MEGADYNE

PART OF THE ETHICON™ FAMILY OF COMPANIES

Date: 03 Jul 2023

Dear Valued Customer,

URGENT FIELD SAFETY NOTICE

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

Important information regarding potential for patient burns and proper steps for cleaning and setup.

Products in Scope:

Product Name	Product Code	UDI-DI	Expiration Dates
MEGADYNE™ MEGA 2000 Patient Return Electrode	0800	10614559100936	May 2023 to Current Date
MEGADYNE™ MEGA SOFT™ Reusable Patient Return Electrode	0830	10614559101797	
MEGADYNE™ MEGA SOFT™ Dual Reusable Patient Return Electrode	0835	10614559101872	
MEGADYNE™ MEGA SOFT™ Pediatric Patient Return Electrode	0840	10614559103395	
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 USERS INVOLVED in the MEGADYNE™ MEGA SOFT™ and MEGA 2000 Reusable Patient Return Electrode cleaning, operating room and patient setup, and device operation during procedures.

To The Attention of:

Operating Room Manager/Surgeon

Purpose of this Letter

The purpose of this letter is to help ensure safe and effective use of the MEGADYNE™ MEGA SOFT™ and MEGA 2000 Reusable Patient Return Electrodes (“Mega Soft pads”) and to bring heightened awareness of the potential for burns and actions you can take which may help mitigate risks related to the Mega Soft pad setup and cleaning process. This letter is a notification and is not a product removal.

Reason for the Voluntary Field Safety Notice

Megadyne Medical Products, Inc. (“Megadyne”) has received reports of patient burns identified after surgical procedures in which Mega Soft pads were used. Megadyne is aware of 63 complaints of serious patient burns globally since April 2018. We have conducted a thorough investigation, and to this point have not identified any design or manufacturing defects, nor have we determined definitive root cause. However, Megadyne has determined that in some instances the Mega Soft pad Instructions for Use (IFU) were not being properly followed. The Mega Soft pad IFU includes proper setup steps, including that the

Mega Soft pad must be thoroughly rinsed after cleaning to ensure residue from cleaning solutions are removed prior to pad use. Failures to follow the Mega Soft pad IFU may contribute to patient burns if cleaning solution residue is not properly rinsed off. Please refer to the Mega Soft pad IFU for complete instructions on use and care. See **pages 3-5** of this letter for important highlights related to proper cleaning and setup of Mega Soft pads. We will notify customers if we identify any additional actions and mitigation steps that may help to further reduce risk and help 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.

Health care practitioners who have used Mega Soft pads during patient procedures should follow those patients post-operatively in the usual manner with no additional action required related to this correction.

Actions Required

1. Share this notification with all users involved in Mega Soft pad cleaning, operating room and patient setup, and device operation during procedures.
2. Confirm that personnel using the Mega Soft pads are following the instructions for use as shown in the photos and bullets below. Copies of the Mega Soft pad IFUs can be found in the product packaging or at https://www.e-ifu.com when Mega Soft pads transition to electronic IFU.
3. Display **Attachment 2** (Cleaning and Care Visual Aid) and **Attachment 3** (Placement and Setup Visual Aid) near the OR for staff reminders regarding Mega Soft pad cleaning and setup.
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 1** (Customer Acknowledgement Letter) to your Johnson & Johnson sales consultant or contact person.
6. Contact your local distributor for additional support as needed.

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.

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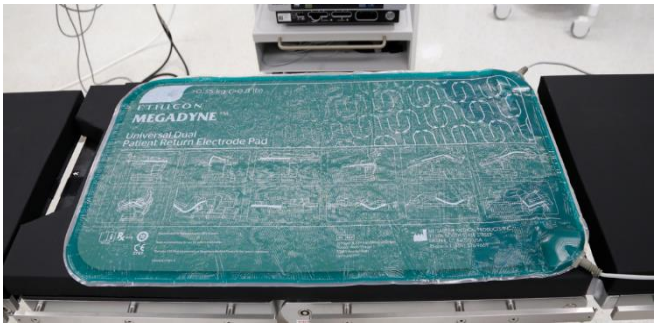
Cleaning the Mega Soft Pad

