Position Statement
Single-use devices

ACIPC Recommends

- Medical devices labelled as single use are not for reuse.
- Medical devices labelled as single patient use items are reprocessed in accordance with the manufacturer's instructions for reprocessing before being reused on the same patient.

1. Introduction

The responsibility of designating a medical device as single use or single patient use lies with the manufacturer and this must be clearly stated on the medical device or in the instructions for use. The Therapeutic Goods Administration (TGA) considers the reprocessing and/or reuse of a single use medical device to be a remanufacture of the device and therefore the original manufacturer is no longer responsible for the performance and safety of the device. Manufacture of medical devices, including remanufacture of single use devices, is regulated by the Therapeutic Goods Administration.

There are a number of reasons why a medical device is labelled as single use. These include:

- The inability of the material used on the device to withstand reprocessing.
- The inability to appropriately clean, disinfect or sterilise the device due to its design features.
- The possibility that the medical device may not achieve the intended level of performance if it is reprocessed and reused[1]

Reprocessing single use devices can lead to:

- Risk of infection transmission
- Device failure and/or degradation
- Issues with biocompatibility of the medical device
- Endotoxic reactions from reprocessing residues[1]

2. Definitions

Single use - the medical device can be used once and then disposed of.

Single patient use - the medical device can be used multiple times on the same patient and can be reprocessed and reused on the same patient in accordance with the manufacturer's instructions for reprocessing.

Reuse of a single use device is considered to be a remanufacture of the device.

3. Legislative Position

Medical devices are defined as follows by the Therapeutic Goods Act 1989[2]:

a. any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
   i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
   ii. diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or handicap;
   iii. investigation, replacement or modification of the anatomy or of a physiological process;
   iv. control of conception;

   and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

b. an accessory to such an instrument, apparatus, appliance, material or other article.

The Therapeutic Goods (Medical Devices) 2007 Regulations[3] require a healthcare facility that reprocesses single-use devices to be licensed as a manufacturer. A healthcare facility that reprocesses single use devices would be considered to be a manufacturer under the Act and thus would be required to conform to the regulation and be subject to audit to ensure compliance.

ACIPC believes that:

- Reprocessing of single use devices must not be undertaken unless the facility is licensed as a manufacturer under Section 41 BG (2) of the *Therapeutic Goods Act 1989*[4] and fully complies with the 2007 Regulations.

ACIPC resolves to:

- Continue to work with industry representatives to promote sustainability in healthcare and identify ways of safely reducing waste from impacting on our environment.

4. References

1. Rutala W, Weber D, Healthcare Infection Control Practices Advisory Committee. *Guideline for disinfection and sterilization in healthcare facilities* 2008. Atlanta, GE: Centers for Disease Control. [http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf Accessed November 2012]
2. Therapeutic Goods Act 1989. [http://www.austlii.edu.au/au/legis/cth/consol_act/tga1989191/ Accessed October 2016]
3. Therapeutic Goods (Medical Devices) 2007 Regulations (see PD2005_399 Single Use Medical Devices (SUDS) Remanufacture) [http://www.comlaw.gov.au/Details/C2007C00652/Download Accessed November 2012]
4. Therapeutic Goods Act 1989 (see Section 41BG (2). [http://www.austlii.edu.au/au/legis/cth/consol_act/tga1989191/ Accessed October 2016]

5. Other relevant documents

1. National Health and Medical Research Council. *Australian guidelines for the prevention and control of infection in healthcare*. 2010. Canberra, Australia: Commonwealth of Australia.
2. Commonwealth of Australia. *Therapeutic Goods (Medical Devices) Regulations, 2002*. [http://www.comlaw.gov.au/Details/F2015C00373. Accessed 9 June 2015].
3. Therapeutic Goods Administration. *Australian regulatory guidelines for medical devices (ARGMD) Part 2 - Pre-market*. Version 1.1, May 2011. Canberra, Australia: Department of Health and Ageing, Commonwealth of Australia. [http://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd. Accessed 9 June 2015.]

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Revision history

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3.0	Oct 2016	Minor edits	T. van de Mortel, ACIPC Policy Chair	ACIPC Board of Directors