



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
<b>Olympus Pneumoliner Containment Device for laparoscopic morcellation</b>	<b>WA90500A</b>	<b>649135</b>

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.



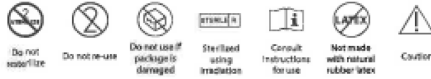
Containment device for laparoscopic morcellation with laparoscopic instrument port

REF WA9D500A LOT 649135 Use by date 2024-03-19 QTY 1

Lot number



(01)05391530440028(17)240319(10)649135



Patent Information <http://www.olympus-surgical.com/Patent/Information/Default.html>  
Patent Pending

en Surgeon must successfully complete the validated training course prior to use. bg Понеж трябва да завърши успешно валидирания курс преди употреба. ca El cirurg ha de completar amb èxit el curs de formació validat abans d'utilitzar el dispositiu. cs Chirurg musí před použitím úspěšně absolvovat validovaný kurz. da Kirurgen skal gennemføre et godkendt kursus før brug af. de Chirurg muss die validierte Schulungsprogramme vor der Verwendung erfolgreich abgeschlossen haben. el Ο χειρουργός θα πρέπει να ολοκληρώσει με επιτυχία το εγκεκριμένο πρόγραμμα εκπαίδευσης πριν από τη χρήση του. es El cirujano debe completar el curso de formación validado antes del uso. et Kirurg peab edukuse validatud kursuse edukalt lõpetama enne kasutamist. fi Le kirurgin on tähttähtä suksessellisesti suoritettava koulutusohjelma ennen laitteen käyttöä. fr Le chirurgien doit terminer avec succès le cours de formation validé avant d'utiliser le dispositif. de Der Chirurg muss das validierte Schulungsprogramm vor der Verwendung erfolgreich abgeschlossen haben. hu O gépésznek fel kell töltenie a validált képzési programot. it Il chirurgo deve completare con successo il corso di formazione convalidato prima dell'uso. ja Kirurg peab edukalt lõpetama kehtivalt kinnitatud haridusprogrammi enne seadme kasutamist. ko Kirurg peab edukalt lõpetama kehtivalt kinnitatud haridusprogrammi enne seadme kasutamist. lt Chirurgas turi būti sėkmingai baigęs patvirtintą mokymo kursą. lv Dzinis ir jābeidzina veiksmīgi ar izmantojamā ierīces izmantošanu. nl De chirurg moet de gevalideerde opleiding met succes voltooien alvorens de te gebruiken. no Kirurg skal gjennomføre et godkjennt utdanningsprogram før Prøve utstyret. orijundevite chirurg must pomyšlele uborizovane obzavestvene skolenje. pl. Este dispozitivul să fie utilizat de chirurgii care au absolvit cu succes o program de formare acreditat. pt O cirurgista tem de finalizar com sucesso o curso de formação validado antes de utilizar o dispositivo. ro Chirurgul trebuie să finalizeze cu succes cursul validat de pregătire înainte de utilizare. ru Понеж хирург должен успешно завершить утвержденную подготовку перед использованием аппарата. sk Chirurg musí pred použitím úspešne absolvovať overený kurz. sl Kirurg mora pred uporabo uspešno opraviti potrdjen program usposabljanja. sv El cirujano debe completar el curso de formación validado antes del uso. sv Kirurgen måste först sluta av den godkända utbildningen före användning.

<b>Hersteller / Manufacturer</b> Constructeur / Fabricante Produttore: Advanced Surgical Concepts Unit 4 Sunnybank Centre, Upper Dargle Road Bray, Co. Wicklow Ireland Tel: +353 (0)1 2864777 Fax: +353 (0)1 2864776 Email: <a href="mailto:info@asc-surgical.ie">info@asc-surgical.ie</a>	<b>Distributed by:</b> Olympus Winter & Be GmbH Huelshoff 61 22045 Hamburg Germany
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### 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

<b>URGENT FIELD SAFETY NOTICE</b> <b>RETURN OF A MEDICAL DEVICE TO THE SUPPLIER (OLYMPUS)</b> <b>PNEUMOLINER WA90500A LOT 649135</b>
[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.