



PART OF THE ETHICON® FAMILY OF COMPANIES

URGENT FIELD SAFETY NOTICE

Megadyne® Mega Power™ Electrosurgical Generator

(Product Code: 1000)

[Date]

Dear Distributor:

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/ or received the Megadyne® Mega Power™ Electrosurgical Generator. **PLEASE DISTRIBUTE THE CUSTOMER NOTIFICATION ATTACHED TO THIS NOTIFICATION TO ALL CUSTOMERS THAT YOU HAVE SHIPPED THE MEGADYNE® MEGA POWER™ ELECTROSURGICAL GENERATOR.**

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

Background:

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.

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In the meantime, Megadyne requests customers follow the Megadyne® Mega Power™ Electrosurgical Generator manual and plug only one device into each channel at a time.

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

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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.

ACTION REQUIRED:

1. Review your shipment records to identify all customers that you have shipped the Megadyne® Mega Power™ Electrosurgical Generator (Product Code: 1000) subject to this Field Safety Notice.
2. Send the customer notification included with this notification to all customers that have received the Megadyne® Mega Power™ Electrosurgical Generator subject to this Field Safety Notice.

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, please contact Ethicon Customer Support Center at 1-877-ETHICON (1-877-384-4266). The Customer Support Center is open Monday through Friday, 7:30 AM to 6:30 PM ET.

Attachments:

Attachment 1: Customer Notification