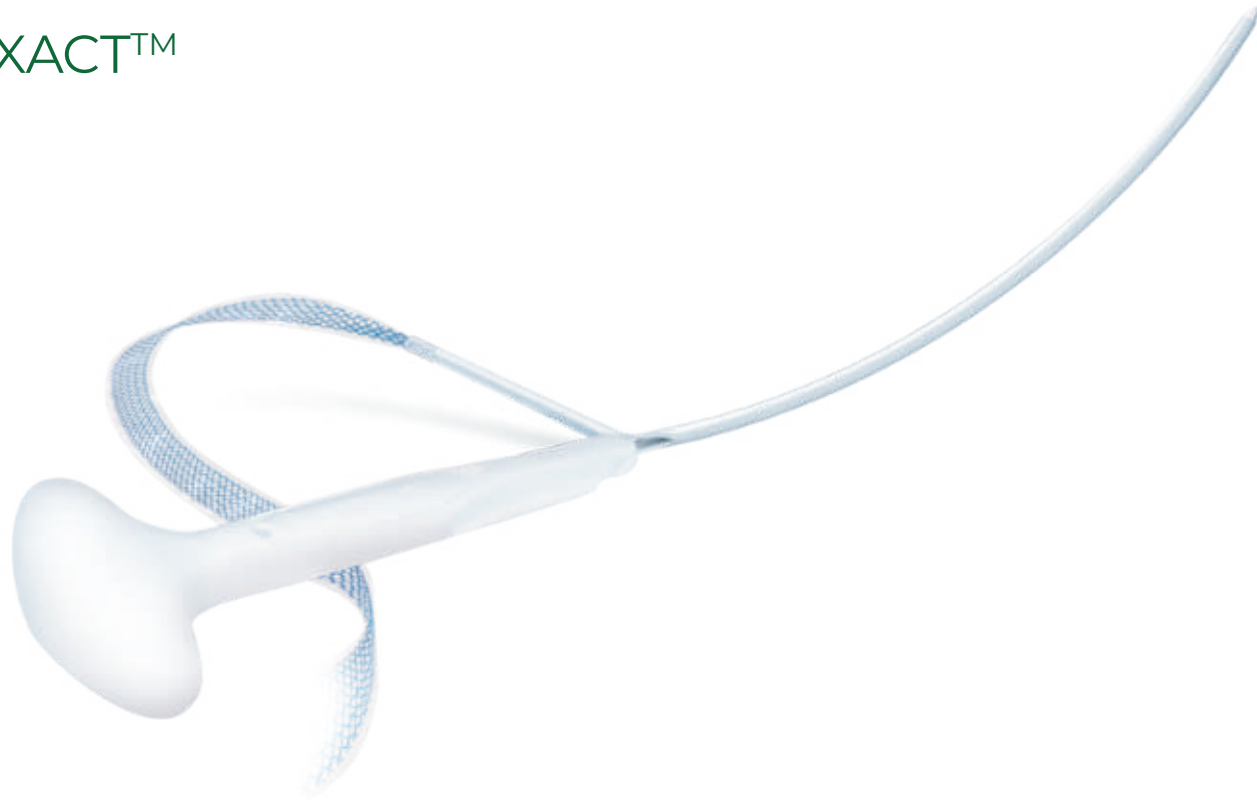

Procedural Guidelines

GYNECARE TVT EXACT™



This information is intended as an overview only.

For complete indications, contraindications, warnings, precautions, and reactions, please reference full package insert.



Rev: 10-545

Key Steps

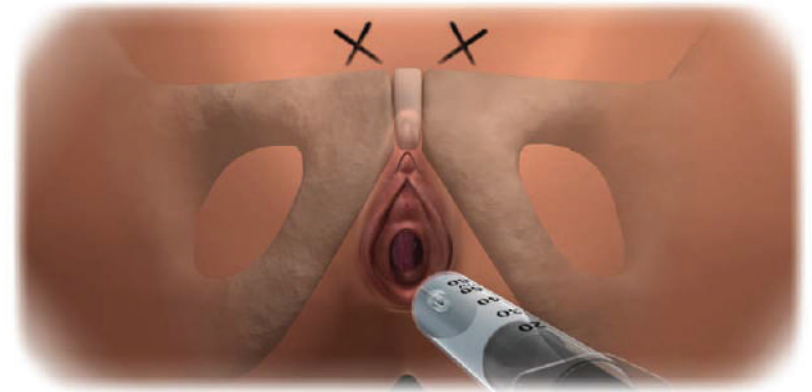
The goal is to pass safely through the retropubic space by staying close to the pubic bone

