FSN Ref: **FSCA Manufacturer Ref: CAR 07-01-2019**

**Urgent - Field Safety Notice (FSN)**

**Electromedical Products International Inc – “Alpha Conducting Solution”**

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| 1. **Information on Affected Devices\*** |
| **1****.** | **1. Device Type(s)\*** |
| **Alpha Conducting Solution** is a solution used with the Alpha-Stim M & AID devices to assist with electrical conductivity. Alpha-Stim devices are electrotherapy stimulation devices for the treatment of anxiety, insomnia, depression and pain. Product is not sterile. |
| **1****.2** | **2. Commercial name(s)** |
|  **“Alpha Conducting Solution” , “ACS” , “ACSR” (ACS Refill)**  |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
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| **1****.** | **4. Primary clinical purpose of device(s)\*** |
|  **Alpha Conducting Solution** is an accessory to the Alpha-Stim devices.  It is applied in drops to the portion of the device that attaches to the patient to increase electrical  conductivity. |
| **1****.** | **5. Device Model/Catalogue/part number(s)\*** |
|  **ACS (15 ml) and ACSR (250 ml)** |
| 1. | 6. Software version |
| Not relevant. |
|  | **7. Affected serial or lot number range** |
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| **Product**  | **Model /size** | **Lot Number**  | **Manufacturing Date**  |
| --- | --- | --- | --- |
| Alpha Conducting Solution  | ACS 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  |
| 041618A-15  | April, 2018  |
| 071618-15  | July, 2018  |
| 102018-15  | October, 2018  |
| ACSR 250 ml | 032014-25  | February 2014  |
| 060515-25  | May, 2015  |
| 101615-25  | October 2015  |
| 011716-25  | November, 2015  |
| 021317-25  | February, 2017  |
| 080117-25  | August, 2017  |
| 010118A-25  | January, 2018  |
| 041618-25  | April, 2018  |
| 071618-25  | July, 2018  |
| 102018A-25  | October, 2018  |

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| 1. | 8. Associated devices |
| Within context of the FSCA e.g. for IVD reagents and platforms. NA |

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| 2 **Reason for Field Safety Corrective Action (FSCA)\*** |
| 2. | **1. Description of the product problem\*** |
| 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.  |
| 2. | **2. Hazard giving rise to the FSCA\*** |
| There have been no reports of harm or injury due to this event; risk of occurrence is small. Customers should be cautious that 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. Solution should not be used; it should be discarded. |
| 2. | **3. Probability of problem arising**Improbable |
| 2. | **4. Predicted risk to patient/users** |
| Overall risk to patient is “LOW”. |
| 2. | **5. Further information to help characterize the problem** |
| EPI has received no complaints or notices of harm due to Alpha Conducting Solution. Solution supplier, Pharmaceuticals Innovations, also has not received any notices of harm. |
| 2. | **6. Background on Issue** |
| EPI was contacted by our solution supplier, Pharmaceutical Innovations, that the solution failed antimicrobial stability testing. They indicated no complaints or harm were received due to the solution, but a voluntary recall of the product was deemed necessary. |
| 2. | 7. Other information relevant to FSCA |
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|  | **3. Type of Action to mitigate the risk\*** |
| **3.** | **1. Action To Be Taken by the User\*****X**  **Identify Solution X Quarantine Device** ☐ Return Device **X**  **Destroy Solution**☐ On-site device modification/inspection☐ Follow patient management recommendations☐ Take note of amendment/reinforcement of Instructions For Use (IFU)☐ Other ☐ NoneProvide further details of the action(s) identified. |
| **3.** | **2. By when should the action be completed?** | **Immediately** |
| 3. | 3. Particular considerations.Is follow-up of patients or review of patients’ previous results recommended? **No follow up is needed.**  **No complaints or notices of harm have occurred.**  **Risk of a problem arising is very small/low.**  **Discontinuing use should mitigation the concern.** |
| **3.** | **4. Is customer Reply Required? \*****(If yes, form attached specifying deadline for return)** | **Recommended,****but not required** |
| **3.** | **5. Action Being Taken by the Manufacturer****X Product Removal** ☐ On-site device modification/inspection☐ Software upgrade ☐ IFU or labelling change☐ Other ☐ None**EPI is asking customers to stop using the product and distributors to cease sales immediately.** **This constitutes a product removal by asking customers to dispose of the material. There is no expectation that product needs to be returned to the manufacturer.** |
| 3 | 6. By when should the action be completed?See table for communication action as follows: |
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| Customer Type | 1st communication | Examples needed: | 2nd communication |
| --- | --- | --- | --- |
| **Distributor** |   **Email** | * Email message
 | Repeat 1st contact after 4 weeks if effectivity was not achieved |
| **Patient& Clinical** | * **Email, bulk service provider including weblink**
* **Postal mail if no phone number or email address is found**
 | * Email message
 | After 4 weeks, if effectivity was not achieved EPI will evaluate if phone call or postal mail if no phone number or email address is found ; or if another email note is the correct action. |
| **EPI Website** |  | * Web page
* form
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| 3. | 7. Is the FSN required to be communicated to the patient/lay user? | **YES, end user should stop using the “Alpha Conducting Solution” and destroy the product.** |
| 3 | 8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? |
| **Email message and link to EPI website will provide direction** |

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|  | **4. General Information\*** |
| **4.** | **1. FSN Type\*** | **RECALL.** |
| 4. | 2. For updated FSN, reference number and date of previousFSN | Provide reference and date of previous FSN if relevant |
| 4. | 3. For Updated FSN, key new information as follows: |
|  | Summarize any key difference in devices affected and/or action to be taken. |
| 4. | 4. Further advice or information already expected in follow-upFSN? \* | Choose an item. |
| 4 | 5. If follow-up FSN expected, what is the further advice expected to relate to: |
| E.g. patient management, device modifications etc. |
| 4 | 6. Anticipated timescale for follow- up FSN | For provision of updated advice. |
| 4. | 7. Manufacturer information(For contact details of local representative refer to page 1 of this FSN*)* |
| a. Company Name | Only necessary if not evident on letter-head. |
| b. Address | Only necessary if not evident on letter-head. |
| c. Website address | Only necessary if not evident on letter-head. |
| **4.** | **8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. \*** |
| 4. | 9. List of attachments/appendices: | If extensive consider providing web-link instead. |
| **4.** | **10. Name/Signature** | Insert Name and Title here and signature below |
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|  | **Transmission of this Field Safety Notice** |
|  | **This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.** (As appropriate)**Please transfer this notice to other organizations** on which this action has an impact. (As appropriate)**Please maintain awareness on this notice** and resulting action for an appropriate period to ensure effectiveness of the corrective action.**Please report all device-related incidents to the manufacturer or its distributor or local representatives**, **and the National Competent Authority of Health of your country, if appropriate, as this provides important feed-back.\*** |

Note: Fields indicated by \* are considered necessary for all FSNs. Others are optional.