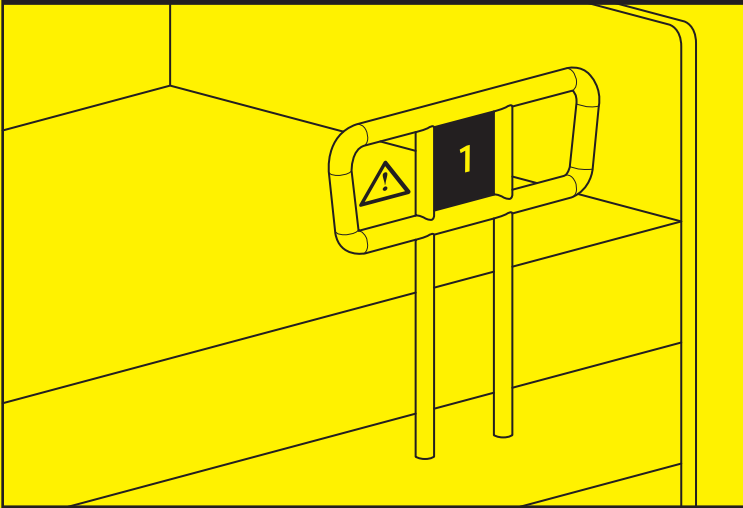




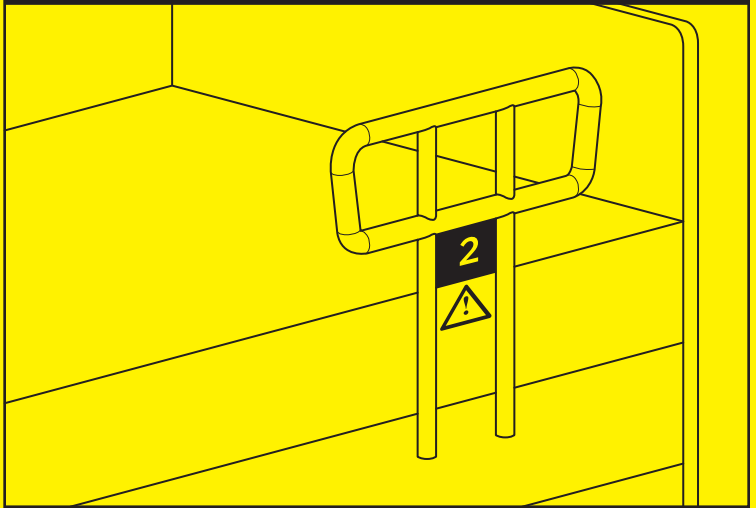
CAUTION - 7 ZONES OF BED ENTRAPMENT
PRUDENCE - 7 ZONES DE PIÉGEAGE AU LIT
PRECAUCIÓN - 7 ZONAS DE APRISIONAMIENTO EN LA CAMA



