

## **Latest News from ETHICON Women's Health & Urology**

### **New ETHICON Women's Health & Urology Device Introduces Unique 'Inside-Out' Obturator Approach To Treat Stress Incontinence**

Somerville, N.J., January 26, 2004 – ETHICON announced today the introduction of GYNECARE TVT\* Obturator System Tension-free Support for Incontinence, a novel surgical device for treatment of female stress urinary incontinence (SUI). This new mid-urethral sling device maintains many of the key elements that made GYNECARE TVT the gold-standard in stress incontinence repair, adds the safety and convenience of the obturator approach, and further optimizes safety with a unique 'inside-out' approach.

The GYNECARE TVT Obturator System 'inside-out' technique passes the mesh device from a small incision in the vagina out to small incisions in the thigh folds. This passage away from the urethra and bladder avoids the retropubic space and therefore reduces the potential for urethral and bladder injury noted with other obturator devices using the 'outside-in' technique. In addition, minimal dissection allows for accurate and precise midurethral placement. Like GYNECARE TVT, the GYNECARE TVT Obturator System uses the same unique PROLENE\* polypropylene mesh used in more than 500,000 SUI procedures worldwide and proven safe and effective with seven years of clinical data.

The GYNECARE TVT Obturator System introduces special, anatomically designed components. The helical passer ensures consistent, repeatable mesh placement. The tip tubing allows smooth, continuous passage of the mesh. And, the winged guide facilitates accurate introduction and passage of the mesh.

GYNECARE TVT combines the use of safe material, PROLENE polypropylene mesh, and a variation of a traditional operation known as a sling procedure to correct stress

urinary incontinence. The PROLENE mesh is inserted through the vagina and positioned without tension underneath the urethra, creating a supportive sling. During movement or exercise, the mesh supports the urethra, allowing it to maintain its seal to prevent urine loss. The tape, therefore, uniquely provides support only when needed, without any unnecessary tension on the urethra (tension-free). In contrast to traditional, “open” surgeries, the GYNECARE TVT treatment is:

- Used in a simple procedure that can be completed within 30 minutes
  - ✓ Offers short recovery time and minimal pain; Patients can go back to their routines in just a day or two.
  - ✓ Most patients will not require catheterization
- Can be performed under local anesthesia in an outpatient setting
  - ✓ Evaluated for success during the procedure. The surgeon asks the patient to cough, and then evaluates whether the tape is providing adequate support and makes any necessary adjustments before leaving the operating room.
- The right mesh implant
  - ✓ Limited foreign body reaction
  - ✓ Resistant to infection
  - ✓ Rapid fibrinous fixation
  - ✓ Excellent tissue ingrowth
  - ✓ Elastic

GYNECARE TVT is not intended for women who are or intend to become pregnant. Women on anticoagulation therapy are also not candidates.

Female SUI is caused by an improperly functioning urethra or excessive movement of the bladder neck. Unlike other types of incontinence, SUI is not a problem of the bladder. Normally, the urethra – when properly supported by strong pelvic floor

