Medline Industries, LP
IMMEDIATE ACTION REQUIRED
Medline 14 Fr Suction Catheter Kits

12/24/2025

Dear Valued Medline Customer:

Medline Industries, LP is issuing a recall for specific item(s) and lot(s) of Medline 14 Fr Suction Catheter Kits (Item number DYND40972, Lot number 48625040001). It has been identified that a smaller open suction catheter, the 8 Fr Suction Catheter, may have been packed within the 14 Fr Suction Catheter Kits instead of the required 14 Fr Suction Catheter. Use of a smaller size suction catheter may lead to difficulty or inability to aspirate liquids or semisolids from a patient's upper airway and may result in hypoxia and/or respiratory failure related to partial or full airway obstruction. Airway obstruction may require immediate emergent medical intervention to prevent respiratory failure and/or death. If the smaller catheter is able to remove secretions from the patient's airway, this may result in a prolonged procedure due to the additional time needed to remove secretions through a smaller size catheter, which may cause airway irritation or prolonged dyspnea. Not all kits from lot number 48625040001 are expected to have the incorrect suction catheter size. Please check your stock/inventory for the affected products and refer to the attached instructions with example images of the correct and incorrect products. Quarantine all affected kits until you have confirmed alternative suction catheters are available for use. Over-labels with instructions to remove and discard the incorrect component if identified will be provided for placement on affected kits prior to use. Upon opening the kit, please confirm which size suction catheter is included within the kit. Please ensure a replacement 14 Fr Suction Catheter from your supply is available during procedures to replace any incorrect product identified. Please notify your Medline Sales Representative if you do not have any 14 Fr Suction Catheters available within your supply. Be advised that there may be kit 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. DYND40972).

Please refer to the enclosed list for all affected item number(s) and affected lot number(s). Upon receipt of your recall response form, over-labels will be provided, which are to be placed on kits that contain the recalled component and will state the affected component shall be removed and discarded from further use.
Please contact your Sales Representative for any questions regarding component credit or replacement.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA'sMedWatch 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 on the enclosed response form. Quarantine all affected product.
2. Please complete and return the enclosed response form listing the quantity of affected product you have in inventory. Even if you do not have any affected product in inventory, please complete and return the response form.
3. Upon receipt of your submitted response form, your account will receive over-labels to place on affected inventory, with instructions for your staff to remove and discard the affected component prior to using the kit. These labels will be provided via FedEx overnight, if applicable.
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 include your customers' quantities on your response form. Upon receipt of your submitted response form, you will receive over-labels to provide to your customers to affix to their affected product.

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.

Confidential - For intended recipients only. Do not Distribute.

Medline Industries, LP. Three Lakes Drive
Northfield, IL 60093-2753
Toll Free: 866.359.1704
Website: medline.com
Email: Recalls@Medline.com
Fax: 866.767.1290

Recall Ref#: R-25-255-FG



Sincerely,

Karin Johnson

Karin Johnson
Product Recall Specialist Sr.
Enclosed: Response Form

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MEDLINE INDUSTRIES, LP

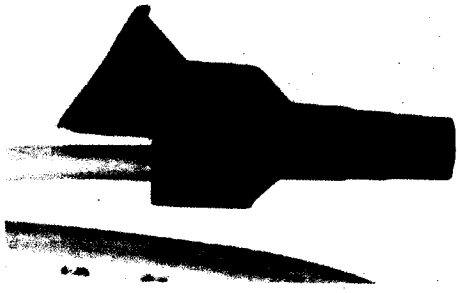
Medline 14 Fr Suction Catheter Kits

Instructions in Reference to Recall R-25-255-FG

1. **Please ensure a replacement 14 Fr Suction Catheter from your supply is available during procedures to replace any incorrect product identified.** Please notify your Medline Sales Representative if you do not have any 14 Fr Suction Catheters available within your supply. Quarantine all affected kits until you have confirmed alternative suction catheters are available for use.

2. Upon opening the affected kit, please confirm which size suction catheter is included. The different sizes can be identified based on the suction catheter connection color.

    a. If the kit includes the 14 Fr Suction Catheter (**green connector**), the suction catheter can continue to be used. The example image below shows the ***correct*** suction catheter (14 Fr Suction Catheter).



    b. If the kit includes the 8 Fr Suction Catheter (**blue connector**), please remove from the kit and discard, and replace it with a 14 Fr Suction Catheter from your supply. The remainder of the kit can continue to be used. The example image below shows the ***incorrect*** suction catheter (8 Fr Suction Catheter). DO NOT USE THIS DEVICE.

