#### **OFFICIAL**

## Fact Sheet for Health Care Professionals

# Single-use Medical Devices

Many medical devices cannot be reprocessed and rendered safe for use between patients. These are labelled "single use" by the manufacturer and may not be reprocessed or re-used in any way.

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

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

## What does single-use mean?

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

## Is single patient use the same as single-use?

No. Single patient use means the device may be used in more than one episode on the same patient only; the device may require some form of reprocessing between each use. Device labelling will identity it is for single patient use. The 2 symbol will not be present as it is used only as defined above and not for single patient use devices. Consult the supplier if in doubt.

## Why shouldn't they be reused?

Serious incidents relating to the reuse of single-use devices have been reported. You may be legally liable for the performance of a single-use device if you reuse or reprocess it.

Reuse can be unsafe because of the risk of:

- cross-infection where the material and design of a device do not allow it to be properly cleaned and/or sterilised between uses.
- > **malfunction** where exposure to chemicals, heat and other aspects of reprocessing are incompatible with the device and damage functional parts.

## Can I sterilise a single-use device that has not been used?

Some single-use devices are supplied unsterile by the manufacturer with instructions for sterilisation prior to use. This may only be done once, in accordance with the instructions.

If single-use devices pass an expiry date or are opened but not used, they must not be reprocessed. They cannot be subjected to reprocessing, even when not used on a patient.

#### References

- 1. Therapeutic Goods Administration (2011, Under Review) Australian Regulatory Guidelines for Medical Devices <a href="http://www.tga.gov.au/industry/devices-argmd.htm">http://www.tga.gov.au/industry/devices-argmd.htm</a>
- Australasian College for Infection Prevention and Control (2024) Position Statement Single-Use Devices <a href="https://www.acipc.org.au/wp-content/uploads/2024/03/Position-statement-Single-use-Devices-Issued-03-2024.pdf">https://www.acipc.org.au/wp-content/uploads/2024/03/Position-statement-Single-use-Devices-Issued-03-2024.pdf</a>

#### For more information

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

www.sahealth.sa.gov.au/infectionprevention

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