Ordering information

Code	Product
TVTRL	GYNECARE TVT EXACT® Continence System (Laser Cut Mesh)
810041B	GYNECARE TVT™ Tension-free Support for Incontinence (Mechanical Cut Mesh)
810041BL	GYNECARE TVT™ Tension-free Support for Incontinence (Laser Cut Mesh)
810051	Introducer Handle (reusable)
810061	Rigid Catheter Guide (reusable)

To order, call 1-800-255-2500. For more information call 1-877-Ethicon or visit www.ethicon.com.

Essential product information

Indications

- The GYNECARE TVT™ Tension-free Support for Incontinence, GYNECARE TVT EXACT® Continence System and GYNECARE TVT™ with Abdominal Guides Tension-free Support for Incontinence, are intended to be used in women as pubourethral slings for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.
- GYNECARE TVT™ Obturator System Tension-free Support for Incontinence and GYNECARE TVT ABBREVO® Continence System are intended to be used in women as suburethral slings for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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 in patients who are on anti-coagulation therapy.
- Do not use the GYNECARE TVT Family of Products in 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 or GYNECARE TVT ABBREVO System procedure.
- 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, patients should 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.

Patient factors

Physicians should use their surgical experience and judgment to determine if PROLENE Mesh is appropriate for certain patients. Patient-specific factors may impair wound healing, which may increase the likelihood of adverse reactions.

Adverse reactions

- Punctures or lacerations or injury of vessels, nerves, structures or organs, including the bladder, urethra, or bowel, may occur and may require surgical repair.
- Improper placement of the GYNECARE TVT Family of Products devices may result in incomplete or no relief from urinary incontinence or may cause temporary or permanent urinary tract obstruction.
- Transitory local irritation at the wound site may occur.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE Mesh may potentiate an existing infection.
- Acute and/or chronic pain
- Voiding dysfunction
- Pain with intercourse which, in some patients may not resolve.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur
- Recurrence of incontinence
- Bleeding including hemorrhage or hematoma.
- One or more revision surgeries may be necessary to treat these adverse reactions.
- PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.

Other Adverse Reactions

- Seroma
- Urge incontinence
- Urinary frequency
- Urinary retention
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse
- Death

References:

1. Nilsson CG, Palva K, Aarnio R, Morcos E, Falconer C (2013) Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 24(8):1265–1269. **2.** Aigmueller T, Trutnovsky G, Tamussino K, et al. (2011) Ten-year follow-up after the tension-free vaginal tape procedure. Am J Obstet Gynecol 205(5):496.e1–5. **3.** Olsson I, Abrahamsson AK, Kroon UB (2010) Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence: a retrospective follow-up 11.5 years post-operatively. Int Urogynecol J 21:679–683. **4.** Nilsson CG, Palva K, Rezapour M, Falconer C (2008) Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. Int Urogynecol J 19:1043–1047. **5.** Bjelic-Radisic V, Dorfer M, Greimel E, Frudinger A, Tamussino K, Winter R (2006) Quality of life and continence 1 year after the tension-free vaginal tape operation. Am J Obstet Gynecol 195:1784-1788. **6.** Magee G, Roy S, Hinoul P, Moretz C, Kozarev R, Waters H, Whitmore K. A real-world comparative assessment of complications following various mid-urethral sling procedures for the treatment of stress urinary incontinence. J Long Term Eff Med Implants. 2012. 22(4): 329–340 **7.** Data on File, Ethicon Inc., Published Sling Data Analysis Mar 2013 **8.** GYNECARE TVT EXACT® Continence System Instructions for Use. Somerville, N.J: Ethicon, Inc. **9.** Ogah J, Cody JD, Rogerson L. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Cochrane Database of Systematic Reviews 2009. Issue 4. Art. No.: CD006375. DOI: 10.1002/14651858. CD006375.pub2 **10.** Data on File, Ethicon, Inc., LC Mesh Test, 2005

Choose GYNECARE TVT™ Family of Products **for Outcomes Surgeons Trust.**

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES
Shaping the future of surgery

Gynecare TVT

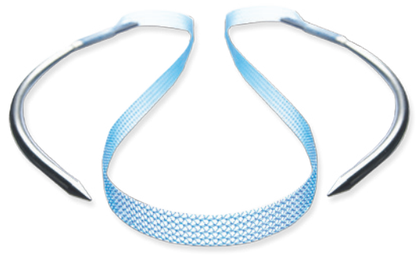
Your choice in retropubic slings...

