

Half Length Bed Rail Bariatric Lightweight Beds

Item # 15021BV-LW

Please read all instructions and warnings carefully, including the Entrapment Risk Guide starting on Page 5, in their entirety before installing this equipment

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1. WARNINGS AND PRECAUTIONS

PLEASE READ ENTRAPMENT RISK GUIDE STARTING ON PAGE 5, AS WELL AS THE FOLLOWING WARNINGS, IN THEIR ENTIRETY BEFORE INSTALLATION AND USE.

WARNING - ENTRAPMENT, STRANGULATION, SUFFOCATION AND FALL HAZARDS

Gaps in and around this product can entrap and kill. People with Alzheimer's disease or dementia, or those who are sedated, confused, or frail, and are at increased risk of entrapment and strangulation. People attempting to climb over this product are at increased risk of injury or death from falls. Always make sure this product is properly secured to bed. If product can move away from bed or mattress, it can lead to entrapment and death.

WARNING - SUFFOCATION / STRANGULATION / ENTRAPMENT HAZARD

If product is installed incorrectly or moves from its initial position gaps can occur which can entrap and kill. People with Alzheimer's disease, dementia or other neurological conditions, or those who are sedated, confused, or frail, are at increased risk of entrapment, suffocation and strangulation.

- NEVER use unless product is tight against mattress, without gaps, and at least 12 ½ in. from headboard and footboard.
- NEVER use with children
- NEVER use on toddler, bunk, water, or inflatable beds, or on beds with mattress toppers or soft compressible pads

WARNING - ENTRAPMENT HAZARD

NEVER use product without properly securing it to bed. Incorrect installation can allow product to move away from mattress, bed frame and/or head or foot boards, which can lead to entrapment and death.

WARNING - ENTRAPMENT HAZARD

Stop using immediately if damaged or broken, or if parts are missing. Stop using immediately if product shifts out of its original position until it is readjusted into the correct position. In addition to contacting the manufacturer directly, consumers should report problems to the CPSC at its website SaferProducts.gov or call 1-800-638-2772, or to the FDA at 1-800-332-1088. For further information, see: cpsc.gov/en/Safety-Education/Neighborhood-Safety-Network/Posters/Adult-Bed-Rails/ and www.fda.gov/bedsafety.

2. INTENDED USE

Bed rails may be used as an assistive device or for fall prevention for individuals utilizing a medical homecare bed. These rails (15021BV-LW) are for use only with Drive DeVilbiss Bariatric Lightweight Beds (Models# 15300LW, 15302LW, and 15303LW) and mattresses measuring between 6" and 10" in height. Use of these rails with any other bed system or any other mattress size than those indicated may create an entrapment risk which can result in injury or death.

3. INSTALLATION INSTRUCTIONS

READ ALL INSTRUCTIONS CAREFULLY BEFORE INSTALLING

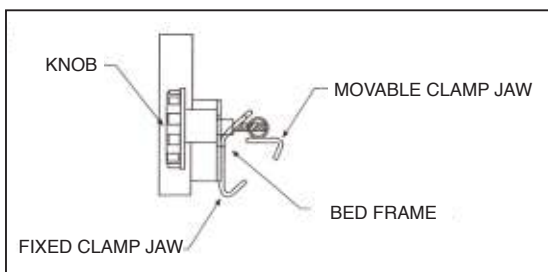


Figure 1



Figure 2

1. Align the fixed clamp jaw to the underside of the bed frame being sure to position the clamp on the appropriate area of the frame designated by the half rail label (Fig. 2).
2. Align the movable clamp jaw on the top side of the bed frame. The movable and fixed clamps will align together and clamp around the bed frame securely.
3. Turn the knob clockwise, moving the clamps closer together, until they are securely tightened to the bed frame.

WARNING

Incorrect mounting can create an entrapment risk which may lead to injury or death.

4. MAINTENANCE

Drive recommends periodic visual inspection of this product by the user, to ensure that all parts and hardware are secure, that components are in good working order and not worn, torn, frayed, loose, or rusted and that there are no obstructions or impediments to normal, safe operation. If any part or mechanism appears to be unsafe or compromised, do not use the product. If you experience problems, please contact the provider that sold you the product or visit www.drivemedical.com/help for more info.

