



UROLOGICAL SOCIETY
OF AUSTRALIA
AND NEW ZEALAND

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Director, Business Improvement Support Section
Therapeutic Goods Administration

Via Email: mmdr.consultation@tga.gov.au

Re Consultation: Alignment with European medical device regulatory framework

The Urological Society of Australia and New Zealand (USANZ), in consultation with its Female Urology Special Advisory Group (FUSAG), has reviewed the submission to the above TGA consultation made by Monash Health (their tracking code: *CONSULT-AWEMDRF-18*) and supports the views and facts contained therein.

In addition to urogynaecologists, a number of USANZ members also have a special interest with expertise in female pelvic floor reconstructive surgery, encompassing the use of transvaginal mesh for stress incontinence (including single incision slings), pelvic organ prolapse, and mesh removal surgery. We agree these should be performed by surgeons with recognised expertise. This expertise allows them to optimally select patients, to carry out the surgery with optimal technique with attention to detail, to follow patients up through audits of functional and anatomical outcome, including presentation of results at major peer-reviewed meetings.

We agree that there are patients who will benefit from transvaginal mesh in prolapse repairs, especially in those where native tissue repairs have failed, and in patients where their occupation involves significant physical activity (e.g. heavy lifting) where native tissue repairs are expected to give inferior results.

By endorsing this document, USANZ is hoping that the TGA will consider the views and position contained therein. It is an important document which has been reviewed by many of this country's peak bodies in female pelvic floor surgery as well as by an international panel of experts. It is important that the welfare of women with stress incontinence and pelvic organ prolapse, especially the more complex cases, is not jeopardized by total cancellation of some of the above mentioned procedures, which can potentially offer quality of life improvement, especially when the more conventional procedures have failed.

Yours sincerely

Peter Heathcote

President

Urological Society of Australia and New Zealand