

Bed Entrapment Guide

Helping You Ensure Your Bed Systems Meet The HBSW Guidelines





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Your Helpful Guide to Bed Safety

The U.S. Food and Drug Administration (FDA) has partnered with representatives from the hospital bed industry and other parties to form the Hospital Bed Safety Workgroup (HBSW). The HBSW has guidelines in place to help you prevent bed entrapment by identifying areas of risk – areas both on the bed and on the body. These guidelines will help you select a bed system to help protect your diverse resident population.

Inside your **Beds & Entrapment guide** from Direct Supply Equipment & Furnishings®, you'll find information clearly explaining these guidelines and the dangers of entrapment, a breakdown of the HBSW's bed system entrapment zones, guidelines to help you determine if bed rails are needed, and different products that can be used to help you improve resident safety in your community.

All to help you protect your residents and your organization.

Help Prevent Injuries and Save Lives

by protecting your residents from bed entrapment

What is Bed Entrapment?

Bed entrapment is a very real concern in Long Term Care communities.

When the HBSW explains entrapment, it's referring to a resident becoming caught by their head, neck or chest in the tight spaces around the bed rail. It can happen when a vulnerable resident attempts to move within or exit his or her bed without assistance. This can be due to a number of reasons, including acute urinary retention, delirium, confusion, pain or agitation. And unfortunately, entrapment can result in serious injuries and even death.

From 1985 to 2009, the FDA received approximately 803 entrapment reports – 480 of which resulted in death. Reports have also identified the most vulnerable population to be the elderly, especially those who are frail, confused, restless and those who do not have full control over their body movements.



FDA Guidelines Overview

In 2006 the FDA took action to reduce the risk of hospital bed entrapment by issuing guidance to the healthcare industry. In the guidance literature, the Hospital Bed Safety Workgroup (HBSW) (a partnership among FDA, the medical bed industry, national health care organizations, patient advocacy groups, and other federal agencies) published three sets of guidelines related to clinical, dimensional and mitigation concerns.



Clinical guidelines: help caregivers assess whether bed rails are appropriate and necessary for a resident's bed system

Dimensional guidelines: help caregivers identify the dangerous zones within the bed system where entrapment may occur

Mitigation guidelines: help caregivers modify their existing bed systems as needed to make them safer

These guidelines are intended to help ensure that those inspecting entrapment cases are well-equipped with the right tools to accurately assess the root of the incidence and determine liability for any injury or fatality. Considering the guidelines and the eldercare population, it's important that you familiarize yourself with ways to protect your residents and your business from bed entrapment.

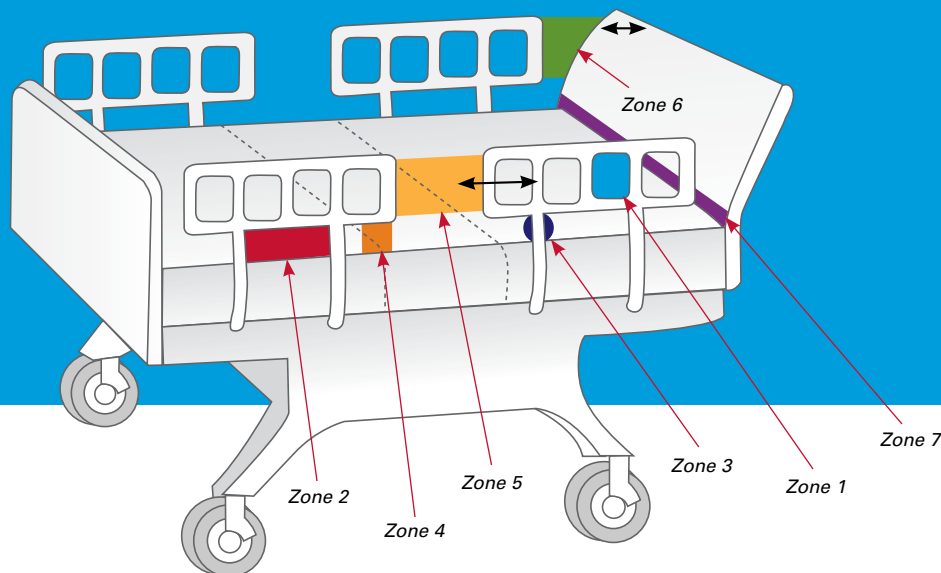
What Systems do the *Dimensional Guidelines* Reference?

