Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Reporting medical device problems: a fact sheet for consumers

No medical device is completely risk free. At times, you may experience some problems with your device. When this happens, tell your doctor or health provider.

You can also make a report to us at the Therapeutic Goods Administration (TGA).

We monitor the safety of medical devices approved for supply in Australia. If you have a problem with a medical device, you should report it. Your information will help us take regulatory action if needed.

Medical device adverse events

A medical device adverse event is a problem that led or could have led to:

- serious illness, injury or death
- permanent injury or damage
- admission to hospital.

Examples include:

- a device alarm not sounding when it should
- a device incorrectly delivering therapy (wrong dose of medication or treatment)
- problems with devices causing ongoing pain, infection, wound swelling
- inaccurate blood glucose monitors
- wearing of hip implants, leading to dislocation or infection
- electrical issues with pacemakers (impedance) or displacement of pacemaker leads.

If you experience an adverse event

Your health professional or healthcare facility can help you report an adverse event or may report on your behalf.

If you experience an adverse event in a hospital or healthcare facility, tell the facility as soon as possible.

If you are concerned about your medical device, talk to your doctor or your health provider.

Report an adverse event

You can report problems with your medical device directly to the TGA through an online form.

If you need help, call the TGA's free phoneline, **1800 809 361**, from 8:30am to 5:00pm AEST, Monday to Friday, or email IRIS@health.gov.au.

You do not need to be certain that the problem is linked to your medical device, just suspicious. Every report to the TGA is important.

What should you include in your report?

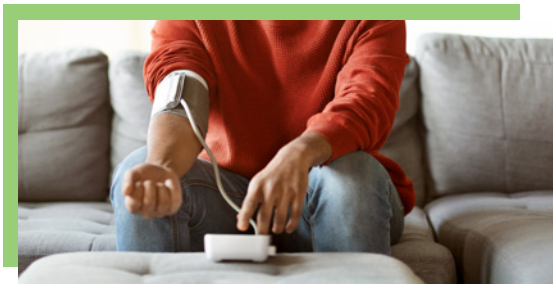
Your report should include information about:

- **you or the person you are reporting for** – age, gender, any underlying health conditions.
- **the device you are reporting about** – brand and model name, Australian Register of Therapeutic Goods (ARTG) number (if known), serial number, batch or lot number. A photo of the device's packaging on all sides works too.
- **the problem/incident** – what happened, when it started and stopped , where did it take place (in your home, a healthcare facility), what you have done to manage it or any symptoms that you are experiencing.

Give as much detail as you can. It will help us to follow up with the medical device manufacturer and Australian supplier.

You may need to ask your health professional or healthcare facility for some of these details. Your medical records may have information about your device if you do not have it available.

If you have a medical implant, you should have patient implant card. The patient implant card will contain information about your device.



How we use information in adverse event reports

The information you provide in a report will help us monitor the ongoing safety of the device. All reports are assessed and included in our Incident Report Investigation Scheme.

Personal information may be used to:

- contact you if further information is required
- investigate the adverse event with suppliers and manufacturers.

Personal information is always kept confidential, but sometimes limited personal information is disclosed to manufacturers and suppliers to assist in investigations. We will get your consent before we disclose personal information.

We review and risk-assess reports to:

- identify events that have a significant risk of harm to the Australian public, where timely intervention and action is critical, or
- consider whether the manufacturer's investigations and actions are sufficient in minimising risk.

Flags that trigger our risk assessment to investigate include incidents that:

- are difficult to detect before use
- may lead to serious injury
- have an unusually high level of occurrence, or
- have accumulated over a short time, even if they are less likely to lead to injury.

Not all reports are investigated. These events are less likely to be investigated:

- isolated incidents (not happened before)
- unlikely to cause death or serious injury
- known to be a common complication or problem, or
- have already undergone investigation, post-market review or recall/safety action.

Medical device manufacturers are responsible for investigating adverse events and complaints about the devices. We work with them.

More information

Search 'Report an adverse event or problem (consumer)' on the TGA website to find out more. The TGA has also published consumer fact sheets to help you as you consider a medical device:

- Five questions to ask your health professional before you get a medical implant
  (also available in English, Arabic, Croatian, Farsi, Greek, Italian, Korean, Mandarin, Spanish, Turkish and Vietnamese)
- Patient information materials for medical implants: a fact sheet for consumers