



TGA Action Plan for Medical Devices UGSA Statement

Updated April 2019

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Progress towards safe and effective treatment for urinary incontinence.

For ten years the Urogynaecological Society of Australia (UGSA) has been a leader in promoting optimal conservative and surgical treatment of female urinary incontinence and pelvic floor dysfunction.

More than 150,000 women in Australia and New Zealand have benefited from a mid-urethral sling treatment for their urinary incontinence. However, as in all areas of medicine some women have had experienced complications and there is a clear imperative for us to look at how we can continue to improve care for all our patients.

Following the Senate mesh inquiry and recommendations from the Australian Commission on Safety and Quality in Health Care, new guidelines have been established for the management of urinary incontinence. These include rigorous standards for training, credentialing, audit and all aspects of patient care.

UGSA strongly supports the recent announcement from the TGA of an “Action Plan for Medical Devices” to provide improved regulations for surgical devices, enhanced reporting of complications and mechanisms for monitoring of surgical implants. The TGA “Action Plan for Medical Devices” is a further step towards ensuring optimal safe and effective care.

Adverse publicity around transvaginal mesh products has resulted in many women not seeking treatment for their urinary incontinence. We believe this is not in our patients’ best interests. Women should be able to access balanced information on the non-surgical and surgical options, including non-mesh surgery, to treat their urinary incontinence. We recommend that women seeking surgical treatment for urinary incontinence ask their surgeon about their training and experience in both mesh and non-mesh procedures.

The Urogynaecological Society of Australia strongly supports all the recent initiatives that focus on guidelines for patient care for women with urinary incontinence, surgical credentialing, audit and more rigorous regulatory requirements for medical devices. Women should feel reassured that there are now strong safeguards around the quality of medical devices and surgical training.

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FAST FACTS:

- Around one in five Australian women might need surgical treatment for prolapse or urinary incontinence. Treatment can improve quality of life.
- 80 per cent of those affected by incontinence are women, with more than half aged 50 and under.
- In 1998 when MUS was first introduced to Australia, 73.3 women per 100,000 (ages >25 years) had surgery for urinary incontinence.
- The MUS rapidly replaced all other surgeries from 2002 and by this time significantly more women were having surgery for their incontinence.
- The peak rate of all surgical procedures was 108 per 100,000 women in 2002. The rate in 2017 was 53 per 100,000 – a fall of 51 per cent.

To get help for bladder and pelvic floor health:

Explore our website: www.ugsa.org.au

- Call the free National Continence Helpline 1800 33 00 66
- Go to www.continence.org.au
- Or talk to your doctor