



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Medical device patient information leaflets and implant cards

Requirements for new and on-market implantable medical devices

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**TGA** Health Safety  
Regulation



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The purpose of this guidance is to help manufacturers and sponsors understand how the TGA interprets regulations, and thus indicate how a manufacturer and/or sponsor can comply.

This is a guide only, and manufacturers and sponsors are encouraged to familiarise themselves with the legislative and regulatory requirements in Australia. If necessary, seek professional advice as it is the responsibility of each manufacturer or sponsor to understand and comply with these requirements.

This document will evolve over time and updates and clarifications will be included as required. Feedback on the guidance is always welcome.

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## Introduction

On 26 October 2017, the government approved regulations to require patient information materials to be supplied with implantable and active implantable medical devices in Australia that meets the following definition;

‘any device, including those that are partially or wholly absorbed, which is intended:

- to be totally introduced into the human body
- to replace an epithelial surface or the surface of the eye
- by clinical intervention and which is intend to remain in place after the procedure.

Any device intended to be partially introduced into the human body by clinical intervention and intend to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device.’

This definition is consistent with the EU Medical Device Regulation 2017/745 (EU MDR).

Patient information materials consist of: [‘What is a patient information leaflet?’](#), and [‘What is a patient implant card?’](#).

From 1 December 2018, manufacturers of all new permanently implantable or active implantable medical devices ([other than those excluded](#)) are required to make available to patients, patient information leaflets with the device. Currently, patient implant cards are required only for all [new transvaginal mesh devices](#).

For further information regarding the timeframes you are required to comply with for your patient implant cards and patient information leaflets please see the [Device Information](#) page.

Patient information materials assist patients to:

- understand the medical device being implanted, both prior to and following surgery
- have informed consent conversations with their health professional
- [report any adverse effects](#) associated with their implanted medical device.

## This guidance

This guidance provides:

- an overview of the requirements for patient information leaflets and implant cards
- information to manufacturers and sponsors on meeting the requirements set out in Clause 13A.2 to 13A.4 of the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#).



### Note

These patient information materials are often referred to as ‘patient device information leaflets’, ‘patient cards’ or ‘implant cards.’

## What is a patient information leaflet?

These are leaflets supplied with the implantable medical device that are provided prior to surgery. The leaflet may also assist patient – doctor discussions to understand:

- the type of medical device being considered and
- the type of medical condition the device is used for.

The leaflet should be **one of many sources of information** that inform a discussion on the decision regarding the implantation.

The leaflet may also be used to:

- provide patients with the name and manufacturer of the device
- information about what may happen after the surgery
- possible adverse events and malfunctions.

The leaflet may also be used during discussions prior to surgery, to explain what to do in case of a suspected device malfunction.

## What is a patient implant card?

A patient implant card is a small, portable card intended to be provided to patients following surgery who have received either:

- a permanent implantable medical device or
- an active implantable medical device.

## Implantable medical devices excluded from this requirement

Clause 13A.1 (b), Schedule 1, part 2 of the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#) (The MD Regulations) lists a number of implantable devices that are excluded from the obligation to provide the patient information materials:

- sutures
- staples
- dental filings
- dental braces
- tooth crowns
- General (endosseous) dental implants\*
- screws
- wedges
- plates
- wires
- pins
- clips
- connectors



### Note

\*Defined as: *A device made from alloplastic materials intended for placement within the jawbone or skull and serves as a substitute for the tooth root and provides a strong and sturdy foundation for replacement of teeth or act as orthodontic anchor.*

Dental implants received by patients during high risk major jaw surgery, such as subperiosteal, transosseous, zygomatic and transcutaneous implants are **not excluded** from the provision of the patient information leaflet and patient implant cards.

## Mandatory requirements

### Patient information leaflets

Clause 13A.3, Schedule 1, part 2 of the MD Regulations requires the following information to be included in patient information leaflets:

Item	Information to be included
1	<ul style="list-style-type: none"> <li>a. the name of the device; and</li> <li>b. the model of the device</li> </ul>
2	<ul style="list-style-type: none"> <li>a. the intended purpose of the device; and</li> <li>b. the kind of patient on whom the device is intended to be used</li> </ul>
3	Any special operating instructions for the use of the device
4	<ul style="list-style-type: none"> <li>a. the intended performance of the device; and</li> <li>b. any undesirable side effects that could be caused by use of the device</li> </ul>
5	Any residual risks that could arise due to any shortcomings of the protection measures adopted as mentioned in subclause 2(2) <sup>1</sup>

<sup>1</sup> 2 Design and construction of medical devices to conform with safety principles (2) Without limiting subclause (1), in selecting appropriate solutions for the design and construction of a medical device so as to minimise any risks associated with the use of the device, the manufacturer must:

(a) first, identify hazards and associated risks arising from the use of the device for its intended purpose, and foreseeable misuse of the device; and

(b) second, eliminate, or reduce, these risks as far as possible by adopting a policy of inherently safe design and construction; and

(c) third, if appropriate, ensure that adequate protection measures are taken, including alarms if necessary, in relation to any risks that cannot be eliminated; and

(d) fourth, inform users of any residual risks that may arise due to any shortcomings of the protection measures adopted.

