

July 9, 2019,

Dear Alpha-Stim® Distributor,

The purpose of this letter is to advise you that Pharmaceutical Innovations, Inc. is voluntarily recalling their *ElectroMist Conductive Spray* which is also sold/distributed by **Electromedical Products International, Inc. (EPI) under our brand name Alpha Conducting Solution**.

Alpha Conducting Solution may be found as part of your *Alpha-Stim M* or *Alpha-Stim AID* device in a small 15 ml size; or it may have been purchased as a replacement to the smaller solution bottle in a 250 ml bottle.

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 Alpha Conducting Solution (ACS) / (PI's) *Electro-Mist* Stability Study failed to meet the requirements for the Antimicrobial Effectiveness Test.

In other words, product samples failed to meet the antimicrobial Test Organisms effectiveness testing for topically used products made with aqueous bases (such as defined in the US Pharmacopeia as 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 through 2019.

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 recognize 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:

Please examine your inventory for any of the conduction solution listed below and;

- 1) Isolate and quarantine these products,
- 2) 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 Distributor /Importer Reply* form to **Cindy Mercer**,
Field Safety Coordinator for EPI at acs@epii.com.

- 3) EPI will send you a confirmation of receipt of the *Field Safety Notice Distributor/Importer Reply* Form for your records.
- 4) All replacement requests must be accompanied by a photograph of actual product, showing lot number, to receive a replacement of similar conducting solution.

Contact Information:

Cindy Mercer, Field Safety Coordinator
Monday through 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 must be reported to acs@epii.com and/or Adverse Event Reporting program, either online or by regular mail.

Sincerely,

Tracey B. Kirsch
President
Electromedical Products International, Inc

Product Number	Lot Number	Manufacturing Date	To Be Destroyed	
			Unit	Box
size				
-ACS- Alpha Conducting Solution 15 ml	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		
	041618-15	April, 2018		
	071618-15	July, 2018		
	102018-15	October, 2018		
-ACSR- Alpha Conducting Solution Refill 250 ml	032014-25	February 2014		
	060515-25	May, 2015		
	101615-25	October 2015		
	011716-25	November, 2015		
	020117-25	February, 2017		
	080117-25	August, 2017		
	010118-25	January, 2018		
	041618-25	April, 2018		
	071618-25	July, 2018		
102018-25	October, 2018			