These FDA entrapment guidelines refer to all existing bed systems in the field, commonly referred to in eldercare as “legacy” beds. The guidelines also take into account the entire bed system, including the bed frame, mattress and any bed accessory such as rails, and any other piece that can be attached to the bed. Changing individual elements to the bed system can mean the difference between a safe bed system and an unsafe one. Luckily, you have product options available that can improve your bed’s safety and reduce the risk of entrapment.

There are some areas of consideration that are excluded from FDA entrapment guidelines. Bariatric beds are excluded because of the different needs and body shapes of bariatric residents. The use of a powered air mattress is viewed as a partial exclusion. They are excluded from the dimensional limit recommendations, except for spaces within the perimeter of the rail (Zone 1). When powered air mattresses are used, the FDA recommends steps are taken to ensure that the therapeutic benefit outweighs the risk of entrapment. Even though bariatric beds and powered air mattresses are excluded from entrapment guidelines, be sure to exercise caution when using these products as entrapment concerns may still be relevant.



Review the complete [dimension guidelines](#) as issued by the FDA.



The Seven Zones of Bed Entrapment

Zone 1

Within the Rail

Any open space between the perimeters of the rail can present a risk of head entrapment. FDA recommended space: less than 4¾"

Zone 2

Under the Rail, Between the Rail Supports or Next to a Single Rail Support

The gap under the rail between the mattress, may allow for dangerous head entrapment. FDA recommended space: less than 4¾"

Zone 3

Between the Rail and the Mattress

This area is the space between the inside surface of the bed rail and the mattress, and if too big it can cause a risk of head entrapment. FDA recommended space: less than 4¾"

Zone 4

Under the Rail at the Ends of the Rail

A gap between the mattress and the lowermost portion of the rail poses a risk of neck entrapment. FDA recommended space: less than 2⅝"

Zone 5

Between Split Bed Rails

When partial length head and split rails are used on the same side of the bed, the space between the rails may present a risk of either neck or chest entrapment.

Zone 6

Between the End of the Rail and the Side Edge of the Head or Foot Board

A gap between the end of the bed rail and the side edge of the headboard or footboard can present the risk of resident entrapment.

Zone 7

Between the Head or Foot Board and the End of the Mattress

When there is too large of a space between the inside surface of the headboard or footboard and the end of the mattress, the risk of head entrapment increases.

Note: Currently, the FDA provides dimensional recommendations for zones 1-4, as 80% of reported entrapment cases have occurred in these zones.

80% of all entrapment cases have occurred in entrapment Zones 1-4.



Clinical Guidelines

Are *Bed Rails* the Best Choice for Your Residents?

Factors to Consider

Though bed rails can serve a variety of resident health and safety purposes, they may also pose a threat to resident safety if they are not absolutely needed.

Because of this consideration, “The Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities, and Home Care Settings” has been issued by the Hospital Bed Safety Workgroup (HBSW) as a comprehensive guide for caregivers to assess and determine a resident’s need for bed rails and additional assistive devices.

According to the HBSW, determining whether bed rails are necessary for your residents involves a thorough assessment. The HBSW recommends first using an interdisciplinary team of staff members and conversations with family members to evaluate the resident’s medical needs and ailments. After this is done, the assessment process should include (but is not limited to) an individualized resident assessment, a sleeping environment assessment and treatment programs and care plans.

The following assessment considerations are not applicable federal, state or local regulations; they are only meant to assist your staff in making decisions about individualized care plans for residents.

Assessment Considerations

The HBSW considers a resident to be at **low risk** of injury when he or she:

- can move to and from the bed to a wheelchair without assistance
- can move to and from the toilet without assistance
- is assessed to be unlikely to fall
- is able to effectively use call alarms

The HBSW suggests considering using a bed without a bed rail for this type of resident.

The HBSW considers a resident to be at **high risk** of injury when he or she:

- cannot move safely from a bed to a wheelchair
- cannot move safely from the toilet without assistance
- has had a previous entrapment episode
- has had previous bed-related injuries, or has fallen from a bed
- has had difficulties using call alarms

For high-risk residents, the HBSW has a few suggestions to think about. Consider placing this resident in an adjustable-height low bed, and supplying a high impact-absorbing bedside mat to prevent injury from falls. If an adjustable-height low bed is not available, consider adding a quarter rail or transfer device to the fixed-height low bed for support. If bed rails must be used, carefully evaluate entrapment zone dimensions and explore mitigation solutions to lessen risk.

