Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

# Medical device patient information materials: a fact sheet for health professionals

## What are medical device patient information materials?

The Australian Government introduced the requirement for suppliers of implanted medical devices to provide more information for patients in the form of patient information leaflets (PILs) and patient implant cards (PICs). This was in response to feedback from consumers about the lack of information available about medical devices, including the risks they pose, and to offer patients access to important information about their implantable or active implantable medical device.

### Patient information leaflet (PIL)

**What is it?** A PIL provides information that can be used to inform discussions on the decision to implant a type of medical device. PILs should be written in easy-to-understand language and include information such as the known risks, warnings, and precautions, expected device lifetime, and monitoring and maintenance advice.

**When should it be given to the patient?** Where possible PILs should be provided to the patient prior to implantation of the device to assist their understanding and help inform discussions and decisions about the device. If this is not possible, then the PIL should be provided after implantation of the device as the PIL contains information on the potential risks of the implanted device and how to report any complications.

### Patient implant card (PIC)

**What is it?** A PIC is used to record the details of the specific device that the patient has implanted. It must include the name and model of the device, the batch, lot, or serial number of the device, and the manufacturer's name, address, and website. The information on the card enables improved traceability of the device if there are an issues or recalls.

**When should it be given to the patient?** The PIC is intended to be provided to the patient after the device is implanted. Patients should be encouraged to keep their PIC in a safe place for future reference.

## Who is responsible for providing PILs and PICs to patients?

It is expected that the medical device manufacturer's Australian representative (the sponsor) will work with healthcare facilities to ensure patients have access to patient information materials.

Patients can be provided with PILs and PICs by health professionals, hospitals, or they can be directed to the sponsor of the medical device where they can access it.

The materials may be in an electronic form (such as downloaded from the manufacturer's website) or a physical document.

Additionally, if the materials are not publicly available, the sponsor may make them available as an on-demand service, where health professionals can request and access the materials from the sponsor at an appropriate time for their patients.

It is important that health professionals highlight to patients the value of patient information materials and assist patients with lower levels of health literacy, or where English is not a first language, to understand the information in a PIL or PIC.

### What if I cannot find a PIL or PIC for my patient?

If you are unable to access a PIL or PIC for your patient, or you have concerns about the content of a PIC or PIL your first point of contact should be the supplier of the device.

Although the requirement for patient information materials came into effect from 1 December 2021, some manufacturers are still implementing their processes. Therefore, you may experience changes to the approach that a manufacturer or sponsor takes to provide the information to patients.

## More information

More information is available on our website; search for medical device patient information leaflets and implant cards.