Clean & Disinfect Mega Soft Pad	Rinse Mega Soft Pad	Dry Mega Soft Pad
		
• **Clean/disinfect the electrode and cable after each patient use (e.g., a mild bleach solution (10:1)).** • **Do not use hydrogen peroxide[1] and limit cleaning agents with alcohol formulations to no more than 70%.** [1]Note: Not applicable for 0800 MEGADYNE™ MEGA 2000 Patient Return Electrode	• **Thoroughly rinse the patient return electrode with clear water after cleaning to remove any residue from cleaning solutions.**	• **After rinsing, dry the patient return electrode prior to next use. As with other medical devices, avoid pooling of chemicals or fluids that may contribute to patient skin breakdown or pressure ulcer formation.**

Patient Setup with the Mega Soft Pad

Do	Do Not
	
• **Do: Place the patient return electrode on the operating surface (Non-metal).** • **Do: For product code 0800 (Mega 2000™) only, place the patient return electrode into the Mega 2000™ Sheath.** • **Do: Inspect the Patient Return Electrode for damage to the outer skin, cable(s), or connector(s).**	• **Do not place the patient return electrode directly onto a metal surface.**

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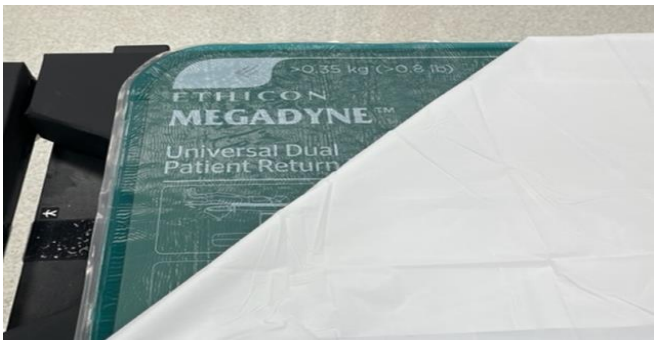
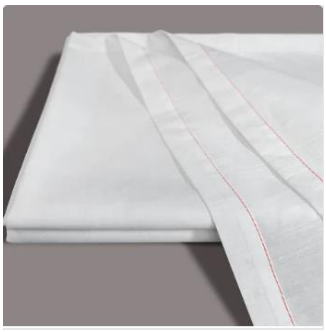
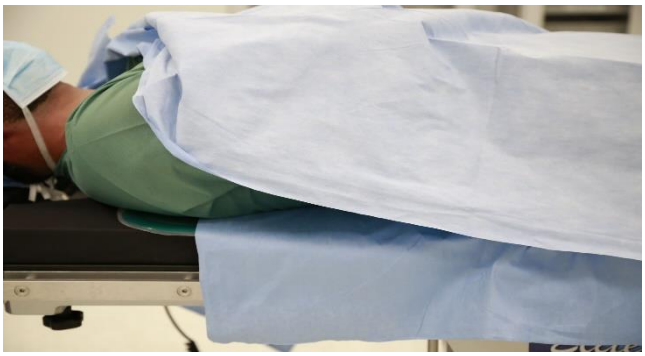
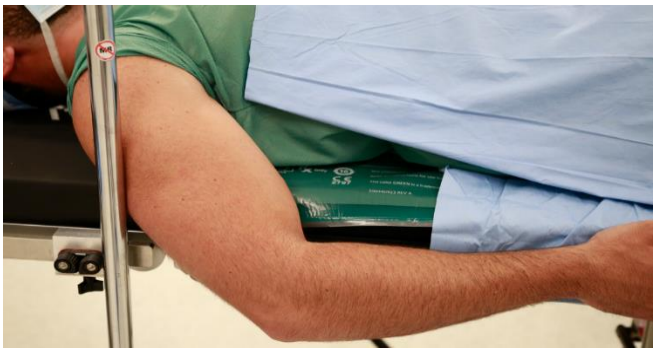
Do	Do Not
	
• **Do: A sheet and draw sheet may be placed over the Patient Return Electrode.**	• **Do not place excessive amounts of linens or other materials between the patient and the Patient Return Electrode.**

Do	Do Not
	
• **Do: Keep the patient away from contact with metal parts that are grounded.**	• **Do not allow the patient to come into contact with metal parts that are grounded.** ○ **Ex: Metal portions of tables, IV poles, warming blankets with foil liner, etc.**