Bed Rails as Restraints

When bed rails serve no medical purpose, the HBSW recommends that they should be avoided and less restrictive interventions should typically be used. When bed rails keep residents from voluntarily getting out of bed, they are deemed physical restraints.

Resident Choice

If a resident, family member or other authorized representative requests that bed rails be used, but the interdisciplinary team has ruled that rails are inappropriate, it's your responsibility to discuss the risks with all parties involved. The resident's right to be involved in their own care plan must be balanced with your duty to provide superior quality care in accordance with applicable state and federal regulations and guidelines.

As always, it's imperative that you educate and train all involved parties (i.e., residents, families, staff and regulatory representatives) about appropriate bed rail use.



Review the complete [dimension guidelines](#) as issued by the FDA.

Take measures to mitigate entrapment risk if bed rails will be used. See pages 20-27.

Bed Rail Alternatives

How to Mitigate the Danger of Falls

Discontinuing the use of bed rails greatly reduces the chance for bed entrapment, but leaves residents vulnerable to potential injuries from falls. Luckily, there are a variety of safety alternatives suggested by the HBSW you can use to help prevent falls and protect your residents when they don't need or use bedrails.



Solutions to reduce fall risk:

Adjustable-height low beds are a restraint-free alternative for residents who are at risk of falling out of bed. The lower bed heights are ideal for ingress and egress as well as safer sleeping.

Bolstered mattresses reduce the risk of resident falls from bed by providing a raised “buffer” between residents and the edge of the bed.

Bed alarms alert caregivers when at-risk residents attempt to exit the bed so assistance can be provided.

Bedside mats can help protect against trauma and reduce the risk of injury by lessening the impact of falls in the unfortunate event one occurs.

A. Adjustable-Height Low Beds

#22637 Invacare CS7 Adjustable-Height Low Bed

B. Bolstered Mattresses

#47189 Direct Supply Panacea® Support Plus Mattress

C. Bed Alert

#34997 Direct Supply Attendant® Deluxe Alert

D. Bedside Mats

#24009 Direct Supply® Panacea® Protector™ Bedside Mat

Solutions to aid residents with repositioning:

Trapezes and assist devices give residents firm support to help them safely reposition themselves in bed.

E. Trapezes

#54638 Trapeze Bar

#54640 Floor Stand

F. Assist Devices

#91864 Halo® Safety Ring

Solutions to aid residents with ingress and egress:

Assist devices offers residents support and stability when entering and exiting their bed.

F. Assist Devices

#91864 Halo® Safety Ring



Mitigation Guidelines & Solutions

Assessing Your Existing Beds

Legacy Beds Guidelines

The threat of bed entrapment within bed rails, bed frames or mattresses is serious, and can result in debilitating chest, head or neck injuries – sometimes even resulting in death. That's why it's important to take every step to reduce the risk of entrapment, in accordance with the dimensional criteria for bed systems, quality assurance and staff and family education.

Mitigation guidelines have been developed by the HBSW to help facilities reduce the risk of entrapment in their existing hospital bed systems, or legacy beds. Intended to be used along with clinical resident assessments, these guidelines focus on modifying your current beds to make them safer for residents.



Review the complete [mitigation guidelines](#) as issued by the HBSW.

The HBSW's Steps to Safety in Your Legacy (Existing) Beds

STEP 1

Assign Responsibility

- Assemble a small, interdisciplinary group of staff members responsible for reducing entrapment risks by measuring existing bed systems and determining effective solutions

STEP 2

Determine High Risk Clinical Units – if appropriate

- When facilities have multiple units serving different resident populations with varying clinical needs, determining which units are at a high risk of entrapment helps to determine bed replacement strategies.
- High-risk units are defined as those with residents of higher acuity levels, units with lower visibility of residents and those with resident monitoring challenges due to staffing shortages

STEP 3

Inventory Bed Systems

- By tracking current beds in use in your facility, you can identify any need for bed replacements as well as the need for new assistive devices

A form to help you complete your bed inventory is on [page 30](#) of this guide.

(continued on next page)

Assessing Your Existing Beds

(continued)

STEP 4

Evaluate Bed Systems for Conformance to FDA's guidelines

- Use the FDA Dimensional Guidelines, which begin on page 20 of this guide, to identify entrapment risk zones
- Use the HBSW Bed Safety Entrapment Kit (shown below) to test the four most dangerous bed zones in a pass/fail assessment fashion



Review the complete [dimension guidelines](#) as issued by the FDA.



