



## About Bed Safety and Patient Entrapment

History: Since 1986, the FDA has been receiving reports of incidences of injury or death due to the entrapment of patients in gaps found in hospital bed systems. The Hospital Bed Safety Workgroup (HBSW), a partnership between representatives of the medical bed and mattress industry, national healthcare organizations, patient advocacy groups, the Veteran's Administration, the FDA, and other federal agencies, began meeting in 1999 to begin researching, validating, and drafting guidelines for mitigating these incidences, including recommended measurements in the seven identified zones.

Span-America is a member of the HBSW, and is assisting the FDA in outreach and education efforts to publicize this Guidance and the Mitigation recommendations. Our catalog contains information on Bed Safety, and products available to help mitigate the danger of entrapment for your patients.





FDA Guidance: The HBSW issued a draft of their proposed guidelines in Fall, 2002. On March 10, 2006, the FDA issued

### **Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment: Guidance for Industry and FDA Staff**

that “provides recommendations intended to reduce life-threatening entrapments associated with hospital bed systems”. The full document can be accessed at <http://www.fda.gov/cdrh/beds>.

This *guidance* contains *nonbinding recommendations* for measured gaps in four zones, test methods for assessing the gaps, and access to a special Tool Kit for performing the measuring of the gaps. This Guidance is not law, and does not supercede existing state laws.

**Summary of FDA Dimensional Recommendations  
and How Span-America can help you comply**

| Zone of Entrapment   | Dimensional Criteria  | How Span can help  |
|--|---|--|
| <p>Zone 1: Within the rail</p>    | <p>&lt;120 mm (4 ¾")</p>  | <p><u>Geo-Mattress with Wings</u> or <u>Gap Cap (High)</u> can help to minimize the gap and make entry into this gap more difficult.</p>   |
| <p>Zone 2: Under the rail, between the rail supports or next to a single rail support</p>  | <p>&lt;120 mm or 4 ¾"<br/>(with appropriate compression of the mattress edge with the Cone and Cylinder Tool)</p>   | <p>All <u>PressureGuard</u> products include the <u>Safety-Edge</u> that resists compression, minimizing risk at this zone.</p> <p><u>Geo-Mattress with Wings</u> or <u>Gap Caps</u> can help to minimize the gap and make entry into this gap more difficult.</p> |
| <p>Zone 3: Between the rail and the mattress</p>    | <p>&lt;120 mm or 4 ¾"<br/>(with appropriate compression of the mattress edge with the Cone and Cylinder Tool)</p>   | <p>All <u>PressureGuard</u> products include the <u>Safety-Edge</u> that resists compression, minimizing risk at this zone</p> <p><u>Geo-Mattress with Wings</u> or <u>Gap Caps</u> can help to minimize the gap and make entry into this gap more difficult</p>   |
| <p>Zone 4: Under the rail at the ends of the rail</p>                                     | <p>&lt;60 mm (2 3/8")<br/>(with appropriate compression of the mattress edge with the Cone and Cylinder Tool)<br/>and<br/>&gt; 60° angled rail construction</p> | <p>All <u>PressureGuard</u> products include the <u>Safety-Edge</u> that resists compression, minimizing risk at this zone</p> <p><u>Geo-Mattress with Wings</u> or <u>Gap Caps</u> can help to minimize the gap and make entry into this gap more difficult</p>   |

No dimensional recommendations are made on Zones 5-7 at this time. However, these Zones can put the patient at risk for entrapment, and should be areas of concern.

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 head or foot board and the mattress end



HBSW recommendations are

Zone 5 & 6: < 60 mm (2 1/3 inches) or > 318 mm (12.5 inches)

Zone 7: < 120 mm (4.75 inches)

#### Links to More Info:

<http://www.fda.gov/cdrh/beds/> is the FDA website containing the final Guidance issued on March 10, 2006, historical sentinel event and safety alerts, a patient/family brochure regarding this topic, and other useful information.

<http://www.visn8.med.va.gov/visn8/patientsafetycenter/bedSafe/default.asp> links to a very comprehensive website by the National Patient Safety Center, a part of the Veterans Affairs Healthcare Network. Includes Powerpoint presentations, education documents, mitigation documents, and many other links.

This issue has become an international one, with many countries and international organizations examining this topic and working on reduction methods.