

MTAA Submission to TGA consultation:

Proposed reclassification of spinal implantable medical devices

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1. Executive Summary

On 11th February 2019, the TGA opened the consultation: *Proposed reclassification of spinal implantable medical devices*. As per the TGA: “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.”

It is proposed that a new classification rule be included in Part 3 Rules for invasive medical devices and implantable medical devices, Schedule 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002*, as follows:

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.

This new classification rule is intended to align with the last paragraph of Rule 8 (Annex VIII, Chapter III) of the EU Medical Devices Regulations (namely Regulation (EU) 2017/745), reproduced below.

Rule 8

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.*

Currently, spinal implants are classified as Class IIb (medium-high risk). The proposed reclassification of spinal implants would result in all spinal implants deemed high risk to be up-classified from Class IIb to Class III (high risk). Sponsors of spinal implants currently in the ARTG will need to submit applications for up-classification with additional design examination evidence.

MTAA believes the scope decided by the TGA should be based on risk that is aligned with the established clinical experience of each spinal implants technology type and supports alignment with the EU MDR risk classification rules and their ultimate interpretation for each spinal implant system. It is also important to time such an implementation carefully and allow an appropriate time lag after implementation in the EU, usually six months.

MTAA’s detailed responses to the questions in the TGA consultation paper are provided in the next pages.

2. MTAA responses to questions in the consultation paper

Q1: *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.)?*

A1: The proposed reclassification of spinal implantable medical devices aligns with the EU MDR, including exemptions – components such as screws, wedges, plates and instruments.

We are aware that the EC is yet to finalise its position on implementing Rule 8 for various spinal implants and it is important that the TGA monitors developments in the EU.

An unintended impact of the reclassification would be divergent opinions in the EU and Australia in application of the new classification rule for specific spinal implants.

A lower risk classification in the EU would result in TGA not accepting CE Marking approvals for ARTG inclusion, resulting in significant challenges in sponsors' ability to supply affected spinal implants in Australia.

Q2: *Are there any further issues and questions we should consider when implementing this change (including areas that can/should be clarified in our guidance)?*

A2: The EU Team NB and NB-MED recently published a document titled **Joint NB Position Paper on Spinal Classification per the MDR**.¹

This document includes a risk-based decision tree (page 3) for a harmonized interpretation and application of **Rule 8** of the EU MDR. The decision tree proposes the following risk classification for spinal implants, focusing on the clinical history of well-established versus non-well-established technologies:

- Class IIb (classification unchanged) - Fusion devices
 - a) Well-established technologies – sampling-based devices (one representative device per generic device group)
 - Exempted devices as per EU MDR Article 18
 - b) Not well-established technologies – full review of the technical documentation similarly to Class III devices, i.e., 100% sampling
 - New technology regarding manufacturing processes, material, innovative design, complex design (e.g., 3D-printed devices)
 - Multiple components or complex wedges, spacers, pins and screws (e.g., expandable)
 - Devices with high clinical risk (e.g., paediatric surgery devices)
- Class III (up-classified) - Non-fusion devices (e.g., dynamic fixation)

¹ Team NB NB-MED Joint NB Position Paper on Spinal Classification per the MDR, 2018-12-07 http://www.team-nb.org/wp-content/uploads/2019/01/Joint-NB-Spinal-Classification-Decision-Tree_final.pdf

The Orthopaedic Surgical Manufacturers' Association (OSMA) has also published a guidance paper providing component detail and information on spinal implant systems in relation to the EU MDR Rule 8 up-classification.

Should the EU formally adopt the joint NB position, we would like the TGA to consider alignment with this approach. In the interest of clarifying what constitutes "well-established technology", we provide the following discussion and examples below.

An internal spinal stabilization construct composed of components assembled by the surgeon is intended to perform the task of spinal alignment and stabilization. The multi-component devices used to assemble an internal spinal stabilization construct can be classified into three categories: bone interfacing components, spacer components and connector components.

The constructs are individualized to accommodate specific patient needs (e.g., different number and levels of the spine, anterior vs. posterior surgical approach, degree of required stabilization, etc.). They allow surgeons to construct an implant system to address an individual patient's anatomic and physiologic requirements. The device components have no standalone purpose on their own, but rather, they are used together to form a system to immobilize and stabilize the spine segments as an adjunct to fusion during bone graft healing and/or fusion mass development for conditions such as acute and chronic instabilities or deformities of the cervical, thoracic, lumbar and sacral spine: spondylolisthesis, degenerative disc disease, fracture, dislocation, spinal deformity, spinal tumour, and failed previous fusion (pseudoarthrosis).