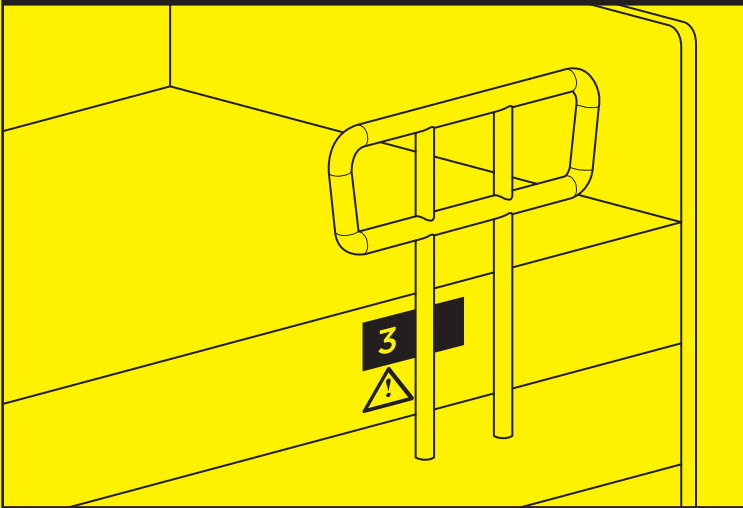
ZONE 1



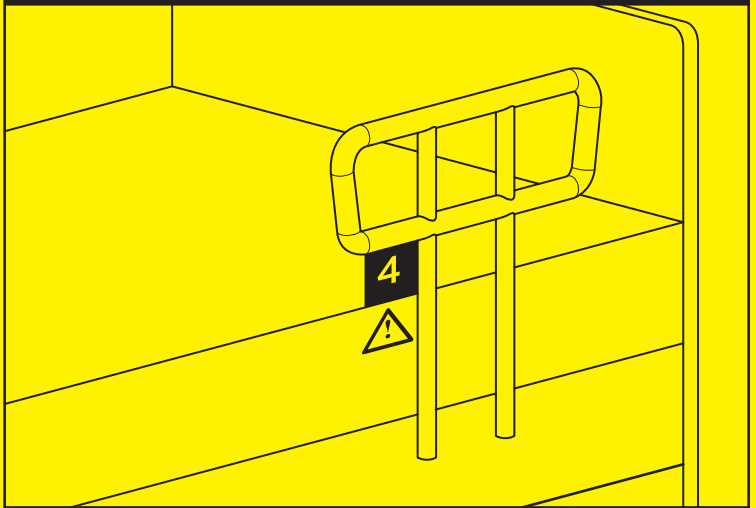
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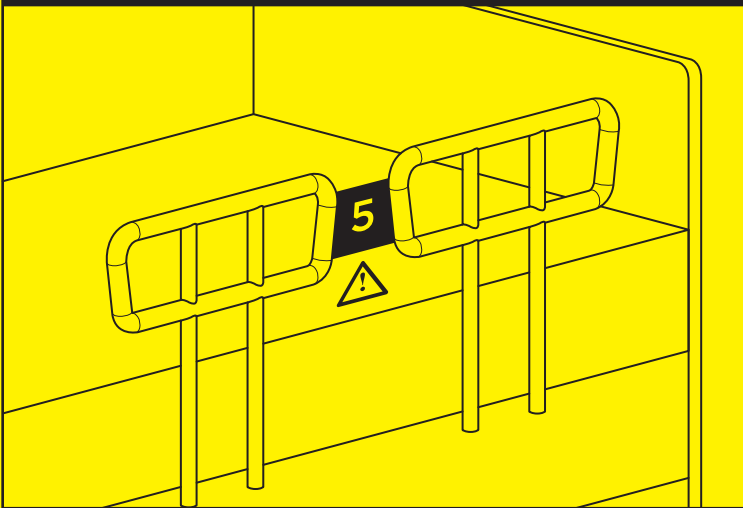
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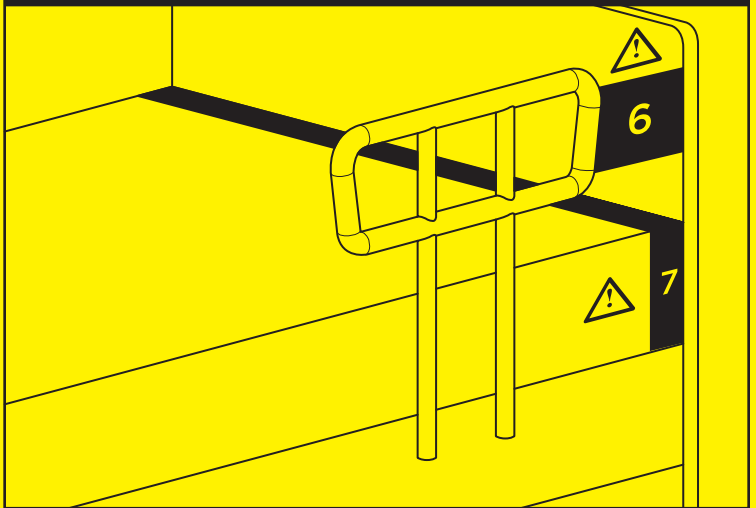
ZONE 4



ZONE 5



ZONE 6&7





BED ENTRAPMENT PREVENTION

HealthCraft would like to advise that there is a risk of life threatening entrapment situations associated with the use of support products (e.g. bed rails, floor to ceiling support poles, etc.) adjacent to a bed or other resting surface.

