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Horizon scanning prioritising summary

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Gynecare TVT Obturator System: Treatment of female stress urinary incontinence.

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PRIORITISING SUMMARY

REGISTER ID: 0000058

NAME OF TECHNOLOGY: GYNECARE TVT OBTURATOR SYSTEM

PURPOSE AND TARGET GROUP: TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---|---|
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established |
| <input checked="" type="checkbox"/> Investigational | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Nearly established | <input type="checkbox"/> Should be taken out of use |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | |
|--|---|
| <input type="checkbox"/> Yes | ARTG number |
| <input checked="" type="checkbox"/> No | <input type="checkbox"/> Not applicable |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Belgium	✓		

IMPACT SUMMARY:

ETHICON, INC. (Johnson and Johnson) have developed the GYNECARE TVT Obturator System with the aim of treating female stress urinary incontinence. The technology is currently not available in Australia. The Obturator System includes new, additional features to the currently available GYNECARE TVT device. FDA Approval to market the device was given in early December 2003 (FDA, 2004).

Indications are for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The GYNECARE TVT Obturator System uses a minimally invasive approach to reinforce the structures supporting the urethra. It allows for an “inside-out” technique to insert a polypropylene tape through the obturator foramens, underneath the urethra, creating a supportive sling. The tape is positioned without tension under the junction between the mid and distal urethra. This technique avoids the retropubic space (unlike conventional TVT procedures) and therefore reduces the potential for urethral and bladder injury associated with some standard TVT procedures. Specifically designed instruments in the GYNECARE TVT Obturator System include a pair of metallic “helical passers”, plastic tubes and an introducer.

The study outcomes of 107 consecutive patients treated with the GYNECARE TVT Obturator System in Belgium, between March 2002 and February 2003, focus on immediate complication rates and do not assess incontinence or de novo urgency rates. The follow up time was short (one

month). This study (level IV evidence) included 74 patients with SUI and 33 patients with pelvic organ prolapse requiring surgical correction, who then underwent the modified TVT procedure. There were no peri-operative complications such as injury to the urethra, vagina, bladder, nerves, bowel or significant bleeding (>100ml). One month after the procedure three patients (2.8%) (2 of the 33 patients with prolapse and 1 of the 74 patients with SUI only) had complete urinary retention and required a tape release procedure with local anaesthetic injection and intravenous sedation. None of these patients re-developed incontinence or a fistula. Mean operative time was 14 minutes and mean hospital stay was 1.8 days for patients with transobturator inside-out operations only.

The study authors are currently conducting further prospective studies in cohorts of patients with isolated SUI.

Australian community-based studies have reported incontinence in 19% of women aged 10-29 years, 40% of women aged 30-44 years, 50% of women aged 45-59 years, 30% of women aged 60-74 years, and 42% of women aged over 75 years (Millard, 1998). In 1998 the cost of urinary incontinence in 1,835,628 community-dwelling women over the age of 18 years was estimated at \$710 million, or \$387 per incontinent woman, comprising \$338 million in treatment costs and \$372 million in personal costs (Doran et al. 2001). An estimated 60% of the Australian women with incontinence in 1998 were aged 40 years or over and the authors projected the total annual cost of incontinence in 20 years' time would be \$1268 million. However, this cost may be an underestimate as female incontinence is often a hidden problem, with women often not seeking treatment due to a perceived stigma.

The total number of urinary incontinence sling (TVT and other) procedures recorded by the HIC (item number 35599) between July 2002 and June 2003 was 3,360. The MBS fee was \$560.55 (HIC, 2003). The total number of other stress incontinence procedures recorded by the HIC (item numbers 35600, 35602, 35605) between July 2002 and June 2003 was 685. MBS fees for these procedures were \$435.15, \$560.55 and \$304.10 respectively.

CONCLUSION:

There is limited evidence available assessing the safety and effectiveness of the GYNECARE TVT Obturator System, however it is predicted that there would be a rapid uptake of this technology in the Australian public health system.

HEALTHPACT ACTION:

It is therefore recommended that this technology be monitored.

SOURCES OF FURTHER INFORMATION:

De Leval, J. (2003). 'Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out', *Eur Urol*, 44 (6), 724-730.

Doran, C. M., Chiarelli, P. & Cockburn, J. (2001) 'Economic Costs of Urinary Incontinence in Community-dwelling Australian Women', *Med J Aust*, 174 (9) 456 - 458

Millard R. (1998) 'The prevalence of urinary incontinence in Australia', *Aust Continence J* 1998; 4: 92-99.

SEARCH CRITERIA TO BE USED:

Stress Urinary Incontinence

Transobturator

Urethra

Suspension