Rev 1: September 2018
FSN Ref: 2019-002-EU-FSN FSCA Ref: 2019-002-EU-FSCA

Date: 28Dec2019

Urgent Field Safety Notice
Device Commercial Name

Mavidon Issues Voluntary Worldwide Recall of All manufactured products including LemonPrep® Tubes and Single use cups, PediaPrep® Tubes and Single use cups, Wave Prep® Tubes and Single use cups, Cardio Prep Single use cups due to possible Burkholderia cepacia contamination

For Attention of*:Hospital/Clinic Risk Manager

Mavidon is voluntarily recalling all lots of products manufactured at our facility including LemonPrep®, PediaPrep® and Wave Prep 4-ounce tubes and single use cups, Cardio Prep single use cups due to contamination with Burkholderia cepacia. We were notified on December 19, 2019 that samples of 114gm tubes of Lemon Prep, collected during a Food and Drug Administration inspection that occurred at our facility on October 15, 2019 were tested and found to be contaminated with Burkholderia cepacia. Out of an abundance of caution, we are recalling all products manufactured at our facility.

Actions to be taken:
1. Hospitals, distributors, and clinics that have any Mavidon products should immediately stop using the product and quarantine it.
2. Fill out the Medical Device Recall form (ANNEX 1) below and email it to CS@mavidon.com
3. We will follow up and give instructions on how to return the product for credit.

Burkholderia cepacia is a multi-drug resistant pathogenic microorganism. Contaminated products with Burkholderia cepacia can potentially result in serious infections, may be life-threatening for patients with compromised immune systems, such as neonates, elderly, pregnant women, cancer patients, but also in previously healthy individuals. To date, Mavidon has received one report of adverse event in a neonate related to this product in recall.

Lemon Prep, Pedia Prep, Wave Prep, Cardio Prep Single Use Cups products have uses which include as abrasive skin prepping lotions, products intended to lower skin impedance and enhance the signal quality at the electrode site, cleaning agents to remove oils and skin residue on patients with normal to oily skin. These were distributed to hospitals, distributors, and clinics in the USA and worldwide. We are including in this recall all of our products that share similar manufacturing processes as it is possible that contamination with B. cepacia may have taken place and gone undetected before distribution. We pledge ourselves to the highest standards of quality and out of abundance of caution we have decided to recall all products made at our facility.

We are contacting you as our records indicate the affected product has been shipped to your

organization. Mavidon is notifying of all of its customers by email and phone of this recall. Contact Mavidon at 800-654-0385 (Monday – Friday, 8:30 AM to 5:00 PM EDT) or by email to cs@mavidon.com.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Mavidon Medical, Mr. Tim Carroll, 6625 White Drive, Riviera Beach, 33407 USA – Phone: 561-585-2227, Fax: 888-913-4311, Email: cs@mavidon.com

Company Name/Logo

Rev 1: September 2018

FSN Ref: 2019-002-EU-FSN FSCA Ref: 2019-002-EU-FSCA

Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Lemon Prep, Pedia Prep, Wave Prep, Cardio Prep Single Use Cups products have uses which include as abrasive skin prepping lotions, products intended to lower skin impedance and enhance the signal quality at the electrode site.
1.	2. Commercial name(s)
	LemonPrep® Tubes and Single use cups PediaPrep® Tubes and Single use cups Wave Prep® Tubes and Single use cups Cardio Prep Single use cups
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	Lemon Prep, Pedia Prep, Wave Prep, Cardio Prep Single Use Cups products have uses which include as abrasive skin prepping lotions, products intended to lower skin impedance and enhance the signal quality at the electrode site.
1.	5. Device Model/Catalogue/part number(s)*
	Add as Appendix if necessary.
1.	6. Software version
	Only where relevant.
1.	7. Affected serial or lot number range
	Where relevant. If not known, use manufacturing/distribution/expiration date as appropriate. Add as Appendix if necessary or provide web-based look-up tool.
1.	8. Associated devices
	Within context of the FSCA eg for IVD reagents and platforms.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Mavidon is voluntarily recalling all lots of products manufactured at our facility including LemonPrep®, PediaPrep® and Wave Prep 4-ounce tubes and single use cups, Cardio Prep due toc ontamination with Burkholderia cepacia
2.	2. Hazard giving rise to the FSCA*
	Burkholderia cepacia is a multi-drug resistant pathogenic microorganism. Contaminated productswith Burkholderia cepacia can potentially result in serious infections, may be life-threatening for patients with compromised immune systems, such as neonates, elderly, pregnant women, cancer patients, but also in previously healthy individuals.
2.	3. Probability of problem arising
	Serious Adverse Health Consequences - Not likely in overall population and population at greatest risk (patients with compromised immune systems) using the product. Medically Reversible or Transient Adverse Health Consequences - Not likely in overall population and remote probability in population at greatest risk using the device.
2.	4. Predicted risk to patient/users
	The impacted products are a topical gel and is used to reduce impedance for EEG and EKG monitoring. It should not be used on broken or irritated skin. Patients with

	Immunocompromised system may be affected by the Burkholderia Cepacia and should be treated by a physician.
2.	5. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue.
2.	6. Background on Issue
	Mavidon was notified on December 19, 2019 that samples of 114gm tubes of Lemon Prep, collected during a Food and Drug Administration inspection that occurred at our facility on October 15, 2019 were tested and found to be contaminated with Burkholderia cepacia. Out of an abundance of caution, we are recalling all products manufactured at our facility.
2.	7. Other information relevant to FSCA
	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☒ Identify Device ☒ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Immediately
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	Immediately

3.	7. Is the FSN required to be communicated to the patient /lay user?	No
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?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg 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	**Mavidon Medical**
	b. Address	**6625 White Drive, Riviera Beach, FL 33407, USA**
	c. Website address	**www.mavidon.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Germany	
4.	9. List of attachments/appendices:	**ANNEX 1 – Medical Device Recall Form**
4.	10. Name/Signature	Insert Name and Title here and signature below

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations 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, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

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

ANNEX 1

Medical Device Recall Form

Please use the below form to inform us of the quarantined products you have. Send this to cs@mavidon.com.

Product Number	Quantity	Lot Number	Who did you purchase from?	PO Used

Your Name:	
Name of Facility:	
Department:	
Corresponding PO #:	
Shipping Address:	
City, State, Country, Zip Code:	
Phone Number:	