

# FDA Entrapment Zones and Guidelines

## Warning:

This product is not recommended for individuals with cognitive problems (difficulty in understanding their surroundings). If you are taking medications that affect your balance or your ability to sit or stand you should consult with a physician before using this product. If the product is not properly used, entrapment, serious injury or death could result. This product is not intended to carry the full weight of an individual. The product is only intended to assist in bed mobility and rising to a sitting position. These instructions must be carefully followed to insure that the product is properly assembled. If you have any questions or concerns please contact Mobility Transfer Systems at 1-800-854-4687. Not for use on hospital style beds

## Serious injury or death can result if this Bed Assist Handle is not properly installed.

DO NOT use this product or any available optional equipment without first completely reading & understanding these instructions. If you are unable to understand the warnings, cautions or instructions, contact customer service at (800) 854-4687 for assistance before attempting to use this equipment otherwise, injury or damage may occur.

ENTRAPMENT MAY OCCUR. Proper patient assessment and monitoring, and proper maintenance and use of equipment is required to reduce the risk of entrapment. Variations in mattress thickness, size or density could increase the risk of entrapment.

Each model has a weight limit. Although this Bed Assist Handle is rated for such use, it may become deformed or broken if excessive force is exerted on the device.

After installation, verify the mattress is in firm contact with the Bed Assist Handle and that the mattress cannot shift away.

This Bed Assist Handle is designed to accommodate a range of beds. If the device does not easily attach to the bed per the instructions, or the mattress does not firmly contact the security bed rail – DO NOT USE. Contact customer service at (800) 854-4687

Visit the FDA website at <http://www.fda.gov> to learn about the risks of entrapment.

## FDA Guidelines for Entrapment Potential Zones of Entrapment

**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

<p style="text-align: center;"><b>Zone 1</b> Entrapment within the rail</p> 	<p style="text-align: center;"><b>Zone 2</b> Entrapment under the rail, between the rail supports or next to a single rail support</p> 
<p style="text-align: center;"><b>Zone 3</b> Entrapment between the rail and mattress</p> 	<p style="text-align: center;"><b>Zone 4</b> Entrapment under the rail, at the end of the rail</p> 
<p style="text-align: center;"><b>Zone 5</b> Entrapment between split bed rails</p> 	<p style="text-align: center;"><b>Zone 6</b> Entrapment between the end of the rail and the side edge of the head or foot board</p> 
<p style="text-align: center;"><b>Zone 7</b> Entrapment between head or foot board and the mattress end</p> 	<p>These guidelines were developed by the FDA for Bed Rails to help prevent entrapment. It is important information to be aware of.</p>