



Choose GYNECARE TVT™  
Family of Products for  
Outcomes Surgeons Trust



Your choice in obturator slings...

# GYNECARE TVT™ Obturator System

Tension-Free Support for Incontinence  
now backed by 13 years of follow-up  
data<sup>1</sup>.

## Time tested

Sustainable success demonstrated in two studies ranging from 5 to 13 years.<sup>1,2</sup>

- 13-year outcomes as reported by Serati et al. (2020)<sup>1\*</sup>
  - 90% objective and 95% subjective cure rate
- 5-year outcomes as reported by Cheung et al. (2014)<sup>2</sup>
  - 95% of women reported they were either cured or experienced improvement.
- 83% of women achieved complete objective cure.<sup>£</sup>

## 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>



\*In a 13-year prospective observational study where 168 women were treated with the Gynecare TVT™ Obturator System

£ Women showed no urine leakage during standardized urodynamic testing, including the cough stress test

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

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, similar tension-free support<sup>5</sup>

12 cm length is sufficient without risk to obturator nerve compared to a full length obturator sling, based on a cadaver study<sup>5</sup>

- Mesh reaches 3 key anatomic structures to provide sufficient support<sup>‡</sup>
- 32% less implanted mesh<sup>6</sup>

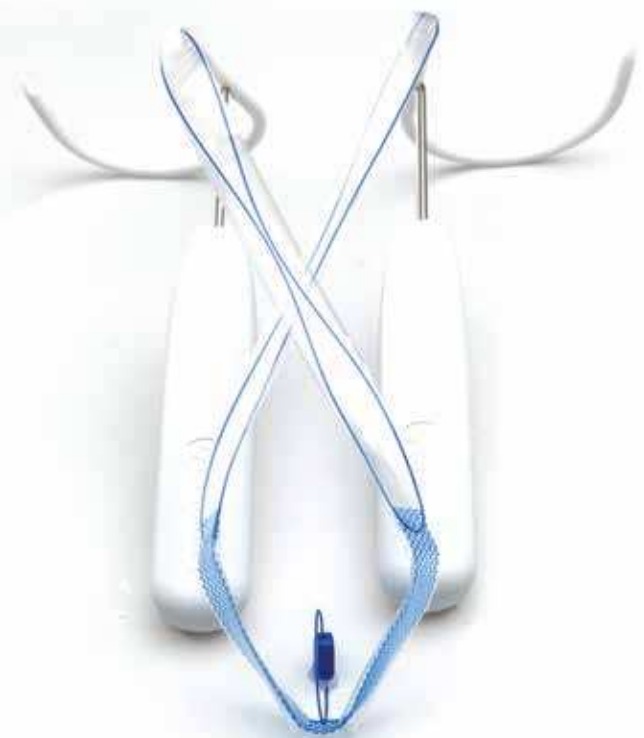
### Comparable to a full length sling

According to a 3-year randomized controlled trial, the Gynecare TVT Abbrevio™ was shown to be as safe and effective as the Gynecare TVT-O in treating stress urinary incontinence in women.<sup>7</sup>

- 87% objective and 94% subjective cure rate
- Demonstrated significantly lower postoperative groin pain, with only 1% of patients experiencing discomfort.

In another prospective, 3-year study of the TVT-ABBREVO procedure.<sup>8</sup>

- No serious late complications or groin-thigh pain were reported<sup>§</sup>



‡ Obturator membrane, obturator internus, and obturator externus

§ Pain was assessed using visual analog scale VAS  $\geq 5$ .

