IRISH MEDICINES BOARD

Notice Information: - Advisory
16 September 2010

Part 1. Product Information

a)	Title:	Cleaning and Decontamination of Reusable Medical Devices
b)	Product Name/Type:	Cleaning and Decontamination of Reusable Medical Devices
c)	Reference:	IMB Safety Notice: SN2010(11)
d)	Manufacturer/Supplier:	Various

Part 2. Target Audience

a) Target Audience:	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 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)

Part 3. Problem/Issue

a) Problem/Issue:	Adverse incidents and safety related problems can arise when the instructions and guidance outlined by the manufacturer in the Instructions for Use (IFU) are not followed correctly. This is particularly important in relation to cleaning and decontamination procedures to be followed for reusable medical devices including, but not limited to, endoscopes and surgical instruments.

Part 4. Background Information

a)	Background Information:	Under the Medical Devices Directives, a manufacturer is obliged to provide adequate information that ensures the safe use of their device. This information is usually provided in the format of either Instructions for Use (IFU) or the operating manual or in some cases both. Please refer to the Irish Medicines Board (IMB) Safety Notice SN2004(06) relating to Instructions for Use provided by the Medical Device Manufacturer in August 2004 for further information (http://www.imb.ie/EN/Medical-Devices/Safety-Notices.aspx). Decontamination is the combination of processes used to render a reusable medical device safe for handling by staff and further use on patients. The effective decontamination of reusable medical devices is essential in minimising the risk of transmission of infectious agents. In defining the decontamination process for a particular device, the manufacturer must consider the risk involved and whether their device is suitable to be reprocessed in this way. The IMB is aware of a number of incidents where users experienced difficulty in cleaning reusable medical devices. Users have found that the IFU and reprocessing instructions provided by the manufacturer did not meet their local requirements. Any concerns relating to the adequacy of the Instructions for Use for a particular device should be reported to the manufacturer and to the IMB. In some instances, it may be prudent to consider the risk benefit ratio in relation to reusable medical devices as part of procurement and purchasing and to ascertain whether an equivalent disposable device is available / more suited to the application in a particular healthcare facility.

Part 5. Action to be taken

a) Action to be taken:

1) Ensure that Instructions for Use are provided with all medical devices used in your hospital / healthcare facility and are read and understood by users prior to the use of a new device. If you have an concerns relating to the adequacy of the Instructions for Use for a particular device, these should be reported to the manufacturer and to the IMB.

2) It is critical that decontamination of a medical device is carried out in accordance with the device manufacturer's instructions. If there is no reprocessing information provided with the device, then the manufacturer should be contacted for guidance. Under the Regulations, reusable medical devices placed on the Irish market after June 1998 must be provided with reprocessing instructions.

3) If the reprocessor (e.g. the hospital Central Sterile Services Department (CSSD)) of the medical device deviates from the instructions provided by a manufacturer with their device, the re-processor must ensure that the new cycles/times/temperature etc are validated and that all risks have been identified and documented. The use of the alternative method must be demonstrated to be equivalent to the manufacturer's instructions and must take into account all risks to patients and users.

4) For medical devices requiring sterilisation:

a. The medical devices should be cleaned prior to sterilisation as outlined in the manufacturer's instructions for use

b. The sterilisation process must be suitable for the device with no compatibility problems;

c. The chemical gaseous process (if applicable) must be safe to use on all sterilised devices. Appropriate environmental controls must also be in place, e.g. with use of ethylene oxide;

d. The process must reach all areas of the device to ensure sterility;

e. The configuration and the packaging are acceptable through the process; and

f. The device must be traceable through all stages of the sterilisation process. 5) Consider the risk benefit ratio in relation to reusable medical devices

5) Consider the risk benefit ratio in relation to reusable medical devices, and whether an equivalent disposable device may be available / more suited to the application in your healthcare facility.

Part 6. Enquiries

a) All enquiries should be made to:

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

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

Download

References

In relation to cleaning and decontamination of reusable medical devices, your attention is drawn to the following guidelines:

a. Section 15 of the IMB Guide: Manufacture of Medical Devices within Healthcare Institutions.

b. Health Service Executive Code of Practice for Decontamination of Reusable Invasive Medical Devices.

c. SN2009(4) Safe and Effective use of Bench-top Steam Sterilisers.

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