Fact Sheet for Health Care Professionals

Single-use Medical Devices

Many medical devices are difficult to reprocess and render safe for use on another patient. These devices are labelled by the manufacturer as "single use". Items labelled as "single use" may not be re-used in any way.

How do I know if a device is for single-use?

It will have this symbol on the packaging or the device (2)



What does single-use mean?

A single-use device is used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.

Is single patient use the same as single-use?

These are not the same. Single patient use means the medical device may be used for more than one episode of use on one patient only; the device may undergo some form of reprocessing between each use. Items should not be labelled as "single patient use" and also contain the symbol (2). If this is the case, the manufacturer should be contacted for clarification.

Why shouldn't they be reused?

Serious incidents relating to reuse of single-use devices have been reported. Also, if you reuse a single-use device you may be legally liable for the safe performance of the device.

Reuse can be unsafe because of the risk of:

- cross-infection inability to clean and decontaminate due to device design
- endotoxin reaction resulting from excessive bacterial breakdown products, which cannot be adequately removed by cleaning
- chemical burns or sensitisation resulting from residues from chemical decontamination agents on materials that can absorb/adsorb chemicals.

Can I sterilise a single-use device?

A few single-use devices are marketed as non-sterile. These may require processing, in line with manufacturer's instructions, to make them sterile and ready for use. You may not resterilise them and after use, they must be disposed of.

References

- 1. Australian Regulatory Guidelines for Medical Devices, May 2011 http://www.tga.gov.au/industry/devices-argmd.htm
- 2. SA Health Reprocessing of Reusable Medical Devices Policy Directive http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical +resources/clinical+topics/healthcare+associated+infections/prevention+and+management+ of+infections+in+healthcare+settings/reprocessing+of+medical+devices

For more information

Infection Control Service **Communicable Disease Control Branch** Telephone: 1300 232 272

www.sahealth.sa.gov.au/infectionprevention

© Department for Health and Ageing, Government of South Australia. All rights reserved. Version 1.4 (Last updated: March 2020)



