UROLOGICAL SOCIETY
OF AUSTRALIA
AND NEW ZEALAND

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TGA proposed regulations on medical devices supported by Urologists

The peak body for Urological Surgeons, the Urological Society of Australia and New Zealand (USANZ) strongly welcomes proposed changes to the use of medical devices in Australia by the Therapeutic Goods Administration (TGA) that would see mandatory reporting of adverse outcomes and bar codes on all medical devices implanted in patients.

Urological surgeons use transvaginal pelvic mesh in mid-urethral slings as one of a range of options to treat incontinence.

"Complications surrounding the use of pelvic mesh has been a high profile issue in Australia and worldwide, and as specialist surgeons we acknowledge there have been some women who have suffered significant adverse effects," said USANZ President, Adjunct Professor Peter Heathcote.

"We welcome and give our support to proposals that would strengthen and improve patient safety in Australia.

"We still believe there is a role for pelvic mesh in the treatment of incontinence, which has been used to successfully treat and improve the quality of life of thousands of Australian women.

"However, like all medical devices there are risks involved and this means there should be complete transparency and patients must be fully-informed of potential complications and be encouraged to ask questions of their surgeon.

"They should also be informed of alternate treatments for their condition.

"We would suggest patients ask their surgeon about their level of training and experience in using mesh devices. Training is key to reducing complications.

"We want to reassure women that urological surgeons are highly trained to use mesh devices for incontinence and also to treat any complications that may arise," said Adjunct Professor Heathcote.

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