5. LIMITED LIFETIME WARRANTY

Your Drive 15021BV-LW half rails are warranted to be free from defects in materials and workmanship for the lifetime of the original consumer purchaser.

This device was built to exacting standards and carefully inspected prior to shipment. This Lifetime Limited Warranty is an expression of our confidence in the materials and workmanship of our products and our assurance to the consumer of years of dependable service.

This warranty does not cover device failure due to owner misuse or negligence, or normal wear and tear. The warranty does not extend to any to non-durable components such as rubber accessories, casters, grips or knobs. These types of components are subject to normal wear and tear and may need periodic replacement.

If you have any questions regarding your Drive warranty, please contact your authorized Drive DME provider.

6. ENTRAPMENT RISK GUIDE

⚠ WARNING TO PROVIDER OR INSTALLER:

Immediately upon installation, this Guide must be given to and identified (i.e., specifically pointed out) for the patient, the patient's family, and any and all of the patient's caregivers. Failure to do so may expose the patient to the risk of serious injury or death as the result of bed rail entrapment.

⚠ WARNING TO USERS AND CAREGIVERS:

DO NOT use your bed rails before reading this Guide in its entirety. Failure to read this information may cause an entrapment risk, which can result in injury or death. If you do not understand any part of this Guide or the warnings on the bed rails, contact the patient's health care provider or equipment provider before using the bed rails. If you do not understand and comply with this Guide, the patient may be exposed to the risk of serious injury or death as a result of bed rail entrapment.

WHAT IS ENTRAPMENT AND HOW CAN IT HAPPEN?

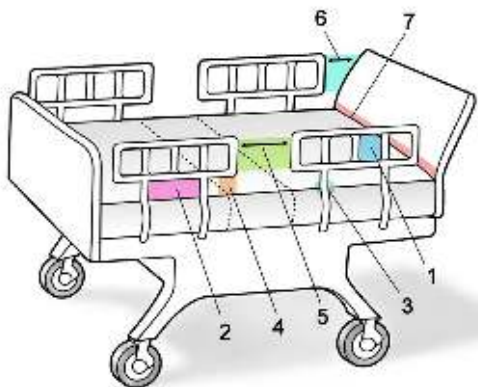
"Entrapment" is defined as an event in which a patient is caught, trapped, or entangled in the spaces in between or around the bed rail, mattress or hospital bed frame. Entrapment can result in serious injury or death.

There are seven "zones of entrapment" in a hospital bed system that present a risk of patient entrapment:

The FDA's Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment provides images of how a patient can become entrapped in each of the 7 zones of entrapment in Appendix E, which is reproduced here:

The seven areas in the bed system where there is a potential for entrapment are identified in the drawing below.

- Zone 1:** Within the Rail
- Zone 2:** Under the Rail, Between the Rail Supports or Next to a Single Rail Support
- Zone 3:** Between the Rail and the Mattress
- Zone 4:** Under the Rail, at the Ends of the Rail
- Zone 5:** Between Split Bed Rails
- Zone 6:** Between the End of the Rail and the Side Edge of the Head or Foot Board
- Zone 7:** Between the Head or Foot Board and the Mattress End

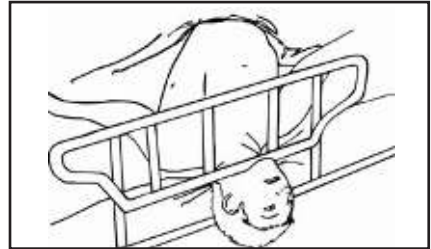


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DRAWINGS OF POTENTIAL ENTRAPMENT IN HOSPITAL BEDS



Zone 1 – Entrapment within the rail



Zone 2 – Entrapment under the rail, between the rail supports or next to a single rail support



Zone 3 – Entrapment between the rail and the mattress



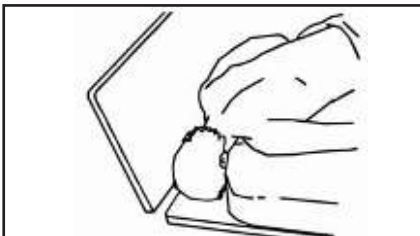
Zone 4 – Entrapment under the rail, at end of rail



