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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This guidance

This guidance provides:

- an overview of the requirements for the patient implant card and the patient information leaflet, (collectively known as consumer information materials) and
- guidance on how manufacturers may meet the requirements set out in Regulations 13A.2 to 13A.4 of the Therapeutic Goods (Medical Devices) Regulations 2002.

The patient implant card may also be known as patient cards or implant cards, and the patient information leaflets, as consumer device information leaflets.

Introduction

On 26 October 2017, the government approved regulations to require certain consumer 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, or
- 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.’

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

Both must be supplied with the medical device.

When used as intended, these consumer information materials will assist patients in:

- understanding the medical device which they have been implanted with
- prior and informed consent conversations with their health professional
- reporting any adverse effects associated with their implanted medical device.

What is a patient implant card?

The patient implant card is a small, portable card intended to be provided to patients (after surgery) who have received either:

- a permanent implantable medical device (except devices that are excluded from this requirement), or
- an active implantable medical device.

The card must contain the name, type and model of the implant they have received. Importantly, the patient card must contain the manufacturer’s contact details (including website details) that will enable patients to seek further information or updates on their implanted device.
What is a patient information leaflet?

These are leaflets (or brochures) supplied with the implantable medical device which contain important information about the device, directed to patients.

The leaflet may be used to assist patient – doctor discussions at the point of care to understand:

- the type of medical device that is being considered for the patient, and
- the type of patients or medical condition the medical device(s) 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 and information about what may happen after the surgery including possible adverse events and malfunctions.

The leaflet may also be used during discussions after surgery, for example to explain how to report adverse events and prompts to visit the doctor if the patient suspects malfunction of the device. Information about how to use or precautions (if any) to take may be included in the discussion.

### Implantable medical devices excluded from this requirement

Regulation 13A.1 (b) lists a number of implantable devices that are excluded from the obligation to provide the consumer information materials:

- sutures
- staples
- dental filings
- dental braces
- tooth crowns
- screws
- wedges
- plates
- wires
- pins
- clips
- connectors

Please note

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 implant cards and patient information leaflet.

### Clarification to this list

Through consultations with stakeholders, the TGA has clarified that general (endosseous) dental implants are not different in their design and risk profile from devices such as screws, plates or pins and subsequently TGA considers that these devices (defined in the text box,) are covered under the list of devices exempt from the patient card and leaflet requirements.

*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.*
The objective of the consumer information materials is to provide consumers with necessary and important information about a medium or high risk device that may be implanted in their body. Devices considered low risk such as haemostatic and sealant agents intended to stop bleeding and which are absorbed by the body, are excluded from the requirement. Devices that are implanted as a component of a system e.g. orthopaedic system are expected to provide patient cards and leaflets for the system and not for individual items.

**Mandatory requirements**

**Patient implant cards**

Regulation 13A.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 of the device (if any)
- the manufacturer's name, address and website address.

**Should warnings be included in the patient card?**

There is no requirement to include warnings on the patient implant card. However in some cases, manufacturers of devices may decide to include some warnings for the benefit of the patients 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).

Warnings and risks associated with the device are mandatory inclusions for the patient information leaflet.

**Patient information leaflets**

Regulation 13A.3 of the MD Regulations requires the following information to be included in consumer device information leaflets:

- information identifying the device, or the kind of device
- the intended purpose of the device
- information explaining how to use the device safely
- other information about the device that the manufacturer considers would be useful for patients.

In particular, the leaflet must include the information outlined in the table Reg13A.3(3) below:
### Information to be included in the patient information leaflet

<table>
<thead>
<tr>
<th>Item</th>
<th>Information to be included</th>
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| 1    | a. the name of the device; and  
    | b. the model of the device    |
| 2    | a. the intended purpose of the device; and  
    | b. the kind of patient on whom the device is intended to be used |
| 3    | Any special operating instructions for the use of the device |
| 4    | a. the intended performance of the device; and  
    | b. any undesirable side effects that could be caused by use of the device |
| 5    | Any residual risks that could arise due to any shortcomings of the protection measures adopted as mentioned in subclause 2(2) |
| 6    | a. warnings about risks that could arise from the interaction of the device with other equipment; and  
    | b. precautions and other measures that, because of those risks, should be taken by the patient or a health professional |
|      | **Example 1**  
    | The risk of electrical interference from electro surgical devices. |
|      | **Example 2**  
    | The risk of magnetic field interference from magnetic resonance imaging devices. |
| 7    | a. the nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken; and  
    | b. symptoms or signs that could indicate that the device is malfunctioning; and  
    | 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  
    | d. the expected device lifetime; and  
    | e. anything that could shorten or lengthen the device lifetime; and  
    | f. precautions and other measures that should be taken at, or near, the end of the expected device lifetime; and  
    | g. other circumstances in which the patient should contact a health professional in relation to the operation of the device |
| 8    | a. the materials and substances included in the device; and  
    | b. any manufacturing residuals that could pose a risk to the patient |
### Item 9

**Information to be included**

- **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
- **b.** The address of the Therapeutic Goods Administration’s website

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**Materials and substances included in the device**

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(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) of Section 23.4 of Annex I.’

The TGA interprets Article 18(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.

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**How the leaflets should be provided**

Sponsors and manufacturers must ensure that consumers and healthcare professionals have ready access to the patient information leaflet. It is expected that unless it is impracticable or inappropriate to do so, the leaflet is provided with a medical device. The access to the leaflet should be free of charge.