## Your choice in retropubic slings...

# GYNECARE TVT™ Retropubic System

Tension-Free Support for Incontinence  
now backed by 17 and 20 years of follow-up  
data, more than any other slings on  
the market.<sup>9,10</sup>

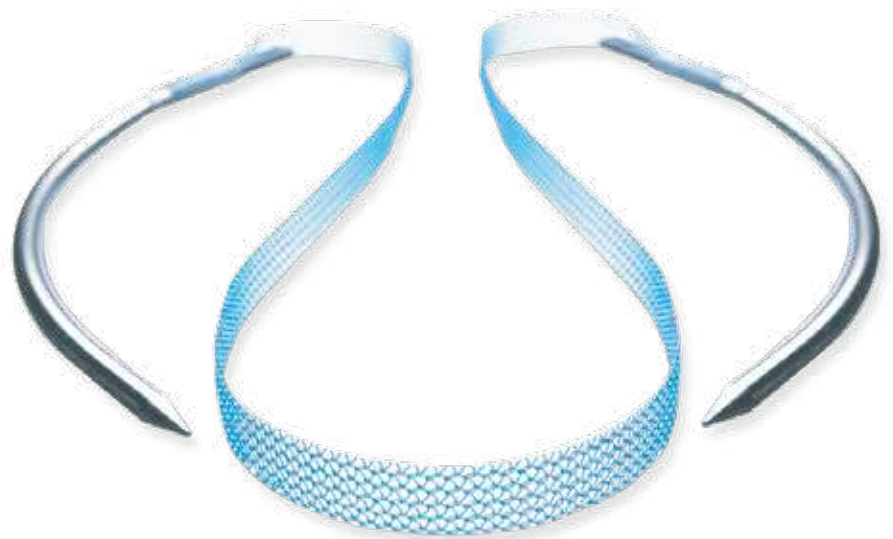
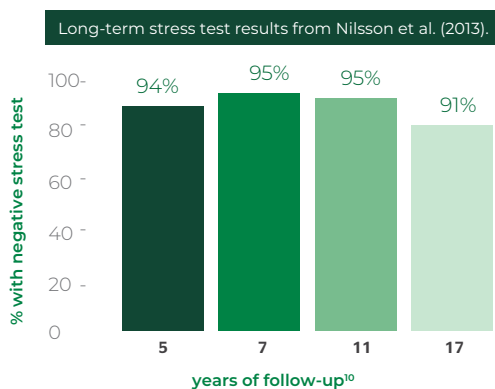
## Time tested

Durable success proven in a 20-year follow up study;  
the longest of it's kind.\*

- No significant decline in subjective and objective cure rates over time.<sup>9</sup>
- At 20-year follow-up:  
89% of patients were subjectively cured 92% were objectively cured.<sup>9</sup>
- At 17-year follow-up by Nilsson et al. (2013):  
87% of women regarded themselves as cured or significantly better  
and 91% were objectively cured.<sup>10</sup>

## Proven outcomes you can trust

- In a 5 year analysis of 6,361 patients treated with various brands of retropubic slings, GYNECARE TVT™ System had significant lower rates of urinary obstruction/retention.<sup>11</sup>
- GYNECARE TVT™ Retropubic System has been evaluated in over 100 RCTs.<sup>12</sup>