A. Bed System Measurement Devices

#96490 Bed System Measurement Device



STEP 5**Initiate Corrective Actions**

- Work with manufacturers: provide them with your bed inventory and ask for appropriate retrofits to correct entrapment in Zone 1
- If retrofits are not available, replace bed rail with one that meets both the manufacturer's and HBSW's recommended dimensions, or cover existing bed rails with see-through rail covers that close the openings in Zones 1 & 5 (see-through covers will allow your residents to see out of the bed, while allowing your staff to see the resident)
- Accurately measure the length, width, depth, compressibility and physical characteristics of your mattresses to ensure spaces fit into the FDA recommended dimensions in Zones 2, 3 & 4 and reduce openings in Zone 7
- Also consider lowering or removing bed rails completely, or replacing full length or older rails with newer, shorter assist rails to reduce entrapment in Zones 1-6. Always assess entrapment risks for new or replacement rails.
- Reduce risk of entrapment in Zone 3 by placing foot end rails in lowest position or by removing foot end bed rails (this will eliminate any unnecessary burden on your nursing staff and also eliminates Zone 5 entrapments)
- If no retrofit, replacement or mitigation solutions exist, it may be necessary to replace the bed system

STEP 6**Guidance for Purchasing Beds**

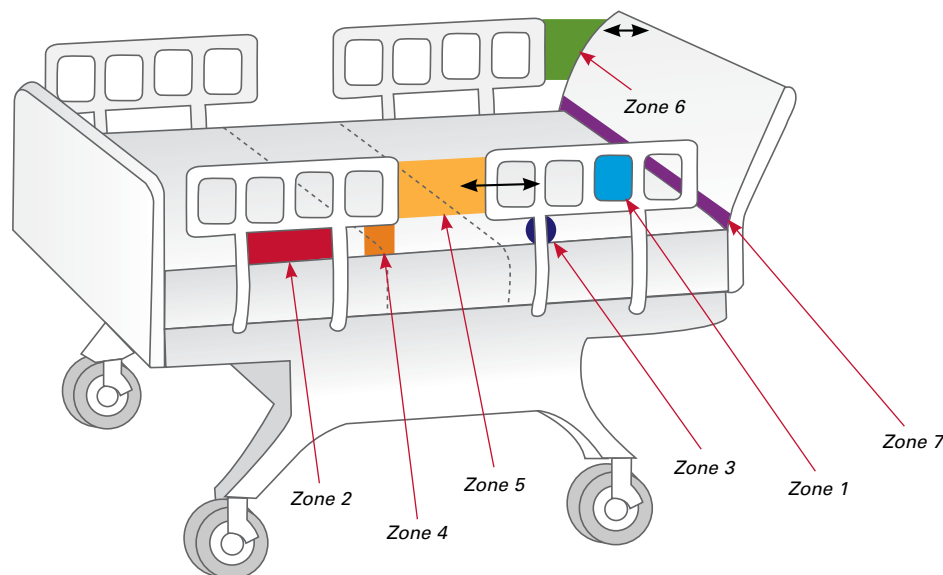
- An integrated approach that considers the inventory of existing beds, options for corrective actions and quality monitors will assist in long-range planning for bed safety. Bed purchases will be most successful from cost/benefit and safety perspectives when purchasers, managers and interdisciplinary staff work together to balance resident and environmental risk factors, resident and staff preferences and cost.

STEP 7**Implement Quality Monitoring**

- Once corrective actions have been taken to reduce the risk of entrapment in your facility, it will be necessary to closely monitor plans of action to ensure your residents stay protected; monitoring should continue on an ongoing basis

Don't hesitate to contact your Direct Supply® Equipment & Furnishings® account manager when you need assistance selecting new mitigation products or full bed systems. We'll help you choose sleeping environments from the many options available. Call us today at **1-800-634-7328**.

