Australian Government
Department of Health
Therapeutic Goods Administration

Medical device patient information leaflets and implant cards

(including acceptance of Implementation Plans)

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TGA Health Safety Regulation

Contents

About this guidance

This guidance provides an overview of:

- the different types of patient information materials (patient information leaflets and patient implant cards);
- when patient information must be supplied;
- how to meet the mandatory requirements for patient information;
- best practice requirements for patient information; and
- what to do if your patient information materials are not compliant.

This guidance refers to requirements set out in clause 13A of Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations).

Our Acronyms and glossary page may be useful to clarify the terms used in this document.

Purpose of this guidance

The purpose of this guidance is to help manufacturers and sponsors understand how the TGA interprets the legislative requirements for patient information materials (patient implant cards and patient information leaflets) and thus understand how they can comply with the legislative requirements.

This is a guide only; manufacturers and sponsors should familiarise themselves with the legislative and regulatory requirements and, if necessary, seek professional advice.

It is the responsibility of sponsors and manufacturers to understand and comply with these requirements.

This guidance will continue to be reviewed and revised, where necessary.

Patient information materials

Purpose

Patient information materials consist of:

- patient information leaflets; and
- patient implant cards.

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; and
- report any adverse events associated with their implanted medical device.

Manufacturer and sponsor responsibilities

The requirements for patient information materials are part of the essential principles in Part 2 of the MD Regulations. Sponsors must ensure that the kind of device included in the Australian Register of Therapeutic Goods ('the Register') under their name complies with the Essential Principles, including the requirements for patient information materials.

Manufacturers are responsible for creating the content of the leaflets and cards. Sponsors must ensure that they have available sufficient information to substantiate that the devices comply with the Essential Principles (including the patient information material requirements), or have procedures in place to obtain any relevant information from the manufacturer to substantiate that the materials comply with the requirements in the Essential Principles.

When patient information materials are required

On 1 December 2018, regulations[1] commenced to require patient information materials to be supplied with:

- implantable medical devices; and
- active implantable devices.

A graduated transition period applied as described in **Attachment 1**.

[1] *Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017*, amending the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Implantable and active implantable devices are defined in the *Therapeutic Goods (Medical Devices) Regulations 2002*

implantable medical device means a medical device (other than an active implantable medical device) that is intended by the manufacturer:

(a) to be, by surgical intervention, wholly introduced into the body of a human being, and to remain in place after the procedure; or

(b) to replace, by surgical intervention, an epithelial surface, or the surface of an eye, of a human being, and to remain in place after the procedure; or

(c) to be, by surgical intervention, partially introduced into the body of a human being, and to remain in place for at least 30 days after the procedure.

active implantable medical device or ***AIMD*** means an active medical device, other than an implantable medical device, that is intended by the manufacturer:

(a) either:

(i) to be, by surgical or medical intervention, introduced wholly, or partially, into the body of a human being; or

(ii) to be, by medical intervention, introduced into a natural orifice in the body of a human being; and

(b) to remain in place after the procedure.

Note

The definition of implantable medical device includes devices that are wholly or partially absorbed by the body. Absorbable devices are not exempt from requirements for patient information materials unless they are only partially introduced and remain in the body for less than 30 days.

Implantable custom made devices and patient matched devices are required to meet the requirements for patient information materials.

Implantable medical devices excluded from this requirement

The following implantable devices, and articles similar to these, are excluded from the obligation to provide the patient information materials:

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

Attachment 2 provides further details of how the TGA interprets the above terms.

Note

While these devices are excluded from the statutory requirement to provide patient information materials, the TGA strongly encourages manufacturers and sponsors to provide patient information materials for these devices as a matter of best practice. Doing so will mean that patients and health practitioners using these devices will benefit from information about the devices in the same way as patients and health practitioners do for non-excluded implantable devices.

Patient information materials that are non-compliant with the Essential Principles

From 1 December 2021, all implantable medical devices are required to have patient information materials available in the form of both Patient Information Cards (PIC) and Patient Information Leaflets (PIL). This date signifies the end of the transition period noted in the above-mentioned Regulation changes (see transition period described in Attachment 1).

For sponsors of medical devices currently in the ARTG, who will not have compliant PICs/PILs in place by 1 December 2021, the TGA will consider approving a consent to import, supply, or export a medical device that does not fully comply with the regulatory requirements. Authorised representatives of a sponsor can apply for a consent to import, supply, or export a medical device that does not comply with the Essential Principles. To ensure continuous supply of an affected device, the consent will need to be in place prior to 1 December 2021.

There are criminal offences under section 41MA and civil penalties under section 41MAA of the *Therapeutic Goods Act 1989*, for persons who import, supply, or export medical devices that do not meet the Essential Principles for safety and performance, unless consent has been granted by the Secretary of the Department of Health.

Consent can also be sought for devices which have an Application for Inclusion in the ARTG. The consent must be in place prior to the device being approved and included in the ARTG.

Electronic Patient Information Cards and Leaflets

On 29 October 2021, amendments to the Therapeutic Goods (Medical Devices) Regulations 2002 came into effect to allow patient information materials for implantable and active implantable devices to be supplied in more flexible (principally electronic) formats. The Regulation changes mean that patient information cards and patient information leaflets can be supplied electronically rather than in hard copy format, as long as they contain all required information and are made available in a way that is readily accessible by the patient concerned. Where this is the case, devices supplied with electronic PICs and/or PILs in a way that is readily accessible by the patient concerned will be considered compliant and consent will not be required for these devices.

Consent application forms

The TGA has modernised the consent application process, moving from a paper form to an online form hosted in the TGA Business Services (TBS) portal https://www.tga.gov.au/tga-business-services

The link to the consent application form is also available on the TGA website:
https://www.tga.gov.au/form/essential-principles-consent-noncompliance

Application Fees

Reduced consent application fees for devices with non-compliant patient information materials

On 29 October 2021, amendments to the Therapeutic Goods (Medical Devices) Regulations 2002 came into effect to introduce a fee concession for sponsors of implantable devices seeking consent to import, supply, or export their devices where they do not have compliant patient information materials. The application fee has been reduced to a flat fee of $30 for each ARTG entry and Application for Inclusion where the application is made solely in relation to non-compliance with EP 13A.

The TGA will apply this fee concession retrospectively, refunding the difference in fees to eligible sponsors who have lodged a consent to supply application solely in relation to non-compliance with EP 13A on or after 1 January 2021. Sponsors that believe they are eligible for a fee refund should contact the TGA at mdconsent@health.gov.au identifying the relevant consent application. If the refund request is validated, it will be forwarded to the Product Billing and Industry Assistance Section who will contact you regarding the refund.

NOTE: For consent applications relating to other Essential Principles (in addition to, or different to, EP 13A), the normal processing fees of $500 for the first and $100 for each subsequent ARTG entry/Application for Inclusion applies.

How do I calculate my fees?

For consent applications relating to non-compliant patient information materials, the fee is $30 per ARTG entry / Application for Inclusion. For example, if your application for consent pertains to 45 ARTG entries, the fees are calculated as $30 x 45 = $1,350.

How to pay

There are two ways to pay the application fee for the consent application.

1. IMMEDIATE PAYMENT – You can pay the applicable application fee for your consent application immediately after completing and submitting the final form in your application. Your application and payment will be linked during processing using the consent application ID which you will provide in the payment details.

2. PAYMENT AGAINST INVOICE - If you require the TGA to raise an invoice for payment, simply complete and submit your application for consent, and the TGA will raise and send the submitter an invoice for the relevant application fees.

NOTE: Applications for consent will not be processed until all applicable fees have been paid in full.

Note about patient implant cards:

In cases where a physical patient implant card is provided, containing the manufacturer's information, with the device and a sticker, containing the device information, is also provided with the device, but the sticker is required to be adhered to the card at the point of care, this is considered compliant with the legislated requirements.

Implementation Plans

Applications for consent will require the submission of an Implementation Plan which details how and when the device(s) will comply with the regulatory requirements for both the PIC and the PIL, and what interim arrangements are in place to enable patients and healthcare providers to access the relevant patient information materials. It is anticipated that a single Implementation Plan may apply to multiple ARTG entries/Applications for Inclusion. As part of the consent application process, sponsors must provide copies of the interim non-compliant patient information, if applicable, to support the information provided in the Implementation Plan.

