Bed Rail Entrapment Risk Notification Guide

EN

NOTICE TO EQUIPMENT PROVIDER:

These instructions, in their entirety, must be provided to the patient, the patient's family and/or the patient's primary day-to-day caregiver at the time of installation of the equipment. Failure to do so may expose the patient to risk of injury or death as the result of Bed Rail Entrapment.

INVACARE®

Yes, you can®

1 BED RAIL ENTRAPMENT RISK NOTIFICATION

NOTICE TO PATIENT, PATIENT'S FAMILY AND/OR PRIMARY DAY-TO-DAY CAREGIVER

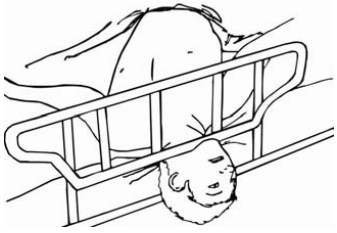
DO NOT use this product without first completely reading and understanding this Bed Rail Entrapment Risk Notification Guide and any additional instructional material such as owner's manuals, instruction sheets and on-product warnings supplied with this product. If you are unable to fully understand this Bed Rail Entrapment Risk Notification Guide, the on-product warnings or any additional instructional material, contact the patient's health care provider and/or your equipment provider before using this equipment. Failure to understand and comply with the information contained in this Bed Rail Entrapment Risk Notification Guide can result in serious injury or death.

BED RAIL ENTRAPMENT

The term "Bed Rail Entrapment" describes an event in which a patient using the bed is caught, trapped, or entangled in the space in or about the bed rail, mattress, or bed frame. Bed Rail Entrapment may result in serious injuries or death by the patient becoming entrapped as shown below:

Entrapment within the bed rail

Entrapment under the bed rail



Entrapment between the rail and mattress

Entrapment under the bed rail at the ends of the bed rail

Entrapment between split bed rails

Entrapment between the end of the rail and the side edge of the head board or foot board

Entrapment between the head or foot board and the end of the mattress

RISK OF ENTRAPMENT

Bed Rail Entrapment is a known risk in the use of bed's equipped with bed rails.

Every patient is unique. Only the patient's medical care provider is familiar with the patient's unique medical condition and needs. Only the patient's medical care provider and/or the dealer from whom you obtained this equipment, upon proper assessment of the patient's medical condition and needs, can evaluate whether this equipment is appropriate for use by any particular patient and assist the patient, the patient's family and/or the patient's primary day-to-day caregiver in assessing the Risk of Entrapment.

Proper patient assessment, equipment selection, frequent patient monitoring, and compliance with instructions, warnings and this Bed Rail Entrapment Risk Notification Guide is essential to reduce the risk of entrapment.

Accessories have been developed in the industry to reduce the openings in existing bed systems that could cause entrapment. Any modification through the use of accessories must be used in conjunction with proper patient assessment prior to intervention. For a full discussion on this topic, see the Hospital Bed Safety Workgroup's "A Guide for Modifying Bed Systems and Using Accessories to Reduce Risk of Entrapment" found at http://www.fda.gov.

Conditions such as restlessness, mental deterioration and dementia or seizure disorders (uncontrolled body movement), sleeping problems, and incontinence can significantly impact a patient's risk of entrapment. Pediatric patients or patients with small body size may also have an increased risk of entrapment.

