



Medline Industries, LP  
Three Lakes Drive  
Northfield, IL 60093

## **MEDLINE INDUSTRIES LP**

### **IMMEDIATE ACTION REQUIRED**

### **URGENT MEDICAL DEVICE FIELD CORRECTION NOTICE**

Dear Medline Customer:

The purpose of this communication is to provide important information including field correction instructions related to Medline Basic and Medlite Homecare Beds. There are two risks which have been identified through post-market surveillance, specifically

- 1) electrical system safety risks which may result in fire and,
- 2) the use of non-Medline accessories with the beds may have the potential for entrapment

Details are included within this communication.

#### **Electrical Safety Risk associated with Medline Basic Homecare Beds**

This communication is applicable to Medline Basic Homecare Beds, SKUs MDR107002E, MDR107002E-4, MDR107003E, MDR107003E-4, and MDR107003ELO.

Medline Industries has identified a potential hazard involving the hand control pendant and associated wires. In rare and atypical scenarios—such as operating the bed above its specified weight limit, encountering an obstruction to bed movement, or experiencing jammed components/motor—the hand pendant and pendant cords may overheat and, in rare instances, pose a risk of fire.

Medline Industries, LP has received a total of (58) complaints associated with reports of pendant sparking, burning, melting, smoking or fire. All units have the potential to exhibit this failure mode related to the pendant; however, the observed occurrence rate is 0.01% across the distributed bed population.

Medline Industries, LP is actively investigating this issue. In the interim, to mitigate this risk, usage guidelines and safety instructions provided with the product should be strictly adhered to as well as the following instructions:

- 1) Do not operate bed above the specified weight limit**
- 2) Ensure none of the bed components are jammed**
- 3) Ensure that there is no obstruction to the movement of the bed**
- 4) Hang the pendant on headboard or footboard when not in use**
- 5) Do not store the pendant on mattress at any time, including while asleep**
- 6) Unplug the bed and call for service if any of the following occur**
  - a. Bed motors appear to be jammed, stalled, or malfunctioning
  - b. The bed pendant controls aren't working
  - c. Pendant wiring is damaged
  - d. Pendant becomes hot to the touch
  - e. Smoke, sparking, or other unsafe electrical conditions

### **Non-Medline Bed Side Rail and Accessory use with Medline Homecare Beds**

This communication is applicable to Medline Basic Homecare Beds, SKUs MDR107002E, MDR107002E-4, MDR107003E, MDR107003E-4, and MDR107003ELO, and Medlite Homecare Beds, SKUs MDR107002L, MDR107003L, and MDR107003LO.

The purpose of this communication is to provide an important reminder regarding the proper use of bed side rails and accessories with Medline Homecare Beds to ensure an optimal experience for end users. Medline Industries, LP has received information through post-market surveillance regarding risk when using non-Medline side rails or accessories, specifically the use of some non-Medline bed accessories may lead to patient injury or death.

Medline Industries, LP has received a total of (18) complaints that were related to misuse with a non-Medline side rail or bed assist bar. The observed occurrence rate is 0.0025% across the distributed bed population.

This communication is a reminder to **ONLY USE MEDLINE SIDE RAILS and MEDLINE ACCESSORIES that are intended for use with** Medline Homecare Beds. When using Medline Side Rails and Medline Accessories, follow all applicable instructions for use. **DO NOT USE** non-Medline side rails or non-Medline accessories, including extension cords, with Medline Homecare Beds. The following Medline Side Rail SKUs are compatible with both the Basic Homecare Beds and the Medlite Homecare Beds: MDS89697 (Clamp-On Half Rail), MDS89698N (Spring Loaded Half Rail), MDS89694N (Spring Loaded Full Rail), and MDS89695N (Economy Full Rail).

Medline Homecare Beds have been rigorously tested and proven safe and effective when used in accordance with the *Instructions for Use* provided with all Medline Homecare Beds.

Use of non-Medline bed side rails and accessories, including extension cords, with Medline Homecare Beds may result in serious damage to bed or *can cause patient injury or death*.

Sincerely,  
*Medline Quality Assurance Team*