The systems consist of an anchor (such as a pedicle screw), longitudinal members (e.g., plates, rods, and/or plate/rod combinations) and transverse connectors. An interconnection mechanism (e.g., offset connector, nuts, screws, sleeves or bolts) may also be utilized. Spacer components (wedges) occupies the place of removed tissue and abuts bone. The anchors or screws form the bone-implant interface, the longitudinal members connect the anchoring members, transverse connectors link the longitudinal members, and the spacer components replace removed tissue or bone, all providing immobilization and stability to the spine in order to facilitate fusion and bone healing.

These constructs are considered to be temporary fixation devices which serve a finite purpose until fusion is achieved. This is in contrast, for example, to a spinal disc arthroplasty implant, which is intended to replace a spinal segment and preserve functionality of that segment.

The most common example of a bone interfacing component is **the screw**. The screw is used in the spinal constructs to anchor the construct to the bone. Other examples of bone interface components used in spinal constructs are staples, hooks and wire.

The second category is **the spacer component**. One common example of such a spacer component is a wedge. The spacer component typically occupies the vertebral or intervertebral space and abuts bone. Spacers may be used in conjunction with other spinal construct components to provide additional alignment and stability of the spine. Bone graft material can be used as a spacer component. Other examples of synthetic spacer components include intervertebral cages and vertebral body replacement cages.

The third category is **connector components**, which connect two or more components in the construct. One common example of such a connector component is a plate; for example, an

anterior cervical plate may connect multiple screws implanted in the anterior vertebral bodies as shown in the radiograph below. Other examples of connector components include rods, cross connectors, locking screws and nuts.

The components used to assemble an internal spinal stabilization construct, as described above, have a long history of clinical use and are considered well established technologies.

Q3: Do you have any comments/views regarding defining the scope of medical devices that should be covered by the term 'spinal implantable medical device'?

A3: The scope of medical devices that should be covered by the term 'spinal implantable medical device' should fully align with the EU MDR and with any applicable formal EC guidance, interpretation and consensus documents.

Q4: Do you have any comments regarding exemption of implantable screws, wedges, plates and instruments from the proposed new classification rule?

A4: The scope of exempt components from up-classification such as screws, wedges, plates and instruments should align with that in the EU MDR and any applicable formal EC guidance, interpretation and consensus documents.

We would also like to make sure that components with an intended purpose equivalent to that of the exempt components but using different names, such as hooks, rods and connectors, are also exempt.

Based on our response to question 2, we would like to further comment that we interpret these components as representative examples of the three types of components of internal spinal stabilization constructs. These are:

1. Bone interfacing components, examples include screws, staples, hooks and wires;
2. Spacer components, examples include wedges, include intervertebral cages and vertebral body replacement cages;
3. Connector components, examples include intervertebral cages and vertebral body replacement cages.

As all of the components mentioned above comprise an internal spinal stabilization construct and perform a similar function or intent to screws, wedges and plates, we would consider them as also exempt.

Q: Do you have any comments regarding the transitional arrangements proposed in this paper?

A: The transitional arrangements proposed in the TGA consultation paper should be aligned with the transitional arrangements for the EU implementation of MDR Rule 8, with an additional time lag of approximately 6 months.

3. Additional MTAA comments

MTAA suggest that prior to ascertaining the pertinent components, systems and construct technologies to be up-classified, a roundtable workshop be set up comprising experienced Spine Society surgeons, CHF representatives, and MTAA and TGA personnel. This would ensure that appropriate decisions are made with clear understanding of the clinical and technical aspects that would determine the risk factors and hence appropriate risk-based classification.

MTAA also is aware that TGA would wish to have knowledge of the detail of all spinal implant systems under an ARTG. We suggest that spinal implants that will remain classified as Class IIb should nonetheless be listed specifically within that ARTG entry to allow transparent identification.

MTAA also suggests that a central spinal implant clinical quality registry be established to truly monitor, review and trace spinal implants throughout Australia.

We would like to thank the TGA for engaging with industry in this matter and are looking forward to achieving a workable solution for this important category of medical devices.