IRISH MEDICINES BOARD
ADVISORY NOTICE

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Single Use & Single Patient Use Medical Devices

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MANUFACTURER/SUPPLIER
Various

TARGET GROUPS
All Hospital Staff
Risk Managers
Theatre Managers
Central Sterile Supply Department (CSSD) Personnel
Clinical Engineering
Medical Physics
Purchasing Managers
Laboratory Managers
General Practitioners/ General Practice Nurses / Assistants
Pharmacists
Dentists / Dental Nurses/ Dental Hygienists / Dental Auxiliaries
Public Hospital Surgical Theatres
Orthodontists
Public Health Nurses /Community Healthcare Workers
Accident & Emergency Staff
Outpatient Departments / Nurse Managers
Podiatrists / Chiropodists /Infection Control Departments
Non-healthcare workers – Tattooists, Body Piercers, Acupuncturists, Beauticians, Cosmetic Practitioners (*Note:* This document is for information purposes only, as sterilised instruments used in this setting are not medical devices)

ISSUE
This advisory notice is intended to provide clarification on the definition of the terms “single use” and “single patient use”, in line with the updated medical devices directive.

BACKGROUND
The general Medical Device Directive (93/42/EEC) distinguishes between devices that are intended by the device manufacturer for single use only and those which are intended for reuse i.e. following suitable reprocessing as recommended by the manufacturer.

Single use devices
A single use device (SUD) is a medical device that is intended to be used on an individual patient during a single procedure and then discarded. Medical devices that are for single use must be clearly labelled with the words “do not reuse”. The

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synonymous terms for “do not reuse” are “single use” or “use only once”. This wording can be replaced by the symbol:

Figure: 1, Symbol for “Do Not Reuse”, taken from EN980: Graphical Symbols for Use in the Labelling of Medical Devices.

A ‘single use device’ is defined under Directive 2007/47/EC, the amendment to the Medical Device Directive 93/42/EEC, where it states that: “single use device" means a device intended to be used once only for a single patient. Examples include stents, orthopaedic implants, catheters, needles and lancets.

A medical device labelled as single use indicates that the device has only been validated and designed for use for a single occasion. It is not intended to be reprocessed and/or used on another patient. The term ‘Single Use’ means that the manufacturer intends the device to be used once and then discarded and considers that the device is not suitable for use on more than one occasion.

In circumstances where a medical device intended by the manufacturer for single-use is reprocessed, the party responsible for placing the reprocessed device on the market or putting it into service assumes the legal responsibility of device manufacturer and must have supporting technical and clinical documentation to demonstrate that the reprocessed device conforms to all the Essential Requirements of the Medical Devices Directive contained in Annex I of 93/42/EEC.

Manufacturers labelling their medical devices as single-use devices are, since March 2010, required to provide information on the characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used as part of the product information.

Single patient use devices

A medical device that is intended for single-patient use means that the device may be used for more than one episode of use on one patient only. The device may be reprocessed between each use as per manufacturer’s instructions. Examples include nebuliser tubing / masks and some infusion equipment.

For Information

The IMB would like to draw your attention to the report on “The Safety of Reprocessed Medical devices Marketed for Single Use”, published by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). In addition, the European Commission has recently provided a report to the European Council and Parliament on the reprocessing of medical devices.

The documents may be accessed at the following locations:

http://ec.europa.eu/dgs/health_consumer/dyna/enews/enews.cfm?al_id=1004

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http://ec.europa.eu/consumers/sectors/medicaldevices/files/pdfdocs/reprocessing_report_en.pdf

ACTION OR RECOMMENDATIONS

1. Be aware of the difference between medical devices intended by the manufacturer for single use and medical devices intended for single patient use.
2. Become familiar with the legislation in this area, in particular the implications for reprocessing of single use devices.
3. Ensure the risks associated with the reuse of single use medical devices are considered at local level, in light of the update to the medical devices legislation and the SCENIHR report.

ENQUIRIES

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

Irish Medicines Board
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Earlsfort Centre
Earlsfort Terrace
Dublin 2

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