

Submission

This submission arises from a direct awareness and knowledge of the medical impacts of a surgical mesh device which was classified as Class IIb prior to its de-registration in November 2014. This follows a review of the clinical evidence used to obtain registration of the Tissue Fixation System (TFS) anchored mini-sling, pelvic mesh device (Formerly ARTG 312657). It also follows a determination by the TGA complaints resolution panel (CRP 2014-04-003, CRP 2014-04-003) which found that the TFS sponsors claims of safety and performance were unsubstantiated, and its marketing claims that the device was a cure for prolapse and symptoms were in contravention of the Therapeutic Goods Act and Therapeutic Goods Advertising Code. As such the proposal to up-classify surgical mesh implants to Class III and proposal to improve public safety and the monitoring framework for medical devices is a positive initiative.

Mandatory review of the clinical evidence and research for medical device registration.

1. There is an *extraordinary lack of scrutiny* of the clinical evidence used to register and or maintain the registration of medical devices. Research data used as clinical evidence to demonstrate the safety and efficacy of medical devices is not currently verified during the regulatory registration process.'
2. Fraudulent or fabricated clinical results are not detected as medical research publications are accepted at face value and are not checked to confirm the research studies were actually done, the results obtained were accurate, or that ethical approval was obtained by the medical facilities the studies were performed at or patient consent was obtained. As such, it is recommend that any reclassification of a surgical mesh medical device from Class II to Class III needs to be in conjunction with an increased level of mandatory regulatory oversight and review of medical research if it is to be relied on to obtain or maintain the registration a medical device and safe use on the public.

Increased levels of transparency for high risk medical devices.

3. There is a *complete lack of transparency* around the clinical evidence used to register and or maintain the registration of medical devices. In matters of public safety, any regulatory constraints to withhold safety & efficacy evidence for medical devices on the basis of commercial confidentiality need to be removed, and the clinical evidence relied on and submitted by sponsors should be placed into the public domain.
4. Class III medical devices are classified as a high risk device and correspondingly this class of devices require the highest level of public disclosure for the safety & efficacy evidence they relies on. Disclosure and transparency does not refer to proprietary manufacturing processes or formulas which should remain as commercial in confidence, but is publication of the clinical evidence, safety & efficacy evidence for the claims which it makes to medical consumers. Increased transparency and disclosure will allow for professional and public scrutiny, deter the use of fraudulent clinical evidence or unsubstantiated claims made by sponsors and lead to increased confidence by the public in the registration and use of high risk medical devices.

Presumption for public disclosure concerning medical device compliance

5. There is currently a *lack of any reasonable information provided to medical consumers* surrounding the regulatory history of medical devices, and there is no information such as an audit trail of design changes made manufacturers regarding the compliance or modification of critical safety information such as 'directions for use' statements.
6. In the current regulatory environment, modified and substantially different medical devices, with different physical properties and risk profiles can be passed off and used on the public under the guise of a single registration justified by sponsors as *'improvements to the devices form'*. Accordingly, for high risk devices there is a requirement that the full regulatory history of devices, both current and cancelled from the ARTG should become a permanent public record. The sequence of approved changes to Class III medical devices such as information pertaining to the risk profile, design and ongoing compliance with regulations should be published. Other leading regulators such as the FDA have a *presumption in support of public disclosure* in all information which relates to the basis of the registration of medical devices which is a model which can be utilised by the TGA.

Reclassification of all implantable surgical mesh medical devices from Class IIb to Class III