For example, if the consent relates to non-compliant patient implant cards due to missing device information, it would be expected that the Implementation Plan would include:

- what information is missing from the card (i.e. the card is missing the device model and batch number);
- how the missing information is going to be provided to the patient or healthcare facility and when will this be provided (e.g., the information is on stickers with the device, but as there are insufficient stickers to adhere to the card, this information will need to be hand written on the card);
- how the non-compliant card will be provided to the patient or healthcare facility and when will this be provided (e.g., a template card will be provided in bulk prior to device being supplied or with the device. Extra cards can be requested from the sponsor or downloaded from the manufacturer's web site);
- what the expectation is of the healthcare facility (if any) to facilitate the convergence of the missing information with the non-compliant card (e.g., the healthcare facility will need to write the information on the template card);
- will there be education sessions provided to the healthcare facility or patient, and if so, when will these be provided (e.g., the sponsor will provide support to the healthcare facilities when products are ordered or supplied);
- when can the healthcare facility or patient expect to receive a compliant patient implant card and how will this change be relayed (e.g., the compliant cards will be introduced for products manufactured from 20 May 2022. Healthcare facilities will be advised by email when the new cards are being included with the device and they are no longer required to add stickers to template cards); and
- a copy of interim non-compliant card, if applicable.

Monitoring of Implementation Plans during the consent period.

If consent is approved, it is expected that sponsors will work towards supplying compliant patient information materials within the consent period as outlined in their Implementation Plan. The TGA will monitor sponsor Implementation Plans throughout the approved consent period to ensure that sponsors are following their plans. Sponsors are required to submit evidence to the TGA of compliant patient information materials at the end of the consent period. Instructions regarding the submission of documents for evidence of compliance at the end of the consent period are provided during the consent approval process.

Compliance with advertising legislation

Patient information leaflets and cards **are not intended for advertorial or promotional purposes.**

Manufacturers and sponsors can reduce the risk of their content being considered promotional (and therefore an advertisement) by:

- presenting only information in a factual and balanced manner;
- not including information about different therapeutic options in a way that implies that the medical device implant is the best option;
- providing a balanced overview of the therapeutic options and their place in recognised therapeutic regimes. This 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; and
- ensuring a leaflet that is non-promotional in content does not 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.

Check the Australian Regulatory Guidelines for Advertising Therapeutic Goods for 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 refer to the Therapeutic Goods Advertising Code (the Advertising Code).

Leaflets and cards that are non-compliant with advertising legislation

Where the leaflets or cards appear not to comply with the advertising legislation, follow-up actions may be undertaken by the TGA.

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

Patient information leaflets

Purpose

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

It is considered best practice to make leaflets available to doctors and potential patients prior to surgery to assist patient-doctor discussions regarding:

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

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; and
- information about possible adverse events and malfunctions.

Mandatory requirements for leaflets

A patient information leaflet must be written **in English** and may also be provided in any other language. It may also include diagrams, drawings or symbols (e.g. MR status symbols).

If a patient information leaflet is supplied in hard copy, the leaflet must be written **in English**, and may also be provided in any other language

- have text that is legible and at least 1 millimetre high. 'Text' includes any:
  - number
  - letter
  - symbol
  - letter or number in a symbol.

You must:

- ensure the leaflet is available and readily accessible by the patient and ensure that the leaflet is written in a way that is readily understood by patients.

The leaflet must include:

- information identifying the device, or the kind of device;
- the intended purpose of the device;
- information explaining how to use the device safely: and
- other information about the device that the manufacturer considers would be useful for patients.
- in particular, the leaflet must include the information listed in the table below (see Clause 13A.3 of the MD Regulations).

Item	Information to be included in leaflets
1	a. the name of the device[2]; 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)[3].
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 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.

[2] Where a Unique Product Identifier (UPI) is applicable to the device, the name of the device to be included in the Patient information leaflet must be the UPI. The UPI is applicable for devices listed under regulation 1.6 of the *Therapeutic Goods (Medical Devices) Regulations 2002*

[3] This is a reference to subclause 2(2) of the Essential Principles: see the MD Regulations.

