



UROLOGICAL SOCIETY OF AUSTRALIA AND NEW ZEALAND

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Urologists support FDA statement on “deceptive claims” for ‘vaginal rejuvenation’ devices

The Urological Society of Australia and New Zealand is warning women about the potential risks associated with the use of so-called ‘vaginal rejuvenation’ laser devices which are being marketed for treating symptoms related to menopause, improving sexual function and urinary incontinence.

Last week the FDA in the United States issued a statement regarding “deceptive health claims” around the use of lasers and other energy-based devices to destroy or reshape vaginal tissue.

While the devices have been approved for use in the treatment of serious conditions such as the destruction of abnormal or pre-cancerous cervical or vaginal tissue as well as genital warts, the safety and effectiveness of these devices has not been evaluated for ‘vaginal rejuvenation.’

There have been reported cases of burns, scarring and pain associated with the use of the devices.

“As specialist surgeons in female pelvic medicine and surgery, urologists are concerned by patients referred to us for management of complications from ‘vaginal rejuvenation’ procedures and support the FDA statement,” says Associate Professor Vincent Tse, Urological Society of Australia and New Zealand Special Advisory Group Leader on Female Urology.

“This is a technology for which there is limited scientific data to support its use for claims associated with vaginal atrophy or incontinence and the FDA has acted wisely. We would encourage the TGA to also review claims made in Australia regarding this technology.

“There may be an important role for laser therapy in women’s health but it is emerging, and women need to be counselled as to the indications, risks and intended benefits of this particular treatment. Doctors and regulators always need to carefully manage the use of any new technology to minimise any risk to patients.

“There is also a substantial psychological risk when a treatment may be marketed to improve sexual function, which is a complex entity and expert diagnosis and management is required,” says Professor Tse.

“We would be concerned if the marketing of unproven treatments not only caused injuries but also kept patients from seeking appropriate, evidence-based therapies to treat their medical conditions.

“Women with incontinence or pelvic floor issues are encouraged to seek advice from their doctor. There are a range of approved treatment options available to women and Urologists are trained to diagnose and offer evidence-based treatment appropriate to the specific case,” says Professor Tse.

To view the FDA Statement:

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm615130.htm>

<https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm615013.htm>

Media enquiries or to arrange an interview: Mobile + 61 402 130 254 or Email edwina@maxicom.net.au

The Urological Society of Australia and New Zealand is the peak professional body for urological surgeons in Australia and New Zealand. Urologists are surgeons who treat men, women and children with problems involving the kidney, bladder, prostate and male reproductive organs. These conditions include cancer, stones, infection, incontinence, sexual dysfunction and pelvic floor problems.