SPINE SOCIETY OF AUSTRALIA

31st March 2019

Consultation: Proposed reclassification of spinal implantable medical devices

Dear Sir/ Madam,

On behalf of the Executive of Spine Society of Australia I would like to submit the following comments regarding the consultation paper " Proposed Reclassification of Spinal Implantable Medical Devices".

We strongly support the need for spinal implants to be “fit for purpose” and for there to be appropriate surveillance consistent with the risk associated with the individual implant type.

We note the background to the discussion paper is the EU Regulation on Medical Devices (2017/745) which recommended amendments to the classification rules, resulting in a re- classification of some implants used in spinal surgery from Class 2B to Class 3. Specifically the EU regulations refer to "Spinal Disc Replacement, Implants or Implantable Devices that come into contact with the spinal column, in which case they are classified as Class 3 with the exception of components such as screws, wedges, plates and instruments" (which are to remain as Class 2B).

Whilst we appreciate that there is obviously some sense in trying to maintain consistency between jurisdictions, the subsequent discussion given in the proposal demonstrates a misunderstanding of the fundamental components and roles of the implants used in spinal surgery and we believe completely misunderstands the risks associated with the use of such implants.

We also have some concerns about the lack of definition about what constitutes “components such as screws, wedges, plates and instruments”, “ancillary components” and “implantable devices intended to provide additional fixation when it is required, such as screws or plates”.

This lack of definition makes it difficult to be certain which particular spinal instrumentation components are the subject of this review, as usually the screws, hooks, plates and rods used in spine surgery are the primary fixation tool rather than “additional fixation”. Therefore, are screws, rods, hooks and plates that are the primary form of fixation included or excluded from this process?

The confusion is exacerbated by the fact that “Bone-screw internal spinal fixation system” is included under examples of “Other implantable devices that come into contact with the spinal column” on page 9, but possibly excluded in the phrases above.

Another example of the lack of definition is the use of the term “wedges.” This is not a term commonly used in spine surgery and its meaning is therefore uncertain

On page 9, justification for the reclassification is given by examples of "some types of device failure".

Most of the failures listed are not primary failures of the spinal implant, but rather failures due to surgical decision making or technique, patient factors etc. In fact the failure of spinal surgical devices is exceptionally rare. The commonest devices to fail in spinal surgery are pedicle screws and rods. Such failures are almost always subacute or chronic and secondary to non-implant related factors, such as pseudarthrosis or failure of fusion. These late implant failures may be associated with some symptoms and possibly the need for revision surgery, but rarely pose significant risk.

I will provide some brief comment.

1. "Failure of a spinal fusion" is rarely significantly associated with failure of instrumentation but is rather caused by an inappropriate surgical construct, failure of surgical technique or patient factors such as cigarette smoking.

2. “Implant or surgical instrument breakage, failure or unexpected behavior occurring during the operation .” This is rare and if it occurs is almost always due to inappropriate manoeuvres performed by the surgeon.

3. “Implant failure/fracture”: This is unusual and almost always related to failure of spinal fusion and prolonged exposure of the implant to micromotion.

4. "Implant migration" in by far the majority of cases is associated with problems of surgical technique and device insertion. I would note that the majority of interbody devices are designed to be spacing devices and not fixation devices. The insertion of interbody spacers allows interbody distraction, neural decompression and reduction of cantilever forces on posterior instrumentation. In the majority of cases, fixation is primarily obtained with either anterior or posterior fixation systems, and not by the interbody device stability. With some interbody devices, late ingrowth into the device can occur providing further device stability. This however is a process that takes weeks or months.

Thus usually, the pedicle screw/rod construct is the primary stabilizing mechanism of the spine whilst the intervertebral device is a secondary mechanism rather than the other way around. Once again, the question of whether the screws, hooks, rods and plates (when acting as the primary, not additional fixation) are included in this review is relevant.

I would note that there are some devices which are designed to be free standing intervertebral devices and have been demonstrated to be effective.

5. "Transitional Syndrome" or proximal junctional kyphosis is a multifactorial problem and not in itself directly the consequence of spinal instrumentation. Proximal junctional kyphosis is more likely to be the result of surgical intervention without satisfactory restoration of sagittal alignment of the spine. This again is more dependent on surgical technique rather than the spinal instrumentation.

6. "Infection" is generally not an implant related problem There has been some work done looking at different metals in pedicle screw systems with respect to infection rates but again predominantly infection seems to be more a consequence of the nature and extent of surgery, the operating environment and circumstance (elective vs emergency), patient factors (Smoking, diabetes, frailty, obesity) etc. rather than the instrumentation in itself.

