

## **GYNECARE TVT\* Family of Products**

### **Essential Product Information for Patient**

#### **INDICATIONS**

The GYNECARE TVT Family of Products: GYNECARE TVT SECUR, GYNECARE TVT, GYNECARE TVT with abdominal guides, and GYNECARE TVT Obturator System are intended to be used in women as suburethral slings for the treatment of stress urinary incontinence (SUI).

#### **CONTRAINDICATIONS**

As with any suspension surgery, these procedures 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 & PRECAUTIONS**

- Do not use the GYNECARE TVT Family of Products for patients who are on anti-coagulation therapy.
- Do not use the GYNECARE TVT Family of Products, for patients who have a urinary tract infection.
- Bleeding or infection may occur post-operatively.
- Transient leg pain lasting 24-48 hours may occur and can usually be managed with mild analgesics after a GYNECARE TVT Obturator System.
- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT Family of Products, the patient should be counseled that future pregnancy may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical information is available about vaginal delivery following sub-urethral sling procedure with the GYNECARE TVT Family of Products, in case of pregnancy, delivery via cesarean section should be considered.
- Post-operatively, refrain from heavy lifting and/or exercise (e.g. cycling, jogging) for at least three to four weeks and to refrain from intercourse for one month. The patients can usually return to other normal activity after one or two weeks.
- Contact your surgeon immediately if there is burning sensation during urination, unusual bleeding, problems voiding or other problems.

#### **ADVERSE REACTIONS**

- Punctures or lacerations or injury to vessels, nerves, bladder, urethra, or bowel may occur during instrument passage and may require surgical repair.
- Improper placement of the TVT device may result in incomplete or no relief from urinary incontinence or may cause urinary tract obstruction.

For additional information, please call 0800 783 9162 to speak to a nurse or visit our website at [www.womenshealthsolutions.co.uk](http://www.womenshealthsolutions.co.uk)

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