Australian Government
Department of Health
Therapeutic Goods Administration

Defining joint replacement medical devices (hip joint; knee joint and shoulder joint) and ancillary medical devices

Version 1.0, April 2015

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <http://www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	Cleared document	Devices Authorisation Branch	16/04/2015

Contents

Purpose of this document

This document provides guidance to manufacturers and sponsors on regulatory amendments defining shoulder, hip and knee joint replacement medical devices and ancillary medical devices. These amendments came into effect on 20 April 2015, to clarify the appropriate classification for various medical devices supplied for use in shoulder, hip and knee joint replacements. The document provides examples of joint replacement medical devices and ancillary medical devices.

Definitions

Definitions have been included in the dictionary of the Therapeutic Goods (Medical Devices) Regulations 2002 for:

- total and partial shoulder, hip and knee joint replacement medical devices;
- ancillary medical devices; and
- hip, knee and shoulder joints.

The definitions are as follows:

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 ancillary devices.

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.

Knee joint means the joint consisting of:

a. the articulations between each of the 2 condyles of the femur and 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.

Practical examples of how the definitions apply

The following section explains how the various parts of the definitions operate in practice, including examples.

Replace or substitute for the articulating surface of the joint

Under paragraph (b)(i) of the joint replacement definition, the articulating surface of joints would be a Class III medical device. It includes devices that replace:

- the ball and/or socket of the hip;
- the two condyles of the femur and the corresponding surface of the tibia and/or the patella or trochlear groove of the femur;
- the ball and/or socket of the shoulder.

Examples include:

Examples of devices that replace the articulating surface of the joint	
Acetabular shells and cups	
Modular femoral head	
Humeral / Shoulder head	
Glenosphere / Lateralised cup	
Inserts	
Articular femoral components	
Patella components	

Provide primary fixation

Under paragraph (b)(ii) of the joint replacement definition, devices which provide primary fixation of the joint replacement to the patient's bone would be a Class III medical device.

Examples include:

Examples of devices that provide primary fixation	
Monoblock femoral stems/ hip stem / humeral shoulder stem	
Femoral and tibial knee stems*	
Glenoid component	
Reverse/inverse glenoid base plate / metaglene	
Tibial baseplate	
Cemented stem	

* If femoral or tibial knee stems are intended by the manufacturer to provide primary fixation to the bone they are to be classified as a Class III medical device. However, if these stems are intended by the manufacturer to be used where the individual requirements of the patient make it appropriate to do so, the device is not to be classified as a Class III medical device.

Intrinsic element of the joint replacement

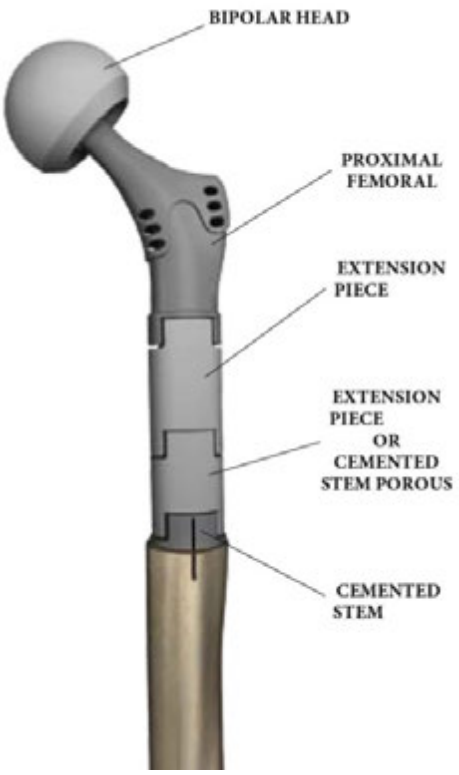
Under paragraph (b)(iii) of the joint replacement definition devices that connect directly or indirectly with the articulating surface and/or primary fixation and operates as an intrinsic element of the joint replacement would be a Class III medical device.

