

Clinical: Women's Health - surgery Proactive Release: 10 July 2019

28 June 2019



Official Information Act (1982) Request

I write in response to your Official Information Act request, acknowledged by us on 21 June 2019. You noted the following, and requested information from us on trans-obturator tape (TOT) use during surgical procedures:

I am a lawyer at John Miller Law. We act for a woman in a case against ACC, regarding the use of trans-obturator tape (TOT) during a procedure she underwent in 2006. Our client tells me that this product has since been discontinued for use in the Counties Manukau DHB.

- I would like to know if this is correct.
- If so, please may I have any documents relating to the discontinuance of this product, and any advice on this product you believe to relevant?

It is correct that the trans-obturator tape (TOT) procedure has not been used at CM Health since 2014. The CM Health Women's Health Services have audit data on the numbers and all types of surgical procedures performed by them for treatment of incontinence from 2010 to the present day.

Between 2010 and 2014, there were 114 trans-obturator tape procedures performed at CM Health. There have been none performed since 2014. All the trans-obturator procedures performed at CM Health prior to 2014 used the American Medical Systems (AMS) Monarch Sling system.

Regarding 'product' discontinuance, the clinical decision to not use a procedure results in no supply procurement occurring.

The decision to discontinue using the TOT for genuine stress incontinence (GSI) was informed by international clinical evidence and research. The decision was based on the findings of emerging clinical and research/evidence-based medicine, and the resulting discussions amongst our current Uro-gynaecologists. These processes are not formally minuted.

Our Uro-gynaecologists currently chose to use the Tension-free Vaginal Tape (TVT) retropubic sling, as a first choice of procedure for stress incontinence.

The international research suggested the TVT procedure have better long-term outcomes for women with low-leak point pressures and intrinsic sphincter defects. There is also some evidence it has better results in women with a high Body-Mass Index (BMI), which applies to 84% of our Counties Manukau women. In addition, there had been some reports in the research literature of women with difficult to treat thigh pain following the TOT sling procedure.

Our surgeons do still reserve the option to use a TOT sling procedure, if a TVT is clinically contraindicated (e.g. where there had been previous surgery – such as previous Burch colposuspension, or a neobladder constructed; and the retropubic space is likely to be scarred and distorted). These decisions are made on a case-by-case basis, following clinical assessment.

The International Uro-Gynaecology Association (IUGA) continues to support the use of both TOT and TVT slings, provided that they are appropriately consented, are placed by a properly trained surgeon, and clinical outcomes and results are clinically audited.

I trust this information satisfactorily answers your query. If you are not satisfied with this response you are entitled to seek a review of the response by the Ombudsman under section 28(3) of the Official Information Act.

Please note that this response or an edited version of this may be published on the Counties Manukau DHB website.

Yours sincerely,

Fepulea'i Margie Apa Chief Executive Officer

Counties Manukau Health