



Date xxxxxxxxxx

Dear Customer,

RE: 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 Codes
Sorbsan Flat	1400, 1410, 1415
Sorbsan Packing	1411
Sorbsan Ribbon	1412
Sorbsan Plus	1420, 1421, 1422, 1423
Sorbsan Plus Border	1420SA , 1421SA, 1422SA, 1423SA
	1400N
	1410N, 1410S,
	1411N, 1411S
	1412N
	1415S
	1420S
Sorbsan Silver	AG1400

Customers will be contacted to advise them if they have been in receipt of affected product.

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 Field Safety Notice 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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or Megan Heitz
Compliance Manager
+1 616.698.7100 x118
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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,

Kelli Jonas
Director of QA/RA