



Buying medical devices

Consumer questions and answers

What is a medical device?

A medical device is any instrument, apparatus, appliance, material or other article that is intended by the manufacturer to:

- diagnose, prevent, monitor, treat or alleviate disease
- diagnose, monitor, treat, alleviate or compensate for an injury or handicap
- investigate, replace or modify the anatomy or a physiological process, or
- control conception, and

does not achieve its principal intended action by pharmacological, immunological or metabolic means.

The term medical device covers a huge range of products, from a simple tongue depressor to a pacemaker that is implanted into the body for long term use.

How do I know that a medical device is approved for use?

Medical devices that are approved for use in Australia have been entered into a national database called the Australian Register of Therapeutic Goods (ARTG), which is maintained by the Therapeutic Goods Administration (TGA). You can access information on the ARTG at: <http://www.tga.gov.au/industry/artg-searching.htm>



Examples of medical devices

- dental and surgical instruments
- dental fillings and amalgams
- orthodontics – eg braces
- syringes and injection needles
- blood pressure monitors
- catheters and drainage tubes
- condoms
- lubricating eye drops
- Magnetic Resonance Imaging (MRI) scanners
- joint implants.

How do I know which is the best device to buy for me?

When buying a medical device it is advisable to only choose a medical device that is recommended by a healthcare professional and has been included on the ARTG.

It is also a good idea to ask for the ARTG number for the device you wish to purchase and search the ARTG for the entry.

Are the devices I buy safe to use?

There will always be some degree of risk associated with using medical devices and one particular device may not be suitable for everyone.

Devices entered onto the ARTG have been certified by the product's Australian supplier as being manufactured according to internationally recognised standards for quality, safety and performance. The manufacturer is required to demonstrate that the benefits for the device outweigh the risks, and that the potential risks associated with using the device have been mitigated as much as possible.

These devices must have adequate instructions for use that include warnings and advisories about situations where the use of the device is contra indicated.

Can I buy medical devices online and import them into Australia?

If you plan to buy a medical device online, there are some important considerations.

Unless a specific exemption has been granted, it is a criminal offence under the Therapeutic Goods Act 1989 to import into, supply in or export from Australia, a medical device that has not been entered onto the ARTG.

One of these specific exemptions enables consumers to import medical devices for their own personal use. However, buying medical devices online does come with additional risks. The device:

- may not meet TGA requirements for safety, quality and performance
- may not be manufactured under the required manufacturing controls
- may not be manufactured using the appropriate or quality materials
- may not be covered by warranty, it could be missing instructions and there may not be any after sales servicing available
- may not be correctly calibrated and could provide false readings or results
- may not be compatible with the Australian electrical standards (for electrically powered devices)
- may have been stored incorrectly or could be outside its expiry date

- may have been recalled due to a defect or safety issue
- may have been subjected to a corrective action due to a manufacturing problem
- may be a copy of a recognised brand name device
- may be second hand (used)
- may be over labelled or repackaged with a different brand name, product name, batch or serial number or a revised expiry date.

Be wary if a device makes claims about miracle cures or can diagnose a range of medical conditions. Seek advice from your healthcare professional about medical devices before buying on the Internet.

Further guidance and up to date information about buying medical devices online or from overseas is available on the TGA website at: <http://www.tga.gov.au/consumers/information-online-internet.htm>

Are second hand devices safe to use?

There are risks associated with buying second hand devices and it is not advisable to buy second hand medical devices from, garage/car boot sales or Internet auction sites. It is also advisable to consider:

- Is the product still covered by the warranty?
- Are the instructions for use included?
- Is there a service provider who can undertake repairs?
- Has the device undergone any repairs or has it been refurbished?

What do I do if I find a suspect medical device?

Consumers who have concerns that a medical device has been supplied in Australia without being included on the ARTG, or that there is a problem with the safety or performance of a medical device, can submit a report to the TGA to investigate. The forms to report to the TGA are available on the TGA website at: <http://www.tga.gov.au/safety/problem.htm>

Alternatively, consumers can report the problem to:

Office of Product Review
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606