Use of Impregnated Chemical Disinfectant Wipe Systems for Reusable Medical Devices

Purpose
This Safety Notice has been developed to advise health services to exercise caution when using Impregnated Chemical Disinfection Wipe Systems, using active ingredients such as isopropyl alcohol, chlorhexidine gluconate, chlorine dioxide and dimethyl oxazolidine, for high-level disinfection of non-lumened reusable medical devices (RMD).

Issue
There are available in the health care sector a range of products, which are marketed as Impregnated Chemical Disinfection Wipe Systems. These are available for use in either a single form impregnated with one chemical ingredient or in a system requiring a sequential application to achieve a theoretical state of cleanliness or high-level disinfection. For example, one such system has been approved by the TGA for high-level disinfection of non-lumened medical devices - including nasendoscopes; transoesophageal cardio probes; trans-vaginal and trans-rectal ultrasound transducers; GI high resolution manometry catheters; and ophthalmic devices - that cannot be fully immersed in liquid disinfectant or sterilants and cannot be sterilised by heat.

The systems using active ingredients, such as isopropyl alcohol, chlorhexidine gluconate, chlorine dioxide and dimethyl oxazolidine, are not intended for use on critical medical devices which must be sterilised prior to use on a patient.

Unlike automated reprocessing systems which have a measured dosage of chemistry and a validated reprocess cycle, impregnated chemical disinfection wipe systems rely on the manual (human) process of applying each wipe in the recommended sequence. This assumes that each and every part of the device has been contacted consistently for the specified period of time.

The devices for which impregnated chemical disinfection wipe systems are intended are not easily stabilised aseptically, which makes it very difficult to ensure and verify that all parts of the device have been contacted by the disinfecting agent consistently at the required concentration for the required time.

Minimising risks when using impregnated chemical disinfection wipe systems that use active ingredients such as isopropyl alcohol, chlorhexidine gluconate, chlorine dioxide and dimethyl oxazolidine:

- Facilities ensure and verify that impregnated chemical disinfection wipe systems are not used in any situation where a RMD is required sterile for an invasive procedure.
- Facilities review their use of impregnated chemical disinfection wipe systems that use active ingredients such as isopropyl alcohol, chlorhexidine gluconate, chlorine dioxide and dimethyl oxazolidine for the high-level disinfection of RMDs.
- Facilities utilising an impregnated chemical disinfection wipe system for high-level disinfection of RMDs evaluate if there are alternative reprocessing systems for which adherence to best practice standards can be more readily ensured and verified.
- Facilities ensure and verify that use of an impregnated chemical disinfection wipe system is in accordance with the RMD’s manufacturer’s instructions.
- Facilities ensure and verify that staff using an impregnated chemical disinfection wipe system are trained and competent in use of the system, and adhere to relevant NSW policies.
- Facilities ensure and verify that impregnated chemical disinfection wipe systems’ manufacturer’s instructions for use are strictly adhered to ensure that all surfaces are cleaned and adequate contact made with the active chemical for the appropriate time.

Suggested actions by Local Health Districts/Networks
1. Distribute this Safety Notice to all relevant staff.
2. Review and revise local protocols in line with this Safety Notice.