The FDA's Seven Zones of Bed Entrapment



Zone 1 **Within the Rail**

Any open space between the perimeters of the rail can present a risk of head entrapment. FDA recommended space: less than $4\frac{3}{4}$ "

Zone 2 **Under the Rail, Between the Rail Supports or Next to a Single Rail Support**

The gap under the rail between the mattress, may allow for dangerous head entrapment. FDA recommended space: less than $4\frac{3}{4}$ "

Zone 3 **Between the Rail and the Mattress**

This area is the space between the inside surface of the bed rail and the mattress, and if too big it can cause a risk of head entrapment. FDA recommended space: less than $4\frac{3}{4}$ "

Zone 4 **Under the Rail at the Ends of the Rail**

A gap between the mattress and the lowermost portion of the rail poses a risk of neck entrapment. FDA recommended space: less than $2\frac{3}{8}$ "

Zone 5 **Between Split Bed Rails**

When partial length head and split rails are used on the same side of the bed, the space between the rails may present a risk of either neck or chest entrapment.

Zone 6 **Between the End of the Rail and the Side Edge of the Head or Foot Board**

A gap between the end of the bed rail and the side edge of the headboard or footboard can present the risk of resident entrapment.

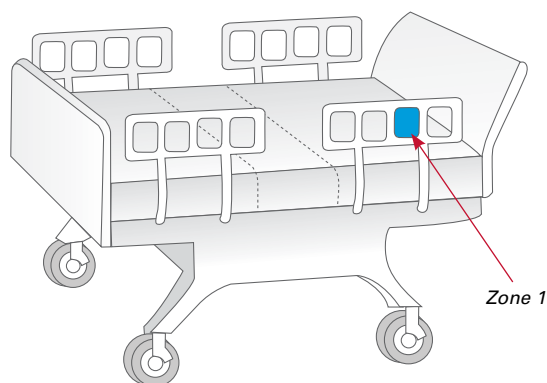
Zone 7 **Between the Head or Foot Board and the End of the Mattress**

When there is too large of a space between the inside surface of the headboard or footboard and the end of the mattress, the risk of head entrapment increases.

Note: Currently, the FDA provides dimensional recommendations for zones 1-4, as 80% of reported entrapment cases have occurred in these zones.

Zone 1: Within the Rail

Any open space between the perimeters of the rail can present a risk of head entrapment. FDA recommended space within this zone is less than 4¾".



Zone 1 Solutions

Mesh side rail protectors and vinyl bedrail pads can be added to help reduce potential entrapment areas in Zone 1. Mesh side rails protectors fit snugly over rails to cover any gaps, and the vinyl bedrail pads can be attached to bedrails with Velcro closures.

A. Thru-View Vinyl Bedrail Pads

#57178 Thru-View Vinyl Bedrail Pads, 60"L x 15"W

#57179 Thru-View Vinyl Bedrail Pads, 72"L x 15"W



B. Mesh Side Rail Protectors

#91919 Mesh Side Rail Protector for rails up to 72"

#91920 Mesh Side Rail Protector for rails up to 36"

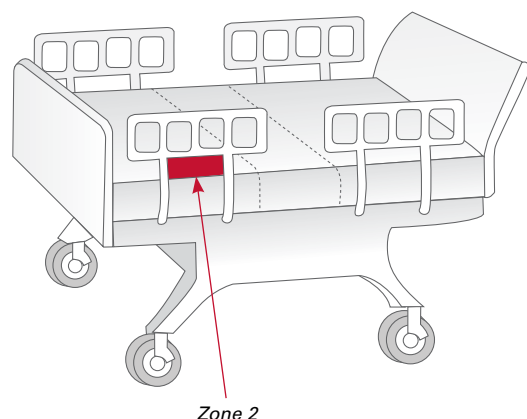
For additional information on products designed to help prevent entrapment, call us today at 1-800-634-7328.



Zone 2:

Under the Rail, Between the Rail Supports or Next to a Single Rail Support

The gap under the rail between the mattress may allow for dangerous head entrapment. FDA recommended space within this zone is less than 4¾".



Zone 2 Solutions

Bedrail pads and safety systems, wedges and positioning devices can be added to help reduce potential entrapment areas in Zone 2. Bedrail pads can be attached to bedrails with Velcro closures and the safety system slides over bedrails to close gaps and provide cushioning.

