MEGADYNE

PART OF THE ETHICON™ FAMILY OF COMPANIES

14 May 2024

URGENT: MEDICAL DEVICE RECALL (REMOVAL)

MEGADYNE™ MEGA SOFT™ Pediatric Patient Return Electrode
Product Code: 0840

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT CODE REFER TO ACTIONS REQUIRED FOR FURTHER INSTRUCTIONS.

Product Name	Product Code	UDI-DI
MEGADYNE™ MEGA SOFT™ Pediatric Patient Return Electrode	0840	10614559103395

Dear Recall Coordinator

Records indicate that you have ordered or received product subject to this recall.
PLEASE DISTRIBUTE THIS INFORMATION WITHIN YOUR FACILITY TO ALL STAFF INVOLVED WHO USE MEGADYNE™ MEGA SOFT Pediatric Patient Return Electrode.

Purpose of this Letter
Megadyne Medical Products Inc. has initiated a voluntary medical device recall (removal) of all distributed lots of the MEGADYNE™ MEGA SOFT™ Pediatric Patient Return Electrode. Megadyne has decided to discontinue and recall the MEGADYNE™ MEGA SOFT™ Pediatric Patient Return Electrode. This removal only impacts the Pediatric Patient Return Electrode, product code 0840. No other product codes are impacted.

Reason for the Voluntary Recall (Removal)
Megadyne has received reports of patient burn injuries in procedures where the Mega Soft Patient Return Electrodes were used. A root cause investigation on the reports included testing which showed a combination of factors when present together may result in potential for thermal injuries.

The combination of these conditions may be more likely when the pad is used with infants and small children. Because the pediatric pad is designed for patients between 0.8 to 50 pounds, which would be predominantly patients under the age of 12, the decision was made to discontinue and recall the 0840 pediatric pad product.

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. Burns could lead to potentially longer-lasting impacts on smaller, pediatric patients.

Health care practitioners who have used Mega Soft Pediatric Patient Return Electrodes during patient procedures should follow those patients post-operatively in the usual manner.

Actions Required

1. Examine your inventory immediately to determine if you have product subject to this recall on hand and quarantine such product(s). If you have product subject to this recall, please quarantine the product, maintain a copy of this notice with the quarantined product, and keep a copy of this notice for your records.

MEGADYNE

PART OF THE ETHICON™ FAMILY OF COMPANIES

URGENT: MEDICAL DEVICE RECALL (REMOVAL)

MEGADYNE™ MEGA SOFT™ Pediatric Patient Return Electrode
Product Code: 0840

2. Communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed. If any product subject to this recall has been forwarded to another facility, contact that facility to arrange a return. Please consider including a copy of this recall letter when communicating.
3. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and email MDFieldActionsUKIrl@its.jnj.com within three (3) business days. **Please return the BRF even if you do not have product subject to this recall**.
4. Customers are required to immediately return all MEGADYNE™ MEGA SOFT™ Pediatric Patient Return Electrodes subject to this recall that are in inventory. To receive credit reimbursement, customers must return product subject to this recall as soon as possible. Any non-affected product will not receive credit reimbursement.
5. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to Sedgwick.
6. If product subject to this recall is contained in a custom kit, please contact your custom kit assembler for return instructions.

If you require any assistance with returning product, please contact MDFieldActionsUKIrl@its.jnj.com

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 you have any further questions related to this notice or if you need any additional communications.

