

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	Quantit y (# of pieces)	Customer	Date of Despatch	Order #
			See Attachi	ment 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:

Kelli Jonas Head of QA/RA +1 616-698-7100 X177 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,

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Kelli Jonas Director of QA/RA

