Medline Industries, LP
IMMEDIATE ACTION REQUIRED
URGENT MEDICAL DEVICE RECALL

1/7/2025

Account Number
Account Name
Address
Cit, St, Zip

Dear Valued Medline Customer:

Medline Industries, LP is issuing a recall for specific item(s) and lot(s) of Proxima Sterile Surgical Gowns, Packs, and Drapes (the Recalled Products). Medline has identified issues related to calibration of the equipment used to sterilize and package the devices. All products were exposed to the validated sterilization and packaging cycles; however, the identified calibration issues have the potential to impact the sterility assurance level (SAL) of the Recalled Products. This creates the potential for a non-sterile device to be placed within the sterile field, or a non-sterile device to be used within a sterile procedure. This could lead to contamination of a sterile field and/or potential for patient infection to occur. Medline has received no reports of infection or other defects related to the sterility of the Recalled Products. The Recalled Products are to be destroyed. Be advised that there may be item number variations based on the unit of measure ordered by your facility, indicated by an H appended to the item number(s) included with this communication. Note, there is no product difference between variations in units of measure, and physical labeling will reflect the base item number (i.e. DYNJP2002S). Refer to the attached guide for instructions on identifying lot numbers. Please refer to the enclosed list for all affected item number(s) and affected lot number(s).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax and to Medline Industries, LP.

REQUIRED ACTION:

1. Immediately check your stock for the affected item number(s) and the affected lot number(s) listed within the recall portal. Quarantine all affected product. Upon completion of the below actions, please destroy affected product.

2. Please use the link and the information below to complete your response form. Please list the quantity of affected product you have in inventory on the form. Even if you do not have any affected product in inventory, please complete and submit the response form.

   Website link: https://recalls.medline.com
   Recall Reference #: R-25-XXX
   Recall Code: <RECALL CODE>

3. Your account will receive credit once the response form is submitted.

4. If you are a distributor, or have resold or transferred this product to another company or individual, you are required by FDA regulations to notify them of this recall communication. Please request that customers destroy any affected product. You should include your customers' quantities on your response form.

If you have any questions, contact the Recall Department at 866-359-1704 or recalls@medline.com.

Please accept our sincere apologies for any inconvenience this may have caused. We, like you, place the health and safety of your patients first and foremost.

Sincerely,
Karin Johnson (kjohnson)
Product Recall Coordinator

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