

There is a risk of entrapment associated with bed rail products. Stander Inc. is committed to informing users of potential entrapment conditions when using bed rails as well as methods to prevent entrapment. Updated versions of this guide are located at www.stander.com.

WHAT IS ENTRAPMENT?

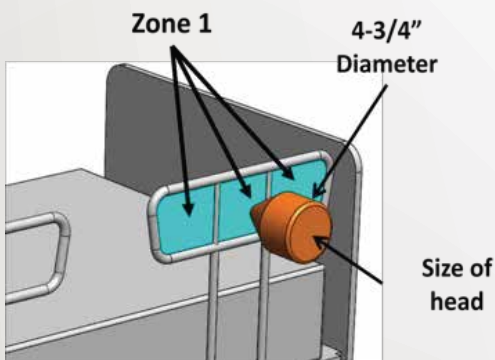
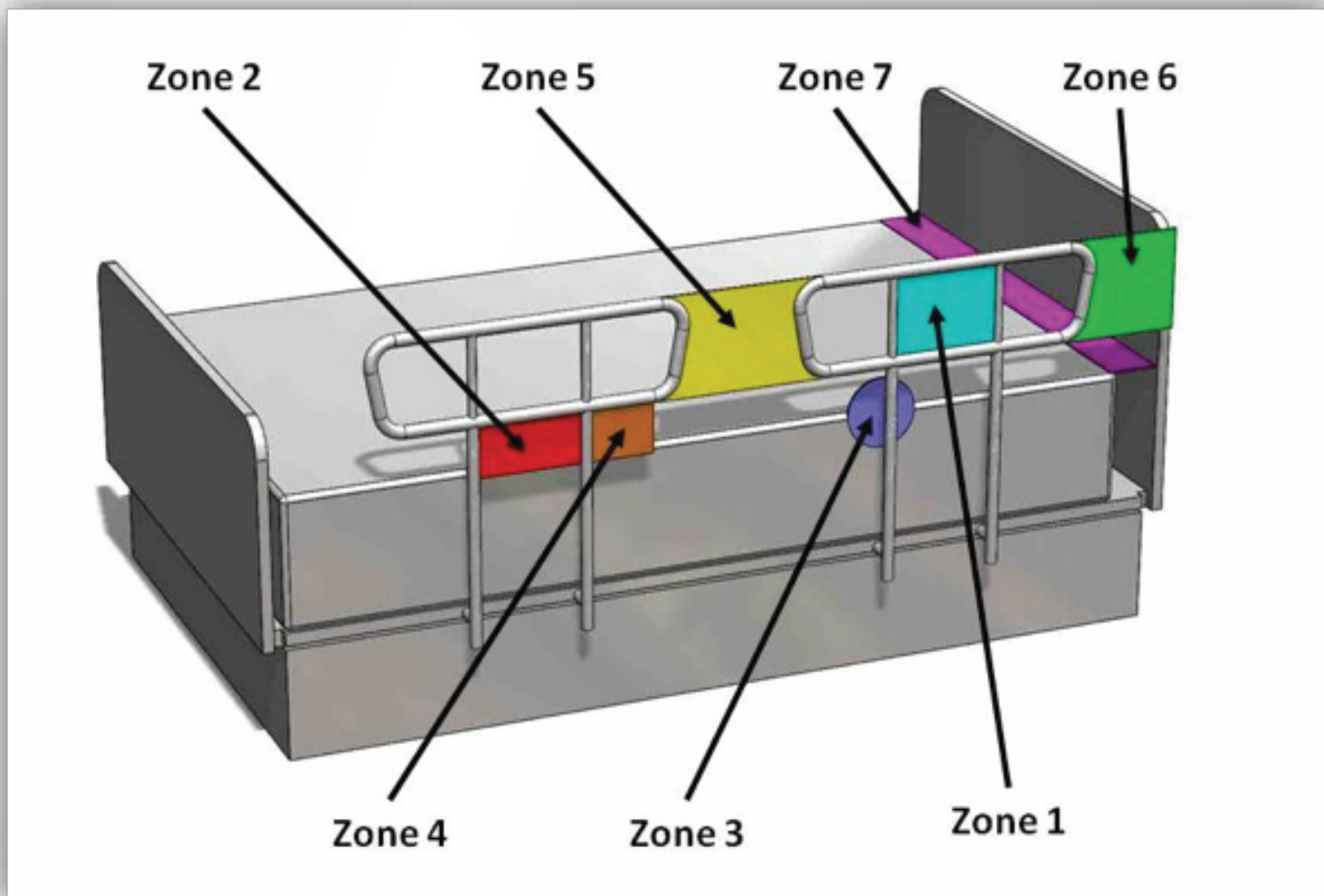
Entrapment is a situation where an individual can become caught by their head, neck, chest or other body parts in the tight spaces around the bed rail or bedside mobility aid. The below picture shows 2 bed rail products being used on a bed for illustration purposes.

