Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Manufacturer's instructions for reprocessing reusable medical devices - the Regulatory perspective

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TGA Health Safety Regulation

The TGA's Role

Device Vigilance and Monitoring section of the Office Product Review TGA, monitors the post market performance and safety of medical Devices included on the Australian Register Therapeutic Goods (ARTG – website http://www.tga.gov.au/industry/artg.htm)

This is done through;

- Incident Report Investigation Scheme (IRIS),
- Medical device product reviews, and
- International liaison.

The TGA does not regulate *users* however, does make recommendations to users on the use of therapeutic products.

Legislative documents

The Therapeutic Goods Act 1989

(the Act)

(ref Chapter 4. Medical Devices)

Therapeutic Goods (Medical Devices) Regulations 2002

(the Regs)

(Sched 1 Parts 1, 2 - Essential Principles)

Australian Regulatory Guidelines for Medical Devices

(ARGMD) Part 3: Post Market - Section 22

(guideline document – not legislated)

Sponsor's of medical devices

- Medical devices manufactured overseas require an Australian **sponsor** to supply the device(s) to the Australian market.
- There are Australian manufacturer's who may also be the Australian sponsor
- TGA works with the **sponsor** to address any issues related to the device(s).

Sponsor's (companies) are responsible under the Act for;

- Ensuring they can obtain information from the manufacturer about the device(s) within a specified timeframe,
- Ensuring device(s) comply with all applicable essential principles (e.g EP 13, as follows...)

Therapeutic Goods (Medical Devices) Regulations 2002
Part 2 - Essential Principle (EP) 13

Information to be provided with medical devices

13.4 Instructions for use

13.4(3) Instructions for the use of a medical device must include information mentioned in the following table that is applicable to the device.

(*Items 1 – 11 not applicable to this discussion*)

Item 12 For a device that is intended by the manufacturer to be supplied in a sterile state:

(a) an indication that the device is sterile; and

(b) information about what to do if sterile packaging is damaged; and

(c) if appropriate, instructions for resterilisation of the device

Item 13 For a medical device that is intended by the manufacturer to be sterilised before use — instructions for cleaning and sterilising the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the essential principles.

... Continued

(*Items 14 -19 not applicable to this discussion*)

Item 20 For a reusable device:

(a) information about the appropriate processes to allow reuse of the device (including information about cleaning, disinfection, packaging and, if appropriate, resterilisation of the device); and

(b) an indication of the number of times the device may be safely reused.

WHO IS A MANUFACTURER?

Defined in s41BG (2) of the *Therapeutic Goods Act*

… the person who, with **a view to supplying the device under the person's name**, does one or more of the following using ready made products:

- assembles
- packages
- processes
- fully refurbishes (defined in Reg 1.5)
- labels
- assigns the intended purpose by means of information supplied, by the person, on or in any one or more of the following:

(i) the labelling on the device;
(ii) the instructions for using the device;
(iii) any advertising material relating to the device;
(iv) technical documentation describing the mechanism of action of the device.

The ***Manufacturer*** of a reusable medical device must determine how the device will be resterilised for reuse because they;

- have validated the reprocessing parameters during the design and manufacture of the device (or a ‘like’ device),
- manufactured the device using materials that are compatible with the sterilising method to be used,
- may have done validation studies on how long the device will last when resterilised using their validated sterilising method OR the number of times a device can be resterilised using their sterilising method,
- have undertaken a risk assessment for the use and reuse of the device(s),
- may not warrant a ‘faulty’ device if reprocessed contrary to their validated sterilising instructions

If there is a *problem* with instructions for reprocessing or you are not sure how to reprocess you should ...

- Contact the ***sponsor*** of the device or the company rep and request assistance with your reprocessing procedures,
- Contact the ***manufacturer*** of the device and request their instructions for reprocessing,
- Report the problem to the ***TGA*** through any of the following reporting channels.

Addresses for Reporting Adverse Events and Incidents to the TGA

The web address for the reporting
http://www.tga.gov.au/consumers/problem-device.htm

Mail report to:
IRIS Coordinator
TGA
PO Box 100
Woden ACT 2606

Fax: (02) 6203 1713

Phone: For information and clarification only
1800 809 361

Email to: iris@tga.gov.au