Examples include:

Examples of devices that are an intrinsic element of the joint replacement	
Taper connection	
Taper adapter	
Adapter sleeve	

Examples of devices that are an intrinsic element of the joint replacement	
Proximal femoral components/ Modular femoral neck /Shoulder humeral body	
Reverse shoulder proximal cup	
Polyethylene insert / Liner	
Hinged knee axles / reinforced yoke / tibial rotating yoke / lock pin	

Devices that are intrinsic elements of the joint replacement may be directly or indirectly connected to the articulating surface and/or primary fixation. The example to the right shows a hip joint replacement:



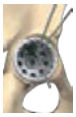
- The bipolar head replaces the articulating surface, so would be a Class III medical device.
- The cemented stem provides primary fixation, so would be a Class III medical device.
- The proximal femoral device directly connects to the bipolar head (the articulating surface) and indirectly to the cemented stem (primary fixation) and without this device the joint replacement would not operate as intended, so it would be a Class III medical device.
- The extension pieces would not be classified as a Class III medical device as these are intended by the manufacturer to be used to provide bone substitution or accommodate anatomical requirements of the patients and are only used appropriate to the individual requirements of a patient. As a result these devices fall within the definition of an ancillary device (outlined below).
- These classifications are not changed by the fact that, for this device, the Class IIb extension pieces are located between two Class III devices.

Ancillary medical devices

The joint replacement definition specifically excludes ancillary devices. While ancillary devices may be required to enable the shoulder, hip or knee joint replacement medical device to operate as intended by the manufacturer, they do not replace the articulating surface of the joint, provide primary fixation or operate as an intrinsic element of the joint replacement and are therefore not classified as Class III medical devices.

Ancillary medical devices may provide additional stability either alone or together with other implantable medical devices, or provide bone substitution or additional fixation to assist in the implantation of the joint replacement where the individual requirements of a patient make it appropriate to do so. Screws, plates and wedges are specifically cited as ancillary devices.

Examples include:

Examples of ancillary medical devices	
Bone screws	
Wedges, augments, tibial and femoral bush components	
Plates / acetabulum cage	
Inverse shoulder inlay spacer (increases offset)	
Acetabulum apical hole plug (optional, intended to cover central hole)	 
Cement restrictor/distal centraliser/proximal spacer	 
Extension pieces	
Diaphyseal segment	
Femoral and tibial knee stems*	

* If femoral or tibial knee stems are intended by the manufacturer to provide primary fixation to the bone they are to be classified as a Class III medical device. However, if these stems are intended by the manufacturer to be used where the individual requirements of the patient make it appropriate to do so, the device is not to be classified as a Class III medical device.

Further reading

Background on up-classification of joint replacements

To obtain greater assurance in the safety and performance of shoulder, hip and knee joint replacement medical devices, the European Commission issued Directive 2005/50/EC. This

amended the classification of the joint replacement medical devices from Class IIb to Class III medical devices. The European Commission released further guidance in January 2007 to clarify the intention of this classification rule.

On 1 July 2012, TGA amended the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations) to align the classification of these devices in Australia with European Union arrangements, and to provide for a parallel level of rigour of premarket assessment of these joint replacement medical devices.

The TGA provided a two year transition period for sponsors of existing Class IIb Australian Register of Therapeutic Goods (ARTG) entries to apply to up-classify their devices. In April 2014 this transition period was extended by 12 months, from 30 June 2014 until 30 June 2015.

The need for definitions

As the reclassification transition period progressed it became apparent that there were differences in interpretation of the classification rules within the Europe Union. Many manufacturers reply on European certification to support market entry in Australia. Given this it was agreed greater clarity was needed on which medical devices are joint replacements and so classified as Class lll medical devices under Australian regulations, and which devices act as ancillary devices to the joint replacement and are Class llb medical devices.

The transition period was extended in part to allow development of a definition of shoulder, hip and knee joint replacement medical devices and ancillary medical devices.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605
http://www.tga.gov.au