1 BED RAIL ENTRAPMENT RISK NOTIFICATION

- Bed rails are intended to prevent an individual from inadvertently rolling out of bed, provide assistance to a patient when repositioning and to provide a sense of security. NEVER use bed rails for restraint purposes where "restraint" means preventing or hindering the patient within the bed from exiting the bed as they wish. Use of rails as a means of restraint significantly increases a patient's risk of entrapment.
- Bed rails are intended to be used as a pair in a bed system. When in use, both side rails must be in the up position, except when the patient is entering or exiting the bed. Use with one side rail up and one side rail down could create an increased risk of entrapment.
- Bed rails and/or their mountings should not be used if they are bent or otherwise deformed. Bent or deformed bed rails and/or bed rail mountings increase gaps and increase the risk of entrapment. DO NOT place pressure upon bed rails while moving the bed. Although bed rails are not rated to any specific patient weight limitation, the bed rails or their mountings may become deformed or broken if excessive side pressure is exerted on the bed rails.
- Mattress overlays or active therapeutic support surfaces (TSS), which support the patient on an air mattress or specialized foam layer, may present an increased risk of entrapment for some patients. The benefit of TSS product use must be weighed against the potential increased risk of entrapment. This risk judgment must be performed by a medical professional.
- Invacare homecare beds are specifically designed and manufactured for use in conjunction with Invacare accessories, including bed rails. Accessories designed by other manufacturers may include variations in bed rail dimensions, mattress thickness, mattress size or density or other factors that have not been tested by Invacare. Use of other manufacturer's products in conjunction with an Invacare homecare bed, may significantly increase the risk of entrapment; as such Invacare does not recommend their use.

The U.S. Food and Drug Administration in partnership with the U.S. Department of Veterans Affairs, Health Canada's Medical Devices Bureau and representatives from national health care organizations and provider groups, patient advocacy groups, and medical bed and equipment manufacturers including the Hospital Bed Safety Workgroup, a collection of experts from the United States FDA, health care professionals and manufacturers of hospital beds, published guidelines regarding body part dimensions as they relate to a bed system's safety. These guidelines, "**Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment"** contain additional information on the risk of entrapment.

Visit the FDA website at http://www.fda.gov and search for "bed rail entrapment" to learn about the risks of entrapment or to view the FDA guidelines document.

The above statements are not intended to be a complete or comprehensive list of all risks of entrapment. Invacare recommends that whenever bed products are used that the patient, the patient's family and/or the patient's primary day-to-day caregiver discuss entrapment risks with the patient's medical care provider.

2 Appendix

SPECIAL NOTE

For your convenience, the January 2008 version of the FDA's bed safety guidelines are provided in this section. The information from the FDA's brochure, published by Hospital Bed Safety Workgroup, is reproduced verbatim, the latest revision of which is available at http://www.fda.gov.

2.1 A Guide to Bed Safety Bed Rails in Hospitals, Nursing Homes and Home Health Care: The Facts

Bed Rail Entrapment Statistics

Today there are about 2.5 million hospital and nursing home beds in use in the United States. Between 1985 and 2005, 691 incidents of patients* caught, trapped, entangled, or strangled in beds with rails were reported to the U.S. Food and Drug Administration. Of these reports, 413 people died, 120 had a nonfatal injury, and 158 were not injured because staff intervened. Most patients were frail, elderly or confused.

* In this brochure, the term patient refers to a resident of a nursing home, any individual receiving services in a homecare setting, or patients in hospitals.

Patient Safety

Patients who have problems with memory, sleeping, incontinence, pain, uncontrolled body movement, or who get out of bed and walk unsafely without assistance, MUST be carefully assessed for the best ways to keep them from harm, such as falling. Assessment by the patient's health care team will help to determine how best to keep the patient safe. Historically, physical restraints (such as vests, ankle or wrist restraints) were used to try to keep patients safe in health care facilities. In recent years, the health care community has recognized that physically restraining patients can be dangerous. Although not indicated for this use, bed rails are sometimes used as restraints**. Regulatory agencies, health care organizations, product manufacturers and advocacy groups encourage hospitals, nursing homes and homecare providers to assess patients' needs and to provide safe care without restraints.

** Invacare bed rails MUST NEVER be used as a means of restraints.

2 APPENDIX

The Benefits and Risks of Bed Rails

Potential benefits of bed rails include:

- Aiding in turning and repositioning within the bed.
- Providing a hand-hold for getting into or out of bed.
- Providing a feeling of comfort and security.
- Reducing the risk of patients falling out of bed when being transported.
- Providing easy access to bed controls and personal care items.

