



Electromedical Products International, Inc.

Urgent Field Safety Notice (DRAFT)
Alpha Conducting Solution

FSCA Ref: CAR 07-01-2019
July 31, 2019

Dear Alpha-Stim® Customer,

The purpose of this letter is to advise you that Pharmaceutical Innovations, Inc. is voluntarily recalling their *ElectroMist Conductive Spray* which is manufactured as a private label for Electromedical Products International, Inc. (EPI) under our brand name *Alpha Conducting Solution*.

No reports of serious injuries and/or deaths have occurred as a result of the failure of the product.

Reason for the Voluntary Recall:

The *ElectroMist / ACS* Stability Study failed to meet the requirements for the Antimicrobial Effectiveness Test. Product samples failed to meet the USP <51> category 2.

- **Frequency of failures and complaints:** We are not aware of any complaints or Vigilance Reports associated with the product.
- **Magnitude of the error:** Lots manufactured from 2014 to 2018.

Risk to Health:

The product may not have the capability to effectively control the contamination of the conducting solution over time. The products failure to prevent contamination could lead to injuries associated with, but not limited to, the following; *Candida albicans*, *Aspergillus niger* *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*.

“How to recognise that the conducting solution may fail.” The contamination, if present, will not be readily visible to the naked eye. It is important that you assume the product is contaminated and follow the directions for return and/or disposal back to EPI.

Actions to be taken by the Customer/User:

Please examine your inventory for any of the conduction solution listed in Attachment 1 and;

- 1) Isolate and quarantine these products,
- 2) Immediately discontinue use;
- 3) Notify any end users, customers or additional facilities within your organization to discontinue use and sale and quarantine those products until final disposition has been determined and performed.

When you have completed these actions return the attached *Field Safety Notice Customer Reply* form to **Cindy Mercer**, Field Safety Coordinator for EPI at acs@epii.com.

- 4) EPI will send you a confirmation of receipt of the *Field Safety Notice Customer Reply* Form for your records.



- 5) All replacement requests must be accompanied by a photograph of the actual product, showing the lot number, to receive a replacement of similar solution.

Contact Information: **Cindy Mercer, Field Safety Coordinator**
 Monday to Friday, 8:30 AM to 3:30 PM, Central Time.
 Phone: +855.477.0037
 Email: acs@epii.com

Adverse reactions or quality problems experienced with the use of this product may be reported to the Cindy Mercier, acs@epii.com, either online or by post.

Transmission of this Field Safety Notice:

This notice must be forwarded to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Sincerely,

Tracey B. Kirsch
 President
 Electromedical Products International, Inc

Product Number	Lot Number	Manufacturing Date	To Be Destroyed	
			Unit	Box
ACS	081914 (15)	June, 2014		
	111715 (15)	October, 2015		
	070116 (15)	July 2016		
	020117 (15)	February, 2017		
	080117 (15)	August, 2017		
	010118 (15)	January, 2018		
	041618 (15)	April, 2018		
	041618 A (15)	April, 2018		
	071618 (15)	July, 2018		
	102018 (15)	October, 2018		
ACSR	032014 (25)	February 2014		
	060515 (25)	May, 2015		
	101615 (25)	October 2015		
	011716 (25)	November, 2015		
	080117 (25)	August, 2017		
	010118 (25)	January, 2018		
	041618 (25)	April, 2018		
	071618 (25)	July, 2018		
	102018 (25)	October, 2018		

Attachment: Response form to send back immediately to:

To **Cindy Mercer**, Field Safety Coordinator for EPI at acs@epii.com.



Field Safety Notice Customer Reply Form

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	CAR 07-01-2019
FSN Date*	31 July 2019
Product/ Device name*	Alpha Conducting Solution
Product Code(s)	1 ACSR 2 ACS
Batch/Serial Number (s) See table below	

Product	Model / size	Lot Number	Manufacturing Date
Alpha Conducting Solution	ACS 15 ml 10 lot #	081914 (15)	June, 2014
		111715 (15)	October, 2015
		070116 (15)	July 2016
		020117 (15)	February, 2017
		080117 (15)	August, 2017
		010118 (15)	January, 2018
		041618 (15)	April, 2018
		041618 A (15)	April, 2018
		071618 (15)	July, 2018
		102018 (15)	October, 2018
	ACSR 250 ml Refill bottles 9 lot numbers	032014 (25)	February 2014
		060515 (25)	May, 2015
		101615 (25)	October 2015
		011716 (25)	November, 2015
		080117 (25)	August, 2017
		010118 (25)	January, 2018
		041618 (25)	April, 2018
		071618 (25)	July, 2018
		102018 (25)	October, 2018



2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		N/A	Comments:	
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A		



<input type="checkbox"/>	Other Action (Define):	
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	acs@epii.com
Customer Helpline	817-458-3293
Postal Address	2201 Garrett Morris Parkway Mineral Wells Texas 76067
Web Portal	www.Alpha-Stim.com
Deadline for returning the customer reply form*	September 09, 2019

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.