



Patient information materials for medical implants: a fact sheet for consumers

Patient information materials help you to learn more about your medical implant.

- You should get a patient information leaflet **before** your procedure. This tells you about the medical implant recommended in your healthcare plan.
- You should get a patient implant card **after** your procedure. The card tells you about the device that has been implanted in your body.

What is a medical implant?

A medical implant is a medical device put into your body which stays there for at least thirty days, or permanently. Common examples of medical implants include:

- artificial hip and knee joints
- breast implants
- pacemakers
- contraceptive implants
- intraocular lenses (for cataracts surgery).

Patient information materials

Patient information leaflets and patient implant cards contain important information about your medical implant. They help you know more about the device that your doctor has suggested to you, or that you received as part of your healthcare plan.

The manufacturer of your medical implant writes the patient information materials. The Australian supplier is responsible for providing the patient information materials.

You can expect patient information materials for most medical implants. Materials can either be a physical document or electronic – downloadable from the manufacturer's website, as an example.

Patient information leaflet

The patient information leaflet tells you:

- what and who the medical implant is for
- how to use it safely
- possible risks and complications
- how long you can use it for
- who to contact for maintenance, or if something goes wrong.

You can use the leaflet to help you ask your health professional about the medical implant, your treatment options, and what medical implant would best suit you.

Patient implant card

The patient implant card records important information about your medical implant. The card includes:

- the medical implant's name and model
- the manufacturer's name, address and website
- batch code, lot number or serial number.

You should keep these details in a safe place where you can easily access it, including on your electronic My Health Record file.

The patient implant card can help you and your health professional identify your medical implant and help the TGA or the implant's manufacturer with investigations or reviews. It helps manufacturers trace implants and improves the ability to communicate with your health professional or your healthcare facility when there are safety updates.

Some medical implants do not need patient information materials

The TGA exempts some medical implants requiring patient information materials, as they are either:

- **Low risk** – like dental fillings, braces and tooth crowns, or
- **Absorbed by the body within six months** – for example, bone fillers sometimes used to stabilise and mend fractures.

To find out if your medical implant is exempted, search '**Medical device patient information leaflets and implant cards**' on the TGA website.

Receiving patient information materials

Your health professional is the best point of contact for you to receive your patient information materials. They can provide you with information about the medical implant being considered or implanted. They can work with suppliers to give you these materials.

Ask for the patient information leaflet **before** you decide to get the medical implant.

Ask for your patient implant card **after** the procedure.

The card will help you quickly identify your implant if you experience a problem or if there are safety updates. The TGA encourages you to keep these materials in a safe and accessible place.



Difficulties obtaining patient information materials

You might not always receive the patient information materials.

Contact your health professional or healthcare facility first if you did not receive the materials. If your health professional or healthcare facility do not have the materials available, they may request it from the manufacturer or Australian supplier. If you have the manufacturer's or supplier's contact details, you can ask for materials directly from them too.

The requirement to supply patient information materials became compulsory in December 2021. Suppliers are working with health professionals and healthcare facilities to ensure you receive the materials. Suppliers of exempt implantable medical devices do not need (but are encouraged) to provide patient information materials.

Contact the TGA if you, your health professional or your healthcare facility have difficulties obtaining these materials from suppliers. Email us at info@tga.gov.au if you think that the materials you received are missing the information we require in these resources.

More information

Search '**Medical device patient information leaflets and implant cards**' on the TGA website.

Report any problems you experience with your implant to the TGA on the TGA website.

You can also search '**Five questions to ask your health professional before you get a medical implant**' on the TGA website. You can use these questions to ask your health professional whether a medical implant is the best option for you. This resource is available in English, Arabic, Croatian, Farsi, Greek, Italian, Korean, Mandarin, Spanish, Turkish and Vietnamese.

