



Safety Information 002/14

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Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Private Health Care

Expert Reference Group

Content reviewed by:

- Pharmaceutical Services Unit, NSW Ministry of Health
- Office of the Chief Health Officer
- Clinical Excellence Commission
- Medication Safety Expert Advisory Group

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PROPOFOL – importance of aseptic technique and safe administration practices

Background

A number of patients across Australia have become unwell with *Ralstonia sp.* sepsis after being administered propofol injection from a single dose vial. This resulted in the issuing of a batch quarantine and Safety Alert 002/14. This Safety Alert was later updated after TGA testing of vial contents showed that unpierced vials were sterile. However a recent case of propofol-associated *Ralstonia sp.* sepsis has drawn attention to the ongoing need to administer this medication carefully.

Although the contents of propofol 1% vials are sterile when unpierced, vials are not antimicrobially preserved. Once the vial is pierced, the contents can support the growth of microorganisms.

The exterior surfaces of vials are not intended to be sterile. Protective plastic flip-off lids act as a shield for the rubber stopper and keep dust and other physical contaminants away from it. The outer surface of a vial rubber stopper/aluminium crimp seal is not sterile unless packaged in a manner indicating end sterilisation of the packaged product has occurred.

Steps to Minimise Risk

- Health professionals are reminded that proper aseptic technique must be strictly followed when administering intravenous injections to a patient. This includes rubbing the outer surface of the rubber stopper vigorously with a 70% alcohol wipe/swab and allowing it to dry before inserting any device into the vial. The patient's injection site/port should be similarly decontaminated prior to injection/infusion as per *GL2013_013 PIVC Insertion and Post Insertion* (http://www0.health.nsw.gov.au/policies/gl/2013/GL2013_013.html).
- The vials must not be used when there is significant moisture under the protective flip-off lid or the lid is missing. They should be returned to the Pharmacy Department.
- In some cases reported to the TGA, propofol had been drawn up but not administered until some hours later. To reduce the microbiological hazard, propofol must be used immediately after drawing up.
- A single infusion of propofol must not exceed 12 hours. At the end of the procedure or at 12 hours, whichever is sooner, both the reservoir of propofol and the infusion line must be discarded and replaced as appropriate.

Local Health Districts / Networks Must

1. Distribute this notice and its attachment to key stakeholders and all clinical departments.
2. Reinforce clinical awareness of the importance of correct aseptic technique in drawing up medications from vials with flip-off lids that are not packaged in a manner indicating end sterilisation of the packaged product, particularly for propofol.
3. Encourage clinicians to take extra caution in using aseptic technique when propofol infusions are in use and ensure that lines and administration equipment are appropriately replaced each 12 hours.

Required actions by Local Health Districts/Networks

1. Forward information to appropriate areas for action.
2. Ensure a system is in place to document actions taken.