Potential risks of bed rails may include:

- Strangling, suffocating, bodily injury or death when patients or part of their body are caught between rails or between the bed rails and mattress.
- More serious injuries from falls when patients climb over rails.
- Skin bruising, cuts, and scrapes.
- Inducing agitated behavior when bed rails are used as a restraint.
- Feeling isolated or unnecessarily restricted.
- Preventing patients, who are able to get out of bed, from performing routine activities such as going to the bathroom or retrieving something from a closet.

Meeting Patients' Needs for Safety

Most patients can be in bed safely without bed rails. Consider the following:

- Use beds that can be raised and lowered close to the floor to accommodate both patient and health care worker needs.
- Keep the bed in the lowest position with wheels locked.
- When the patient is at risk of falling out of bed, place mats next to the bed, as long as this does not create a greater risk of accident.
- Use transfer or mobility aids.
- Monitor patients frequently.
- Anticipate the reasons patients get out of bed such as hunger, thirst, going to the bathroom, restlessness and pain; meet these needs by offering food and fluids, scheduling ample toileting, and providing calming interventions and pain relief.

When bed rails are used, perform an on-going assessment of the patient's physical and mental status; closely monitor high-risk patients. Consider the following:

- Lower one or more sections of the bed rail, such as the foot rail.
- Use a proper size mattress or mattress with raised foam edges to prevent patients from being trapped between the mattress and rail.
- Reduce the gaps between the mattress and side rails.

Which Ways of Reducing Risks are Best?

A process that requires ongoing patient evaluation and monitoring will result in optimizing bed safety. Many patients go through a period of adjustment to become comfortable with new options. Patients and their families should talk to their health care planning team to find out which options are best for them.

Patient or Family Concerns About Bed Rail Use

If patients or family ask about using bed rails, health care providers should:

- Encourage patients or family to talk to their health care planning team to determine whether or not bed rails are indicated.
- Reassure patients and their families that in many cases the patient can sleep safely without bed rails.
- Reassess the need for using bed rails on a frequent, regular basis.

To report an adverse event or medical device problem, please call FDA's MedWatch Reporting Program at 1-800-FDA-1088.

For additional copies of the brochure, see the FDA's website at http://www.fda.gov/cdrh/beds/

For more information about this brochure, contact Beryl Goldman at 610-335-1280 or by e-mail at bgoldman@kendaloutreach.org. She has volunteered to answer questions.

For information regarding a specific hospital bed, contact the bed manufacturer directly.

Developed by the Hospital Bed Safety Workgroup

Participating Organizations:

- AARP
- ABA Tort and Insurance Practice Section
- American Association of Homes and Services for the Aging
- American Health Care Association
- American Medical Directors Association
- American Nurses Association
- American Society for Healthcare Engineering of the American Hospital Association
- American Society for Healthcare Risk Management
- Basic American Metal Products
- Beverly Enterprises, Inc.
- Care Providers of Minnesota
- Carroll Healthcare
- DePaul College of Law
- ECRI
- Evangelical Lutheran Good Samaritan Society
- Hill-Rom Co., Inc.
- Joint Commission on Accreditation of Healthcare Organizations
- Medical Devices Bureau, Health Canada
- National Association for Homecare
- National Citizens' Coalition for Nursing Home Reform
- National Patient Safety Foundation
- RN+ Systems
- Stryker Medical
- Sunrise Medical, Inc.
- The Jewish Home and Hospital
- Untie the Elderly, The Kendal Corporation
- U.S. Food and Drug Administration

Updated January 2008

Invacare Corporation www.invacare.com

Yes, you can.

USA
One Invacare Way
Elyria, Ohio USA
44036-2125
800-333-6900

Canada
570 Matheson Blvd E Unit 8
Mississauga Ontario
L4Z 4G4 Canada
800-668-5324

Part No 1171780 Rev A - 2/11