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URGENT FIELD SAFETY NOTICE **Megadyne® Mega Power™ Electrosurgical Generator** **(Product Code: 1000)**

[Date]

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

Megadyne Medical Products, Inc. (“Megadyne”) is issuing a voluntary Field Safety Notice for all existing Megadyne® Mega Power™ Electrosurgical Generator devices. Competent Authorities are aware of this action.

Our records indicate that you have ordered /received the Megadyne® Mega Power™ Electrosurgical Generator. **PLEASE DISTRIBUTE THIS INFORMATION TO ALL PERSONNEL RESPONSIBLE FOR OR WHO MAY USE the 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	All	Capital Equipment – Electrosurgical Generator

Megadyne Medical Products, Inc. (“Megadyne”) is issuing a voluntary Field Safety Notice to inform customers of a reported second degree burn (3mm X 5mm that did not result in any permanent scarring) to a patient caused by two devices incorrectly plugged into the same output port (channel) at the same time. Megadyne Medical Products, Inc. (“Megadyne”) requests customers to follow the Megadyne® Mega Power™ Electrosurgical Generator manual and plug only one device into each channel at a time.

Incorrect plugging of two devices into one channel causes the generator to power both devices when either of the two devices is 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.

According to 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).”

Moreover, Megadyne Medical Products, Inc. (“Megadyne”) decided to reinforce importance of correct method of plugging devices into a generator therefore is providing an additional label to be applied to Megadyne® Mega Power™ Electrosurgical Generator by the customer. Updated label and instructions on how to apply the label will be sent to customers in a follow-up notification.

URGENT FIELD SAFETY NOTICE

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

This Field Safety Notice affects all Megadyne® Mega Power™ Electrosurgical Generators.



Correct



Correct



Incorrect

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.

Refer to Attachment 1 for assistance in identifying the product subject to this Field Safety Notice.

URGENT FIELD SAFETY NOTICE

Megadyne® Mega Power™ Electrosurgical Generator

(Product Code: 1000)

IDENTIFICATION OF THE PRODUCT SUBJECT TO THIS FIELD SAFETY NOTICE:

The products subject to this Field Safety Notice 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 Field Safety Notice 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.

If you have additional questions regarding this Field Safety Notice or to report any customer complaints, please contact [Add appropriate contact info here].

Attachments:

Attachment 1: Product Identification Tool

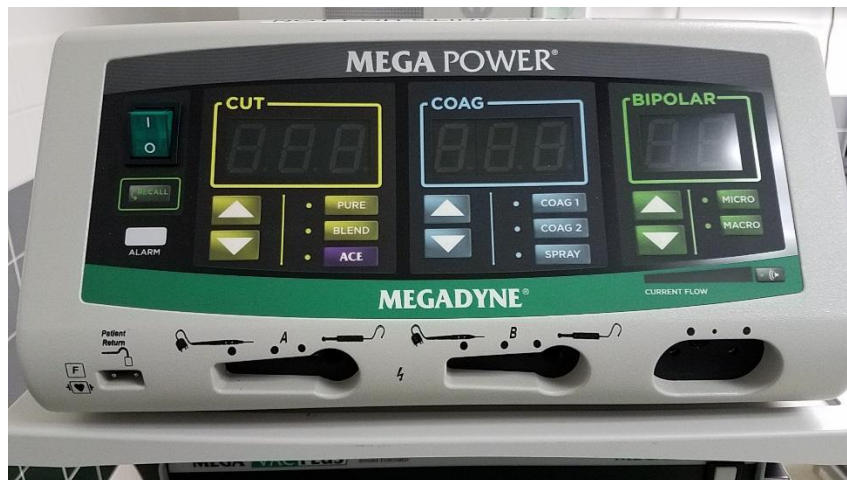
URGENT FIELD SAFETY NOTICE

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 Field Safety Notice. All Megadyne® Mega Power™ Electrosurgical Generators are subject to this Field Safety Notice.

FRONT VIEW OF MEGA POWER ELECTROSURGICAL GENERATOR:



REAR VIEW OF MEGA POWER ELECTROSURGICAL GENERATOR:

