Australian Government

Department of Health

Therapeutic Goods Administration

Consultation: Proposed reclassification of spinal implantable medical devices

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TGA Health Safety Regulation

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Introduction

The Australian Government endorsed a significant program of reform to further strengthen the regulation of medicines and medical devices in Australia. As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates these products, and is responsible for implementing the Government's reforms.

In 2015, the Report of the *Expert Panel Review of Medicines and Medical Devices Regulation* (MMDR) made 58 recommendations for reform of the regulatory framework for medicines and medical devices in Australia. The Australian Government Response to the Review of Medicines and Medical Devices Regulation was released in September 2016. The Government accepted 56 MMDR recommendations including Recommendation Twenty[1] which addressed matters within the remit of the TGA. This Recommendation provided that the regulation of medical devices, wherever possible and appropriate, align with the European Union (EU) framework including the classification of medical devices.

Background

Medical devices are regulated in Australia having regard to the risks (to the individual or public health) considered in the context of the device's intended use. All devices carry some level of potential risk, and the TGA applies scientific and clinical expertise to ensure assessments and decisions are made based on the balance between the benefits and the risks.

The risk classifications of medical devices take into account factors such as potential harm, level of invasiveness, reliance on power, where in the human body the device is used, terms of use, the end user (consumers or a person with appropriate knowledge and expertise), etc.

The TGA periodically reviews classification rules for medical devices to ensure they continue to be appropriate. When undertaking such reviews, the TGA has regard among other things, to the international best regulatory practice and any emerging issues.

This ensures sustainability of the Australian regulatory system for medical devices, appropriateness and robustness of assessments, and timeliness of access to medical devices.

This consultation

> **The focus of this paper is** to obtain feedback on a proposal for the reclassification of spinal disc replacement implants or implantable devices that come into contact with the spinal column with some exception (screws wedges, plates and instruments).

The EU Regulation on medical devices (2017/745)[2] (EU MD Regulation) introduced several amendments to the classification rules effectively reclassifying some categories of medical devices to higher risk classes.

[1] Sansom L, Delaat W, Horvath J. Review of Medicines and Medical Devices Regulation: Recommendations to the Minister for Health on the Regulatory Frameworks for Medicines, Medical Devices, Complementary Medicines and Advertising of Therapeutic Goods, July 2015, p. 10.

[2] The Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

The EU MD Regulation explains that the new requirements increase the robustness of the assessment process, and that the classification rules take into account the potential risks associated with the technical design and manufacture of the devices. The rules also take into account the level of invasiveness and potential toxicity of certain devices introduced into the human body as well as the place where the device performs its action in or on the human body.

The Australian Government's reforms aim to improve the scope, clarity and appropriateness and operation of regulations governing medical devices. This consultation paper considers the EU regulatory framework as an input into the review and reform of the Australian regulatory requirements for medical devices classification. While the new classification rule in the EU more appropriately reflects the intended use and the risk of medical devices, this paper considers the extent to which a similar approach will be appropriate in the Australian regulatory context, to further our aim of enhancing the smooth functioning of the medical devices market while also achieving high standards of quality, safety and performance.

Potential changes: summary

Aim

Having regard to the amendments implemented by the EU MD Regulation, consider introducing a new classification rule, which is appropriately tailored for the Australian regulatory context, for spinal implantable medical devices. In the EU MD Regulations these are referred to as:

> *"…spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments."*

Proposals

It is proposed that a **new classification rule** be included in the *Therapeutic Goods (Medical Devices) Regulations 2002*, to align with the last paragraph of Rule 8 (Annex VIII, Chapter III) of the EU Medical Devices Regulations (namely Regulation (EU) 2017/745).

Effect

All spinal implantable medical devices (excluding some ancillary components would be reclassified from Class IIb (medium-high risk) to Class III (high risk).

Your feedback

Are you a consumer, industry stakeholder, healthcare provider, patient, industry representative body, consumer advocacy group or other interested party?

We seek your views on the potential reclassification and implementation strategy. Your input will assist us to address any unintended consequences and inform the proposal and the regulatory amendment process.

On page 14 there is a list of questions to help you address the proposal in your feedback.

Please refer to page 14 on How to submit your feedback to the TGA.

Please note

This consultation **closes on 31 March 2019**.

Before providing feedback, it is important to read the explanatory material that follows.

Where do I find the classification and definition of spinal implantable medical devices?

EU

Regulation (EU) 2017/745 (the EU MD Regulation) specifies the rules that govern the classification of a medical device.

Rule 8[3] prescribes the classification of particular groups of implantable and long-term surgically invasive medical devices. **The last paragraph of this rule** relates to spinal implantable medical devices:

> 'All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:
>
> *… are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments.'*

Note

In general, screws, wedges, plates and instruments perform an ancillary role that may not present the same level of risks as the risks associated with the use of primary/main implantable medical device.

The EU appears to have considered this and subsequently made the decision to exempt these devices from this rule and continue to classify them as Class IIb instead of Class III.

The EU MD Regulation does not explicitly define the spinal implantable medical devices.

There is a definition of *implantable devices* in the EU MD Regulation, and TGA is consulting on the possible alignment of this definition separately.[4]

[3] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, Annex VIII, Chapter III – Classification Rules, 5.4 Rule 8 (OJ L 117, 5.5.2017, p. 143). See also Chapter V, Section 1, Article 51.1 – Classification of Devices, (OJ L 117, 5.5.2017, p. 49).

[4] See *Consultation: Changes to a number of definitions and scope of the medical device regulatory framework in Australia* https://www.tga.gov.au/consultation/consultation-changes-number-definitions-and-scope-medical-device-regulatory-framework-australia, Appendix A, Table A2, p.15

Australia

The classification rules for medical devices in Australia are prescribed in Schedule 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002*[5] (the Australian MD Regulations).

The current classification rules relevant to medical devices within the scope of the last paragraph of EU Rule 8 and principles for applying these rules under the Australian MD Regulations are outlined in 'Current classification of these devices in Australia' (page 11 of this paper).

For the purpose of these classification rules, the *implantable medical device* means a medical device (other than an active implantable medical device) intended by the manufacturer to be, by surgical intervention, wholly introduced into the body of a human being, and to remain in place after the procedure.[6]

Medical devices subject to the last paragraph of EU MD Regulation Rule 8

The last paragraph of EU MD Regulation Rule 8, classifies spinal implantable medical devices, specifically referring to spinal disc replacement implants and implantable devices that come into contact with the spinal column, with the exception of screws, wedges, plates and instruments.

What are spinal implantable medical devices?

There are two major categories of spinal implantable medical devices: fusion and non-fusion implants.

Spinal fusion implants include cages, plates, or rods. Examples of non-fusion spinal implants include artificial discs and expandable rods.

Spinal implantable medical devices are used in different parts of the spine (cervical, thoracic, lumbar and sacral) to rectify different health problems that among other things often cause back pain. These problems include, but are not limited to, arthritis of the spine, deformities of the spine (including scoliosis - abnormal curvature of the spine), spondylolisthesis, herniated discs, trauma, spinal tumours, etc.

It is accepted that carefully selected patients with many spinal pathologies can benefit from spinal surgery where implants are used. However there are also significant risks and possible harms associated with these devices if devices do not perform as intended.

Spinal cages

A **spinal fusion procedure** often uses a **spinal cage**. There are many different reasons for performing a spinal fusion. For example, a patient with a collapsed disc can experience significant pain due to increased pressure on the surrounding nerve roots. Therefore the goal of the procedure is to hold two bones apart while encouraging them to join. Respectively the purpose of implanting spinal cage is to increase the space for nerve roots, stabilise the spine, restore spine alignment, which can relieve pressure on the nerve roots and reduce the pain.

[5] Classification rules for IVD medical devices are prescribed in Schedule 2A; see also *Therapeutic Goods Act 1989*, s. 41DB and *Therapeutic Goods (Medical Devices) Regulations 2002*, Part 3, Div. 3.1.
[6] Dictionary (r. 1.3) of the Australian MD Regulations

Spinal cages are hollow rectangular or cylindrical devices, usually intended to provide support and stability. They usually have porous walls that allow the bone graft that is often used during the spinal fusion surgery to grow into the cage.

As spinal cages are porous, the bone grafts generally grow from the vertebral body through the cage and into the next vertebral body. It is this fusion that restores the height of the spine and stabilises the vertebrae as they fuse together. The spinal cage then becomes a permanent part of the spine.

Cages can be used in different spinal segments, including the lumbar, cervical and thoracic spine. Wherever they are used, they have similar roles and similar biologic aspects. However, the size of the cage and load specifications may differ in the different spinal segments.

The material used for spinal cages is usually titanium, or tantalum, or polyetheretherketone (PEEK). Some cages may combine two materials (e.g. a PEEK cage coated in titanium). Different materials may present somewhat different benefits and risks in the use of spinal cages. For example, a porous metal sponge cage has the structural, functional and physiologic properties of cancellous bone (i.e. the spongy form of bone found inside the vertebrae), meaning a bone graft harvest procedure is usually not necessary. PEEK, on the other hand, shares several properties with cortical bone (i.e. the hard bone found on the outside of the vertebrae) such as resistance to compressive loading. It also has radiolucent properties, meaning it can be imaged easily; titanium can create artefact in both CT and MRI scans, limiting visualisation of adjacent structures.

However, overall the use of any spinal cage is still associated with the high risk.

Spinal disc replacement implants

Artificial disc replacements are examples of spinal implants used in **non-fusion procedures**. Total disc replacement is a surgical procedure in which a diseased or damaged intervertebral disc is replaced with an artificial disc in order to restore the normal function and movement of the spine.

There are a number of different spinal disc designs. Each is unique in its own way, but all maintain the same goal: to reproduce the size and function of a normal intervertebral disc.

In most cases, total artificial spinal disc replacements substitute both the annulus and nucleus with a device that will simulate spinal anatomy. Some recently developed designs of spinal disc replacement devices comprise the nucleus (centre) of the intervertebral disc only, leaving the annulus (outer ring) in place.

The composition of an artificial spinal disc is an important factor in its development. It must be made of materials that are safe to be implanted in the human body, do not cause allergic reactions and do not damage other parts of the spine. Ideally, an artificial spinal disc would be made of a material that could be easily seen on an x-ray or other imaging as it would be easier to monitor it over time. Artificial spinal discs are made of a range of materials including medical-grade metals, ceramics and plastics. The device must be able to maintain proper intervertebral spacing, allow for the full range of motion and provide stability. It must come in a variety of sizes to accommodate patient height and spacing needs. Like a natural spinal disc, the artificial spinal disc must act as a shock absorber, especially if it is going to be used in several levels of the spine at one time. Finally, the artificial spinal disc must be very durable. For example, if a patient undergoes a lumbar disc replacement at the age of 35 years, ideally, to avoid the need for revision surgery, the artificial spinal disc would need to last at least 50 years.

Other implantable devices that come into contact with the spinal column

Other implantable devices that come into contact with the spinal column include (but not limited to) devices used to replace anatomical structures in the spine such as the lamina, facet joints and other bony elements.

There are several types of such devices, including:

- **Anatomic facet replacement system** (AFRS): A technology that helps to restore normal spinal motion at the involved levels. The AFRS consists of a precision instrumentation set and an anatomic facet implant family whose design is based upon a comprehensive computed tomographic morphology study of the facet joint. The system utilises traditional pedicle screw fixation of its superior and inferior facet implants.
- **Vertebral bone filler**: A sterile substance intended to be used to replace cortical/cancellous bone in a vertebral body to stabilize vertebral compression fractures caused by cancer, osteoporosis or trauma. The device is typically a sterile powder of a synthetic polymer (e.g. polymethylmethacrylate (PMMA)) that is mixed with its sterile diluent prior to implantation and designed to be implanted during a balloon kyphoplasty or vertebroplasty procedure. This device does not contain an antibiotic agent. After application, this device cannot be reused.
- **Orthopaedic cement**: A substance made from methylmethacrylate, polymethylmethacrylate, esters of methacrylic acid or copolymers containing PMMA and polystyrene. It is used in arthroplastic procedures of the joints for the fixation of polymer or metallic prosthetic implants to the living bone. In the case of bone pathologies, it may be used as a filler.
- **Bone graft**: An artificial bone substitute[7] for implantation or transplantation when bone is lost due to trauma or osteoporosis.

Note

Orthopaedic cement or bone graft may include an antibiotic.

Any antibiotic in Australia, if used separately, is considered to be a medicine. Any medical device that incorporates or is intended to incorporate, as an integral part, a substance that if used separately, would be a medicine, and is liable to act on a patient's body with action ancillary to that of the device, is classified as Class III[8]. Also such medical devices require manufacturers to obtain a conformity assessment certificate issued by the TGA before sponsors may apply for inclusion of the device in the Australian Register of Therapeutic Goods (ARTG).

Subsequently, orthopaedic cement **or** ***bone graft*** **containing antibiotics** already must be included in ARTG as Class III medical devices, and therefore amendments proposed in this consultation paper are not applicable to these devices.

- **Bone-screw internal spinal fixation system**: An assembly of multiple sterile implantable devices intended to provide immobilisation and stabilisation of spinal segments and used in

[7] Bone grafts that are bone taken from the patient or cadaver are not medical devices and are not considered in this paper.
[8] Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 2, Cl. 5.1

the treatment of various spinal instabilities or deformities. Also used as an adjunct to spinal fusion (e.g. for degenerative disc disease). Otherwise known as a pedicle screw instrumentation system, it typically consists of a combination of anchors (e.g. bolts, hooks, pedicle screws or other types), interconnection mechanisms (incorporating nuts, screws, sleeves, or bolts), longitudinal members (e.g. plates, rods, plate/rod combinations) and/or transverse connectors. Sterile disposable devices associated with implantation may be included.

Note

The name of these devices refers to 'screw' however generally different components of these systems include different devices and not only screws.

- **Cervical facet joint distractor**: A sterile wedge-shaped device intended to be inserted within a cervical facet joint (spinal joint) for joint distraction. The distraction is intended to facilitate nerve root decompression and stabilisation of the spine in the treatment of various spinal conditions. It is typically fenestrated or barbed and may incorporate a screw to expand to shape and/or to provide fixation within the joint and cervical spine stabilisation. It typically includes single-use instruments for implantation (e.g. chisels, rasps).

Why reclassify spinal implantable medical devices?

The location in the body where the devices perform their action is one of the determining factors when deciding on the classification of medical devices.

The spine is an integral part of the human body that has a unique and complex structure. The main functions of the spine are to protect the spinal cord, nerve roots and several internal organs, and provide structural support and balance to maintain an upright posture.

Spinal implants can provide significant benefits to patients with diseases or injuries of the spine and can contribute to improvements in quality of life. For example, reduction in the back pain increases productivity, reduces dependence on medications, and in general facilitates more activity, leading to improvements in quality of life.

However as with any implantable device, there are high-risks of harm and complications associated with the use of these products, especially if their design/performance is not fit for purpose.

Research into spinal implant failure has found a multitude of different factors that result in corrosion and wear. 'Wear' is defined as a mechanical breakdown of the implants while 'corrosion' is an electro-chemical process that results in the degradation of metal.

The type and degree of force applied to a particular implant placed at a specific location along the spine, inside the body is also one of the important risk factors that must be considered, as it affects the risk of the device failing, and thereby its associated morbidity and mortality, especially, given the close proximity of spinal implants to the spinal cord, the great vessels and vertebral arteries. Some other complications observed include metallosis, which may affect the nervous system. In other cases, the construct of a device has been observed to be associated with debris particles and associated inflammatory process, and migration of devices in the region, which have the potential for serious effects in proximity to the spinal cord.

It is recognised that different spinal implantable devices for similar intended purposes may be associated with different rates of complications, however overall there is the potential for significant harms affecting related human body structures.

Some **types of device failure** associated with spinal implants are:

- **Failure of spinal fusion:** The bone may not fuse as desired at the operated levels due to the move, slip or breakage of the implant used to secure the fusion during surgery.
- **Implant or surgical instrument breakage, failure or unexpected behaviour occurring during the operation**: This can lead to serious injuries such as damage to blood vessels and nerves leading to paralysis or even death, and may be related to problems with the design of the instruments and the implant.
- **Implant failure/fracture:** Spinal implants may erode, fracture/break, dislodge or have other problems after the surgery that result in recurrence of the initial health problem, pain, nerve impingement, and eventually in revision surgery.
- **Implant migration:** Sometimes after surgery, usually before the healing process has progressed to the point where the cage is firmly attached by scar tissue or bone growth, an intervertebral fusion cage might move out of place. If the cage moves too far, it may not be doing its job of stabilizing the two vertebrae. If it moves in a direction towards the spine or large vessels, it may damage those structures. A problem with implant migration may require a second operation to replace the cage that has moved.
- **Transitional syndrome:** In a healthy spine vertebrae/discs work together to absorb and distribute the pressure or force placed on the spinal column. If one or two segments are not working properly, the neighboring ones have to take on more. So if there is a spinal fusion anywhere in the spine, the segment next to fusion will begin to take on the extra load. Over time this can cause increased wear and tear to these neighboring vertebrae/discs. New pain may be felt coming from the newly damaged segment. This is called a transitional syndrome.
- **Infection:** Spinal implant infection is not common but may be associated with implantation of any device and may result in local effects compromising the cord and as with any implant, may require removal of the implanted devices, with secondary surgery posing additional risk compared to the primary procedure.

