



Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) Regulation 2015

Select Legislative Instrument No. 46, 2015

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 regulation.

Dated 16 April 2015

Peter Cosgrove
Governor-General

By His Excellency's Command

Fiona Nash
Assistant Minister for Health

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1 Name

This is the *Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) Regulation 2015*.

2 Commencement

This instrument commences on the day after it is registered.

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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Therapeutic Goods (Medical Devices) Regulations 2002

1 Division 11.2 (heading)

Repeal the heading, substitute:

Division 11.2—Transitional provisions relating to joint replacements

11.22A Purpose of this Division

This Division includes transitional provisions relating to:

- (a) the *Therapeutic Goods (Medical Devices) Amendment Regulation 2012 (No. 1)*; and
- (b) the *Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) Regulation 2015*.

2 Subregulation 11.22(1)

Repeal the subregulation, substitute:

- (1) This regulation applies to a joint replacement medical device.

Note: *Joint replacement medical device* is defined in the Dictionary.

3 At the end of Division 11.2

Add:

11.23 Refund of fees in relation to inclusion of certain devices in the Register as Class III medical devices

- (1) This regulation applies in relation to an implantable medical device if:
 - (a) the device is of the kind referred to in subregulation 11.22(1) of the old Regulations; and
 - (b) the device is not a joint replacement medical device; and
 - (c) an application to include the device in the Register as a Class III medical device was made on or after 1 July 2012 and before the commencement of the amending Regulation.

Note: Subregulation 11.22(1) of the old Regulations referred to an implantable medical device that is intended by the manufacturer to be any of the following:

- (a) a total or partial shoulder joint replacement;
- (b) a total or partial hip joint replacement;
- (c) a total or partial knee joint replacement.

- (2) The Secretary may refund any fee paid in relation to the application.
- (3) If any annual charge has been paid in respect of the inclusion of the device in the Register as a Class III medical device, the Secretary may refund the difference between the annual charge paid and the annual charge that would have been payable in respect of the inclusion of the device in the Register as a Class IIb medical device.
- (4) In this regulation:

amending Regulation means the *Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) Regulation 2015*.

old Regulations means these Regulations as in force immediately before the commencement of the amending Regulation.

4 Subclause 3.4(2) of Schedule 2

Omit “(3) and (4)”, substitute “(3), (4) and (4A)”.

5 Paragraph 3.4(4)(e) of Schedule 2

Omit “or”.

6 Paragraph 3.4(4)(f) of Schedule 2

Repeal the paragraph.

7 After subclause 3.4(4) of Schedule 2

Insert:

- (4A) If the device is a joint replacement medical device, the device is classified as Class III.

8 Dictionary

Insert:

ancillary medical device means an implantable medical device that:

- (a) consists of screws, plates or wedges; or
- (b) is intended by the manufacturer to be used to:
 - (i) provide stability for an implantable medical device that is intended to (either alone or together with one or more other implantable medical devices) replace the shoulder joint, hip joint or knee joint; or
 - (ii) provide bone substitution in relation to, or additional fixation for, any such device; or
 - (iii) otherwise assist any such device;where the individual requirements of a patient make it appropriate to do so.

hip joint means the ball and socket formed by the reception of the head of the femur into the cup-shaped cavity of the acetabulum.

joint replacement medical device means an implantable medical device:

- (a) that is intended by the manufacturer to operate (either alone or together with one or more other implantable medical devices) as a replacement (in whole or in part) for the shoulder joint, hip joint or knee joint; and
- (b) that (either alone or together with one or more other implantable medical devices):
 - (i) replaces or substitutes for the articulating surface of a shoulder joint, hip joint or knee joint (in whole or in part); or
 - (ii) provides primary fixation to the bone for the replacement articulating surface; or
 - (iii) connects directly or indirectly with an implantable medical device that has a function mentioned in subparagraph (i) or (ii) and operates as an intrinsic element of the joint replacement;

but does not include an ancillary medical device.

knee joint means the joint consisting of:

- (a) the articulations between each of the 2 condyles of the femur and the corresponding surface of the tibia; and
- (b) the articulation between the patella and the trochlear groove of the femur.

shoulder joint means the ball and socket formed by the reception of the head of the humerus onto the glenoid cavity of the scapula.

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