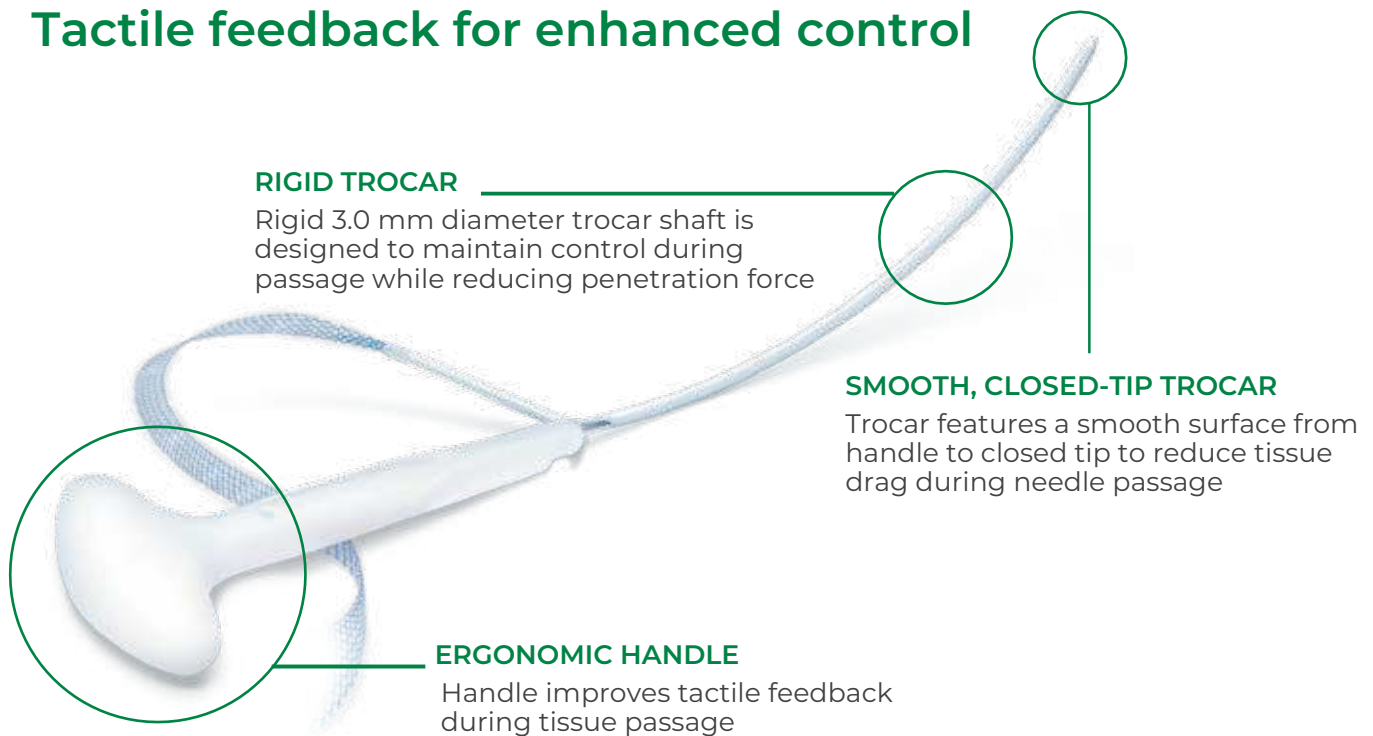


\* In a bicenter, prospective analysis of 52 women. At the 20-year follow-up, 36 out of the original 52 patients (69.2%) were available for evaluation.



# GYNECARE TVT EXACT™ Contenance System built upon many years of GYNECARE TVT™ 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™ Contenance System are the same and designed so that the trocar maintains contact with posterior aspect of the pubic bone.<sup>14</sup>
- The Design of GYNECARE TVT™ with retropubic bottom to top approach has demonstrated significantly lower perforation and voiding dysfunction rate vs. top to bottom.<sup>12</sup>
- Laser-cut mesh.<sup>13</sup>



For more information visit [calderamedical.com](https://calderamedical.com)

#### GYNECARE TVT™ FAMILY OF PRODUCTS 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 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 as sub-urethral slings for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic 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.

##### WARNING 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, 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.

##### 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

**Consult your doctor to discuss the potential benefits and risks of your treatment options and whether PROLENE™ mesh is appropriate for you. For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.**