Current classification of these devices in Australia

There are currently no specific definitions and/or classification rules related to spinal implantable medical devices. The classification rules that apply to these devices are set out in Schedule 2, Part 3 of the Australian MD Regulations as follows:

> ***Rule 3.4 – Surgically invasive medical devices intended for long-term use and implantable medical devices***
>
> *(1)* This clause applies to:
>
> *a. a surgically invasive medical device that is intended for long-term use; and*
>
> *b. an implantable medical device.*
>
> *(2)* Subject to subclauses (3), (4) and (4A), the device is classified as Class IIb.

Proposed reclassification

If the proposed reclassification takes effect, it will mean that any spinal implantable medical device (excluding ancillary components) will be reclassified from Class IIb to

Class III. Classification of implantable devices intended to provide additional fixation when it is required such as screws or plates will remain as Class IIb.

Sponsors of Class III medical devices in Australia are required to include each device in the Australian Register of Therapeutic Goods (ARTG) separately, with an individual unique product identifier (UPI) to improve their traceability. Medical devices of the high risk classification require the most stringent assessment of manufacturers' quality management systems and assessment of technical documentation related to each device, rather than that of a representative device from a group of similar devices[9]. Sponsors will be required to obtain manufacturers' *conformity assessment documents* and provide them to the TGA to demonstrate procedures appropriate for a Class III medical device when submitting applications for inclusion of their medical devices in the ARTG. Finally the Class III device applications are also subject to a mandatory audit assessment by the TGA, including assessment of the clinical evidence.

Strengthened assessments are intended to drive the manufacture of better quality, reliable spinal implants that are fit for purpose.

Proposed action

It is proposed that a **new classification rule** be included in Part 3 (Rules for invasive medical devices and implantable medical devices), Schedule 2 in the *Therapeutic Goods (Medical Devices) Regulations 2002*, to align with the last paragraph of the EU MD Regulation Rule 8:

The device is classified as Class III if it is:

- an *implantable medical device* intended by the manufacturer *to be used as a spinal disc replacement or to come into contact with the spinal column*

Note: This rule does not apply to implantable devices intended to provide additional fixation when it is required such as screws, wedges, plates or instruments.

What will change for sponsors?

Sponsors who supply, or plan to supply, in Australia medical devices to which the last paragraph of Rule 8 applies will be required to provide manufacturer's *conformity assessment documents* appropriate to devices of this classification.[10]

If the regulatory changes take effect, sponsors of spinal implantable medical devices will be required to apply for inclusion of their medical devices in the ARTG as Class III.

[9] *Therapeutic Goods (Medical Devices) Regulations 2002*, r.3.6 and Schedule 3 – Conformity assessment procedures
[10] Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018 (F2018L01410) <https://www.legislation.gov.au/Details/F2018L01410>

Important to note – amendments to Prostheses list

Some implantable devices are entered on the Prostheses List in order for the devices to be reimbursed by private health insurers. When the TGA reclassifies medical devices to a higher classification, if a Class III ARTG inclusion application is successful, the TGA issues a new ARTG entry for the device.

Sponsors should remember that they will be required to update their Prostheses List listings in order to remain on the Prostheses List.

Transitional arrangements

In Europe, the transitional arrangements for all new medical devices lawfully placed on the market that have pre-market authorisation in the form of a valid EC Certificate[11] can remain on the market until the expiry date of that EC Certificate or until 27 May 2025, whichever is the earliest.

The TGA proposes that the new classification for **new medical devices in Australia**—that is, a device included in the ARTG following successful completion of applications submitted to the TGA on or after the commencement date of the amended regulations—would start from August 2020.

If the application for ARTG inclusion for a medical device is **submitted to the TGA before the date the proposed amendment takes effect**, it is proposed that the device will be subject to the transitional arrangements and will have four (4) years to transition.