A. Cocoon™ Safety Systems

#30341 Cocoon, 30", 57" or 79"L

B. Split-Rail Vinyl Bedrail Pads

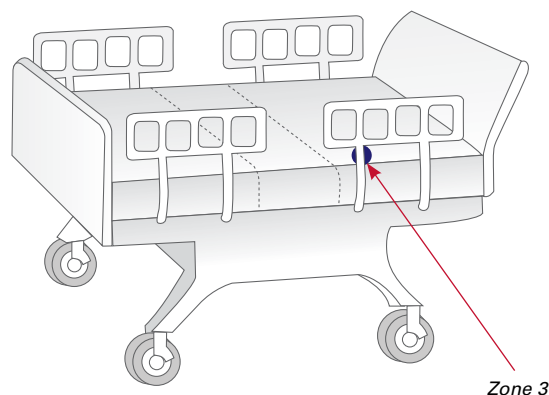
#90201 Split-Rail Vinyl Bed Rail Pad

For additional information on products designed to help prevent entrapment, call us today at 1-800-634-7328.



Zone 3: Between the Rail and the Mattress

This area is the space between the inside surface of the bed rail and the mattress, and if too big it can cause a risk of head entrapment. FDA recommended space within this zone is less than 4¾".



Zone 3 Solutions

Roll control bolsters and gap guards can be added to help reduce potential entrapment areas in Zone 3. Roll control bolsters can be placed around residents to help prevent them from rolling near the sides of the bed, and gap guards fill the gap (up to 3") between the mattress and siderails.

A. Roll Control Bolsters

#A1745 Double-Unit Roll Control Bolster



A. #A1745

B. Gap Guards

#13031 Gap Guard, 35"L

#13030 Gap Guard, 70"L

For additional information on products designed to help prevent entrapment, call us today at 1-800-634-7328.

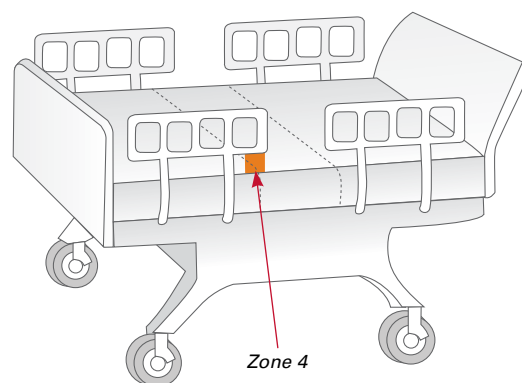


B.

Zone 4:

Under the Ends of the Rail

The gap between the mattress and the lowermost portion of the rail poses a risk of neck entrapment. FDA recommended space within this zone is less than 2%".



Zone 4 Solutions

Bedrail pads and side bolsters can be added to help reduce potential entrapment areas in Zone 4. Bedrail pads fit snugly over rails to cover and gaps, and side bolsters can be placed around residents to help prevent them from rolling near the sides of the bed.

A. Anti-Entrapment Bedrail Pads

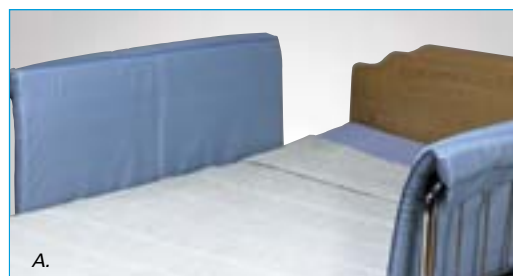
#90199 Anti-Entrapment Bed Rail Pad

B. Ultra-Soft Bolsters

#24441 Ultra-Soft Bolster, 8" x 24"

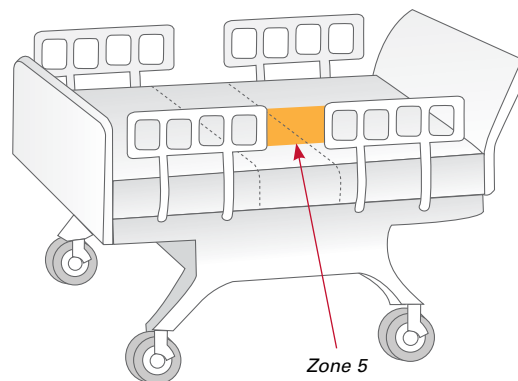
#24440 Ultra-Soft Bolster, 6" x 18"

For additional information on products designed to help prevent entrapment, call us today at 1-800-634-7328.



Zone 5: Between Split Bedrails

This space is created when partial length head and split rails are used on the same side of the bed, presenting a risk of either neck or chest entrapment. The FDA has not provided dimensional recommendations for this zone.



Zone 5 Solutions

Full-length bedrail bumpers and bedrail wedge pads can be added to help reduce potential entrapment areas in Zone 5. Both solutions add a padded layer between residents and the sides of the bed, and cover the bedrails.

