MEGADYNE

PART OF THE ETHICON™ FAMILY OF COMPANIES

December 8, 2023

# URGENT: MEDICAL DEVICE CORRECTION

## 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 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 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 patients 25 lbs. and over) and 0840 (indicated for patients from 0.8 lbs. and up to 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 the 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 > 0.8 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 fax or email it to Sedgwick at 888-214-7430 or Ethicon5627@sedgwick.com 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 Sedgwick at the phone number shown below.
7. If you need additional copies of this communication or have questions about returning the BRF, please contact Sedgwick at 888-843-0254 and reference Event # 5627.

If you have additional questions regarding this communication or to report any product complaints, please contact the Ethicon Resource Department at 1-877-ETHICON (1-877-384-4266). The Ethicon Resource Department is open Monday through Friday, 8:00 AM to 5:00 PM ET.

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 United States Food and Drug Administration. Recent guidance from the FDA has encouraged the use of electronic communications for conveying voluntary recall communications for FDA-regulated products to reduce notification timelines. If you would like to receive future voluntary recall communications electronically, please provide your contact information via the following link and a registration email will be sent to the contact information provided: https://novasyte-smart.my.site.com/jnjcontactcollection.

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program online, by regular mail or by fax:

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail:
  Use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm
  Mail to: MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

**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 fax this form to Sedgwick at 888-214-7430 or e-mail the form to Ethicon5627@sedgwick.com **within 3 business days.**

[Account Name]
[Account Address]

| | |
|---|---|
| Your Name and Title: | Date: |
| Email Address: | Telephone Number: |
| J&J Account Number: [Account Number] | |
| Signature*:<br><br>**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: |