ARE THERE ANY GUIDELINES TO HELP PREVENT ENTRAPMENT?

The U.S. Food and Drug Administration (FDA) and the Hospital Bed Safety Workgroup (HBSW) have established the following guidelines to help prevent entrapment. These guidelines are categorized by seven zones.

THE SEVEN ZONES OF BED ENTRAPMENT

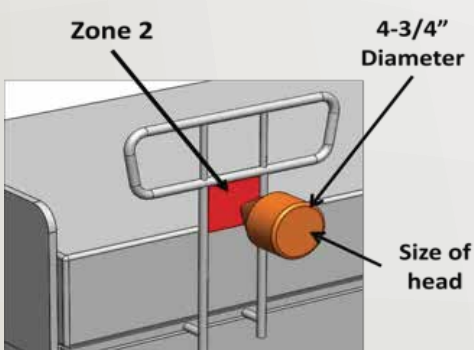
Entrapment is a situation where an individual can become caught by their head, neck, chest or other body parts in the tight spaces around the bed rail or bedside mobility aid. The picture to the right shows 2 bed rail products being used on a bed for illustration purposes.



ZONE 1 - WITHIN THE RAIL

Any open space between the perimeters of the rail can present a risk of head entrapment. The FDA recommended space is less than four and three quarters of an inch (4-3/4").

Some Stander products have included a fabric material cover around part, or all, of the bed rail. This cover helps reduce the risk of entrapment. The product should never be used when the cover is not securely attached. The cover should only be removed to clean it.

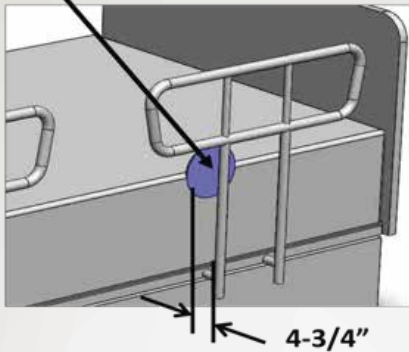


ZONE 2 - UNDER THE RAIL, BETWEEN THE RAIL SUPPORTS OR NEXT TO A SINGLE RAIL SUPPORT

The gap under the rail between the mattress, may allow for dangerous head entrapment. The FDA recommended space is less than four and Three quarters of an inch (4-3/4").

Stander recommends zone 2 be well below the top of the mattress to reduce risk of entrapment.

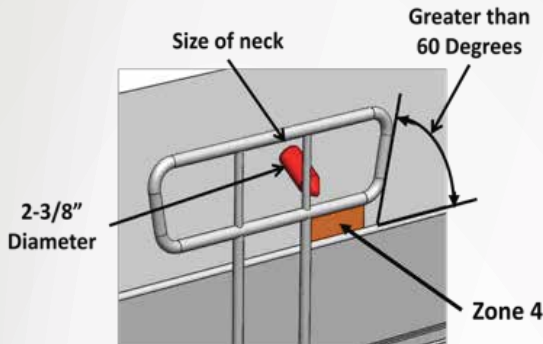
Zone 3



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. The FDA recommended space is less than four and three quarters of an inch (4-3/4").

Some Stander bed rails include a safety strap that holds the bed rail against the side of the mattress. The safety strap must always be used. Do not remove the safety strap from the bed rails or user will be at risk of entrapment.