A. Full Bedrail Bumpers

#84399 36"L x 14"H

#84400 48"L x 14"H

#84423 72"L x 14"H



A. #84423

B. Direct Choice® Bedrail Wedge Pads

#93155 Direct Choice Bedrail Wedge, 35"L

#93154 Direct Choice Bedrail Wedge, 70"L

For additional information on products designed to help prevent entrapment, call us today at 1-800-634-7328.

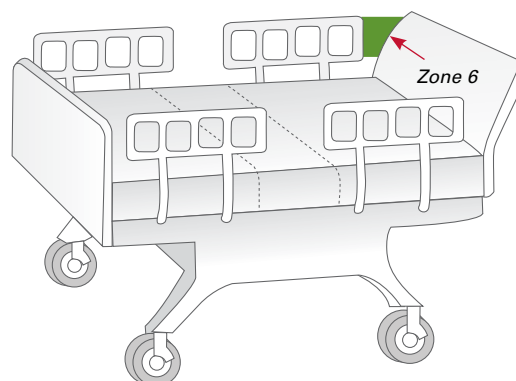


B. #93154

Zone 6:

Between the End of the Rail and the Side Edge of the Head or Foot Board

Refers to the gap between the end of the bedrail and the side edge of the headboard or footboard, which can present the risk of head entrapment. The FDA has not provided dimensional recommendations for this zone.



Zone 6 Solutions

Bedrail wedge pads and horseshoe wedges can be added to help reduce potential entrapment areas in Zone 6. Both solutions add a padded layer between resident and the sides of the bed, and cover the Zone 6 gap.

A. Bedrail Wedge

#13025 Bedrail Wedge, 35"L

#13024 Bedrail Wedge, 70"L

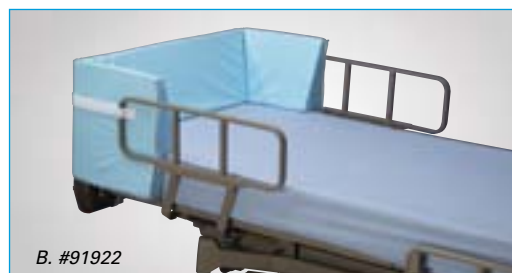
B. Horseshoe Wedge

#91922 Horseshoe Wedge

For additional information on products designed to help prevent entrapment, call us today at 1-800-634-7328.



A. #13024

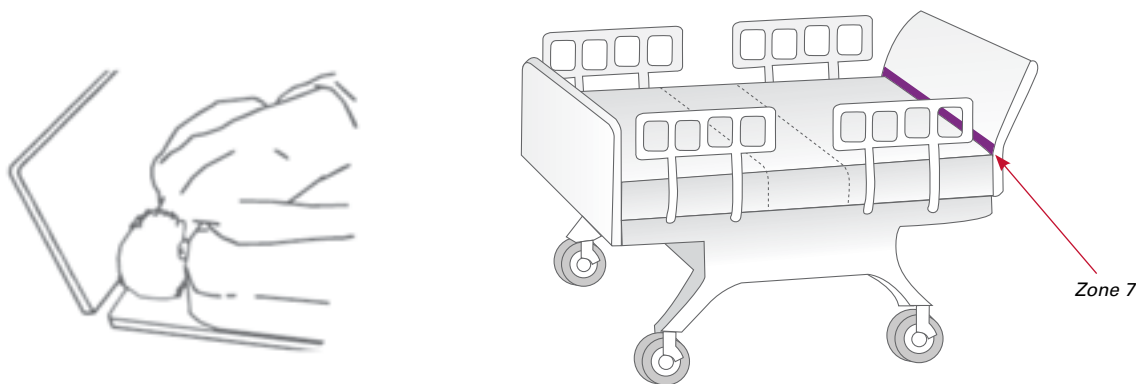


B. #91922

Zone 7:

Between the Head or Foot Board and the End of the Mattress

Refers to the gap between the end of the mattress and the inside surface of the headboard or footboard. A space that's too large can increase the risk of head entrapment. The FDA has not provided dimensional recommendations for this zone.



Zone 7 Solutions

Mattress extenders and mattress safety straps can be added to help reduce potential entrapment areas in Zone 7. Mattress extenders fill in the gap with additional material, while safety straps keep mattresses in place so that they don't shift, and gaps don't appear.

