Re-use of Single Use Devices (SUDs)
1. SINGLE USE MEDICAL DEVICES

**Single Use Devices (SUDs)** are medical devices that are labelled by the original manufacturer as “single use” or “single patient use”.

**Single Use**: If a device is for single use, the manufacturer’s intention is that the device can only be used once and should then be disposed of.

**Single Patient Use**: If a device is for single patient use, the manufacturer’s intention is that the device can be used multiple times on one patient. Single patient use devices are able to be reprocessed and re-used on the same patient in accordance with the manufacturer’s instructions.

**Do not re-use symbol**: The internationally recognised symbol described in ‘ISO 15223-1:2012(E) Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied’ means DO NOT RE-USE. This indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. The synonyms for this symbol are “single use” or “use only once”.

**Do not re-sterilise symbol**: The internationally recognised symbol described in ‘ISO 15223-1:2012(E) indicates a medical device that is not to be re-sterilised.

SUDs are classified according to their potential risk to a human body. Therapeutic Goods Administration (TGA) classification is as follows:

- **Class I**: Low-medium risk devices, including devices that are sterile and/or have a measuring function,
- **Class IIa**: Low-medium risk devices,
- **Class IIb**: Medium-high risk devices,
- **Class III**: High risk medical devices, and
- **Class AIMD**: Active Implantable Medical Devices. These are treated in a similar way to Class III medical devices.

Re-use of any medical device potentially increases the risk of cross infection or contamination. Additional risks are associated with re-use of SUDs. These include material degradation, bio-compatibility reactions, endotoxin reactions caused by residues from the cleaning and sterilisation process and device failure, because SUDs were not designed or validated for re-use.

2. BACKGROUND

In 2001, the Australian Health Ministers Advisory Council (AHMAC) agreed that any re-use of SUDs is a manufacturing activity requiring regulation by the TGA. The regulation for re-manufacturing was introduced in December 2003. A 2-year “phase in” period was allowed for implementation of these requirements up to December 2005. The National
Co-ordinating Committee on Therapeutic Goods (NCCTG) twice extended the transition period with the legislation full implemented for all classes of medical device from 1 July 2007.

Under the current legislation, SUDs may only be re-used if the device is re-manufactured according to the TGA regulations. Re-manufacturing can only be performed by a facility that has been approved and licensed by TGA. At present, while an opportunity exists for a re-manufacturing facility under the new regulations, Australia does not have a licensed re-manufacturer for SUDs.

3. REGULATION SURROUNDING SUDs

- Therapeutic Goods Act 1989
- Therapeutic Goods Regulations 1990
- Therapeutic Goods (Medical Devices) Regulations 2002

4. RELATED NATIONAL AND WA HEALTH POLICIES

- National Health and Medical Research Council (NHMRC)
  Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010)

5. FURTHER ACTIONS THAT ARE REQUIRED OF ALL WA PUBLIC HEALTH FACILITIES

All public health facilities:

- must ensure compliance with TGA in using SUDs and
- should hold adequate supplies of SUDs to ensure patient safety is not compromised.

6. MORE INFORMATION

- Further advice regarding SUDs in Western Australian Hospitals can be obtained from Medical Engineering & Physics, Royal Perth Hospital on (08) 9224 2500.
- More information on the regulation of the re-manufacture of SUDs, including links to the relevant Australian Government legislation, is available on the TGA website at: http://www.tga.gov.au/ or from the TGA information line for medical devices on 1800 141 144.