GYNECARE TVT EXACT® Continence System

This information is intended as an overview only.

Please refer to the INSTRUCTIONS FOR USE included with this device for indications, contraindications, warnings, precautions and other important information about GYNECARE TVT EXACT® Continence System.
Key Steps

The goal is to pass safely through the retropubic space by staying close to the pubic bone.
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Patient Prep Steps 1-4

STEP 1: Mark the exit points and inject suburethral local anesthesia

- Place patient in dorsal lithotomy avoiding hip flexion greater than 60°
- Insert 18 French Foley catheter and leave it to drain
- Inject local anesthesia submucosally at the level of the mid urethra
  **Note:** This creates a space between the vaginal wall and the periurethral fascia

STEP 2: Perform dissection

- Make a sagittal incision no more than 1.5 cm long starting at 1.0 cm cephalad from the urethral meatus
  **Note:** This incision is positioned over the mid urethra and will allow for subsequent passage of the Implant
- Make two 0.5 to 1.0 cm paraurethral lateral dissections to accommodate the tips of the Trocar Sheaths
- Locate the reference exit points which are 2 cm on each side of the midline, immediately above the pubic symphysis
  **Note:** The position of the exit points helps avoid the inferior epigastric vessels
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Patient Prep Steps 1-4

STEP 3: Perform retropubic hydrodissection

- Start at the needle exit sites and pass an 18 gauge spinal needle along the back of the pubic symphysis until the needle touches the endopelvic fascia
- Inject 30-50 cc of saline (or local anesthesia) on each side
  
  Note: Hydrodissection opens up the retropubic space to further minimize risk of bladder puncture during retropubic Trocar passage

STEP 4: Displace bladder and prepare product

- Confirm the bladder is empty
- Insert the GYNECARE TVT Reusable Rigid Catheter Guide into the channel of the 18 French Foley catheter
- Secure the Trocar Sheath to the Trocar Handle by hooking the Trocar Sheath Cut-out onto the Trocar Sheath Lock on the Trocar Handle
- Gently push the tip of the catheter toward the posterior lateral wall of the bladder opposite to the intended Trocar Sheath passage
- Place the Trocar Shaft inside one of the two white Trocar Sheaths
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Patient Prep Steps 5-7

STEP 5: Pass through dissected space

- Use the dominant hand to hold the Trocar Handle
- Use the non-dominant hand to control initial insertion of the device by placing index finger under the anterior vaginal wall, just lateral of the suburethral incision
- Orient the Trocar Sheath Tip horizontally in the frontal plane during the initial submucosal passage in the paraurethral dissected space
- Pass the Tip of the Trocar Sheath until it reaches the end of the dissected space

STEP 6: Perforate urogenital diaphragm

- During perforation of the urogenital diaphragm, lower the Trocar Handle to ensure that the Trocar Sheath Tip passes vertically while staying in close contact with the back of the pubic symphysis
  
  **Note:** Care should be taken to avoid placing excessive pressure on the Needle Tip
- Advance the Trocar Sheath Tip through the urogenital diaphragm into the retropubic space
  
  **Note:** Resistance is reduced once the Trocar Sheath Tip enters the retropubic space
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**Patient Prep Steps 5-7**

**STEP 7: Pass through retropubic space**

- Move the non-dominant hand from the vagina to the suprapubic exit point
- Aim towards the pre-marked abdominal exit sites and advance the Trocar Sheath through the retropubic space

**Note:** Keep the Handle low to ensure that the Trocar Sheath Tip stays in close contact with the pubic symphysis
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Patient Prep Steps 8-11

STEP 8: Complete passage and release trocar sheath

- Advance Trocar Sheath Tip through the rectus muscle and the skin
  **Note:** If desired, make a skin incision at the point where the Trocar Sheath Tip tents the skin
- Grasp exposed Trocar Sheath Tip with a clamp
- Push Trocar Sheath laterally and off the Trocar Sheath Lock and carefully withdraw the Trocar Shaft from within the Trocar Sheath
  **Note:** DO NOT PULL the Trocar Sheath up any further

STEP 9: Repeat steps 5-8 on contralateral side

- Push tip of Foley catheter to displace the bladder to the contralateral side
- Repeat the technique on the contralateral side
STEP 10: Perform cystoscopy

- Remove the 18 French Foley catheter
- Perform a cystoscopy to confirm bladder integrity

STEP 11: Complete implant placement & close

- Pull Trocar Sheaths gently upwards to bring the Implant loosely under the mid urethra
- Adjust the Implant so that leakage is reduced, allowing only a few drops of urinary leakage to occur under stress. For this, use patient feedback, i.e., coughing with a full bladder
- Cut the Implant bilaterally close to the Trocar Sheaths and clamp the Implant Sheath (avoid clamping the Implant)
- Remove each Implant Sheath carefully
- Place blunt instrument (eg. scissors or forceps) between the urethra and Implant to stabilize Implant during Implant Sheath removal
- Make any final Implant adjustments
- Cut ends of the Implant just below skin level
- Close vaginal and abdominal skin incisions
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 sub-urethral 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, 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.
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Essential Product Information

- 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.