A. Mattress Extenders

#84424 4"L x 35"W x 6"H

#84425 6"L x 35"W x 6"H

#84426 8"L x 35"W x 6"H



B. Mattress Safety Straps

#75895 Mattress Safety Straps, 26"L

For additional information on products designed to help prevent entrapment, call us today at 1-800-634-7328.



Additional Beds Information

After weighing the risks of bed entrapment and implementing steps to help reduce the risk of serious situations in your community, there are other bed-related issues your staff should also be aware of. We've highlighted a few concerns, including the use of restraints, staff ergonomics and safety certifications as outlined by relevant authorities.

HCFA's Definition of Physical Restraints

The HCFA (Health Care Financing Administration), a division of the Department of Health & Human Services, has set forth definitions and mandates surrounding the use of physical restraints.

"Used improperly, restraints, including side rails, can pose a serious health and safety risk to nursing home residents. Under HCFA's requirements for nursing homes that receive Medicare and Medicaid funding, restraints should only be used when other, less severe alternatives fail to address a resident's medical needs, and the benefits outweigh the potential risks. In such cases, the nursing home must ensure that any restraints are used safely and properly."

HCFA further defines physical restraints as "any manual method or physical or mechanical device, material, or equipment attached or adjacent to the individual's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body." HCFA also mandates that restraints may only be used when absolutely necessary to treat a resident's medical symptoms.

OSHA Guidelines to Protect your Staff

To help reduce musculoskeletal disorders (MSDs) in the long term care profession, the U.S. Department of Labor Occupational Safety & Health Administration (OSHA) has developed guidelines outlining proper ergonomics for nursing staff.

To help prevent such MSDs as lower back pain, rotator cuff injuries and carpal tunnel, OSHA provides processes for protecting your staff, and identifies challenges and solutions to resident lifting and repositioning within bed systems.

Several key areas are highlighted in the OSHA guidelines including:

- Transfer to and from: Bed to Chair, Chair to Toilet, Chair to Chair, Car to Chair
- Lateral Transfer to and from: Bed to Stretcher, Trolley
- Transfer to and from: Chair to Stretcher
- Reposition in Bed: Side-to-Side, Up in Bed
- Reposition in Chair: Wheelchair and Dependency Chair
- Transfer a Resident Up From the Floor

UL and IEC Safety Standards

As all products evolve and mature, so do the associated safety standards. The intent of a product's relevant safety standard is to ensure the product is safe and effective for its intended environment and use.

Certification of beds is performed by an independent certified testing agency, and each bed's labeling reflects its safety status.

The current applicable standards, as they apply in the United States for bed systems, are UL 60601-1.

Many beds surpass 60601-1 requirements and conform with the more stringent IEC 60601-2-38 standards. The standards address:

Pinch Points – stricter standards keep beds safe and comfortable for residents and caregivers

User Manual – more thorough to help ensure you get essential bed system safety information

Threshold Tests – only allow the most durable and reliable beds to pass to securely protect residents and caregivers

Stability Tests – helps ensure your residents and caregivers are safe

Noise – reduces excessive and unnecessary bed usage noise to enhance your eldercare environment

Suspension Systems – tighter guidelines keep beds properly functioning at a more secure height

Safety Factors – elevated requirements allow residents and caregivers to put more trust in bed and operation

Additional Information

You can find more information on these guidelines at the websites listed below:

OSHA MSD

http://www.osha.gov/ergonomics/guidelines/nursinghome/final_nh_guidelines.html

UL 60601-1

<http://ulstandardsinfolinet.ul.com/scopes/60601-1.html>

Sample Format for Bed System Inventory

This page can be photocopied and used to complete your bed system inventories, as described on page 17 of this guide.

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Taking Cost Out of Healthcare®



This guide provides general information about healthcare beds and the FDA's and HBSW's guidance on entrapment. Direct Supply, Inc. does not provide legal or medical advice, medical care, or treatment recommendations. The information provided in this guide is not comprehensive and is not a substitute for medical, legal or other professional consultation and advice. Medical and regulatory information changes constantly and some of the information in this guide may have changed or be outdated or may vary by each locale, resident and patient. This guide is not a substitute for your sole responsibility for the care, needs assessment, treatment, monitoring, safety and welfare of your patients and residents and having appropriate training, policies, equipment safeguards, staff and procedures in place at all times. © 2010-2012 Direct Supply, Inc. No Claim to Orig. U.S. Govt. Works. Trademarks are the property of their respective owners.