IRISH MEDICINES BOARD

Notice Information: Medical Devices - Advisory 14 October 2004

Part 1. Product Information

a)	Title:	Sterile Devices
b)	Product Name/Type:	Sterile Devices
c)	Reference:	SN2004(09)
d)	Manufacturer/Supplier:	Various

Part 2. Target Audience

a)	Target Audience:	Risk Managers; Nursing Managers; Theatre Managers; Wound Care Departments; Stores Personnel; Laboratory Managers

Part 3. Problem/Issue

a)	Problem/Issue:	Damaged packaging may compromise the sterility of a medical device

Part 4. Background Information

a)	Background Information:	Over the past three years, the IMB has been notified of medical devices that have been discovered with damaged packaging, which could potentially compromise the sterility of the device. Several of these incidents have resulted in device recalls.

Part 5. Action to be taken

a)	Action to be taken:	Examine all packaging before use to ensure that there are no defects e.g. holes, tears, items caught in the seal. Do not use any devices that are found to have defective packaging. Ensure that care is taken when using blades or sharp implements to open the outer packaging / boxes. Ensure that all devices are stored as recommended by the manufacturer, with adequate space and away from sharp edges or objects. Advise the IMB of any devices that you discover with defective packaging

Part 6. Enquiries

a)	All enquiries should be made to:	All adverse incidents relating to a medical device should be reported to the: Medical Devices Department Irish Medicines Board Earlsfort Centre Earlsfort Terrace Dublin 2 If you have any enquiries, you may contact the Medical Devices Department at: Telephone: +353-1-6764971 Fax: +353-1-6767836 Email: medicaldevices@imb.ie Website: www.imb.ie SN2004(09): Sterile Devices

Part 7. Keywords

a)	Keywords:	Sterile Devices