Applications

At the date that the proposed amendment takes effect:

- **All new applications for marketing approval** (ARTG inclusion) for spinal implantable medical devices submitted to the TGA on or after the date when amended regulations take effect must be for a Class III medical device.
- **Sponsors of devices already included in the ARTG**, or those for which applications have been submitted before regulatory amendments take effect, must apply to have their device/s re-entered as Class III medical devices. All applications to reclassify devices must be submitted to the TGA by the end of the transition period. Where an application to reclassify has been submitted to the TGA and a decision has not been determined by the end of the transition period (i.e. is still under assessment), it is proposed that the device can continue to be supplied under the existing Class IIb ARTG entry until the Class III application is finalised (including applications not finalised at the end of the transition period).
- For those devices for which transitional provisions apply, sponsors must notify the TGA of all such devices presently supplied under the existing Class IIb ARTG entry within six (6) months of the amended regulations taking effect. These devices can continue to be supplied for the duration of the transition. If the sponsor has not notified the TGA within this period, they will no longer be eligible for the transitional arrangements.

[11] EC certificates issued in accordance with EU Directive 93/42/EEC and which comply with the requirements in para. (2) of Article 120 of the EU MD Regulation.

- If any **application for ARTG inclusion for a device with the current classification is in progress** on the date the regulations come into effect, it may continue. If the application is successful, the device will be included with the current classification (i.e. Class IIb). The sponsor must then reapply to include their device in the ARTG as Class III, as per requirements set out under the transitional arrangements.

Fees and charges

Normal **application** and **audit assessment fees** will apply for applications for inclusion in the ARTG.

Normal annual charges will apply for Class III entries in the ARTG following reclassification.

Engagement

Wherever practicable, the TGA will:

- liaise with the healthcare sector, patient associations and industry peak bodies to inform and raise awareness about this proposal
- provide relevant material on the TGA website.

Feedback notes

It is important to note that while we intend to take the European medical device framework into account, the Australian legislative instruments are structured differently and there is variation in the legal terminology acceptable in each jurisdiction. We acknowledge that legislation cannot always be successfully replicated across jurisdictions. Therefore, your views on the impacts of reclassifying these spinal implantable medical devices to Class III are very important to us.

When considering the proposed measures, assume that the EU MD Regulation definitions and terminology and the last paragraph of Rule 8 apply to a spinal implantable medical device in the context of the Australian MD Regulations. You also may wish to consider the possible impact of the proposed alignment by referring to descriptions of relevant devices and their functionality.

Please also keep in mind that current and future technological developments may potentially bring more categories of medical devices under this classification rule.

What we invite you to do

In your submission, we ask you to consider the questions below and provide comments related to any other matter outlined in this consultation paper.

Questions

- What impacts—including any that are unintended—do you anticipate the proposed reclassification may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?
- Are there any further issues and questions we should consider when implementing this change (including areas that can/should be clarified in our guidance)?

- Do you have any comments/views regarding defining the scope of medical devices that should be covered by the term '*spinal implantable medical device*'?
- Do you have any comments regarding exemption of implantable screws, wedges, plates and instruments from the proposed new classification rule?
- Do you have any comments regarding the transitional arrangements proposed in this paper?

How to submit

Complete the online consultation submission form to upload your submission in either pdf or word format.

You can also submit your feedback directly to the TGA by email at: devicereforms@tga.gov.au. If you do so, **please ensure your submission is accompanied by a cover sheet**.

This consultation closes on 31 March 2019.

Enquiries

If you have any questions relating to submissions please direct them to: devicereforms@tga.gov.au.

Appendix A - Some examples of spinal implants

There are many categories of implantable medical devices that will be subject to the classification set up in the last paragraph of Rule 8. In addition to the groups identified early in this paper, some of the specific examples of spinal implants are provided below.

- Bone-screw internal spinal fixation system
- Ceramic spinal fusion cage
- Cervical facet joint distractor
- Cervical total disc replacement prosthesis
- Fixation device, internal, spine, construct
- Interspinous spinal fixation implant
- Intervertebral disc filler
- Lumbar total disc replacement prosthesis
- Metal-polymer composite spinal fusion cage
- Polymeric spinal fusion cage
- Posterior lumbar spine prosthesis
- Prosthesis, internal, spine, disc
- Prosthesis, internal, spine, vertebral body
- Spinal dynamic-stabilization system
- Spinal fixation plate, non-biodegradable
- Spinal fusion sphere
- Spinal internal fixation system, interlaminal
- Spinal internal fixation system, intervertebral body
- Vertebral body cement-containing implant

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