Zone 5 – Entrapment between split bed rails



Zone 6 – Entrapment between the end of the rail and the side edge of the head or foot board



Zone 7 – Entrapment between head or foot board and the mattress end

NOTIFICATIONS REGARDING USAGE OF BED RAILS TO PREVENT ENTRAPMENT

- **Do not use bed rails without proper medical assessment and monitoring of the patient.**

This guide is not a substitute for medical advice. Bed rails are not appropriate for every patient, and only the patient's medical care provider and/or medical equipment provider can properly assess whether bed rails are appropriate for the patient, and assist the patient, the patient's family and the patient's caregivers evaluate the risk of entrapment. This proper medical assessment, as well as consistent and frequent patient monitoring and compliance with this Guide and all other warnings, instructions and manuals, are necessary to reduce the risk of entrapment.

- **Ensure proper consideration of specific medical conditions and size before using bed rails.**

Patients with conditions that impact movement and mobility, including but not limited to seizure disorders, dementia or other mental deterioration, and restlessness, are at a higher risk of entrapment. In addition, pediatric patients or patients with small body size may also be at increased risk of entrapment. The patient's medical care provider must take these factors into account when assessing whether bed rails are appropriate.

- **Do not use bed rails as restraints.**

Bed rails are meant to prevent the patient from unintentionally rolling out of bed and assist the patient when repositioning in bed. Bed rails are not intended to be used as part of any effort to restrain the patient (in other words, to prevent the patient from getting out of bed or moving around as they choose). **NEVER use bed rails for restraint purposes.** Doing so will significantly increase the risk of entrapment.

- **Do not use broken, bent or deformed bed rails.**

NEVER use a bed rail if the rail or its mounting is broken, bent, or deformed in any way. Use of bed rails with broken, bent or deformed mountings will increase gaps in the zones of entrapment, and an increased risk of entrapment.

- **Do not use bed rails where one side is up and the other side is down.**

Bed rails are intended to be used in a pair, and when in use, each one must be in the "up" position, unless the patient is entering or exiting the bed. If the rails are used with one in the "up" position and one in the "down" position, an increased risk of entrapment may occur.

- **Do not use other brands' accessories with Drive beds.**

Drive does not recommend using other brands' bed rails or mattresses with a Drive bed. Other brands' rails and mattresses may have different dimensions, and Drive has not tested them in conjunction with Drive beds. Use of other brands' accessories in conjunction with a Drive bed may increase the risk of entrapment.

- **Proceed with extreme caution if using mattress overlay or TSS.**

The use of any type of mattress overlay, topper, or active therapeutic support surface (TSS) may cause an increased risk of entrapment. A medical professional must assess the benefit of such an accessory in light of the potential increased risk of entrapment before use.

- **Consider all possible factors that affect the risk of entrapment.**

This list and this Guide are not a complete list of all issues to be considered when assessing the appropriateness of bed rails for a patient, or any patient's risk of entrapment. The patient, the patient's family, and the patient's caregivers should discuss the risk of entrapment with the patient's medical care provider before the use of bed rails.

FDA INFORMATION AND GUIDANCE ON BED RAILS

The following is the FDA's brochure entitled "A Guide to Bed Safety Bed Rails in Hospitals, Nursing Homes and Home Health Care: The Facts." The latest version of the brochure is available at www.fda.gov.

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 January 1, 2009, 803 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, 480 people died, 138 had a nonfatal injury, and 185 were not injured because staff intervened. Most patients were frail, elderly or confused.

*The term patient refers to a resident of a nursing home, any individual receiving services in a home care setting, or patients in hospitals.

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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 home care providers to assess patients' needs and to provide safe care without restraints.

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. providers to assess patients' needs and to provide safe care without restraints.
- 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.

DEVELOPED BY THE HOSPITAL BED SAFETY WORKGROUP

Participating Organizations:

- AARP
- ABATort 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 Home Care
- 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

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 this brochure, see the FDA's website at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/default.htm>

For more information about this brochure, contact Beryl Goldman at 610-388-5580 or by e-mail at bgoldman@kcorp.kendal.org. She has volunteered to answer questions.

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



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