MEGADYNE®

PART OF THE ETHICON™ FAMILY OF COMPANIES

GiGATT International Marketing Pte Ltd

Company Registration No. 200506343C
GST Registration No. 200506343C

Megadyne® Mega Power™ Electrosurgical Generator
(Product Code: 1000)

7th June 2018

Dear Operating Room Supervisors, Chief of Surgery, and Biomedical Engineering Manager:

Our records indicate that you have ordered or received the Megadyne® Mega Power™ Electrosurgical Generator. **PLEASE DISTRIBUTE THIS INFORMATION TO ALL PERSONNEL RESPONSIBLE FOR Megadyne® Mega Power™ Electrosurgical Generator.**

PLEASE FOLLOW THE MEGADYNE® MEGA POWER™ ELECTROSURGICAL GENERATOR MANUAL AND DO NOT PLUG TWO DEVICES INTO THE SAME PORT (CHANNEL) FOR THE PRODUCT LISTED BELOW.

PRODUCT NAME	PRODUCT CODE	Serial Numbers	DESCRIPTION / SIZE
Mega Power Electrosurgical Generator	1000	[redacted]	Capital Equipment – Electrosurgical Generator

Megadyne Medical Products, Inc. ("Megadyne") has been informed of a reported burn to a patient caused by incorrectly plugging two devices into the same output port (channel). **For that reason, we are issuing a voluntary medical device correction to inform customers of the issue and request customers follow the Megadyne® Mega Power™ Electrosurgical Generator manual and only plug one device into each channel at a time.**

Per the user manual (reference 3000158-01), "Only one active device may be plugged into each channel at a time (i.e., either the 3-prong pencil cord, or phone plug style cord)."

When incorrectly plugging two devices into one channel, the generator powers both devices when either of the two devices are activated. It is possible that exposure to the second activated device may lead to a burn injury (up to second-degree) to the patient or operator if the second device is not in use and rested on top of the patient.

Correct

Correct

Incorrect

This correction affects all Megadyne® Mega Power™ Electrosurgical Generators.

[redacted]

URGENT: MEDICAL DEVICE CORRECTION NOTIFICATION
Megadyne® Mega Power™ Electrosurgical Generator
(Product Code: 1000)

Health care practitioners who have treated patients using the Megadyne® Mega Power™ Electrosurgical Generator should follow those patients post-operatively in the usual manner with no additional action required.

Megadyne is developing an additional label to apply to your generator. Updated labeling will be sent to you in a follow up notification with directions on how to apply the label. In the meantime, Megadyne requests customers follow the Megadyne® Mega Power™ Electrosurgical Generator manual and only plug one device into each channel at a time.

Refer to Attachment 1 for assistance in identifying the product subject to this correction.

This medical device voluntary correction has been communicated as necessary to appropriate health authorities, including the U.S. Food and Drug Administration (FDA).

[redacted]

[redacted]

URGENT: MEDICAL DEVICE CORRECTION NOTIFICATION
Megadyne® Mega Power™ Electrosurgical Generator
(Product Code: 1000)

IDENTIFICATION OF THE PRODUCT SUBJECT TO THIS CORRECTION:

The products subject to this correction in your inventory can be identified by product code. The product code (1000) can be determined by using the Product Identification Tool within Attachment 1.

ACTION REQUIRED:

1. Communicate this issue to all relevant operating room, biomedical engineering, and anyone else in your facility who needs to be informed. If any of the devices subject to this correction have been forwarded to another facility, please contact that facility and forward this notification to them.

2. Keep this notice visibly posted for awareness for all Megadyne® Mega Power™ Electrosurgical Generator users.

At Megadyne, our first priority is to support the needs of our customers and their patients, and that includes the safe and effective use of our products. We recognize this is disruptive to your facility and we apologize for any inconvenience this may cause.

[redacted]

[redacted]

Felicia Chen

GiGATT International Marketing Pte Ltd

cc: Chairman Medical Board and relevant Head of Departments

Acknowledge by:

Sr Wendy Yam

[redacted]

