MEGADYNE

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Date

URGENT: FIELD SAFETY NOTICE

MEGADYNE™ MEGA SOFT™ and MEGA 2000™ Reusable Patient Return Electrodes

Important information regarding potential for patient burns and instructions that the following product codes should not be used for patients that are neonatal, infant, and children under the age of 12 years old

Product Name	Product Code	UDI-DI
MEGADYNE™ MEGA 2000™ Patient Return Electrode	0800	10614559100936
MEGADYNE™ MEGA SOFT™ Reusable Patient Return Electrode	0830	10614559101797
MEGADYNE™ MEGA SOFT™ Dual Reusable Patient Return Electrode	0835	10614559101872

Dear Operating Room Supervisors, Recall Coordinator, and Director of Materials Management:

PLEASE DISTRIBUTE THIS INFORMATION WITHIN YOUR FACILITY TO ALL STAFF INVOLVED in set up, cleaning and use of the MEGADYNE™ MEGA SOFT™ and MEGA 2000™ Reusable Patient Return Electrodes.

Purpose of this Letter
The purpose of this letter is to communicate an important change to the intended use population of the MEGADYNE™ MEGA SOFT™ and MEGA 2000™ Reusable Patient Return Electrodes to help ensure safe and effective use.

MEGA SOFT and MEGA 2000 Reusable Patient Return Electrodes, listed in the table above, are now limited to use in patients age 12 years or older. MEGA SOFT and MEGA 2000 product codes should not be used for patients that are neonatal, infant, and children under the age of 12 years old. This is inclusive of product codes 0800, 0830 and 0835. This change in intended use population is consistent with the changes we made to the Universal and Universal Plus in December 2023 (product codes 0845, 0846, 0847 and 0848.)

This letter is a notification of a product correction and is not a product removal. All serial numbers of the product codes listed above are affected by this recall action.

Reason for the Voluntary Correction
Megadyne Medical Products, Inc. ("Megadyne") has received reports of patient burns identified after surgical procedures in which Mega Soft pads were used, including product codes 0800, 0830, and 0835. Product codes 0800, 0830, and 0835 were approved for use in patients over 25 lbs (11.3 kg); however, to mitigate the potential risk to health in the population of children under 12 years of age, Megadyne is taking this corrective action to now limit use to patients age 12 years or older.

Users should continue to follow the current Mega Soft Instructions for Use (IFU) except for this new limitation in population of intended use. We will notify customers if we identify any additional actions that may help to ensure safe use of the products.

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Risk to Health

Megadyne has received reports of patient burn injuries up to and including third-degree burns associated with use of Mega Soft pads including product codes 0800, 0830, and 0835. We have conducted a thorough investigation and have not identified any design or manufacturing defects. Starting in June 2023, a letter was sent to customers to bring awareness of reports of burn injuries potentially associated with the use of Mega Soft pads. There have been no reported burn injuries under 12 years of age for the 0800, 0830 and 0835 product codes since that letter was distributed, however the potential for thermal injury exists as with other Mega Soft pads.

Health care practitioners who have used Mega Soft and Mega 2000 pads during patient procedures should follow those patients post-operatively in the usual manner.

Actions Required –

1. Share this notification update with all users of Mega Soft and Mega 2000 pads.
2. Confirm that personnel using the Mega Soft and Mega 2000 pads understand the intended use is changing to patients aged 12 years and older.
3. Post a copy of this communication to remind staff not to use the Mega Soft and Mega 2000 pads on patients under 12 years old. Although the current Mega Soft and Mega 2000 have printing of > 25 lbs (>11.3kg) on the pads, they should only be used for patients aged 12 years and older, and over labeling of the pad is not required.
4. If any subject product has been forwarded to another facility, contact that facility to share this information. Please share a copy of this notification when communicating.
5. Complete the Business Reply Form (BRF) **Attachment 1** confirming receipt of this notice and fax or email it to [Insert Affiliate Information] within three (3) business days.
6. As a reminder, it is important to follow proper cleaning, placement and setup steps for the Mega Soft and Mega 2000 pads. Failure to follow the Mega Soft and Mega 2000 pad IFU may contribute to patient burns.
7. If you need additional copies of this communication or have questions about returning the BRF, please contact [Insert Affiliate Information] and reference FSCA# 2370372.

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to your Sales Representative, directly to Megadyne, or your National Health Authority.

If medical engagement is requested, please have the Healthcare Provider submit the request using the Medical Information Request website: https://www.jnjmedtech.com/mir

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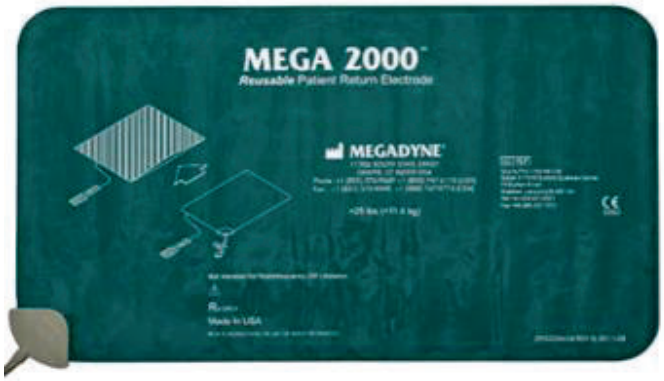
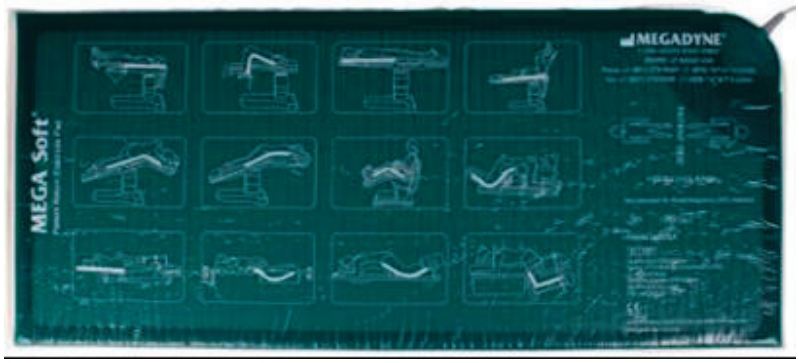
Attachments

Attachment 1: Business Reply Form for Update to Intended Use Population

Please refer to the photo below to identify the MEGADYNE™ MEGA 2000™ Reusable Patient Return Electrodes



Please refer to the photo below to identify the MEGADYNE™ MEGA SOFT™ Reusable Patient Return Electrodes



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Attachment 1: Business Reply Form for Update to Intended Use Population (Product Codes 0800, 0830, 0835)

Business Reply Form (BRF)

Your timely response to this notification is requested. Please complete and fax this form to [Insert Affiliate Information] **within 3 business days.**

[Account Name]
[Account Address]

Your Name and Title:	Date:
Email Address:	Telephone Number:
J&J Account Number: [Account Number]	
Signature*: **Your signature provides confirmation that you have received and understood this notification and completed the required actions.*	

Are you replying for addresses beyond the address listed above?

☐ Yes ☐ No

Have you notified all appropriate hospital staff of this notification?

☐ Yes ☐ No

If yes, please add additional addresses and J&J Account Number(s) here:

Account Name, Address, and J&J Account Number: