



Date: 25May2016

Dear Customer,

## RE: URGENT MEDICAL DEVICE RECALL FIELD SAFETY NOTICE (FSN)

**FSN No:** AR1245  
**Device:** Sorbsan Calcium Alginate Dressings (Flat, Ribbon, Packing, Plus and Border) and Sorbsan Silver Calcium Alginate Dressing (Flat)

Background:

Please be advised that Aspen Medical has become aware of an issue related to the application of an incorrect expiry date to a number of Sorbsan dressings. Product effectiveness may be impacted if used past a three year shelf life. Please stop use of the product immediately (refer to 'customer actions' below for additional instructions). Products affected are listed below:

Product Name	Product Code	Lot Number	Quantity (# of pieces)	Customer	Date of Despatch	Order #
See Attachment 1						

### Customer Actions:

1. Please stop using the product immediately.
2. Place the product in quarantine to be returned or destroyed.
3. Aspen customers will receive either credit or replacement product at no cost, for returned product or a returned completed Certificate of Destruction. Please use Return Authorization Number **ASPEN R02-2016** when returning the product.

Product to be returned should be sent to the following address:

Aspen Medical Europe Ltd  
Clinitron House  
Excelsior Rd  
Ashby-de-la-Zouch  
Leicestershire, LE65 1JG  
UK

This Medical Device Recall advises you of the situation together with the action to be taken. Please review the Field Safety Notice and complete the applicable form.



If you have any questions or concerns, please contact:

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kelli.jonas@aspensurgical.com

or Megan Heitz  
Compliance Manager  
+1 616.698.7100 x118  
megan.heitz@aspensurgical.com

Your help and support in this matter is much appreciated.

Please accept our sincere apologies for the inconvenience this situation may have caused.

Yours faithfully,

A handwritten signature in black ink that reads "Kelli R. Jonas".

Kelli Jonas  
Director of QA/RA