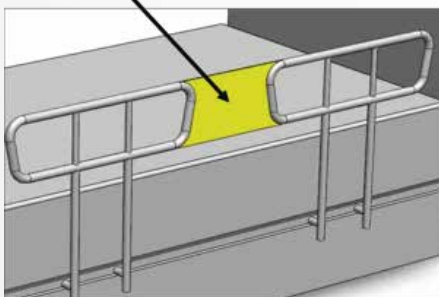


ZONE 4 - UNDER THE RAIL AT THE ENDS OF THE RAIL

A gap between the mattress and the lowermost portion of the rail poses a risk of neck entrapment. The FDA recommended space is less than two and three eighths of an inch (2-3/8"). Also, install the bed rail such that the angle at the end of the bed rail relative to the top of a mattress is greater than 60 degrees.

Stander recommends that zone 4 be well below the top of the mattress to reduce risk of entrapment.

Zone 5

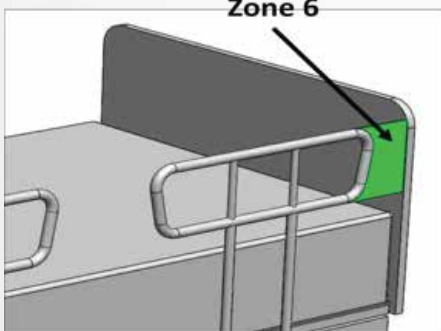


ZONE 5 - BETWEEN SPLIT BED RAILS

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 head, neck, or chest entrapment.

The FDA has not established a distance between rails; however, Stander recommends that users do not use bed rails in this orientation.

Zone 6



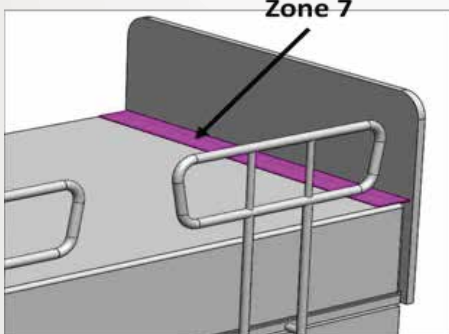
ZONE 6 - BETWEEN THE END OF THE RAIL AND THE

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 entrapment of the head, neck, or chest.

The FDA has not established a distance between the end of the bed rail and the side edge of the headboard or footboard.

Zone 7



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.

The FDA has not established a distance between the inside surface of the headboard or footboard and the end of the mattress.

BED RAILS & ENTRAPMENT: WHAT CONSIDERATIONS NEED TO BE MADE BEFORE INSTALLING OR USING BED RAILS?

At least two assessments should be made by those who are using bed rails and those who are installing bed rails.

1. Installation assessment – Improper installation of bed rails has resulted in serious injury and even death. Complying with the suggested recommendations relating to the 7 zones of entrapment by the U.S. Food and Drug Administration (FDA) and the Hospital Bed Safety Workgroup (HBSW) are essential.

The type of bed and mattress should be assessed before installation. Adjustable frame beds, air mattresses, water beds, light weight foam mattresses, are some examples that may affect the 7 zones of entrapment in a negative manner. Head and foot boards also contribute to entrapment as shown in zone 6 and 7. The frame that connects the head and foot boards may also contribute to entrapment by creating a space between the inside surface of the bed rail and the mattress as shown in zone 3.

Stander includes safety devices on certain bed rails to help prevent entrapment. Typical safety devices are sewn bed rail covers (pouch organizers) and safety straps. Stander's bed rails must never be used if these safety devices are not present or not installed properly. Failure to use these safety devices will increase the risk of injury or death.

2. User assessment – It is important for those who are installing the bed rail, and those who will be using the bed rail, to assess if those using the bed rails are susceptible to entrapment. Individuals who have problems with memory, sleeping, incontinence, pain, uncontrolled body movement, who get out of bed and walk unsafely without assistance, frail, weak, confused, restless, under the influence of drugs or any substance that could affect their judgment, are susceptible to entrapment. Even those individuals who are capable of using bed rails responsibly are at risk, so it is important for those who are installing the bed rail and those using the bed rail to be aware of these risks and make the decision to accept liability for these risks.