

Date: 22 Dec 2023

URGENT: FIELD SAFETY NOTICE **MEGADYNE™ MEGA SOFT™ Universal and Universal Plus** **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 SOFT™ Universal Patient Return Electrode	0845	10614559103906
MEGADYNE™ MEGA SOFT™ Universal Dual Patient Return Electrode	0846	10614559104248
MEGADYNE™ MEGA SOFT™ Universal Plus Patient Return Electrode	0847	10614559104842
MEGADYNE™ MEGA SOFT™ Universal Plus Dual Patient Return Electrode	0848	10614559104859

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

To The Attention of:

Operating Room Manager/Surgeon

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™ Universal and Universal Plus Reusable Patient Return Electrodes to help ensure safe and effective use.

Mega Soft Universal and Universal Plus Reusable Patient Return Electrodes, listed in the table above, are now limited to use in patients age 12 years or older. Mega Soft Universal and Universal Plus 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 0845, 0846, 0847, and 0848.

The indications and instructions for use for product codes 0800, 0830, 0835 (indicated for all patients from 11.3 kg (25 lbs) and up) and 0840 (indicated for patients from 0.35 kg (0.8 lbs) and up to 22.7 kg (50 lbs) remain unchanged.

This letter is a notification and is not a product removal.

Reason for the Voluntary Correction

Johnson & Johnson Megadyne Medical Products, Inc. (“Megadyne”) has received reports of patient burns identified after surgical procedures in which Mega Soft pads were used. Megadyne is taking this corrective action to mitigate the potential risk to health in the population of children under 12 years of age. We have conducted a thorough investigation, and have not identified any design or manufacturing defects, nor have we determined definitive root cause for the reports.

We are initiating updates to the Instructions for Use (IFU) and product labeling to reflect that these product codes should not be used in patients under 12 years old. The IFU update will be made available on the physical IFU copy or electronically, if applicable, at <https://www.e-ifu.com>. 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.

Risk to Health

Johnson & Johnson Megadyne has received reports of patient burn injuries up to and including third-degree burns requiring intervention which may lead to prolonged hospital stay, scarring, and additional surgeries in both pediatric and adult patients. Severe burns could lead to potentially long-lasting impacts on patients especially under the age of 12 years.

Health care practitioners who have used Mega Soft 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 Universal and Universal Plus pads.
2. Confirm that personnel using the Mega Soft Universal and Universal Plus pads understand the intended use population 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 Universal and Mega Soft Universal Plus pads on patients under 12 years old. Although the current Mega Soft Universal and Mega Soft Universal Plus have printing of > 0.35 kg (0.8 lbs) 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. Inform Johnson & Johnson if further facilities are affected.
5. Review, complete, sign, and return the attached Attachment A (Customer Acknowledgement Letter) to your Johnson & Johnson sales consultant or contact person.
6. As a reminder, it is important to follow proper cleaning, placement and setup steps for the Mega Soft pad. Failure to follow the Mega Soft pad IFU may contribute to patient burns. Copies of **Cleaning and Care Visual Aid** and **Placement and Setup Visual Aid** are available by contacting your Johnson & Johnson sales consultant or contact person.
7. Contact your local distributor for additional support as needed.

Johnson&Johnson

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

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to your local distributor.

We apologize for any inconvenience that this notification may cause and we appreciate your cooperation with our request. Should you have any inquiries, please do not hesitate to contact your Johnson & Johnson sales consultant or contact person.

Thank you for being an Ethicon Megadyne Customer.

Kind Regards,

Ng, Kay Lee Haema
Johnson & Johnson Sdn. Bhd.,
Commercial Quality Associate Manager

Attachments

Attachment A: Customer Acknowledgement Letter

Johnson & Johnson

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Attention: Hospital Personnel

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By signing this letter, I am confirming that I have read and understood the notification.

Hospital name: _____

Name/Title (please print): _____

Phone Number: _____

Signature and Date: _____

Note: If the verification section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual in Attachment A: Customer Acknowledgment Letter. Your timely response to this notification is requested.

Please complete and return Attachment A: Customer Acknowledgment Letter to our Johnson & Johnson sales organization.