

Patient Safety Alert

Veterans Health Administration Warning System
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- Item:** Enclosed Bed systems manufactured by Vail Products Inc, models: 500, 1000, and 2000.
- Specific incident:** On March 25, 2005 the Food and Drug Administration (FDA) issued a "Preliminary Public Health Notification: Vail Products Enclosed Bed Systems" with recommendations for users based on cited safety problems (FDA notification attached). FDA advises hospitals to stop using the Vail 500, 1000, or 2000 enclosed bed systems immediately and move patients to alternate beds. However, if continued use of these beds is the only reasonable option, FDA further advises that certain safety precautions be taken.
- Actions:**
1. VA facilities may continue to use Vail enclosed beds on a case by case basis only when there is a clinical determination that this is in the best interest of patient care. Vail enclosed beds, similar to all enclosed bed systems, may be considered in the continuum of care for certain types of patients and disease states. In certain instances, use of enclosed beds provides the most humane and least restrictive care modality.
 2. **By close of business (COB) March 31st 2005:**
 - a) Visually ensure that Vail enclosed beds meet the requirement for mattress gaps as spelled out in the VHA Patient Safety Alert on bed entrapment risk from 2001: <http://vaww.ncps.med.va.gov/alerts/BedEntrap.doc> Accomplish this by pushing the mattress to one side with the side rails in the up and latched position. Also, measure the gaps at the foot and head of the bed with the mattress pushed to one end and the head and foot rails in the up and latched position. The gaps must be less than 2 and 3/8 inch (60 mm) horizontal distance at the widest spot.
 - b) If using a Vail enclosed bed with side rails visually confirm that the side rails and the bolsters at the head and foot are up and properly latched, except when patient is entering or exiting the bed, or if the caregiver needs access to the patient. (Side rails should be up at all other times as a patient can get their head

between the mattress and the bottom vinyl cover presenting a suffocation hazard.)

c) Visually inspect Vail enclosed beds for any defects and repair or replace as soon as is practical with patient safety as the deciding factor. Inspect for broken welds at the joint on the frames and visually inspect the sleeping surface and components such as, but not limited to, zippers, netting, and Velcro connection points for proper attachment and function.

d) Ensure that Vail enclosed beds with a high-low adjustable mechanism such as the Vail 1000 are not left in the up position when the patient is unattended. Additional hazards are created by the bed left in this position.

e) Ensure that you are using only the mattress recommended by Vail and the gap complies with the criteria from action (a) above.

f) If using other enclosed beds, follow actions a) through e) as applicable.

3. By close of business (COB) April 29, 2005:

a) Ensure that your local written protocol or policy on enclosed beds incorporates:

- inspecting mattress gaps at regular and appropriate intervals (e.g., new patients, new mattresses, once a month)

- keeping the side rails and end bolsters of enclosed beds (such as Vail) in up position

- regularly visually inspecting any enclosed bed systems for any degradation of materials, parts, or mechanisms and addressing as needed (e.g., new patients, once a month)

- ensuring that beds will not be left in up position when patient is unattended.

- inspecting enclosed beds for any mechanical or material defects before accepting for purchase or lease, and ensuring that the appropriate mattress accompanies the bed before put in service.

Addl. Information:

The VA National Center for Patient Safety has a sample, enclosed bed protocol at:

<http://vaww.ncps.med.va.gov/SampleEnclosedBedProtocol.doc>

Source:

FDA

Contact:

VA National Center for Patient Safety (734)-930-5890.
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