

**Notice Information: - Advisory
10 June 2010**

Part 1. Product Information

a) Title:

b) Product Name/Type:

Part 2. Target Audience

a) Target Audience:

Part 3. Problem/Issue

a) Problem/Issue:

Part 4. Background Information

a) Background Information:

Following a number of fatal incidents in Europe, including where a child became entrapped in the side rails of adult size hospital beds, the Irish Medicines Board (IMB) issued Safety Notice SN2006(01) relating to Hospital Beds in Paediatric Wards in January 2006.

As the prevalence of such incidents across Europe has continued in recent years, the IMB is providing further recommendations for healthcare institutions and emphasising that heightened vigilance and monitoring of this issue is required to ensure patient safety. The IMB also wishes to highlight that this issue may not be limited to children and consideration should also be given to other vulnerable bed occupants (e.g. elderly patients).

Part 5. Action to be taken

a) Action to be taken:

1) Ensure that the appropriate staff members are advised of this notice.

2) Review the current practice in your institution and initiate the appropriate measures to reduce the likelihood of a similar incident occurring.

3) When conducting a risk assessment of patient beds/cots, relevant staff should consider that each bed occupant, mattress, bed and side rail combination is unique and therefore a comprehensive risk assessment is required to ensure patient safety. As part of such an assessment, relevant staff should pay particular attention to the following seven areas in the bed system where there is a potential for entrapment. (See Diagram on page 2 of attached pdf document. Source: US Food and Drug Administration).

4) Paediatric beds should be used for children. If paediatric beds are not available, ensure that appropriate risk mitigation measures are taken to ensure patient safety.

5) Staff should ensure that occupants of hospital cots are appropriately monitored.

Part 6. Enquiries

a) All enquiries should be made to:

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board

Human Products Safety Monitoring

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

[Click here](#) to Download a PDF version of the Safety Notice

Part 7. Keywords

a) Keywords:

Hospital Beds / Cots