

MEDICAL DEVICE SAFETY NOTICE

Sterile Devices IMB Safety Notice: SN2004(09)

MANUFACTURER/SUPPLIER

Various

TARGET GROUPS

Risk Managers
Nursing Managers
Theatre Managers
Wound Care Departments
Stores Personnel
Laboratory Managers

ISSUE

Damaged packaging may compromise the sterility of a medical device.

BACKGROUND

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.

ACTION OR RECOMMENDATIONS

- 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.

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NOTICE

- Advise the IMB of any devices that you discover with defective packaging

ENQUIRIES

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
e-mail: medicaldevices@imb.ie
Website: www.imb.ie

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NOTICE