

GYNECARE TVT* Tension-free Support for Incontinence FACT SHEET

What is GYNECARE TVT Tension-free Support for Incontinence?

The GYNECARE TVT system is an innovative, minimally-invasive and simple surgical device alternative for the effective treatment of *female stress urinary incontinence* with proven long-term results. To date, more than 75,000 patients worldwide have been treated with the GYNECARE TVT system. Clinical studies have demonstrated an 86 percent success rate, and most patients notice immediate improvement.

How Does the GYNECARE TVT Device Alleviate Stress Urinary Incontinence?

Female stress urinary incontinence is caused by an improperly functioning urethra; it is not a problem of the bladder. Normally, the urethra – when properly supported by strong pelvic floor muscles and healthy connective tissue – maintains a tight seal to prevent involuntary loss of urine. When a woman suffers from stress urinary incontinence, however, weakened muscle and pelvic tissues are unable to adequately support the urethra in its correct position. As a result, during normal movement as pressure is exerted on the bladder from the diaphragm, the urethra cannot retain its seal, permitting urine to escape.

The GYNECARE TVT system combines the use of a safe material, PROLENE* polypropylene mesh tape, with a traditional surgical procedure known as the sling, to correct stress urinary incontinence. The PROLENE mesh tape is woven through pelvic tissue and positioned underneath the urethra, creating a supportive sling. When pressure is exerted, the tape applies an adequate amount of support to the urethra, allowing it to keep its seal. The tape, therefore, uniquely provides support only when needed, without any unnecessary tension on the urethra (it is *tension-free*).

Key Patient Benefits of the GYNECARE TVT Device:

- ◆ **Simple Procedure.** A procedure using the GYNECARE TVT system can be completed within 30 minutes under local anesthesia by a trained surgeon, and patients may return home the same day. As a result, the GYNECARE TVT system offers a short recovery time and minimal pain.
 - In contrast, of the many surgical treatments currently in use for treating SUI, most involve general anesthesia, extensive surgery, and a lengthy recuperation.

Other Unique Advantages of the GYNECARE TVT Approach:

- ◆ **No traditional surgical anchors required.** As the tape passes through several pelvic tissue layers, friction is created which secures the tape in place. Over time, the natural in-growth of tissue into the mesh reinforces and restores connective tissue between the vaginal wall, urethra and pelvic floor muscles.

This friction allows the tape to be tension-free and helps to minimize the risk of complications that tension brings to other surgical procedures.

*Capitalized names are trademarks of ETHICON, INC.

- ◆ **Local anesthesia permits in-procedure evaluation.** The surgeon asks the patient to cough, and then evaluates whether the tape is providing adequate support and makes any necessary adjustments. This intra-operative test allows the surgeon to assess results of surgery before leaving the operating room, which improves cure rates.
- ◆ **Provides support only when needed.** The mesh tape loosely supports the middle of the urethra rather than the bladder neck and, therefore, uniquely provides tension-free support only when needed. This reduces the need for catheterization.
- ◆ **Safe.** There have been no cases of PROLENE polypropylene tape rejection to date.

Is GYNECARE TVT appropriate for pregnant women or women who want to become pregnant?

As with any surgery of this kind, this procedure should not be performed in pregnant patients. Additionally, because the mesh-like tape will not stretch significantly, GYNECARE TVT should not be used in women who plan future pregnancy.

Risks Associated with GYNECARE TVT:

All surgical procedures carry risks. Although rare, complications associated with GYNECARE TVT include injury to blood vessels of the pelvic sidewall and abdominal wall, hematomas, and bladder and bowel injury.

GYNECARE TVT Tension-Free Support for Incontinence is marketed by GYNECARE, the women's health division of ETHICON, INC.

Consumers who want more information about GYNECARE TVT Tension-free Support for Incontinence can call toll free at 1-888-GYNECARE or visit the web site at www.gynecare.com & www.controlurineloss.com.

*Capitalized names are trademarks of ETHICON, INC.