MEGADYNE

PART OF THE ETHICON™ FAMILY OF COMPANIES

[Insert Date]

URGENT: FIELD SAFETY NOTICE

MEGADYNE™ Suction Coagulators

Product Codes: 004125, 004225, 0042-25, 004325

– Voluntary Product Recall (Removal) –

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

PRODUCT NAME	PRODUCT CODE	EXP DATE RANGE	UDI/GTIN	DESCRIPTION / SIZE
MEGADYNE™ Suction Coagulators	004125	June 30, 2023 - October 31, 2027	10614559105146	Suction Coagulator, Handswitching, 10 Fr, 6 inch (15.24cm)
MEGADYNE™ Suction Coagulators	004225	June 30, 2023 - October 31, 2027	10614559105153	Suction Coagulator, Handswitching, 8 Fr, 6 inch (15.24cm)
MEGADYNE™ Suction Coagulators	0042-25	June 30, 2023 - July 31, 2025	10614559102923	Handswitching Suction Coagulator, 8 Fr 25 Unit Case
MEGADYNE™ Suction Coagulators	004325	June 30, 2023 - October 31, 2027	10614559105160	Suction Coagulator, Handswitching, 12 Fr, 6 inch (15.24cm)

Please utilize **Attachment 1** for assistance in identifying subject products.

Dear Operating Room Supervisors, Materials Management Personnel, and Chief of Surgery,

Records indicate that you have ordered or received product subject to this recall.

PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE MEGADYNE™ Suction Coagulators

Purpose of this Letter

Megadyne Medical Products, Inc. (“Megadyne”) has initiated a voluntary medical device recall (removal) of all distributed lots of hand-controlled MEGADYNE™ Suction Coagulators within the expiration ranges listed above. This removal only impacts hand-controlled devices. Foot-controlled devices are *not* impacted.

Reason for the Voluntary Correction

Megadyne identified a potential issue during internal testing on the Suction Coagulator product family which may lead to fluid ingress into the handpiece. Fluid ingress can lead to intermittent device activation, non-activation, or self-activation when plugged into the electrosurgery unit (ESU).

Risk to Health

When the issue presents as non-activation or intermittent device activation, the user may not be able to continue the procedure and must use a new or alternative device or method to continue the procedure.

Once a non-activation or intermittent device activation occurs, users will likely be able to detect the device issue through either function abnormalities, observation of patient/user impacts or both.

When the issue presents as self-activation, inadvertent thermal injury may occur. The extent of thermal damage to tissue depends on anatomic location involved in the procedure. Most thermal injuries from

device self-activation should not need substantial treatment because of the user's ability to immediately observe the event and move the device away from patient tissue, making any exposure time very brief. However, thermal damage to unintended organs/tissues/vessels may require significant surgical intervention to prevent permanent impairment of patient body structure/ function.

In addition to potential impact to patients, fluid ingress may result in the device operator experiencing mild shock. Based on the voltage and current involved in this situation, potential harm includes tingling feelings and small burns.

Megadyne identified this issue during internal testing and we are not aware of any patient or user injury caused by this issue. Health care practitioners who have treated patients using this product should follow those patients post-operatively in the usual manner with no additional action required related to this removal.

ACTION 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 maintain a copy of this notice with the quarantined product and keep a copy for your records.
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 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 return to [Enter Affiliate Information] 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 return unused MEGADYNE™ Suction Coagulators subject to this recall that are in inventory immediately. To receive credit reimbursement, customers must return product subject to this recall no later than September 30, 2023 to [Enter Affiliate Information]. Any non-affected product and any product returned after the date specified 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 [Enter Affiliate Information]

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Other Information

At Megadyne, our first priority is to our customers and their patients, and that includes the safe and effective use of our products. We recognize the recall of this product may be disruptive to your facility and we appreciate your assistance in this matter.

If you have additional questions regarding this voluntary product recall or require any assistance with returning product, please contact [Enter Affiliate Information].

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, please contact your local Sales Representative.

ATTACHMENTS:

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

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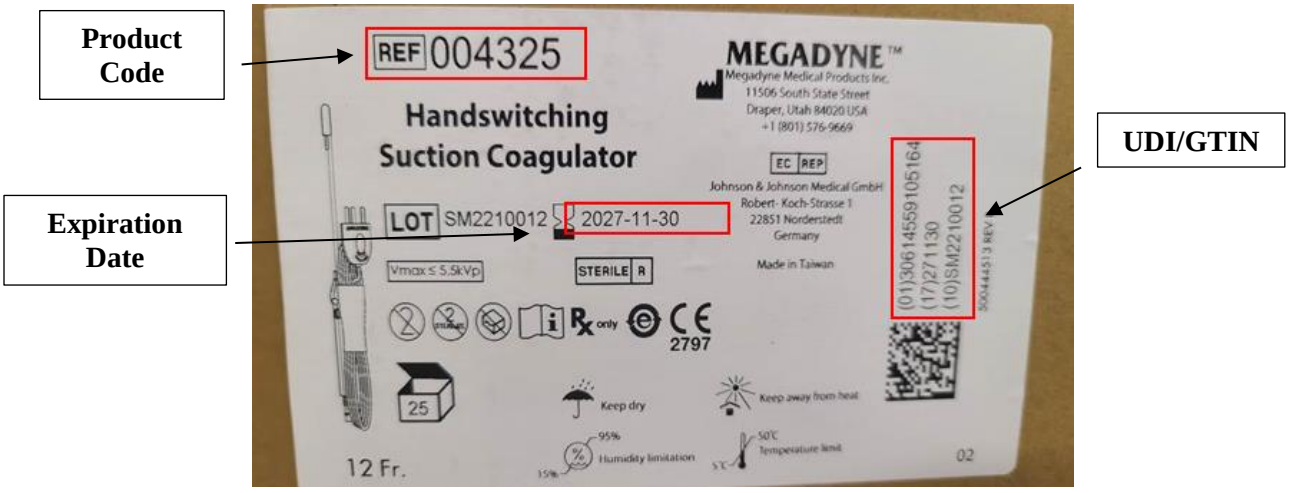
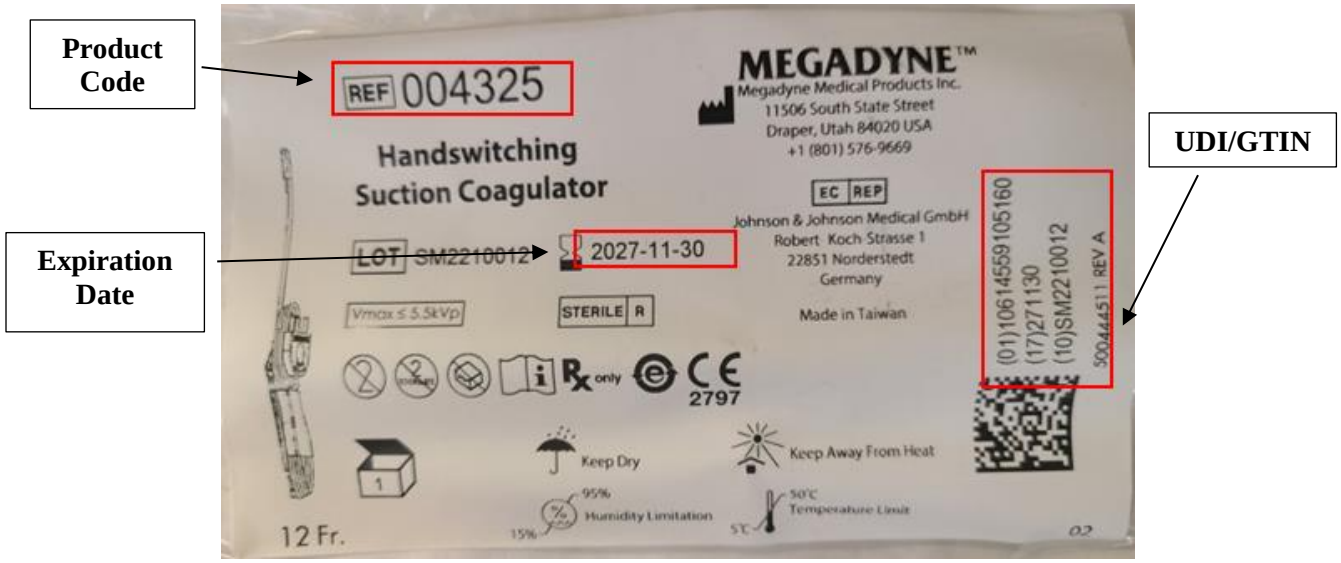
Attachment 1: Product Identification Tool

Please refer to the below to identify the location of the subject product code, expiration date, and UDI for impacted MEGADYNE™ Suction Coagulators by using the packaging labels.

Sales Unit Box



Individual Unit



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Attachment 2: Business Reply Form

Business Reply Form (BRF)

Your timely response to this recall notification is requested. Please complete this form and fax or email it to Sedgwick at [INSERT FAX NUMBER] or e-mail the form to [EMAIL ADDRESS] **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.

[Account Name]
[Account Address]

Your Name/Title:	Date:
Email Address:	Telephone Number:
J&J Account Number:	
Reference PO for Credit, if needed:	
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	PRODUCT LOT	EXP DATE	QUANTITY RETURNING (EACHES)