

Single Use Medical Devices (SUDs) Remanufacture

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Population Health - Infection Control
Personnel/Workforce - Occupational Health & Safety

Summary Outlines legislation re remanufacture of single use medical devices and specifically infection control implications.

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Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations - Non Declared, Community Health Centres, Divisions of General Practice, NSW Dept of Health, Private Hospitals and Day Procedure Centres, Public Health Units, Public Hospitals

Distributed to Public Health System, Community Health Centres, Divisions of General Practice, NSW Department of Health, Public Health Units, Public Hospitals, Private Hospitals and Day Procedure Centres

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Compliance with this policy directive is mandatory.

CIRCULAR

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Remanufacture Of Single Use Medical Devices (SUDs)**1.0 INTRODUCTION**

This document is a compliance support policy developed to assist Health Services and licensed private facilities to meet their legal obligations under the following:

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

In particular, it covers requirements related to the re-manufacture of single use medical devices (SUDs).

In December 2003 the Commonwealth Therapeutic Goods Administration (TGA) implemented the regulation of the remanufacture of SUDs. This means that any facility wishing to remanufacture a medical device labelled 'single use' or 'single patient use' will need to comply with the regulatory requirements for a manufacturer of medical devices as described in the *Therapeutic Goods Act 1989* and the *Therapeutic Goods (Medical Devices) Regulations 2002*.

2.0 RELATED NSW HEALTH POLICIES

C/2002/45 Infection Control Policy

3.0 ISSUES TO CONSIDER BEFORE REMANUFACTURING SUDs

Before making a decision to become a manufacturer you need to identify the devices you wish to re-manufacture. It may also be worthwhile to undertake an analysis of the costs involved with reprocessing as apposed to opting for a single use policy.

When a SUD is remanufactured for reuse the intended purpose and design specifications for the device are altered from single use to reusable, the device is refurbished and undergoes a number of steps of manufacture. The person responsible for undertaking these activities is considered to be a manufacturer and needs to comply with the therapeutic goods legislation relating to the manufacture of medical devices

Distributed in accordance with circular list(s):

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In accordance with the provisions incorporated in the Accounts and Audit Determination, the Board of Directors, Chief Executive Officers and their equivalents, within a public health organisation, shall be held responsible for ensuring the observance of Departmental policy (including circulars and procedure manuals) as issued by the Minister and the Director-General of the Department of Health.

This means that any facility wishing to remanufacture medical devices labelled as "single use" or "single patient use" will need to comply with the regulatory requirements for a manufacturer of medical devices as described in the Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002.

4.0 RISKS ASSOCIATED WITH REMANUFACTURE OF SUDs

The potential risks of cross infection / contamination associated with using inadequately cleaned and sterilized medical devices is well known, however additional risks associated with remanufacturing SUDs such as device failure, material degradation, biocompatibility and endotoxic reactions caused by the residues from reprocessing are less known but do raise significant concern.

5.0 OPTIONS FOR REMANUFACTURE OF SUDs

Health care facilities wishing to reuse SUDs may either:

- become a manufacturer;
- find a manufacturer to undertake the re-manufacture of the SUDs; or
- adopt a single use only policy.

6.0 INITIAL AUDIT OF REMANUFACTURING FACILITY

Before you request the TGA to undertake an initial audit of your remanufacturing facility, you will need to have implemented and hold documentation on:

- the quality management system you have in place for re-manufacturing the device/s. The Standard for manufacturer's of medical devices is ISO 13485:2003,
- the remanufacturing process that will ensure at a minimum:
 - the materials used to make the original device will not be affected;
 - the cleaning, disinfection and sterilization processes are effective;
 - endotoxins do not exceed the allowable limit for medical devices; and
 - the device will continue to perform as originally intended.
- how the remanufactured device meets the Essential Principles for safety and performance;
- the design dossier/technical file for the remanufactured device;
- the system you have in place for:
 - tracking the number of times the device is re-manufactured and reused, and
 - tracing the device to the batch/serial number of the original device.

7.0 FEES AND CHARGES

The *Australian Medical Device Guidelines - Fees and Charges Guidance Document No. 6* (accessed from the TGA website) details the fees and charges payable for:

- applications for the inclusion of medical devices in the Australian Register of Therapeutic Goods (ARTG);
- issuing certificates of conformity assessment for medical devices;
- conformity assessment audits;
- surveillance audits, and
- other activities controlled under the Therapeutic Goods Act 1989.

8.0 FURTHER INFORMATION

More information on the regulation of the remanufacture of SUDs including links to the relevant Australian Government legislation, is available on the TGA website at: www.tga.gov.au or from the TGA information line for medical devices on 1800 141 144.

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