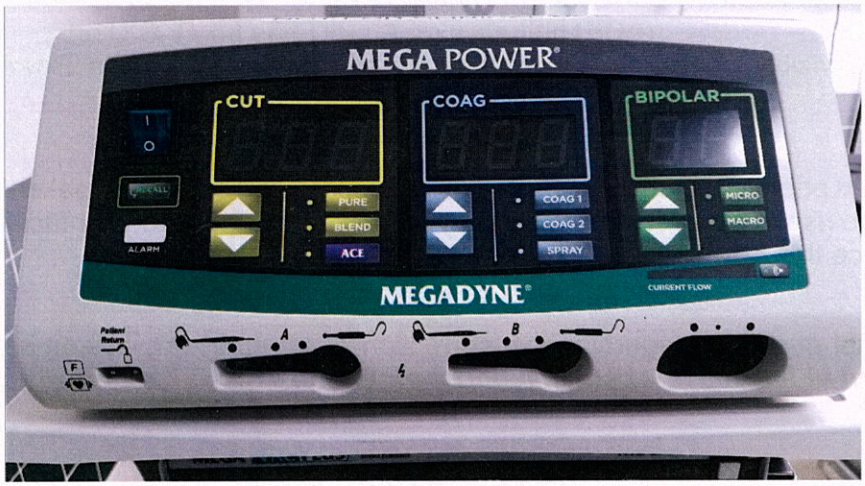
National University Hospital

URGENT: MEDICAL DEVICE CORRECTION NOTIFICATION
Megadyne® Mega Power™ Electrosurgical Generator (Product Code: 1000)

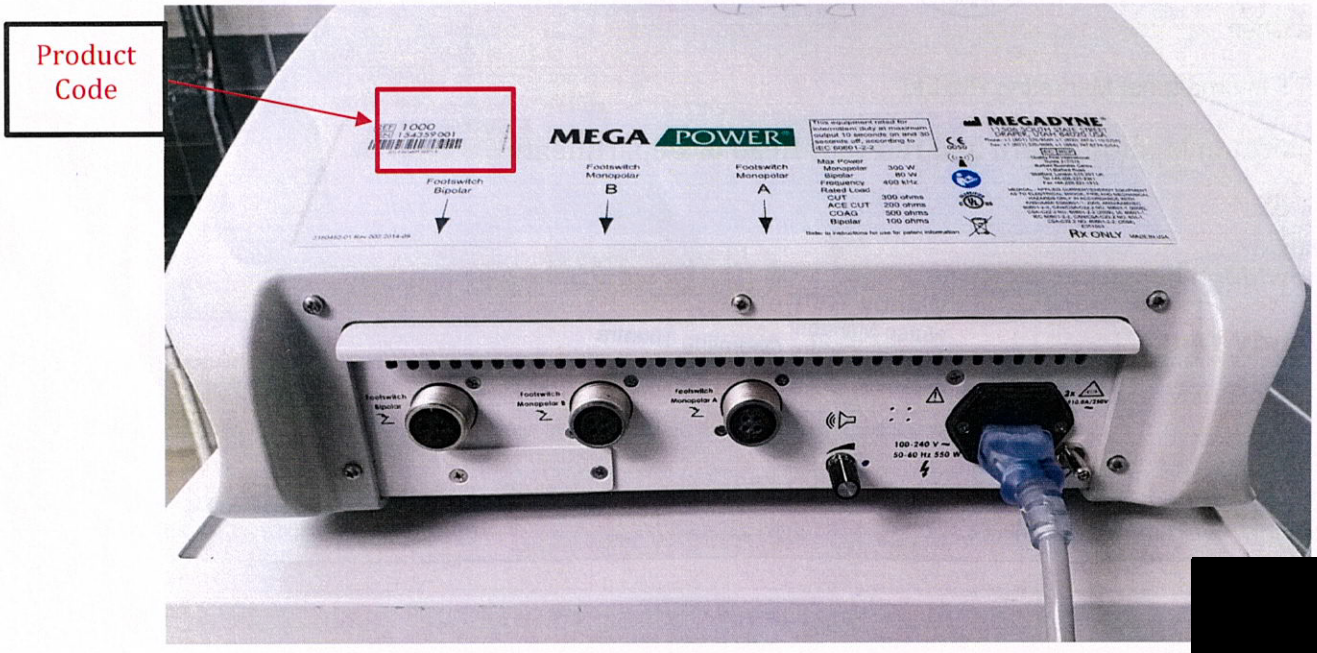
ATTACHMENT 1: Product Identification Tool for Megadyne® Mega Power™ Electrosurgical Generator.

This tool will help customers identify the Megadyne® Mega Power™ Electrosurgical Generator subject to this correction. All Megadyne® Mega Power™ Electrosurgical Generators are subject to this correction.

FRONT VIEW OF MEGA POWER ELECTROSURGICAL GENERATOR:



REAR VIEW OF MEGA POWER ELECTROSURGICAL GENERATOR:



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