FIELD SAFETY NOTICE

diagnosys

January 31, 2020

RE: MAVIDON LemonPrep™ Recall Notice

Dear Valued Customer,

You are receiving this Field Safety Notification because our records indicate you have purchased LemonPrep™ product from Diagnosys LLC, Diagnosys part # D-204, either in an accessory kit as part of an ERG system, or on a purchase order for accessory parts.

This is a follow-up to a Recall Notice that Mavidon, the manufacturer of LemonPrep™, issued on September 13, 2019. Mavidon is now in the process of notifying customers, Hospital and clinics to **STOP** using all LemonPrep™ **IMMEDIATELY**, due to potential contamination with Burkholderia cepacia.

Attached is a copy of Mavidon's Voluntary Worldwide Recall Notice, which is dated January 7, 2020. Please work with Mavidon, as instructed in their Recall Notice.

Commercial name of affected product: LemonPrepTM 4 oz. Tubes
Manufacturer, Mavidon®, MFG Part Number MD0019-T

Under the terms of our Distributor Agreement it is the Distributor's responsibility to share recall information with customers that purchase an affected product. Please confirm that you have received this notice and that appropriate action has been taken to contact customers. We apologize for any inconvenience this may have caused.

If you have any questions or require additional information, feel free to contact me at the address below.

Sincerely,

[redacted]

Stephen F. Yedinak
Vice President of Operations and Quality
Diagnosys LLC, 55 Technology Drive, Suite 100,
Lowell MA 01851, Office: 978-458-1600, x129

Amended 1/07/2020

Collodions, Removers and Acetone have been removed from the Recall dated 12/23/19

Mavidon Issues Voluntary Worldwide Recall

of 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
***Burkholderia cepacia* contamination**

Mavidon
800-654-0385

FOR IMMEDIATE RELEASE – 12/23/2019 – Rivera Beach, Florida

Mavidon is notifying customers, Hospital and clinics to STOP using Lemon Prep, Pedia Prep, Wave Prep, Cardio Prep, IMMEDIATELY due to potential contamination with *Burkholderia cepacia*.

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 and due to potential 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 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 worldwide recall all of our products 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.

Medical Device Recall

Please use the below form to inform us of the quarantined products you have.

Send this to cs@mavidon.com for domestic customers

Product Number Quantity	Lot Number	Who Did You Purchase From?	PO Used

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

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm (http://www.fda.gov/MedWatch/ report.htm)
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/ getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre- addressed form, or submit by fax to 1-800-FDA-0178

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