7. All surgical mesh medical devices should be classified as Class III
8. The following mandatory requirements be implemented in conjunction with the re-classification to Class III, to recognise the high risk profile of the devices and the improve the level of safety assurances required for use of the devices on the public and mitigate the risks associated with a lack of transparency around clinical research evidence.
 - a) The corresponding Trocar instruments to implant surgical mesh medical devices be classified as Class II (medium risk) given the risks to the patient and injury caused during the surgical procedures to implant the mesh.
 - b) Class III surgical mesh medical devices to be physically sighted by the Therapeutic Goods Administration as part of approval process and specification and design catalogued as a permanent record of the approved device. It is unsatisfactory that high risk medical devices be approved via an overseas conformity assessment process without any physical sighting of the device in Australia by the TGA as part of the regulatory approval process.
 - c) Sponsors of Class III medical devices to have a mandatory requirement to carry public liability insurance and confirmation of that insurance by way of an annual certificate of currency be submitted to the TGA and published on the public record.
 - d) Sponsors of Class III medical devices to have a mandatory requirement to provide a written declaration accepting responsibility and liability for the accuracy, honesty and independence of clinical research

evidence submitted by them to support the registration of the surgical mesh medical devices, and this declaration be published on the public record.

- e) The clinical research evidence provided by sponsors to support the registration of their surgical mesh medical devices be verified by the Therapeutic Goods Administration or its representative to determine if the research was actually conducted, the data exists and stated ethical approvals were granted and written patient consent to the research was obtained. This is to recognise that the publication and use of false clinical research documents has been used to support the registration and use of surgical mesh devices on the Australian public.
 - f) The clinical research evidence provided by sponsors to support the registration of their surgical mesh medical devices be published on the public record to enable transparency and independent validation. It is unacceptable that claims of commercial confidentiality override the transparency required in matters of public safety and assurance. It is clear that commercial confidentiality has been used by sponsors of surgical mesh medical devices, to conceal the absence of any clinical evidence to support their safety and efficacy and use on the public.
9. Sponsors be required to provide proof of the safety and efficacy of surgical procedures to implant surgical mesh implants in order to achieve registration of the medical device. This may include ASERNIP-s testing or similar as a mandatory requirement, to provide an assurance the device and actually be implanted in a safe and effective manner.
10. The transition period be shortened to a six month period.

Introduction of formal requirements for medical device manufacturers to provide patient implant cards and product information directed at consumers for all implantable medical devices.

- 11. Formal requirements for medical device manufacturers to provide patient implant cards be implemented.
- 12. The requirements be extended to sponsors of medical devices, not just manufacturers.
- 13. The following supporting requirements be considered to support the successful implementation of a patient implant card system.
 - a. A mandatory requirement for sponsors to submit an electronic record of product information such as serial numbers, batch production and product expiry dates to the Therapeutic Goods Administration. This information to be supplied on an ongoing routine basis prior to the use of any device on the public.

- b. The digitised product information be available to all health authorities to associate with the electronic medical records of patients and to link to the submission of adverse event reports by health facilities, medical practitioners and patients, in order to aid the analysis of health care impacts and aid in the recall
- c. A permanent record of the Patient Card Information, including the manufacturers 'directions for use' be digitised, catalogued and permanently displayed on the Australian Register of Therapeutic Goods (ARTG). Any changes submitted by a sponsor to this information be catalogued as a permanent reference and record of changes to the Patient Card Information. This is to recognise the Sponsors may continually make changes to Patient Card information, such as new risks and warnings and this information should be disclosed to the public along with the date of that change.
- d. A permanent record and audit trail of medical device registrations, cancellations, regulatory actions and or sponsor withdrawals be permanently published and searchable on the TGA website. This is to recognise that there is a complete lack of information available to the public regarding the regulatory history and audit trail of medical devices, while surgical mesh implants are permanent, and consumers should reasonable be able to access a regulatory history relating to the products they have been implanted with.
- e. A mandatory requirement that the information contained in the patient implant card to form part of the electronic medical record of patients.
- f. The record of patient informed consent processes be digitised to capture and record that patient implant card information has actually been received by patients. In particular it should be recognised that record keeping and documentation of consent processes by medical practitioners is poor, unreliable and non-digitised.
- g. The record of informed consent processed be digitised to capture and record the surgical procedures and Medicare item numbers agreed to by the patient. This is to recognise that the costs of the health system and Medicare are triggered by a manual and poorly documented informed consent process, outsourced to medical practitioners, but which should instead have clear communication and digitised recording to allow improved oversight by Medicare and Health regulators.
- h. The transition period be reduced to six months.

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