Item	Information to be included in leaflets
8	a. the materials and substances included in the device[4]; and b. any manufacturing residuals that could pose a risk to the patient.
9	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[5].

For additional ways to make the leaflets user-friendly: please see Best Practice for Patient information leaflets and patient implant cards, at **Attachment 3**.

Complete information

It is expected that the patient is provided with full and complete information about their device, without the need to refer to further information. Statements such as "*consult your doctor about possible side effects*" and "*please see the full list of precautions and contraindications in the instructions for use*" are not appropriate, as the patient may not have access to these resources. Warnings about magnetic resonance (MR) conditions should be present, and provided in a way which is readily understood by patients. Incomplete information or references to alternative sources make it more difficult for the patient to access the required information and the TGA may consider that the information in the leaflet is not written in a way that is readily understood by patients (see Clause 13A.3(4), Schedule 1, part 2 of the MD Regulations).

Adverse events – urogynaecological meshes and breast implants

The table of mandatory information for patient information leaflets requires that any undesirable side effects that could be caused by use of the device must be included in the patient information leaflets (see Item 4b, Clause 13A.3 of the MD Regulations).

For urogynaecological meshes and breast implants, the TGA expects that, to comply with Item 4b, manufacturers must include certain known adverse events for these devices in the patient information leaflets. Known adverse events that have been derived from the extensive post-market reviews of these products are listed in **Attachments 4 and 5**. However, these lists are not intended to be exhaustive - manufacturers are obliged to review and update the lists if further undesirable side effects arise over time.

[4] Materials and substances included in the device, including (but not limited to) manufacturing residuals, medicinal substances, materials of microbial origin, stable derivatives of human blood or human plasma and animal origin materials that could potentially 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) 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.

[5] The TGA website's internal pages may require updating from time to time. The Patient Information Leaflet (PIL) should state the TGA website as <https://www.tga.gov.au> and direct the patient or consumer to report a problem or adverse event.

How and when to provide leaflets

You must provide the patient information leaflet to the patient concerned, however the MD Regulations do not prescribe the manner in which the leaflet must be provided.

The TGA expects sponsors and manufacturers to ensure the leaflet:

- can be readily accessed by consumers and healthcare professionals;
- can be accessed free of charge; and
- is available as early as possible, so that medical practitioners and patients can use it to inform their discussions on the proposed course of treatment.

Electronic leaflets

Where leaflets are provided in hard copy , sponsors are strongly encouraged to provide electronic patient information leaflets to enable early access to information for healthcare professionals and patients.

When providing electronic leaflets, ensure:

- patients are made aware of how to access the electronic versions; and
- patients can easily navigate the manufacturer's website and find the correct leaflet.

Sponsors and manufacturers are expected to keep sufficient information to establish that:

- electronic leaflets have been provided with the device; and
- the requirements of clause 13A.3 of the MD Regulations have been met.

Sponsors may be requested to provide this information to the TGA.

Note

Like hard copy leaflets, electronic patient information leaflets must contain the information required in clause 13A.3 of the MD Regulations. On 29 October 2021, amendments to the Therapeutic Goods (Medical Devices) Regulations 2002 came into effect to allow patient information materials for implantable and active implantable devices to be supplied in more flexible (principally electronic) formats.

Leaflets for a 'kind of device'

It is permissible to have one patient information leaflet to cover multiple devices if they meet all of the following criteria. They:

- are manufactured by the same manufacturer;
- have the same sponsor;
- have the same device classification;

- have the same device nomenclature system code[6];
- share the same intended purpose; and
- share the same warnings, precautions, and user risks.

The leaflet should:

- clearly identify the devices intended to be covered by the leaflet; and
- list the name and model of each device.

Date stamping and version control

For both hard copy and electronic patient information leaflets, you should:

- clearly state the date of release of the information;
- have processes in place for version control; and
- ensure earlier versions of the document (even those for products considered obsolete) remain accessible to the public.

[6] This is a reference to the Global Medical Device Nomenclature System Code, as set out in ISO 15225:2000(E): see s 41BE(3) of the *Therapeutic Goods Act 1989* and regulation 1.7 of the MD Regulations

Patient implant cards

Purpose

A patient implant card is a card intended to be provided to a patient following surgery when the patient has received:

- an implantable medical device; or
- an active implantable medical device.

The purpose of patient implant cards is to ensure that patients are aware of the details of the device that they have been implanted with and that health practitioners can also identify particular devices. The cards should also better enable the traceability of the device and patient in order to more quickly and effectively alert patients and health practitioners to safety issues such as precautions or recalls.

Mandatory requirements for implant cards

A patient implant card (see clause 13A.4 of the MD Regulations):

- must be available and readily accessible by the patient
- must be written **in English**, and may also be provided in any other language;
- may also include diagrams, drawings or symbols (e.g. MR status symbols); and

If a patient implant card is supplied in hard copy, the card must:

have text that is legible and at least 1 millimetre high. 'Text' includes any:

- number
- letter
- symbol
- letter or number in a symbol.

You must include the following information on the card (see Clause 13A.2 of the MD Regulations):

- 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); and
- the **manufacturer's** name, address and website address.

Other details you may wish to include

Although not required, you may also include the **sponsor's** details if you wish.

There is also **no** requirement to include **warnings** on the patient implant card. You 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).

There are additional things that you can do to make the cards user-friendly: please see Best Practice for Patient information leaflets and patient implant cards, at **Attachment 3**.

How to provide implant cards

The patient implant card should be provided to the patient concerned as soon as practical. This will allow health professionals and patients rapid access to the information.

You may wish to provide additional space on the card for healthcare professionals to insert:

- the name of the surgeon; and
- the name of the hospital where the procedure was undertaken.

You may supply bar codes on stickers with a device as a means of identifying the device. This is acceptable, provided the stickers:

- are durable; and
- contain the required information and are in the correct form: see Mandatory requirements for implant cards.

In cases where physical patient implant cards containing some of the information and stickers containing the remainder of the required information are both provided with the device, but the sticker is required to be adhered to the card at the point of care, this is considered compliant.

Electronic patient implant cards

In addition, or alternatively, to physical cards, you may also provide patient implant cards electronically. However, the card must include all required information (see Clause 13A.2 of the MD Regulations). Care must be taken to ensure that electronic patient implant cards are able to be easily accessed by the patient from the provided website and the correct information/card can be found.

Review by the TGA

Patient information leaflets and patient implant cards will be assessed when the TGA undertakes assessment or review of medical devices as part of its regulatory activities. This includes during:

- TGA's conformity assessments;
- application audits; and
- 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 in the MD Regulations.

If the manufacturer holds a conformity assessment certificate issued by the TGA for implantable devices that are already supplied in Australia, applicants will be required to include patient information leaflets and patient implant cards as part of the 'Information to be provided with medical devices' that is routinely reviewed during an application for recertification of an existing conformity assessment certificate. Manufacturers may also be asked to submit patient implant leaflets or cards for review as part of any other regulatory activity.

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.

The patient information materials will be useful to patients and healthcare professionals lodging an adverse event report. Certain devices (e.g. urogynaecological meshes and breast implants) are subject to specific requirements about which known adverse events should be included in the patient information leaflets, so as to comply with the requirement to disclose undesirable side effects – see **Attachments 4 and 5**.

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; and
- details of the medical device suspected of causing the adverse event (including the UDI if available).

Go to Reporting adverse events on the TGA website for more information on how to report an adverse event.

Glossary

Term	Meaning
Active implantable device	See the definition in the Introduction.
Implantable device	See the definition in the Introduction.
Intended performance	Performance means the ability of the device to achieve its intended purpose as stated by the manufacturer.
Intended purpose of the device	See definition in section 41BD(2) of the Act and Dictionary of the *Therapeutic Goods (Medical Devices) Regulations 2002*.
Kind of medical device	See definition in section 41BE of the Act.
Magnetic Resonance (MR)	Resonant absorption of electromagnetic energy by an ensemble of atomic nuclei situated in a magnetic field.
Manufacturers of medical devices	See definition in section 41BG of the Act.
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 model of device on the market.
Unique Product Identifier (UPI)	This means the unique product identifier given to the device by its manufacturer to identify the device and any variants.
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; • the manufacturer; and • how to use the device safely.

Attachment 1: Timetable for transition

From 1 December 2018, manufacturers and sponsors of all **new** implantable or active implantable medical devices (other than those excluded) have been required to make available to patients, **patient information leaflets** with the device.

A "new" device means one that:

- is in the Register because of an application made on or after 1 December 2018.

From 1 December 2018, manufacturers and sponsors of new urogynaecological mesh devices have been required to provide **patient implant cards** with their devices. New devices that are not urogynaecological mesh devices must be accompanied by **patient implant cards** from 1 December 2020.

A graduated transition period applies for existing medical devices. An "existing" device means one that:

- is in the Register because of an application made before 1 December 2018, regardless of the date the device was included in the Register (referred to as a *pre-commencement entry* in the MD Regulations).

From 1 December 2021, all implantable or active implantable devices will require patient implant cards and patient information leaflets, unless they are specifically excluded from these requirements. Some examples are included below the table.

	Patient Information Leaflet (PIL)	Patient Implant Card (PIC)
Urogynaecological mesh		
New devices	1 Dec 2018	1 Dec 2018
Existing devices	1 Dec 2019	1 Dec 2019
Surgical mesh		
New devices	1 Dec 2018	1 Dec 2020
Existing devices	1 Dec 2021	1 Dec 2021
Implantable devices (other than those exempted)		
New devices	1 Dec 2018	1 Dec 2020
Existing devices	1 Dec 2021	1 Dec 2021

Examples

(a) a device is included in the Register on 15 July 2018 – it is an "existing" device – a PIC and PIL must be provided with the device from 1 December 2021.

(b) An application to include a device is made on 20 October 2018 and the device is included in the Register on 20 December 2018 – it is an "existing" device – a PIC and PIL must be provided with the device from 1 December 2021.

(c) An application to include a device is made on 22 May 2020 – it is a "new" device and requires a PIC to be provided with the device from 1 December 2020 and a PIL immediately (i.e. from commencement of supply).

(d) An application to include a device is made on 12 December 2020 – it is a "new" device and requires a PIC and PIL to be provided with the device immediately (i.e. from commencement of supply).

Attachment 2: Implantable medical devices excluded from requirements

A number of implantable devices are excluded from the obligation to provide patient information materials (patient information leaflets and patient cards).

Clause 13A.1(b), Schedule 1, part 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002* lists the excluded devices (suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip, connector or similar article).

This attachment explains how the TGA interprets the terms listed in the MD Regulations.

Notes

As a matter of best practice, the TGA strongly encourages manufacturers and sponsors to provide patient information materials for ALL devices (including those listed in this attachment).

The information provided in this attachment does not include an exhaustive list of devices which may/may not be exempt.

Sutures

Sutures are considered to be any structure intended to hold together two opposing ends. For example:

- the two ends of a wound; and
- the rotator cuff to the humerus.

Sutures have other characteristics. They can be:

- monofilament/multifilament;
- absorbable/non-absorbable; and
- natural/synthetic.

Sizes vary for both the suture thickness and the needle that is attached.

Sutures can be attached to other devices, such as in the case of a suture anchor, where a suture is attached to an anchoring device. The suture in this case still has the same purpose. It aims to bring together two or more structures together (depending on how many sutures are attached to the suture anchor). A suture anchor is not considered to be a suture.

Staples

Staples are considered to be a device identical in appearance to the household stationary ‘staple’. They serve to hold two ends together, for example two bones in the feet during fusion surgery. Staples can also be used instead of sutures to hold a wound together, or to fix mesh onto tissues such as in the case of a hernia.

They are usually of metallic composition.

Dental fillings

Dental fillings are considered to be any filling substance used to repair a tooth cavity.

Dental braces

Dental braces are considered to be a combination of brackets and wires, or other materials, used externally on the tooth to correct alignment. This includes both the traditional metallic braces and non-metallic braces, such as 'Invisalign'.

Tooth crowns

Tooth crowns are considered to be any device that covers an existing tooth.

Screws

Screws are considered to be a monoblock device with a raised helical thread intended to fix two solid objects together. They have a slotted head, to allow for tightening using a driver. They can achieve this fixation in combination with a plate or rod.

Medical screws are often made from a metal such as stainless steel or titanium, however, recent advancements have seen the growth of biodegradable screws used in specific applications.

Exempt
Blocking screw
Cap screw
Set screw
Fiducial screw
Set Screw
Pedicle Screw
Laminar Screw

Wedges

Wedges are considered to be a device, with a constant/uniform thickness or tapering thickness, that is inserted between two structures to secure or separate them.

Plates

Plates are considered to be a flat or contoured device with screw holes that are used to provide reduction, stability and fixation.

They can have varying thicknesses and are usually composed of stainless steel or titanium. The can accommodate different types of screws (e.g. locking or compression screws). They can be malleable or rigid.

Wires

Wires are considered to be singular continuous pieces of metal (identical to the everyday wire) used to re-attach bone fragments or provide stability.

Pins

Pins are considered to be a straight piece of metal used to stabilise bones. They are commonly used to hold a reduction whilst the surgeon attempts to achieve more permanent and reliable fixation (pin is removed once fixation is achieved). Very rarely, they are used independently by surgeons for permanent fixation.

Clips

Clips are considered to be a device used to hold a part or thing together with another.

For example, an arterial clip is used to close off a small vessel (i.e. bring the walls of the vessel together).

Connectors

Connectors are considered to be devices which attach two or more different components to one another.

Similar articles

Exempt	Not Exempt
Anchor/suture anchor Clamp	Spine Rod
Transverse cross links/cross connectors	Locking rings
Cleat	Intramedullary Nails
Button/cable plug	Interspinous spacer
ICD adaptor	
ICD extender	
ICD Splitter	
Dental Abutment	
Fracture pins	
Cables	
Cerclage wires	

Exempt	Not Exempt
Fracture pins Lead anchoring sleeve Laminar hook Grip plate Occipito-Cervical and Cervical Spinal Plates Thoracolumbar and Lumbosacral Spinal and Buttress Plates Interspinous Plates Bone Cement Plug Centraliser Pin Plug/Port Plug/Blind Plug Lead end cap (rubber) Blanking plugs for acetabular screw holes Non expandable cage Augments General (endosseous) dental implant Washer Nut Bolt Screw hole plug Screw-on sleeve	

Further examples of Devices that are/are not excluded from requirements include:

- **Exempt as these devices do not meet the definition of an implantable medical device:**
  - Eye irrigation solutions
  - Opthalmic Viscoelastic Devices – used during surgery for 20-30 mins
  - Distractors (non-implantable)
  - Multi-Lead Trialing Cable for Spinal Cord Stimulation
  - Tunneling tools
- **Not Exempt as these devices meet the definition of an implantable medical device and are not excluded under Clause 13A.1(b):**
  - Viscosupplements for dermal or intra-articular applications
  - Absorbable collagen based material

- Haemostatic Matrix
- Absorbable cranial mesh
- Resorbable Stent
- Silicone sheets and strips
- Bone cement
- Bonewax
- Impantable tissues
- Tape for wound closure
- Pledgets / absorbable (sponge) pledgets (where they are implanted)
- Staple line reinforcement material / Buttressing

Attachment 3: Best practice for patient information leaflets and patient implant cards

In addition to the legislated requirements, there are other features of leaflet and card design that can be very helpful for patients. The below information, which includes feedback from patients, is not mandatory, but is included to further improve the way this information can best be provided.

General design principles

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

- age of users;
- target patient group;
- literacy of users; and
- 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.

Leaflets that are very long or unnecessarily complex may not be useful to patients (in addition to being unlikely to meet the requirement that they be readily understood by patients).

User-friendly design

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 the TGA may consider that the information in the leaflet is not written in a way that is readily understood by patients (see Clause 13A.3(4), Schedule 1, part 2 of the MD Regulations).

Attachment 4: Breast Implants – specific information to be included about adverse events

The following tables outline the known adverse events (side effects/complications) and potential adverse symptoms demonstrated against breast implant devices as at the time of publication of this guidance[7]. See Adverse events – urogynaecological meshes and breast implants in the main part of this guidance for further details.

