IRISH MEDICINES BOARD

Notice Information: Medical Devices - Advisory 13 August 2004

Part 1. Product Information

a)	Title:	Instructions for Use provided by the Medical Device Manufacturer
b)	Product Name/Type:	Instructions for Use provided by the Medical Device Manufacturer
c)	Reference:	SN2004(06)
d)	Manufacturer/Supplier:	Various

Part 2. Target Audience

a)	Target Audience:	All Hospital Staff; Risk Managers; Theatre Managers; Clinical Engineering; Medical Physics; Purchasing Managers; Laboratory Managers

Part 3. Problem/Issue

a)	Problem/Issue:	Adverse incidents and safety related problems could arise when the instructions and guidance outlined in the manufacturers instructions for use are not followed correctly.

Part 4. Background Information

a) Background Information:

Medical devices can range from walking sticks to bone cement to pacemakers to in-vitro diagnostic kits. The range is broad and complex. Examples include surgical sutures, bandages, blood bags, irrigation solutions intended for mechanical rinsing, X-ray equipment, drug delivery pumps, HIV test kits, pregnancy test kits. Under the Medical Devices Directive 93/42/EEC and the In-vitro Diagnostic Medical Devices Directive 98/79/EC, a manufacturer is obliged to provide adequate information that ensures the safe use of his device. This information is usually provided in the format of either instructions for use (IFU) or the operating manual or in some cases both. The instructions for use is therefore a key tool that professional users should use to determine the: intended purpose of the device functioning, calibration and operation of the device management of the device commissioning of the equipment e.g. imaging and laboratory equipment repair and maintenance sterilisation or decontamination e.g. endoscopes storage e.g. heat or light sensitive devices decommissioning limitations of the device performance characteristics The instructions for use are also a valuable reference guide or training tool for staff. Staff using a device for the first time should read and understand the IFU prior to using the device. While this puts extra demands on the health care system it is essential in the interest of patient safety. Inappropriate device use and inappropriate device management can result when the instructions for use are not adequately examined.

Part 5. Action to be taken

a) Action to be taken:

Ensure that instructions for use are provided with all medical devices used in your hospital. Review the instructions for all devices and confirm that the device is being used and managed as intended by the manufacturer. Ensure that the instructions for use are stored in a location close to the device or accessible to those staff using the device. Ensure that the instructions for use are read and understood by users of a device before a new device is used in your healthcare facility. Staff using a device for the first time should read and understand the IFU prior to using the device. Ensure that procedures are put in place that all instructions for use are replaced when the manufacturer issue a new revision or when the device is changed. Ensure that the instructions for the user are provided with all devices that are given to patients when leaving hospital or issued to patient in the community. Ensure that patient / carers read and understand the instructions for use.

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(06): Instructions for Use provided by the Medical Device Manufacturer

Part 7. Keywords

a)	Keywords:	Instructions for Use provided by the Medical Device Manufacturer