CONTINENCE NURSES SOCIETY AUSTRALIA INC

Update on single versus reuse of urinary catheter drainage bags and catheters for intermittent catherisation

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Acknowledgements

This document was developed for the Continence Nurses Society Australia (CoNSA) by members of its Professional Issues and Education Sub Committee, and a working party consisting of:

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Disclaimer

The information is intended as general guidance for members of the CoNSA who provide advice to clients with urethral or suprapubic indwelling urinary catheters and clients who perform intermittent catheterisation.

CoNSA has used reasonable endeavors to ensure that the information contained on this document was correct at the time the document was created, modified and published. CoNSA recommends members check for currency of the information – particularly as guidelines from the Therapeutic Goods Administration are continually being updated.

The Therapeutic Goods Administration

The Australian Government Department of Health Therapeutic Goods Administration (TGA), in collaboration with the medical devices industry sector, has developed a consolidated reference document detailing the Australian regulatory requirements for medical devices to assist sponsors and manufacturers to understand the regulatory requirements (2011). All manufacturers and suppliers of medical devices must comply with the following regulatory requirements:

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

In the Australian context, urinary catheter drainage bags (day and night bags) and catheters for intermittent catheterisation are classed as 'medical devices' (https://www.tga.gov.au/australian-register-therapeutic-goods) and are **usually** labelled for single use only.

Key points

- The TGA recommends ***all single-use medical devices or systems should not be reprocessed for reuse*** unless they are approved for reprocessing and the manufacturer has provided instructions for reprocessing.

- Whilst the TGA does not regulate nursing, it does advise '***Healthcare professionals may be professionally liable for any harm visited on the patient if the information they provide to consumers contradicts the information provided in the manufacturer's 'Instructions for Use'.***

- ***In a negligence case the nurse may be required to provide the evidence on which his/her recommendations for cleaning were based. This situation applied long before the implementation of regulation for the re-manufacture of single-use devices'.***

CoNSA Recommendations

- Nurses who provide advice to clients about using medical devices that are labelled for single use should be aware of the TGA guidelines.
- Nurses who provide advice to clients about using a medical device should check and adhere to the manufacturer's 'Instructions for Use'.
- Organisational policies and practices should align with the TGA guidelines.

Reference

The Australian Regulatory Guidelines for Medical Devices (ARGMD) V1.1, May 2011. Retrieved 7th June 2017 from: https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd