



Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017

I, General the Honourable Sir Peter Cosgrove AK MC (Ret'd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 14 December 2017

Peter Cosgrove
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health

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1 Name

This instrument is the *Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	1 December 2018.	1 December 2018

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Part 1—Surgical mesh

Therapeutic Goods (Medical Devices) Regulations 2002

1 Subclause 3.4(4A) of Schedule 2

Repeal the subclause, substitute:

- (4A) The device is classified as Class III if it is:
- (a) a joint replacement medical device; or
 - (b) surgical mesh.

Part 2—Patient information

Therapeutic Goods (Medical Devices) Regulations 2002

2 After clause 13.4 of Schedule 1

Insert:

13A Patient implant cards and patient information leaflets

13A.1 Scope of clauses 13A.2 to 13A.4

Clauses 13A.2 to 13A.4 apply to a medical device that is:

- (a) an implantable medical device or an active implantable medical device;
and
- (b) not a suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip or connector.

13A.2 Patient implant cards for implantable devices

- (1) A card (a *patient implant card*) that meets the requirements of subclause (2) and clause 13A.4 must be provided with the medical device.
- (2) The card must include the information mentioned in the following table.

Information to be included in a patient implant card	
Item	Information to be included
1	(a) the name of the device; and (b) the model of the device; and (c) the batch code, lot number or serial number of the device; and (d) the unique device identifier of the device (if any)
2	The manufacturer's name, address and website

13A.3 Patient information leaflets for implantable devices

- (1) A leaflet (a *patient information leaflet*) that meets the requirements of subclauses (2) to (4) and clause 13A.4 must be provided with the medical device.
- (2) The leaflet must include the following information:
 - (a) information identifying the device, or the kind of device;
 - (b) the intended purpose of the device;
 - (c) information explaining how to use the device safely;
 - (d) other information about the device that the manufacture considers would be useful for patients.
- (3) In particular, the leaflet must include the information mentioned in the following table.

Information to be included in patient information leaflet

Item	Information to be included
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 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
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

- (4) The information in the leaflet must be written in a way that is readily understood by patients.

13A.4 Form of patient implant cards and patient information leaflets

- (1) The information required by clause 13A.2 or 13A.3 to be included in a patient implant card or patient information leaflet:
- (a) must be included in English; and
 - (b) may also be included in any other language.

Note: The information may also include diagrams or drawings.

- (2) Any number, letter, symbol, or letter or number in a symbol, used in a patient implant card or patient information leaflet must be:
- (a) legible; and

(b) at least 1 millimetre high.

3 Dictionary

Insert:

device lifetime, in relation to a medical device, means the period, indicated by the manufacturer, during which:

- (a) the device can be safely used; and
- (b) the characteristics and performance of the device are not affected by its age.

patient implant card has the meaning given by clause 13A.2 of Schedule 1.

patient information leaflet has the meaning given by clause 13A.3 of Schedule 1.

residual risk for a medical device has the meaning given by subclause 2(3) of Schedule 1.

unique device identifier of a medical device means a unique device identifier assigned to the device by the manufacturer in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, as in force on 1 December 2018.

Part 3—Application and transitional provisions

Therapeutic Goods (Medical Devices) Regulations 2002

4 In the appropriate position in Part 11

Insert:

Division 11.5—Transitional provisions relating to the Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017

11.28 Definitions

In this Division:

amending regulations means the *Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017*.

finally determined has the meaning given by subregulation 11.29(5).

inclusion day for an entry of a kind of medical device in the Register means the day on which the inclusion of that kind of device in the Register commences.

pre-commencement entry: an entry of a kind of medical device in the Register is a *pre-commencement entry* if that kind of medical device is included in the Register because of an application made before 1 December 2018 (whether the inclusion day for the entry occurred before, on or after 1 December 2018).

unique product identifier, in relation to a medical device, means the unique product identifier given to the device by its manufacturer to identify the device and any variants.

11.29 Surgical mesh—application of amendments

Applications and entries other than pre-commencement entries

- (1) The amendment made by Part 1 of Schedule 1 to the amending regulations applies on and after 1 December 2018 in relation to the following:
 - (a) an application for a kind of medical device to be included in the Register, if the application is made on or after 1 December 2018;
 - (b) an entry of a kind of medical device in the Register that is not a pre-commencement entry.

Pre-commencement entries

- (2) Subject to subregulation (3), the amendment made by Part 1 of Schedule 1 to the amending regulations applies in relation to a pre-commencement entry of a kind of medical device on and after:
 - (a) if medical devices of that kind are urogynaecological mesh—1 December 2020; or
 - (b) otherwise—1 December 2021.

- (3) However, the amendment does not apply in relation to the pre-commencement entry before the day mentioned in subregulation (4) if:
- (a) the person applies under the Act:
 - (i) on or after the inclusion day for the pre-commencement entry; and
 - (ii) on or after 1 December 2018; and
 - (iii) before the day mentioned in subregulation (2);to have a kind (the *new application kind*) of medical device included in the Register; and
 - (b) the person gives to the Secretary a notice under regulation 11.30 in relation to the pre-commencement entry; and
 - (c) the unique product identifier of the devices of the new application kind is the unique product identifier, or one of the unique product identifiers, stated in the notice.
- (4) For the purposes of subregulation (3), the day is the day after the day on which:
- (a) the person withdraws the application mentioned in paragraph (3)(a); or
 - (b) that application lapses under section 41FK of the Act; or
 - (c) that application is finally determined.
- (5) The application is *finally determined* at the first time both the following conditions are met:
- (a) a decision has been made whether or not to grant the application;
 - (b) there is no longer any possibility of a change in the outcome of the decision.

11.30 Surgical mesh—Secretary must be notified of unique product identifiers of devices supplied under pre-commencement entries

- (1) For the purposes of subsection 41FN(5A) of the Act, a person must give to the Secretary a notice in accordance with subregulation (2) if:
- (a) a kind of medical device is included in the Register in relation to the person; and
 - (b) the entry of that kind of device is a pre-commencement entry; and
 - (c) medical devices of that kind are surgical mesh.
- (2) The notice must:
- (a) be in writing; and
 - (b) state:
 - (i) the unique device number assigned to that kind of device under section 41FL of the Act; and
 - (ii) the unique product identifier given to each medical device (if any) of that kind that the person supplies in Australia; and
 - (c) be given to the Secretary before the later of:
 - (i) 1 May 2019; and
 - (ii) the day occurring 2 months after the inclusion day for the entry.

11.31 Patient information—application of amendments*Devices other than urogynaecological mesh*

- (1) The amendments made by Part 2 of Schedule 1 to the amending regulations apply on and after the day mentioned in column 1 of an item of the following table:
- (a) to the extent that the amendments relate to a patient implant card or patient information leaflet mentioned in column 2 of the item; and
 - (b) in relation to:
 - (i) an application for a kind of medical device to be included in the Register; or
 - (ii) an entry of a kind of medical device in the Register; mentioned in column 3 of the item;
 if devices of that kind are not urogynaecological mesh.

Entries and applications relating to medical devices other than urogynaecological mesh			
Item	Column 1	Column 2	Column 3
	Day amendments start applying	Card or leaflet	Application or entry
1	1 December 2018	patient information leaflet	(a) an application made on or after 1 December 2018; or (b) an entry that is not a pre-commencement entry
2	1 December 2020	patient implant card	(a) an application made on or after 1 December 2020; or (b) an entry that is not a pre-commencement entry
3	1 December 2021	(a) patient implant card; or (b) patient information leaflet	a pre-commencement entry

Urogynaecological mesh

- (2) The amendments made by Part 2 of Schedule 1 to the amending regulations apply on and after the day mentioned in column 1 of an item of the following table in relation to:
- (a) an application for a kind of medical device to be included in the Register; or
 - (b) an entry of a kind of medical device in the Register; mentioned in column 2 of the item, if devices of that kind are urogynaecological mesh.

Entries and application relating to urogynaecological mesh		
Item	Column 1	Column 2
	Day amendments start applying	Application or entry
1	1 December 2018	(a) an application made on or after 1 December 2018; or (b) an entry that is not a pre-commencement entry
2	1 December 2019	a pre-commencement entry
