of the blister tray. The blister tray label is shown below.



Lot number

Actions to be taken by the end user:

Our records indicate that your facility has purchased one or more of the above-referenced Pneumoliner. Therefore, Olympus requires that you take the following actions:

1. Immediately assess any affected product you have in stock and quarantine any affected product.
2. Your Olympus representative will contact you to arrange collection of the products. Olympus will issue a credit or replacement to your facility for your affected product.
3. Please note on the enclosed FSN Reply Form the serial number available in your facility and that you have received, understood, and followed this information.
4. Send the completed Reply Form back to your Olympus representative ([xxx]) latest by [XXXX] regardless of whether you have any affected inventory at your facility.
5. If you have further distributed the products listed, identify your customers, forward them this Field Safety Notice, appropriately document your notification process and let us know the end-customer feedbacks accordingly.

Your National Competent Authority has been informed of this Field safety Notice.

Olympus regrets any inconvenience this action may have caused and fully appreciates your prompt cooperation. If you have any questions or concerns, please do not hesitate to contact me directly at [phone number] or at [e-mail address].

Sincerely,

REPLY FORM – QIL 154-013

URGENT FIELD SAFETY NOTICE RETURN OF A MEDICAL DEVICE TO THE SUPPLIER (OLYMPUS) PNEUMOLINER WA90500A LOT 649135
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[**Date]**

Please check ALL appropriate boxes.

☐ I have read and understand the **Field Safety Notice** instructions provided in the xx September 2021 letter.

☐ I have checked my stock and have quarantined inventory consisting of

[ ] boxes
[ ] pieces

Any adverse events associated with recalled/failed product? ☐ Yes ☐ No

If yes, please explain:_____

Name (Signature) _____

Name (Print) _____

Position _____

Please scan / email your completed paper form response to XXXX latest by XXXX.