GYNECARE TVT™ Retropubic System Tension-free Support for Incontinence now backed by 17 years of follow-up data—more than any other sling on the market[1]

Time tested

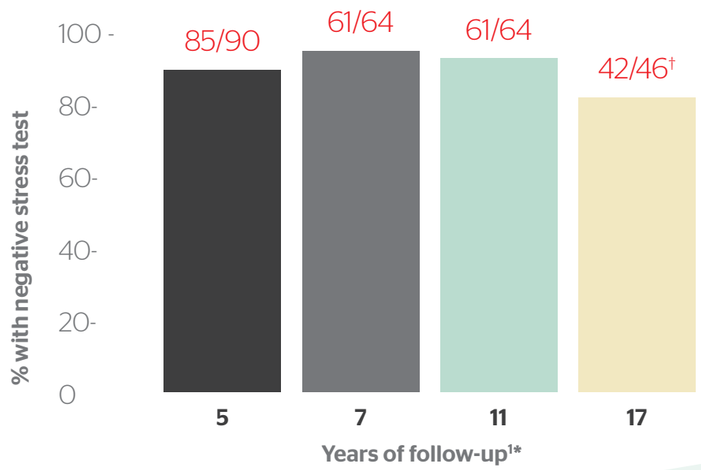
Sustainable success proven in a 17-year follow up study; the longest of its kind.[1*]

- No significant decline in efficacy rates between 5 and 17 years based on patients available for follow up[1*]
- 84-91% objective cure rate[1-5]
- 57-77% subjective cure rate[1-5]



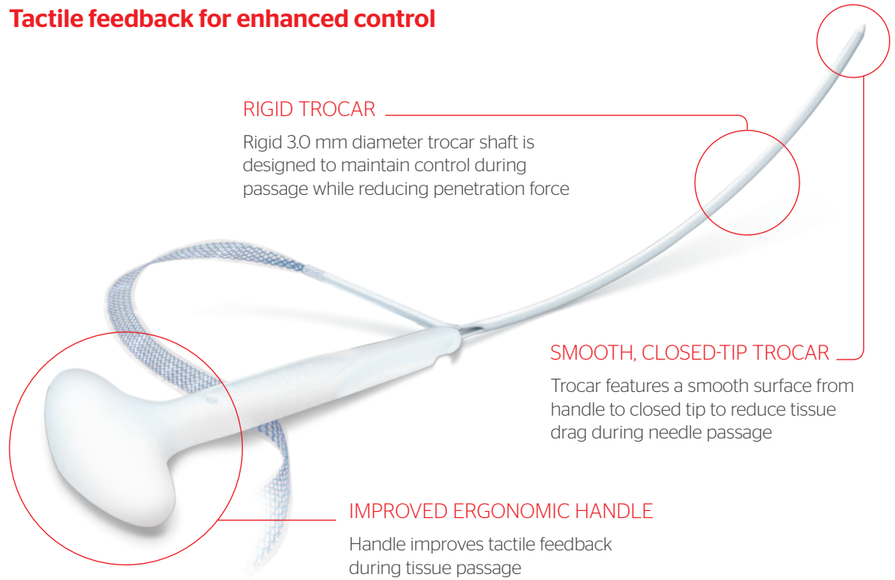
Proven outcomes you can trust

- In a 5 year analysis of 6,361 patients treated with various brands of retropubic slings, GYNECARE TVT Retropubic System had significantly lower rates of urinary obstruction/retention[6]
- GYNECARE TVT Retropubic System has been evaluated in over 100 RCTs[7]



GYNECARE TVT™ Continence System built upon many years of GYNECARE TVT™ Retropubic System Tension-free Support for Incontinence success.

Tactile feedback for enhanced control



Same dependable design

- The trocar curvature and tip radius of GYNECARE TVT™ Tension-free Support for Incontinence and GYNECARE TVT EXACT Continence System are designed so that the trocar maintains contact with the posterior aspect of the pubic bone[8]
- The Design of GYNECARE TVT with a retropubic bottom to top approach has demonstrated significantly lower perforation and voiding dysfunction rate vs. Top to bottom.[9]
- Laser-cut mesh[10]

* In a multi-center, prospective analysis of 90 women † % of patients cured out of evaluable patients at 17 years