Attachments

Attachment 1: Product Identification Tool
Attachment 2: Business Reply Form (BRF)

MEGADYNE

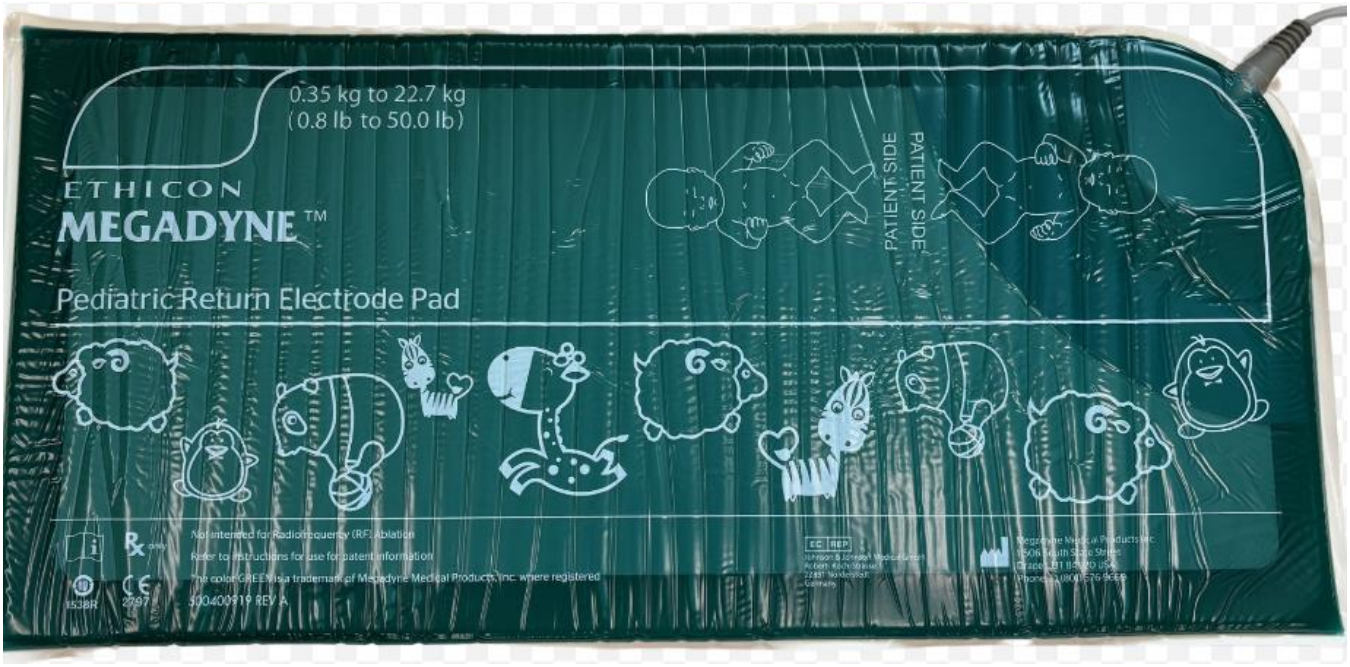
PART OF THE ETHICON™ FAMILY OF COMPANIES

URGENT: MEDICAL DEVICE RECALL (REMOVAL)

MEGADYNE™ Suction Coagulators

Attachment 1: Product Identification Tool

Please refer to the photo below to identify the MEGA SOFT™ Pediatric Patient Return Electrode.



MEGADYNE

PART OF THE ETHICON™ FAMILY OF COMPANIES

URGENT: MEDICAL DEVICE RECALL (REMOVAL)

MEGADYNE™ MEGA SOFT™ Pediatric Patient Return Electrode
Product Code: 0840

Attachment 2: Business Reply Form for MEGA SOFT™ Pediatric Patient Return Electrode

Your timely response to this recall notification is requested. Please complete this form and email it to MDFieldActionsUKIrl@its.jnj.com **within 3 business days, even if you do not have product subject to this recall to return.**

If you have product subject to this recall to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

Your Name/Title:	Date:
Email Address:	Telephone Number:
Hospital Address:	
Collection Department:	
Signature*: **Your signature provides confirmation that you have received and understood this notification.*	
Your comments are welcome.	

Product Inventory – *please check one*

☐ We have NO inventory of product subject to this recall (removal).

☐ We have product subject to this recall (removal) and are returning the following products:

PRODUCT CODE	SERIAL NUMBER

Note: Use additional BRF sheet if additional space is needed to record serial numbers.