IRISH MEDICINES BOARD

MEDICAL DEVICE
SAFETY NOTICE

Reusable Needle Holders / Blood Tube Holders
IMB Safety Notice: SN2006(05)

SAFETY NOTICE

MANUFACTURER / SUPPLIER

Various

TARGET GROUPS

Accident and Emergency Department
All Wards
Biochemistry Departments
Blood Transfusion Laboratories
Directors of Pathology and Laboratory Services
District Nurses
Haematology Laboratories
Immunology Laboratories
Infection Control Teams
General Medical Practitioners
Medical Directors
Microbiology Laboratories
Outpatient Departments
Phlebotomists
Risk Managers
Supplies Managers
Theatre Managers

ISSUE

The risk of needle stick injuries and the risk of cross contamination of patient blood with blood borne pathogens from the use of reusable blood tube / needle holders.

BACKGROUND

It has been brought to the attention of the Irish Medicines Board (IMB) that in addition to the risk of needle stick injuries associated with reusable blood tube / needle holders there is a potential risk of cross-infection of patients with blood borne pathogens in circumstances where

reusable blood tube / needle holders become contaminated and are not decontaminated before re-use. This risk has also been identified by professionals and manufacturers and has been highlighted by the US based Occupational Safety and Health Administration, US National Association of Phlebotomists, ECRI (Emergency Care Research Institute) amongst others.

The IMB has determined that both single use and reusable devices are used in the variety of healthcare settings in Ireland e.g. GP surgeries, hospitals, clinics and nursing homes.

Information obtained by the IMB from users suggests that, in the case of some reusable devices:

- The written information provided by the manufacturer is limited and does not always provide sufficient details of how the device can be adequately decontaminated between use;

- The practice of visual inspection between use of reusable devices for macroscopic evidence of contamination may not be sufficient in the prevention of cross contamination.

- Some reports suggest that manufacturers recommend devices be used on a finite number of occasions. The control and management of this recommendation may not be realistic in a healthcare setting.

The IMB is continuing to following up these concerns with the relevant manufacturers.

ACTION OR RECOMMENDATIONS

The IMB recommends that all healthcare facilities conduct a review and analysis of the reusable blood tube / needle holders that are in use in their facility.

In general:

1. Determine the type of devices that are in use in your facility e.g. single use or reusable devices.

2. Examine the recommendations outlined by the manufacturer in the instructions for use.

3. Review / implement local policy for the use / decontamination of such devices.

4. If necessary consult with the local / regional infection control team to ensure compliance with local policy on the use, safety and sterilisation of reusable blood tube / needle holders.

SAFETY NOTICE

For Single Use Devices:

- Ensure that procedures are in place to ensure that single use devices are only used once.

- Ensure that facilities are in place ensure the safe disposal of the device.

For Reusable Devices

- Ensure that all staff using these devices are familiar with the manufacturer's recommendations for decontamination.

- Ensure that the manufacturer's recommendations for decontamination are completed following every use.

- Ensure that your local / regional infection control team are satisfied with the level of decontamination between uses of reusable blood tube / needle holders.

- Ensure that procedures are in place to ensure the safe disposal of the reusable device.

REPORTING OF ADVERSE INCIDENTS

All adverse incidents relating to a medical device should be reported to the Medical Devices Department at the IMB.

Adverse incidents may be reported via the **on-line vigilance reporting system,** which can be accessed in the medical devices section of the IMB website www.medicaldevices.ie, or by completing a **User Adverse Incident Report Form (DSF-4-01-01/4)**, which is available on request from the IMB or may be downloaded from the IMB website.

ENQUIRIES

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

Irish Medicines Board
Medical Devices Department
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

If you have any enquiries, you may contact the Medical Devices Department at:

Telephone: +353-1-6764971
Fax: +353-1-6344033
Email: medicaldevices@imb.ie
Website: www.imb.ie

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