7. “Spinal arthroplasty” complications in the short term usually relate to sizing and insertion of the device which is an issue of surgical technique rather than one of implant failure.
   They are however designed as a mobile device with a long life span.
   Any bearing surface will inevitably demonstrate wear over time and should be followed into the longer term.

There are a number of differences between the functioning of spinal disc replacements when compared to arthroplasty in other joints, particularly hip and knee replacement.

i) Spinal arthroplasties are exposed to only small ranges of movement (typically 6° - 10°) as opposed to ranges of motion in excess of 100° for hip and knee arthroplasty. This is associated with significantly different wear rates of the bearing surface.

ii) The other consideration is that a spinal intervertebral disc replacement is not being placed into a synovial joint such as the hip or knee. In hip or knee replacement, as the bearing surface wears, particles are consumed by macrophages in the synovium. The macrophagic response to particulate debris results in osteolysis and subsequent loosening of the joint replacement. In the absence of there being synovial tissue in the disc space (apart from one or two case reports) changes consistent with osteolysis have not been seen in spinal arthroplasty. In a case series detailing findings at revision surgery between two and nearly twenty years postoperatively, wear of the polyethylene core was noted universally. However, in this series, the predominant mechanism of failure of the index surgery was related to surgical technique or progressive disease. Implant migration where osteolysis was present occurred only in a few cases

However as spinal arthroplasty is designed to be a potentially life-long mobile device we believe that it should be in Category 3.

In summary, we believe that –

1) The problems with the currently available screw, hook and rod spinal internal fixation systems are very rarely primarily implant related, but rather due to problems of surgical decision making, surgical technique, patient factors etc.. These should remain Class 2b.
   We would note the possible difficulty associated with new manufacturers entering the market. This however could be dealt with in a more cost effective manner by a more robust system of device failure reporting.

2) The problems associated with interbody spacers and cages are generally not primarily implant related ,but rather due to surgical decision making, surgical technique, patient factors etc.. These should remain Class 2b

3) There are some types of cages such as expandable cages or stand-alone cages, where there is a greater risk of implant problems. With these, a case can be made for this type of implant to be Class 3

4) The problems of spinal disc arthroplasty are usually of surgical decision making, surgical technique, patient factors etc.. However due to the motion involved and the proposed longevity, a higher level of monitoring is required. These should be Class 3.

5) Novel or custom devices should be Class 3

With respect to specific questions in the consultation paper -

1. What impacts, including any that are unintended, do you anticipate the proposed reclassification may have for yourself and other stakeholders (such as consumers, health care professionals, health organisations, industry etc.?

This proposed reclassification will put an increased burden on the spinal implants industry. It may have some impact on the market place in that some manufacturers may decide not to offer the device for sale in Australia given the increased regulation.

2. Are there any further issues and questions which we should consider when implementing this change (including areas that can/should be clarified in our guidance).

a) The question of reporting of medical device failure has not been addressed. Current responsibility for reporting failure of a device rests

on hospital and industry. The majority of implants that fail do not necessarily come to surgical revision, or have surgical revisions which do not require retrieval/replacement of the implant.
Further consideration should be given to stronger reporting requirements of failures with respect to medical devices.

b) On page 12, is the statement, “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.”
We feel that the methodology used for ”traceability” is of extreme importance. It is essential that the requirement for individual packaging be limited to implants that are required only infrequently in the operative procedure. Each time an individually packed implant is required a staff member has to leave the operating theatre, find the correct package, return to the operating theatre, approach the surgical field to check the correct size etc and then approach the surgical nurses’ table and open and deliver the implant. This leads to considerable delay and the potential to interfere with the sterile surgical field. Individual packaging should therefore be limited to only implants where it is absolutely essential.

3. Do you have any comments/views regarding defining the scope of medical devices that should be covered by the term, "spinal implantable medical device"?

I have commented on our opinion on different implant types above

4. *Do you have any comments regarding exemption of implantable screws, wedges, plates and instruments from the proposed new classification rule?*
We feel that screws, hooks, plates and rods should be exempted from any change in their Class classification irrespective of whether they are the primary or additional mode of fixation. Changing categories fails to appreciate the real cause of implant failure in this group, and thus does not contribute to improved patient outcomes and safety.

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

We are unable to comment on the impact of the transitional arrangements as proposed.

Regards

Michael Johnson,
President,
Spine society of Australia
'president@spinesociety.org.au