

**Notice Information: Medical Devices - Advisory
13 June 2002**

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

Part 2. Target Audience

- a) Target Audience:

Part 3. Problem/Issue

- a) Problem/Issue:

Part 4. Background Information

a) Background Information:

The Irish Medicines Board received reports of pressure relief mattresses being soiled with body fluids. The mattresses involved consisted of a foam core with a zip, waterproof cover. It is well published that mattresses can be damaged in a number of ways including puncture, delamination due to inadequate cleaning or drying, condensation and general wear and tear associated with the hospital environment. Damage of this nature may pose significant infection control hazard to patients and staff. Soiling is not always evident on superficial inspection of the cover and may not be detected unless the inside of the mattress covers are inspected on a regular basis. While checking mattresses it is sometimes evident that although the foam remains intact, the cover has failed through normal wear and tear. Manufacturers vary in the ways they manufacture their products, sometimes certifying the mattress and the cover together, sometimes separately and for different lengths of time. This should be borne in mind when purchasing mattresses, devising relevant specifications, auditing or condemning products.

Part 5. Action to be taken

a) Action to be taken:

Implementation of a local policies to address the regular care, maintenance and cleaning of mattresses and covers. This should include guidance on regular mattress audits. Following the manufacturer's recommended care and cleaning procedures as supplied. Inspecting inner and outer surfaces of covers and their zip fasteners regularly for signs of damage or misuse. If the cover is stained, soiled or torn, the core should be examined and evidence sought from the infection control nurse as it may harbour micro-organisms. If the core is wet or badly stained the mattress should be withdrawn from service. Seek the advice of Infection Control Nurses in cases of heavy soiling or infection as general cleaning procedures are unlikely to be adequate.

Part 6. Enquiries

a) All enquiries should be made to:

For more information on the vigilance system for medical devices, please refer to the IMB Guidance Note 7: Guidance Notes on the Vigilance System for Medical Devices. If you have any enquiries, you may contact the Medical Devices Department at: Medical Devices Department Irish Medicines Board Earlsfort Centre Earlsfort Terrace Dublin 2 Telephone: +353-1-6764971 Fax: +353-1-6767836 Email: vigilance@imb.ie Website: www.imb.ie SN2002(02): Foam Mattresses - Prevention of Cross-Infection

Part 7. Keywords

a) Keywords:

Foam Mattresses: Prevention of Cross-Infection