The term "entrapment" describes a situation in which a patient's neck, head, chest, torso, or other body part is caught, trapped, or entangled in the space in or about an adjacent support surface (e.g. bed rail, support pole, etc.) and the bed's mattress, or frame. Patient entrapment may result in injury or death.

To illustrate, the Hospital Bed Safety Workgroup (HBSW) and the U.S. Food and Drug Administration (FDA) have defined seven numbered "zones" or spaces in and around hospital bed systems where patients could potentially become trapped (see attached figures Zone 1-7) This information may also be applied to home style beds. Actual entrapments have been reported in six of these zones, with Zones 1, 2, 3, and 4 accounting for approximately 80% of entrapment events reported to the FDA.

7 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 4.75" / 120mm. HealthCraft's Assista-Rail has open spaces that adhere to the rail spacing recommendation of FDA.

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 4.75" / 120mm. HealthCraft's Smart-Rail is height adjustable against the side of the bed, and we recommend the gap between the bed top surface and the rail be set to match the FDA recommendation: less than 4.75" / 120mm.

ZONE 3 - BETWEEN THE RAIL AND THE MATTRESS

This area is the space between the inside surface of the bed rail and the mattress. If too large of a space it can cause a risk of head entrapment. FDA recommended space: less than 4.75" / 120mm. All HealthCraft bed rails include a safety strap that holds the bed rail tight against the side of the mattress. The safety strap must always be used to reduce the risk of injury or death.

Note that this gap may also be created by a fixed structure alongside a bed such as an I.V. pole or a floor to ceiling support pole. If a support pole is being used beside the bed, we recommend a pole gap of less than 2.375" / 60mm, or greater than 12" / 305mm.

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 2.375" / 60mm. HealthCraft's bed rails do not have this gap. If using the SuperPole with SuperBar (pivot and lock support arm), this gap will be present in certain positions. Exercise caution when using this product. The SuperBar should be stored in a neutral position when not in use (perpendicular and away from the bed). As an added precaution, it is recommended that the SuperBar arm be located at least 12" / 305mm above the top surface of the mattress.

ASSESSMENTS PRIOR TO INSTALLING AND USING BED RAILS

HealthCraft advises caution and informed assessment prior to considering the use of a support product from two perspectives:

1. Installation Assessment - Improper installation of bed rails or support products can result in serious injury or death. Compliance with the recommendations relating to the 7 Zones of Bed Entrapment is required. There are several external factors that need to be considered, including: mattress compression, mattress movement, mattress types, bed construction, head and foot board attachment, bed type (home vs. hospital), possible articulation of the bed and impact upon entrapment possibilities, etc. Regular inspection and assessment of zones is recommended.
2. User Assessment - It is essential that the person using the bed rail or support product understands and fully accepts the associated risks. There are numerous mind and body conditions that can and will elevate that individual's susceptibility to entrapment: for example, individuals having problems confusion, uncontrolled body movements, memory, sleeping, incontinence, pain, frailty, weakness, restlessness, or influences of any substance that could affect their judgement are susceptible to entrapment. HealthCraft will not be liable for injury or death.

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. No established FDA recommendation. Health Canada recognizes this area as a potential for entrapment and encourages manufacturers and facilities to report entrapment events at this zone. HealthCraft does not recommend the use of two bed rails on the same side of the bed.

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. There is no established FDA recommendation. Health Canada recognizes this area as a potential for entrapment and encourages manufacturers and facilities to report entrapment events at this zone.

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. There is no established FDA recommendation. Health Canada recognizes this area as a potential for entrapment and encourages manufacturers and facilities to report entrapment events at this zone.