Do	Do Not
• **Do: Prevent skin-to-skin contact. For example, dry gauze could be used to prevent skin-to-skin contact.** • **Do: When high frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes.**	• **Do not have skin-to-skin contact. For example, contact between the arms and body of the patient should be avoided.**

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• **Do: Monitoring systems incorporating high frequency current limiting devices are recommended.**	• **Use of needle monitoring electrodes is not recommended.**

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,

Jennifer Tseng

Digitally signed by Jennifer Tseng
DN: c=US, o=JNJ, ou=Subscribers, cn=Jennifer Tseng, 0.9.2342.19200300.100.1.1=1027382
Reason: I am approving this document
Date: 2023.07.03 17:02:32 +08'00'
Adobe Acrobat Reader version: 2020.013.20064

Jennifer Tseng
Johnson & Johnson Sdn. Bhd.,
Head of Commercial Quality Malaysia & Indonesia

Attachments

Attachment 1: Customer Acknowledgement Letter
Attachment 2: Cleaning and Care Visual Aid for OR Use
Attachment 3: Placement and Setup Visual Aid for OR Use

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Attachment 1: Customer Acknowledgement Letter

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.

MEGADYNE™ MEGA SOFT™

Reusable Patient Return Electrode

Cleaning and Care

Below is a reinforcement for key instructions for use of the MEGADYNE™ Patient Return Electrode Pads. Please reference the IFU for complete instructions. Any additional questions, please reach out to our Ethicon Sales Representative.

DO

Step 1: CLEAN

- Clean/disinfect the Patient Return Electrode Pad and cable (e.g., a mild bleach solution (10:1)).

Step 2: RINSE

- **Thoroughly rinse the Patient Return Electrode Pad with clear water to remove any residue from cleaning solutions.**
- **Running water is not required for rinsing;** may be wiped with a wet cloth.

Step 3: DRY

- **Completely dry** both sides of the Patient Return Electrode Pad after each cleaning.
- **Ensure bed is completely dry** before placing the Patient Return Electrode Pad on the OR table.

DO NOT

- **Do not use hydrogen peroxide or hydrogen peroxide-containing materials to clean the Patient Return Electrode Pad.**

- **Do not use disinfectant containing more than 70% alcohol to clean the Patient Return Electrode Pad.**

Please follow the IFU instructions for the Mega 2000™ Patient Return Electrode Pad with the Mega 2000™ Sheath for Cleaning and Care.

Johnson & Johnson Sdn. Bhd.,
Level 8, The Pinnacle, Persiaran Lagoon, Bandar Sunway,47500
Petaling Jaya, Selangor, Malaysia.
Registered under Act 737 with Registration no: GC2965522-109913
250825-230613
For Healthcare Professionals Only

MEGADYNE™ MEGA SOFT™

Reusable Patient Return Electrode

Placement and Setup

Below is a reinforcement for key instructions for use of the MEGADYNE™ Patient Return Electrode Pads. Please reference the IFU for complete instructions. Any additional questions, please reach out to our Ethicon Sales Representative.

DO

Step 1: PLACE

- Place the Patient Return Electrode Pad on a non-metal surface (e.g., padded or draped surface).

Step 2: DRAPE

- Although the Patient Return Electrode Pad is safe to use with direct patient contact, we recommend that the Patient Return Electrode Pad is draped with a thin bed linen or sheet between the patient and Patient Return Electrode Pad.

Best Practice

- Maximize patient contact with the Patient Return Electrode Pad.
- Minimize excessive layers between the patient and the Patient Return Electrode Pad.

DO NOT

- **Do not place the Patient Return Electrode Pad directly on a metal surface.**
- **Do not allow the patient to come in contact with metal parts that are grounded when placed on the Patient Return Electrode Pad.**
- **Do not use excessive amounts of linen or other materials between the patient and the Patient Return Electrode Pad.**
- **Do not allow cleaning solutions or rinse water to come into contact with metal connectors.**
- **It is not recommended to use needle monitoring electrodes with the use of the Patient Return Electrode Pad.**

Please follow the IFU instructions for the Mega 2000™ Patient Return Electrode Pad with the Mega 2000™ Sheath for Cleaning and Care.

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