

GYNECARE TVT Tension-free Vaginal Tape (TVT) System, TVT Single Use Device, TVT Reusable Introducer, TVT Reusable Rigid Catheter Guide Package Insert

INDICATIONS

The TVT device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The TVT introducer and rigid catheter guide are available separately and intended to facilitate the placement of the TVT device.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

Do not use TVT procedure for patients who are on anticoagulation therapy.

Do not use TVT procedure for patients who have a urinary tract infection.

- Users should be familiar with surgical technique for bladder neck suspensions before employing the TVT device. It is however important to recognize that TVT is different from a traditional sling procedure in that the tape should be located without tension under mid-urethra.

- Acceptable surgical practice should be followed for the TVT procedure as well as for the management of contaminated or infected wounds.

- The TVT procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimise risks.

- Retropubic bleeding may occur postoperatively. Observe for any symptoms or signs before releasing the patient from hospital.

- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.

- The rigid catheter guide should be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley Catheter.

- When removing the rigid catheter guide, open the handle completely so that the catheter remains properly in place.

- Do not remove the plastic sheath until the tape has been properly positioned.

- Ensure that the tape is placed with minimal tension under mid-urethra.

- PROLENE mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material.

- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.

- Post-operatively the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can return to other normal activity after one or two weeks.

- Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize TVT device. Discard opened, unused devices.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.