MEGADYNE

PART OF THE ETHICON™ FAMILY OF COMPANIES

11-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

Dear Valued Customer,

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.

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

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 electronically at 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
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 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.
5. Complete the Business Reply Form (BRF) **Attachment A** confirming receipt of this notice and return it to jnjmedical-ch@its.jnj.com (Johnson & Johnson AG) within three (3) business days.
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 jnjmedical-ch@its.jnj.com (Johnson & Johnson AG).
7. If you have any further questions related to this notice or if you need any additional communications, please contact your local Sales Representative or jnjmedical-ch@its.jnj.com (Johnson & Johnson AG).

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

This action is being taken with the knowledge of the Swiss National Health Authority.

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.

Attachments
Attachment A: Business Reply Form for Update to Intended Use Population

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

Business Reply Form (BRF)

Your timely response to this notification is requested. Please complete and email this form to jnjmedical-ch@its.jnj.com **within 3 business days.**

Account Name:	Account Address:
Your Name and Title:	Date:
Email Address:	Telephone Number:
J&J 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

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

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