Information for consumers

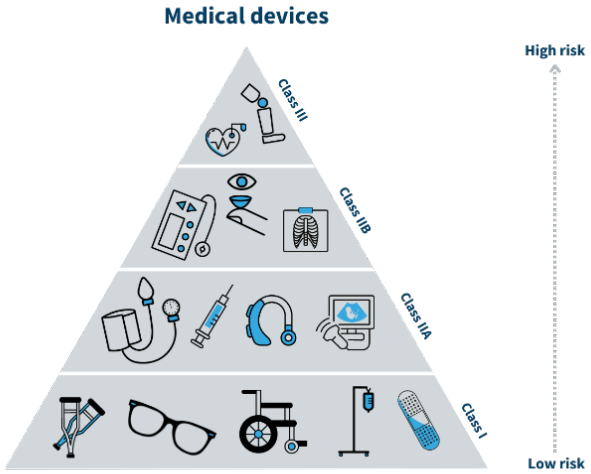
TGA Medical Device Reforms

Making medical devices safer

Medical devices have been used to support our health and wellbeing for centuries. The world's oldest prosthetic devices were toes for amputees, made in ancient Egypt, from wood and leather. Contact lenses and x-ray machines, bandages and band aids – even the CPAP machine you may have by your bedside – make up the hundreds of thousands of medical devices that are used to detect, prevent or manage medical issues. It is essential, therefore, that medical devices perform optimally.

There are various types of medical devices, and they are classed according to the level of risk they may pose. Low risk devices – like reading glasses and surgical gloves – may be used outside your body; while higher risk devices – like joint replacements, breast implants and pacemakers – are surgically inserted inside your body and may remain there. Others can be customised in hospitals or clinics specific to your needs and are called patient-matched devices. Today, 3D printing is even used to create some of these devices!

While most of these medical devices are safe, there have been cases where a device has caused harm or unexpected health issues to patients. In 2010, for example, some silicone breast implants were found to contain harmful substances and needed to be recalled. Similarly, in 2017, a Senate inquiry commenced in Australia into transvaginal mesh implants (used to prevent urinary incontinence and pelvic organ prolapse), as the use of these devices caused adverse effects, such as chronic pain, in women around the world.



Examples of medical devices and the class types for different levels of risk

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Where do medical devices come from?

Some medical devices are made in Australia, while others are imported from around the world. But before any device is used in this country, it must be checked and approved by the Australian Government's Therapeutic Goods Administration (TGA) and be included in the Australian Register of Therapeutic Goods (ARTG).

Why are these changes needed?

Following the 2017 Senate inquiry, the TGA, which regulates medical devices and monitors their performance at the national level, introduced new changes to improve patient safety. These changes have been legislated by Parliament and are called the "Medical Device Reforms".

The TGA has three aims under these reforms:

1. improve how new devices get on the market
2. strengthen monitoring and follow-up of devices already in use
3. provide more information to patients about the devices they use.

These changes include introducing a new system using universal codes known as the Unique Device Identifier (UDI), which will make it easier to identify and track medical devices. The TGA is developing a database for Australian UDIs (known as the AusUDID) to provide complete and accurate information about the devices made available in Australia.

Although it is uncommon, when a medical device is faulty, it is important to locate and remove these devices from hospital and chemist shelves, and quickly identify and notify patients that they may be affected. Likewise, it is important for information about a medical device, including potential side effects, to be officially registered, which helps with device monitoring, as well as patient awareness and safety.

The reforms mean that there are some new responsibilities for the medical device industry, healthcare professionals and healthcare services in Australia.

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Better information for patients

As a patient or consumer, under these new reforms you must be given information by a healthcare professional (such as your doctor) on your implantable medical device. There are two stages when this must happen.

- BEFORE the device is implanted: Patient Information Leaflets (PILs) should be provided to you and include information identifying the device, the purpose of the device, how to use the device safely, and information on how to report any medical device adverse event or concern.
- AFTER the device is implanted: Patient Implant Cards (PICs) should be provided to you and include the name and model of the device, batch/lot number and serial number of the device, and the manufacturer's name, address and website.

The TGA's guide, "Five questions to ask your health professional before you get a medical implant", can be accessed at www.tga.gov.au/products/medical-devices/specific-types-medical-devices/five-questions-ask-your-health-professional-you-get-medical-implant.

This resource can also be printed in 10 languages: Arabic, Croatian, Farsi, Greek, Italian, Korean, Mandarin, Spanish, Turkish and Vietnamese.

Reporting issues or concerns about a medical device

It is mandatory for health professionals, such as your doctor, to report an adverse event related to any medical device. As a patient or consumer, these reforms now allow you to also report any issues or concerns you may have about your medical device directly to the TGA.

Should you experience an issue or concern about your medical device, we encourage you to report this both to your doctor and to the TGA at https://www.tga.gov.au/safety/reporting-problems/report-adverse-event-or-problem-consumers.

The Clinical Excellence Commission is supporting patients, consumers and NSW Health staff through the reforms. Visit its dedicated page at https://www.cec.health.nsw.gov.au/keep-patients-safe/medical-device-governance-program. You can also subscribe via this page to receive updates about these reforms. Email enquiries to cec-medicaldevicegovernance@health.nsw.gov.au

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