Cadwell Industries, Inc.
04/22/2024

URGENT: MEDICAL DEVICE RECALL

IOMAX Cortical Module

(1) Attention to Distributor:

DanMedik Sdn. Bhd.
9-1, Block E2 Dataran Prima
Jalan PJU 1/42A, 47301, Petaling Jaya
Selangor, MALAYSIA
Phone: +603 78872629

Dear Device Customer/Distributor,

(2) Purpose of this letter

Cadwell Industries, Inc. is voluntarily recalling a limited number of Cascade IOMAX Cortical Modules manufactured between 12/12/2023 and 2/15/2024.

The IOMAX™ is an electroneurodiagnostic medical device which measures and displays the electrical signals generated by the nervous system. It acquires the data necessary to perform EMG, EP, and EEG testing. IOMAX™ is intended to be used by personnel trained to perform the intended tests. The system is used primarily in a clinical and/or hospital setting to diagnose neurological abnormalities. It is also used to acquire the data necessary to perform intraoperative monitoring of neural pathways during surgical procedures. It is intended for use during the duration of the surgical procedure and for preoperative and postoperative testing.

Serious injuries and/or deaths could occur due to the failure mode associated with this recall. We have reports of zero **deaths and** zero **serious injuries.**

(3) Reason for the Voluntary Recall:

An assembly error was discovered on the Cortical Module (PN 190296-200). A Cortical Module insulator that is used to provide an electric barrier between circuit boards for TCS-9, LCS, and other internal parts was found to be installed incorrectly. The insulator provides clearance between safety critical components and incorrect installation does not meet the minimum creepage/air gap required to meet IEC 60601-1.
IOMAX Cortical Modules manufactured between 12/12/2023 and 2/15/2024 may have been shipped with the insulator installed incorrectly.

Frequency of failures and complaints: There are zero reported failures or complaints associated with the problem.

- **Adverse events**: No adverse events have been reported to date.

(4) Risk to Health:

4a) If the insulator is incorrectly installed, it is possible for arcing to patient connections to occur. The resulting risk to the patient is unintended electric shock.

4b) The issue is not detectable by the user. The issue can only be detected upon disassembly of the unit which can only be completed by Cadwell Industries, Inc.

(5) Actions to be taken by the Customer/User:

Cease use of the device immediately and return all identified devices to Cadwell Industries, Inc.

Please complete the attached response form and return via email to quality@cadwell.com.

(6) Product Identification and Distribution Information:

Product and Distribution Information Table		
Serial Number	Sales Order Number	Date Shipped
19029603AA0124007	SI-0022274	2/15/2024
19029603AA0124012	SI-0022324	2/16/2024

(7) Action taken by Cadwell:

Cadwell Industries, Inc. is recalling and replacing or repairing all affected devices from the field.

(8) Attachment:

Acknowledgement and Product Replacement Form (separate sheet)

Authorized by:
Name: Becky Corral

Signature: BCorral

Title: Director, QARA

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.

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Product Replacement Form

Response is Required

Distributor Information:
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IOMAX Cortical Module

I have read and understand the instructions provided in the 4/22/2024 recall letter. **Yes** ✓

Have there been any adverse events associated with the recalled product? **Yes** ___ **No** ✓

If yes, please explain:
These product had been distributed to our customers and we have reached them. There is no any adverse event associated with the recalles product.

Recalled Product Information Table		
Serial Number	In Stock*	Distributed**
19029603AA0124007		✓
19029603AA0124012		✓

*Please place a checkmark in this column if you have possession of the device
** Please place a checkmark in this column if the device has been distributed to a customer

All devices shall be returned immediately. For distributed devices please reach out to your customers immediately to coordinate the device return to Cadwell.

For return and exchange or repair instructions please contact johnk@cadwell.com

I have identified and notified my customers that were shipped or may have been shipped this device and will obtain and return the devices to Cadwell Industries, Inc.

I have consulted my jurisdiction's regulatory standards or health agency for mandatory reporting requirements and will take appropriate action and notify Cadwell if necessary.

Signature of Receipt _____ **Date** 04/25/2024

Name/Title	Daniel Chan, General Manager
Telephone	+60122722273
Email address	danielchan@danmedik.com

Please email completed form to quality@cadwell.com