##### REFERENCES:

1. Serati, M., Braga, A., Caccia, G., Torella, M., Ghezzi, F., Salvatore, S., & Athanasios, S. (2020). TVT-O for treatment of pure urodynamic stress urinary incontinence: Efficacy and adverse effects at 13-years follow-up. *Neurourology and Urodynamics*, 39(5), 1423-1429.
2. Cheung, R. Y., Chan, S. S., Yiu, K. W., & Chung, T. K. (2014). Inside-out versus outside-in transobturator tension-free vaginal tape: A 5-year prospective comparative study. *International Journal of Urology*, 21(1), 74-80. doi:10.1111/iju.12196
3. Published Sling Data Analysis. March 2013. Ethicon, Inc.
4. Magee G, Roy S, Hinojui 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):329-40. doi: 10.1615/longtermeffmedimplants.2013007383. PMID: 23662664.
5. Hubka, P., Nanku, O., Masata, J., Martani, A., & Svabik, K. (2016). TVT ABBREVO: cadaveric study of tape position in foramen obturator and adductor region. *International Urogynecology Journal*, 27(7), 1047-1050. <https://doi.org/10.1007/s00192-015-2822-3>
6. Kurian, A., Narang, S., Han, H.C. Tension-free vaginal tape-Abbrevio procedure for female stress urinary incontinence: a prospective analysis over 22 months. *Singapore Med J*. 2017 Jun;58(6):338-342. doi: 10.11622/smedj.2016149. Epub 2016 Sep 9. PMID: 27609506; PMCID: PMC5474530.
7. Zullo, M. A., Schiavi, M. C., Luffarelli, P., Prata, G., Di Pinto, A., & Oliva, C. (2020). TVT-O vs. TVT-Abbrevio for stress urinary incontinence treatment in women: a randomized trial. *International Urogynecology Journal*, 31(4), 703-710.
8. Braga, A., Caccia, G., Ruggeri, G., Regusci, L., Papadia, A., & Serati, M. (2020). 3-Year follow-up of tension-free vaginal tape—ABBREVO procedure for the treatment of pure urodynamic stress urinary incontinence: efficacy and adverse effects. *International Urogynecology Journal*, 31(4), 739-744.
9. Braga, A., Caccia, G., Papadia, A., Castronovo, F., Salvatore, S., Scancarello, C., Torella, M., Ghezzi, F., & Serati, M. (2022). The subjective and objective very long-term outcomes of TVT in the COVID era: A 20-year follow-up. *International Urogynecology Journal*, 33, 247-253. <https://doi.org/10.1007/s00192-022-05949-9>
10. Nilsson, C. O., 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. *International Urogynecology Journal*, 24(8), 1265-1269.
11. Magee, G., Roy, S., Hinojui, P., Moretz, C., Kozarev, R., Waters, H., & Whitmore, K. (2012). A Real-World Comparative Assessment of Complications Following Various Mid-Urethral Sling Procedures for the Treatment of Stress Urinary Incontinence. *Journal of Long-Term Effects of Medical Implants*, 22(4), 329-340.
12. Ford, A.A., Rogerson, L., Cody, J.D., Aluko, P., Ogah, J.A. Mid-urethral sling operations for stress urinary incontinence in women. *Cochrane Database Syst Rev*. 2017 Jul 31(7):CD006375. doi:10.1002/14651858.CD006375.pub4. PMID: 28756647; PMCID: PMC6483329.
13. LC Mesh Test. 2005. Ethicon, Inc.
14. GYNECARE TVT EXACT™ Continence System Instructions for Use. Somerville, NJ: Ethicon, Inc.

# ORDERING INFORMATION

All customers can place an order by emailing [sales@calderamedical.com](mailto:sales@calderamedical.com).

Code	Item Description
810041B	GYNECARE TVT™ Retropubic System, Blue Mesh
810041BL	GYNECARE TVT™ Retropubic System, Blue Laser Cut Mesh
810051	GYNECARE TVT™ Introducer Handle, Reusable
810061	GYNECARE TVT™ Rigid Catheter Guide, Reusable
810041A	GYNECARE TVT™ with ABDOMINAL GUIDES (Suprapubic)
TVTRL	GYNECARE TVT EXACT™, Blue Laser Cut Mesh
810081	GYNECARE TVT™ Obturator System, Blue Mesh
810081L	GYNECARE TVT™ Obturator System, Blue Laser Cut Mesh
810041	GYNECARE TVT™ Retropubic System, UNDYED mesh
830041	GYNECARE TVT™ Retropubic System, UNDYED mesh (Box of 3)
830041B	GYNECARE TVT™ Retropubic System, Blue Mesh (Box of 3)
830041BL	GYNECARE TVT™ Retropubic System, Blue Laser Cut Mesh (Box of 3)
TVTOML	GYNECARE TVT ABBREVO™, Blue Laser Cut Mesh

\*Product availability may vary by country. Please check with your distributor to confirm.