Item	Information to be included
6	<p>a. warnings about risks that could arise from the interaction of the device with other equipment; and</p> <p>b. precautions and other measures that, because of those risks, should be taken by the patient or a health professional</p> <p><b>Example 1</b></p> <p>The risk of electrical interference from electro surgical devices.</p> <p><b>Example 2</b></p> <p>The risk of magnetic field interference from magnetic resonance imaging devices.</p>
7	<p>a. the nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken; and</p> <p>b. symptoms or signs that could indicate that the device is malfunctioning; and</p> <p>c. precautions and other measures that should be taken by the patient if the performance of the device changes or the patient experiences any of the symptoms mentioned in paragraph (b); and</p> <p>d. the expected device lifetime; and</p> <p>e. anything that could shorten or lengthen the device lifetime; and</p> <p>f. precautions and other measures that should be taken at, or near, the end of the expected device lifetime; and</p> <p>g. other circumstances in which the patient should contact a health professional in relation to the operation of the device</p>
8	<p>a. the materials and substances included in the device<sup>2</sup>; and</p> <p>b. any manufacturing residuals that could pose a risk to the patient</p>
9	<p>a. a notice that any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration; and</p> <p>b. the address of the Therapeutic Goods Administration's website</p>

<sup>2</sup> Materials and substances included in the device, including manufacturing residuals that could pose a risk to patients, are to be included in the leaflet (consumer device information). This is consistent with ensuring devices are safe, and aligns with Article 18(1)(d) of the EU MDR which requires the provision of 'any other information to ensure safe use of the device by the patient, including the information in point (u)<sup>2</sup> of Section 23.4 of Annex I.'

The TGA interprets Article 18(1)(d) to include not only materials intended to be in contact with a patient, but also any materials that may contact a patient through unintentional means, such as through manufacturing residues, leaking, leaching etc., as they could pose a potential health risk.

## Patient implant cards

Clause 13A.2, Schedule 1, part 2 of the MD Regulations requires the following information to be on patient implant cards:

- the name of the device
- the model of the device
- the batch code, lot number or serial number of the device
- the unique device identifier (UDI) of the device (if any)
- the manufacturer's name, address and website address.

## Should warnings be included in the patient information materials?

It is **mandatory** to include warnings and risks associated with the device, in the patient information leaflet.

There is **no** requirement to include warnings on the patient implant card. Device manufacturers may decide to include some warnings, for the patient's benefit, where it is appropriate (e.g. about possible interactions with other electronic equipment such as airport security scanners or magnetic resonance imaging (MRI) equipment for pacemakers or intra-ocular lenses).

## How the patient information leaflets should be provided

Sponsors and manufacturers must ensure that consumers and healthcare professionals have ready access to the patient information leaflet, free of charge. It is expected that the leaflet be provided with a medical device unless provided electronically.

## Electronic patient leaflets

Electronic patient leaflets may be provided where it is not practical to provide hard copies directly with the device — as long as healthcare facilities and patients are made aware of these materials.

If you are considering electronically based leaflets, care must be taken to ensure that patients are able to easily navigate the manufacturer's website and find the correct leaflet.

The TGA should be notified of the timeframe for publication and any actions taken by the manufacturer (or sponsor) to comply with Clause 13A.3 when requested. This may include, but is not limited to, providing a risk mitigation strategy and action plan to inform patients and hospitals of where to retrieve the e-leaflet, and whether and when the paper copy will be supplied.

If directed to a leaflet on the manufacturer's website, the [Therapeutic Goods Advertising Code](#) should be considered.



Please note

Like hard copy leaflets, electronic patient information leaflets must contain the information required in Clause 13A.3 for the MD Regulations.



## Leaflets for a ‘kind of device’

It is acceptable to have one patient information leaflet to cover multiple devices if they:

- are manufactured by the same manufacturer
- have the same sponsor
- have the same device classification
- share the same intended purpose
- share the same warnings, precautions, and user risks

The devices intended to be covered by the leaflet should be clearly identified and listed by name and model of each device.

## Date stamping and version control

Both paper-based and electronic patient information leaflets should clearly state the date of release of the information and if applicable, the jurisdiction. The leaflet should be appropriate to each jurisdiction. Processes should be in place for version control. Earlier versions of the document (even those for products considered obsolete) should remain accessible to the public.

## How the patient implant cards should be provided

In its simplest form, the patient implant card may be provided as a physical card the size of standard business card or bank card. This will allow a health professional or patient ‘rapid access to the information’.

To assist patients, manufacturers can provide additional space for healthcare professionals to insert the name of the surgeon and/or hospital where the procedure was undertaken. Manufacturers may supply bar codes on stickers with their device as a means of identifying the device. This is acceptable, provided the stickers:

- are durable
- are written complying with Clause 13A.4
- contain the [required information](#).

Physical patient implant cards are the preferred option though the information may also be provided electronically. If you are considering electronically based patient implant cards, care must be taken to ensure that patients are able to easily navigate the manufacturer’s website and find the correct information.

