

## Ordering information

Code	Product
TVTOML	GYNECARE TVT ABBREVO® Contenance System (Laser Cut Mesh)
810081	GYNECARE TVT™ Obturator System Tension-free Support for Incontinence (Mechanical Cut Mesh)
810081L	GYNECARE TVT™ Obturator System Tension-free Support for Incontinence (Laser Cut Mesh)

**To order, call 1-800-255-2500. For more information call 1-877-Ethicon or visit [www.ethicon.com](http://www.ethicon.com).**

### Essential product information

#### Indications

- The GYNECARE TVT™ Tension-free Support for Incontinence, GYNECARE TVT EXACT® Contenance 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® Contenance 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. Serati M, Bauer R, Cornu JN et al. TVT-O for the treatment of pure urodynamic stress incontinence: efficacy, adverse effects, and prognostic factors at 5-year follow-up. *Eur Urol*. 2013 May;63(5):872-8. Epub 2012 Dec 20
2. Cheng D, Liu C. Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up. *Eur J Obstet Gynecol Reprod Biol*. 2012 Apr;161(2):228-31. Epub 2012 Feb 13
3. Data on File, Ethicon Inc. Published Sling Data Analysis Mar 2013
4. Magee G, Roy S, Hinoull 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
5. Data on File, Ethicon, Inc. Fixation Cadaver Study, 2010
6. Hinoull P, Bonnet P, Krofta L, Waltregny D, de Leval J. An anatomic comparison of the original versus a modified inside-out transobturator procedure. *Int Urogynecol J*. Vol 22, number 8, page 997-1004, 2011.
7. Waltregny D, Thomas A, Blockx C, de Leval J. Three year results of a prospective randomized trial comparing the original inside-out transobturator (TVT-O™) procedure with a modified version using a shortened tape and reduced dissection for the treatment of female SUI (abstract). In: ICS, 2012 Oct 15-19; Beijing, China

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## Your choice in obturator slings...

# GYNECARE TVT™ Obturator System Tension-Free Support for Incontinence now backed by 5 years of follow-up data.<sup>1</sup>

### Time tested

Sustainable success demonstrated in two 5-year follow-up studies.<sup>1,2</sup>

- Serati 5-year outcomes:<sup>1\*</sup>
  - 90% objective and subjective cure rate
- Cheng 5-year outcomes:<sup>2</sup>
  - 92% cured
  - No difference between year 1 and 5

### Outcomes you can trust

- GYNECARE TVT Obturator System has been evaluated in 63 RCTs<sup>3</sup>
- Patients treated with GYNECARE TVT Obturator System had lower rates of urinary obstruction/retention and urinary tract infection, leading to overall lower rates of the urological complications studied<sup>4†</sup>



## With the GYNECARE TVT ABBREVO® Continence System you can be confident that you are delivering consistent efficacy with less mesh.<sup>5</sup>

### Less mesh, same tension-free support<sup>5</sup>

- Similar initial fixation with a 12cm mesh compared to a full length obturator mesh, based on a cadaver study<sup>5</sup>
  - Mesh reaches 3 key anatomic structures to provide sufficient support<sup>‡</sup>
- 84% less mesh in adductor magnus muscle<sup>6</sup>
- 38% less implanted mesh<sup>6</sup>



### Comparable to a full length sling

A modified obturator system (similar to GYNECARE TVT ABBREVO System) was shown to be as safe and effective as GYNECARE TVT™ Obturator System Tension-free Support for Incontinence, according to a 3-year randomized controlled trial.<sup>7</sup>

- 89% objective and 84% subjective cure rate
- 35% fewer patients experienced groin pain immediately after surgery<sup>§</sup>
- 50% reduction of immediate post-op pain and severity on day 0 and 1<sup>§</sup>

\* In a 5-year prospective observational study, where 191 women were treated with GYNECARE TVT Obturator System

† In a 5-year analysis of 9,754 women treated with various brands of obturator slings

‡ Obturator membrane, obturator internus, and obturator externus

§ Pain was assessed using a visual analog scale (VAS) graded from 0 to 10; 0 corresponds to absence of pain; 10 corresponds to the worst pain