

November 21th, 2012

Urgent Field Safety Notice: FSCA_RE12001

Product: Alteco® LPS Adsorber, REF LPS-33-100-46

To whom it concerns,

Alteco Medical AB is hereby voluntarily recalling (Field Corrective Safety Action) the below listed batches of the product Alteco® LPS Adsorber, REF LPS-33-100-46. The reason for the product recall is that the sterile barrier of the product, i.e. the sterile pouch in which the product is packed, may be compromised and we cannot assure sterility on the outside of the product. If not handled in accordance with the IFU and standard care, the outermost consequence for the patient may be serious infection.

The following batches are concerned:

Batch No.	Exp. Date	Batch No.	Exp. Date
L1002-LPS1009	2013-02	L1110-LPS1016	2014-10
L1007-LPS1010	2013-07	L1202-LPS1018	2015-02
L1008-LPS1011	2013-08	L1204-LPS1019	2015-04
L1103-LPS1012	2014-03	L1206-LPS1020	2015-06
L1107-LPS1015	2014-07		

Please contact your customers and inform them to immediately discontinue the use, put any remaining products in quarantine and return them to us. This also concerns all products on stock at your company. Please fill in the enclosed Recall Confirmation Form and return the form together with the recalled products. Please also scan and send the form via e-mail to us on the following address:

info@altecomedical.com

Return the products in accordance to the instructions attached to the following address as soon as possible but no later than 21st of December 2012:

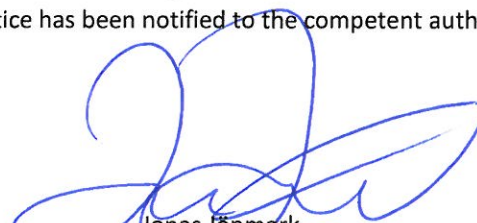
Alteco Medical AB
Höstbruksvägen 8
SE-226 60 Lund
Sweden

We sincerely apologize for any inconveniency and the additional workload this may cause you and your customers. This action is in accordance with our strong commitment to patient safety and to regulatory requirements.

We will of course provide you with replacement products according to the Recall Confirmation Form. The undersigned hereby also confirms that this notice has been notified to the competent authorities in respective country.

Yours sincerely,


Roger Petersson
QA Manager


Jonas Jönmark
President

Alteco Medical AB

Alteco Medical AB

Appendix 1: Recall Confirmation form.

Batch no.	No. of products from stock, returned to Alteco Medical AB	No. of Products from clinics, returned to Alteco Medical AB	Total no. of products returned

Performed by, signature	
Name in block letters	
Date	

Distributors Company Name	
Contact Person	
Address	

Shipping instructions:

Unique RGA no. to mark the shipping with:	
--	--

How to package the products

Let the products remain in their 4 pcs boxes and pack them together in larger boxes, add padding if necessary. Mark the boxes with the unique RGA-number above. We will use UPS as the transporter. Please inform us with the number of boxes and the weight and we will book the transportation of the products accordingly. We will then provide you with the necessary shipping documents.

Alteco Medical AB thanks you and appreciates your great effort.