## How patient information materials should be written

### Leaflets and Cards

Clause 13A.4 Schedule 1, part 2 of the MD Regulations states how patient information leaflets and patient cards should be presented:

- Must be **included in English**, and may also be provided in any other language
- May also include diagrams, drawings or symbols (e.g. MR status symbols)
- The text must be legible and at least 1 millimetre high. ‘Text’ includes any:

- Number
- Letter
- Symbol
- Letter or number in a symbol.

The information must be provided in a way that ensures that it is easily understood by consumers. Leaflets that are very long or unnecessarily complex may not be useful to patients.

For further information please see the [Best Practice for Patient information leaflets and patient implant cards](#).

## Compliance with advertising legislation

Patient information leaflets and cards are **not intended for advertorial or promotional purposes**. To reduce the risk of content being considered promotional (and therefore an advertisement):

- Only present information in a factual and balanced manner.
- Do not include information about different therapeutic options in a way that implies that the medical device implant is the best option.
- A balanced overview of the therapeutic options and their place in recognised therapeutic regimes can be provided in supporting materials, but comparative statements (e.g. newer/ more effective/better tolerated/ more evidence to support use than XXX, etc.) should not be used.
- A leaflet that is non-promotional in content can inadvertently (or unintentionally) become part of an advertisement if, for example, it is published on a sponsor website with promotional statements about the company's superior manufacturing characteristics, etc. It can also become part of an advertisement if it is presented in a way that facilitates patients 'shopping' for a device that might address their disease, condition, ailment etc.

The [Australian Regulatory Guidelines on Advertising Therapeutic Goods](#) provides more guidance about the characteristics of content that is likely to be considered **promotional**.

If you are concerned that a leaflet may be considered promotional or could be found to be used in a promotional way, you should consider the Therapeutic Goods Advertising Code (the [Advertising Code](#)).

## Non-compliant leaflets and cards

Where the leaflets or cards appear not to comply with the advertising legislation, a complaint to the TGA may arise.

For more information about complaints, go to the TGA's [Advertising hub](#).

## Reviews by the TGA

Patient information leaflets and cards will be assessed when the TGA undertakes assessment or review of medical devices as part of its regulatory activities. These include during TGA's conformity assessments, application audits or post-market reviews.

Sponsors must be able to obtain the required information from the manufacturers and provide it to the TGA if requested, in order to demonstrate compliance with the Essential Principles.

If the manufacturer holds a conformity assessment certificate issued by the TGA, the manufacturer has an obligation to notify the TGA where the information provided with the device (including patient information leaflet and patient implant card) has significantly changed (i.e. obligation to notify the TGA of [substantial changes](#)).

Safety related changes should be managed in accordance with the [Uniform Recall Procedure for Therapeutic Goods](#), to ensure appropriate notification is provided to affected consumers.

## Reporting adverse events

The patient information materials will be useful to patients and healthcare professionals lodging an adverse event report.

Adverse events are unintended and sometimes harmful occurrences, associated with the use of a therapeutic good, and include incidents involving medical devices.

Sponsors must report adverse events to the TGA, but anyone can report a suspected adverse event.

Reports should include as many details as possible including:

- contact details for the reporter to assist the TGA in case follow up information is required
- a description of the adverse event
- details of the medical device suspected of causing the adverse event.

For more information on how to report an adverse event, go to [Reporting adverse events](#) on the TGA website.

# Glossary

## **Intended purpose of the device**

See definition in section 41BD(2) of the Act and Dictionary of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

## **Intended performance**

Performance means the ability of the device to achieve its intended purpose as stated by the manufacturer.

## **Kind of medical device**

See definition in section 41BE of the Act.

## **Written, printed or graphic information on the medical device or packaging**

Printed information supplied on (or with) the device or packaging. Includes information identifying the:

- device
- manufacturer
- explaining how to use the device safely.

## **Manufacturers of medical devices**

See definition in section 41BG of the Act.

## **Magnetic Resonance (MR)**

Resonant absorption of electromagnetic energy by an ensemble of atomic nuclei situated in a magnetic field.

## **Implantable device**

Refers to any device, including those that are partially or wholly absorbed, which is intended:

- to be totally introduced into the human body, or
- to replace an epithelial surface or the surface of the eye,

by clinical intervention and which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device.

## **Residual risks**

This means any potential risks that remain that are associated with the use of the device that is outside the risks already identified and the precautionary steps identified by the manufacturer.

## **Unique Device Identifier (UDI)**

Means a series of numeric or alphanumeric characters that is created through internationally accepted device identifier and coding standards and that allows unambiguous identification of specific device on the market.

## Version history

<b>Version</b>	<b>Description of change</b>	<b>Author</b>	<b>Effective date</b>
V1.0	Original publication	Medical Devices Branch, Therapeutic Goods Administration	15/10/2018
V1.1	Update to e-leaflets and to correct the dates sponsors and manufacturers are to comply with implant cards or leaflets	Medical Devices Branch, Therapeutic Goods Administration	07/08/2019

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