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**Electronic leaflets**

Electronic leaflets may be used where it is not practical to provide hard copies directly with the device. In this instance sponsors should make healthcare facilities aware of the availability of electronic leaflets for communicating to patients. The manufacturer’s website provided on the patient card should have direct links to specific information about the medical device and the electronic leaflet.

If hard copies of the leaflet are provided, electronic leaflets (i.e. links to the leaflet on the manufacturers’ website) may be used where printed updates of the leaflet are not yet available.

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 and any actions taken by the manufacturer (or sponsor) to comply with Regulation 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 must be adhered to.

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1 **Point (u) of Section 23.4** - Information in the instructions for use states ‘in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed’
Please note

The electronic patient information leaflet must contain the information required in Regulation 13A.3.

Additionally, the Therapeutic Goods Advertising Code must be met.

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, and
- 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 consumer information materials should be written

Cards and leaflets

Regulation 13A.3 (4) states how patient information cards and patient information leaflets should be presented:

- Must be provided 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.
Compliance with advertising legislation

The leaflet is 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.
- Leaflets with non-promotional content should not be used in a promotional context. 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 consumers '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 ensure that it complies with all applicable regulations in the Therapeutic Goods Advertising Code (the Advertising Code).

Non-compliant leaflets

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

For more information about what happens with complaints, go to the TGA's Advertising hub.

Recommendations and best practice

In addition to the legislated requirements, there are other features of card and leaflet design that can be very helpful for consumers. This information is not mandatory, but is included to further improve the way this information is provided.

General design principles

When designing your card or leaflet, think about the recipient of the device by considering:

- age of users
- target patient group
- literacy of users
- visual acuity

This part of the guidance will assist you with some of these considerations.
Use simple language

Wherever possible, plain language should be used so that information is easy to understand. Vague and unnecessarily complex language should be avoided. Manufacturers or sponsors may wish to use readability assessment programs available in many word processing programs.

Manufacturers are responsible for the content of the leaflets. Sponsors are responsible for ensuring that the Essential Principles are met for inclusion of the device into the Australian Register of Therapeutic Goods.

User-centred design of labels

You should consider the recipient of the device and any specific requirements they might have.

For example, if your device is likely to be implanted in the elderly, you may consider using larger text than the minimum requirement.

Use of images in the leaflet

It can be useful to use pictures or images (diagrams or drawings) to describe the device. For example, images showing where on the body the device would be implanted, or a list of where the device may be implanted could be helpful to patients.

If images are used, they must not be used in such a way as to promote a particular device or make or model of the device, over other alternative therapies or devices (see Compliance with advertising legislation).

Colour contrast

Colour contrast is an important tool in ensuring legibility of text for consumers and it may facilitate better understanding of the device and its functionality.

The Vision Australia colour contrast analyser can be used to assist you in deciding on how to present your text. This is available on the Vision Australia website.

Using other aspects in addition to colour

Individuals can perceive colours differently, some people are colour-blind and colours can look different in different lighting conditions. For these reasons, if colour was the only element used to distinguish information on a patient implant card for example, it may be difficult or confusing to identify the required information and we may consider this to be unacceptable under Regulation 13A.3(4).

We recommend that other features such as font type, size and shape are also used to distinguish any information provided.

Acceptable web addresses

A card or leaflet may include the address of the manufacturer’s website, a QR code, or other machine readable code that directs users to the manufacturer’s website.

The device leaflet must be controlled by the manufacturer, and the manufacturer must ensure regular updates and versioning as part of their quality management system. The leaflet and links to the leaflet must meet the Advertising Code.
It is recommended that websites used are such that:

- the manufacturer has full control over the content, and the sponsor may have link to the manufacturer’s website.
- If the sponsor placed a copy of the device leaflet on their website, that sponsor must ensure that the leaflet is correct and that it is the current version. The date when it was updated last should be clear.

**Physical or electronic patient cards**

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

The manufacturer may provide additional space for healthcare facilities to insert the name of the surgeon and/or hospital where the procedure was undertaken. Some manufacturers have been supplying bar codes on stickers with their devices as a means of identifying the device. This is acceptable, provided the stickers:

- are durable
- are in a human readable format
- contain the requisite information.

Considering the intent, physical cards are a preferred option to reach the majority of the population at this time. It is possible that the information may be presented by electronic means or included in a patient’s electronic health record at some point into the future.

Further information will be prepared to guide manufacturers should electronic means of distribution become available.

**Reviews by the TGA**

The patient information leaflets and patient 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

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 everyone can play an important role in monitoring the safety of therapeutic goods in Australia by reporting suspected adverse events to the TGA.

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.

The consumer information materials will be useful to consumers and healthcare professionals in the event an adverse event report needs to be lodged.

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.

MR environment

The three dimensional volume of space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.50 mT field contour (5 gauss (G) line). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories.

MR Safe

An item that poses no known hazards resulting from exposure to any MR environments. Using the terminology, "MR safe" items are electrically nonconductive, non-metallic, and nonmagnetic items such as a plastic Petri dish.
**MR Conditional**

MR Conditional - an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. “Field” conditions that define the MR environment include static magnetic field strength, spatial gradient magnetic field, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item (e.g., the routing of leads used for a neurostimulation system), may be required.

**MR Unsafe**

An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environments. MR unsafe items include magnetic items such as a pair of ferromagnetic scissors.

**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 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.

**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**

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

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