

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE PRODUCT REMOVAL, DISCONTINUATION, & MARKET EXIT

This document contains important information for your equipment.

Please review the following information with anyone who needs to be aware of the contents of this communication. It is important to understand the implications of this communication.

Date: October 14, 2026

Subject: PRODUCT REMOVAL, DISCONTINUATION, & MARKET EXIT – All Medline Brand beds, including homecare beds, bariatric beds, and long-term-care beds, and their associated pendants, accessories, replacement parts, and bed-containing order packages

To: Medline Customer

Affected Products: Refer to **Attachment 1** for a list of the SKUs within the scope of this notice.

PURPOSE OF THIS LETTER

The purpose of this letter is to inform you that Medline Industries, LP (“Medline”) is executing a voluntary field action to initiate a product removal, discontinuation, and market exit of all Medline Brand beds, including homecare beds, bariatric beds, and long-term-care beds, and their associated pendants, accessories, replacement parts, and bed-containing order packages.

This notice is being issued as a follow-up to customers who were sent previous communications regarding Medline Basic Homecare Beds, Medlite Homecare Beds, and Basic Homecare Bed Pendants, and as an initial notification to customers who were not sent those prior communications. This notice applies to all Medline Brand beds SKUs, associated pendants SKUs, accessories SKUs, replacement parts SKUs, and bed-containing order packages SKUs, and is related to 1) electrical system safety risks that may result in fire, and 2) entrapment risk from the use of any bed accessories.

REASON FOR FIELD ACTION & CLINICAL RISK ASSESSMENT

Issue Description:

1. Electrical Safety Risk

Description of the Issue and Circumstances Under Which It Can Occur:

Medline has identified a potential fire hazard involving Medline Brand beds, hand-control pendants, control/motor boxes, and actuators/motors. Under certain conditions, including but not limited to excessive system loading, jammed components or motors, damage to or fluid ingress into the pendant, the use of extension cords, or the use of non-Medline or unapproved pendants or accessories, the bed's electrical components may overheat.

Risks to Health

Overheating of the bed's electrical components may progress to smoking, sparking, melting, burning, and/or fire. These events may increase the risk of adverse health consequences, including electrical shock and burns. If a fire occurs, there is the potential for serious injury or death, including burns, chronic respiratory conditions resulting from smoke inhalation, post-traumatic stress disorder (PTSD) related to fire incidents, or fatality. Medline has received reports of adverse events associated with this issue.

2. Entrapment Risk

Description of the Issue and Circumstances Under Which It Can Occur:

Medline has received information through post-market surveillance regarding risk when using any bed accessories. Specifically, the use of bed accessories may lead to entrapment.

Risks to Health

There is a potential risk of entrapment or asphyxiation if: 1) Medline Brand beds are used with any bed accessories, 2) if a user lays on a pendant being used with the bed, or 3) if the bed is used with loose or wobbly rails. Entrapment or asphyxiation may result in patient injury or death. Medline has received reports of adverse events associated with this issue.

USER ACTIONS

Immediate Actions

1. Immediately unplug the bed and any associated battery packs or batteries from the bed or accessories.
2. Do not use the electrical functionality of the bed. You may continue to use the Medline Brand bed with a mattress in manual mode only until you replace the bed.

3. You may only make electrical adjustments to the bed in emergency situations (e.g., choking, CPR).
4. If the bed is plugged back in for emergency use, do not use extension cords.
5. If the bed is plugged back in for emergency use, ensure that the Medline Brand bed pendants and power cords are routed and secured.
6. Do not use any bed accessories, including side rails, with Medline Brand beds.

Follow Up Actions

1. Medline will provide our customers with a label containing safety instructions to place on Medline Brand beds. If you do not receive a label from the provider or distributor from whom you purchased or received the bed by November 30, 2026, please contact Medline Recall Customer Service at 800-950-0128, option 7.
2. If you received a Medline Brand bed within the last 5 years, please contact the provider or distributor from whom you purchased or received the bed to determine whether you are eligible for a reimbursement and/or credit.
3. To facilitate the removal and replacement of the affected Medline Brand beds, you may contact the provider or distributor from whom you purchased or received the bed for further information.
4. If you purchased your bed directly from Medline, please contact Medline Recall Customer Service at 800-950-0128, option 7.

REPORTING AN ADVERSE EVENT

Any adverse event, including but not limited to adverse events related to the electrical system safety risks and entrapment risk from the use of any bed accessories should be reported.

- Report the event to Medline according to the instructions provided in this notification.
 - Email: QualityAssurance@medline.com
 - Phone: 1-800-950-0128 option 5
- Report any serious injury or adverse event associated with use of the circuit in accordance with applicable facility procedures and regulatory reporting requirements.

Reporting to the FDA MedWatch Serious Injury Reporting Program:

- Online: By completing and submitting the report online at:
www.fda.gov/medwatch/report

- Regular mail or Fax: Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

If you have any questions, contact Medline Recall Customer Service at 800-950-0128 option 7.

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
Product Recall Specialist Sr.
Medline Industries, LP