No.	Known adverse events
1	Capsular Contracture - occurs when the scar tissue or **capsule** that normally forms around the implant tightens and squeezes the implant, potentially causing hardness, pain or deformity
2	Breast pain, including extension to axillae and chest wall
3	Changes or loss in sensation to the nipple, breast, or skin over the breast
4	Rupture- intracapsular, extracapsular, or silent - of silicone filled implants
5	Deflation (+/- rupture) of saline filled implants
6	Asymmetry (one breast appears different in size or shape to the other)
7	Breast tissue thinning
8	Delayed wound healing
9	Skin breakdown and extrusion of the implant
10	Haematoma
11	Seroma
12	Infection and/or Inflammation
13	Malposition and/or Displacement
14	Ptosis
15	Skin rash
16	Wrinkling, folding or Rippling
17	Dissatisfaction with the result
18	Breast implant associated cancer
19	Lumps or collections in breast and axillae

[7] See Version history at end of this document.

Attachment 5: Urogynaecological meshes – specific information to be included about adverse events

The following table outlines the known adverse events that may be associated with urogynaecological meshes at the time of publication of this guidance[8]. See Adverse events – urogynaecological meshes and breast implants in the main part of this guidance for further details.

No.	Known adverse events
1	Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel.
2	Transitory local irritation at the wound site.
3	Foreign body response i.e. wound breakdown, extrusion, erosion, exposure, fistula formation and/or inflammation.
4	Mesh extrusion, exposure, or erosion into vagina or other structures or organs.
5	Mesh may potentiate an existing infection.
6	Over-correction (too much tension applied to the tape) may cause temporary or permanent lower urinary tract obstruction.
7	Acute and/or chronic pain.
8	Voiding dysfunction.
9	Pain during intercourse (dyspareunia).
10	Loss of sensation during intercourse (apareunia).
11	Pain or discomfort to the patient's partner during intercourse (due to exposed mesh).
12	Neuromuscular problems including acute and/or chronic pain or weakness in the groin, thigh, leg, pelvic and/or abdominal area.
13	Recurrence of incontinence.
14	Bleeding including haemorrhage or haematoma.
15	Seroma.

[8] See Version history at end of this document.

No.	Known adverse events
16	De novo (new) or recurrent urinary incontinence.
17	Urinary frequency.
18	Urinary retention.
19	Adhesion formation.
20	Atypical vaginal discharge.
21	Mesh migration.
22	Allergic reaction/hypersensitivity.
23	Abscess.
24	Swelling around the wound site.
25	Recurrent prolapse.
26	Contracture.
27	Scarring.
28	Excessive contraction or shrinkage of the tissue surrounding the mesh.
29	Vaginal scarring, tightening and/or shortening (stenosis).
30	Constipation or defecation dysfunction.
31	Granulation tissue formation.
32	Wound breakdown (dehiscence)
33	Necrosis (tissue death)

Version history

Version	Description of change	Author	Effective date
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	08/07/2019
V1.2	Re-order and make expression of some information clearer, add further detail about timing and presentation of PICs and PILs (including adverse events for certain devices), and consolidate other TGA website information on the same subject matter into this document	Medical Devices Authorisation Branch and Medical Devices Surveillance Branch, Therapeutic Goods Administration	November 2020
V1.3	Amend *Attachment 1: Timetable for Transition* to more clearly explain the operation of the transition timeframes	Medical Devices Authorisation Branch and Medical Devices Surveillance Branch, Therapeutic Goods Administration	January 2021
V1.4	Update *Attachment 2: Implantable medical devices excluded from requirements* to add additional devices and provide clarity	Medical Devices Authorisation Branch and Medical Devices Surveillance Branch, Therapeutic Goods Administration	August 2021
V1.5	Amend to include information on obtaining consent to import, supply or export a medical device that does not meet the Essential Principles for sponsors that will not have compliant patient information materials by 1 December 2021	Medical Devices Authorisation Branch and Medical Devices Surveillance Branch, Therapeutic Goods Administration	October 2021
V1.6	Amend to include information on Regulation changes in relation to reduced consent application fees, exempt items	Medical Devices Authorisation Branch and Medical Devices Surveillance Branch,	October 2021

Version	Description of change	Author	Effective date
	and provision of electronic patient information materials	Therapeutic Goods Administration	
V1.7	Amend to update information on consent application process for non-compliant devices	Medical Devices Authorisation Branch and Medical Devices Surveillance Branch, Therapeutic Goods Administration	December 2021

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Reference/Publication #