Patient Prep

Steps 1-4

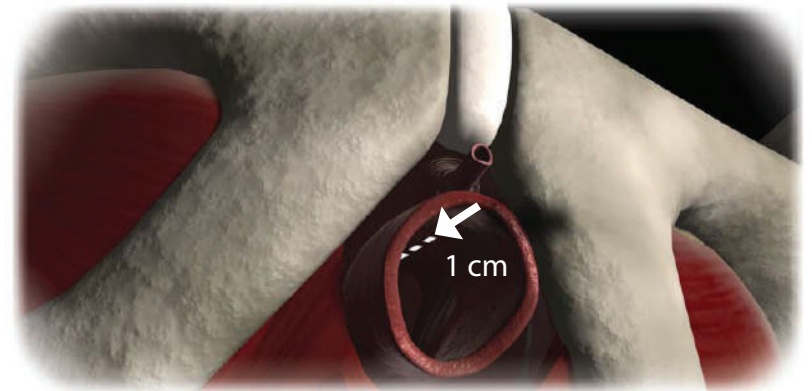
STEP 1: Mark the exit points and inject suburethral local anesthesia

- Before the patient is prepped and draped, she should be placed in the lithotomy position, taking care to avoid hip flexion greater than 60 degrees
- Insert an 18 French Foley catheter into the bladder and leave it to open drainage.
- At the level of the mid-urethra, inject a small amount of local anesthesia submucosally to create a space between the vaginal wall and the peri-urethral fascia.



STEP 2: Perform dissection

- Using a small scalpel, make a sagittal incision no more than 1.5 cm long starting approximately 1.0 cm cephalad from the urethral meatus.
Note: This incision will be positioned over the mid-urethral zone and will allow for subsequent passage of the Implant.
- With a small pair of blunt scissors, make two small para-urethral lateral dissections (approximately 0.5 to 1.0 cm) to accommodate the tips of the Trocar Sheaths.
- Identify the two Trocar Sheath exit sites, which should be 2–2.5 cm on each side of the midline, immediately above the pubic symphysis. Either mark these sites or, if desired, place two small 3–4 mm transverse stab incisions at the intended exit site.



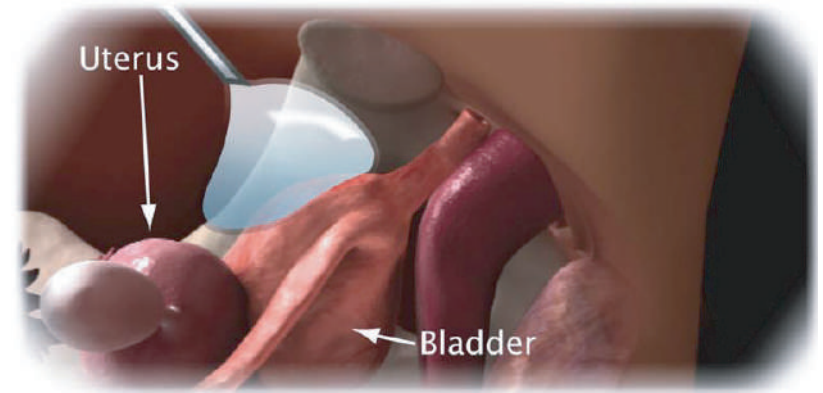
Note: In order to avoid the inferior epigastric vessels, it is important that the intended exit sites be not more than 2.5 cm from the midline. It is important that the exit sites for the Trocar Sheath passages be near the midline and close to the superior aspect of the pubic bone in order to avoid anatomic structures in the abdomen, inguinal area and lateral pelvic sidewall.

Patient Prep

Steps 1-4

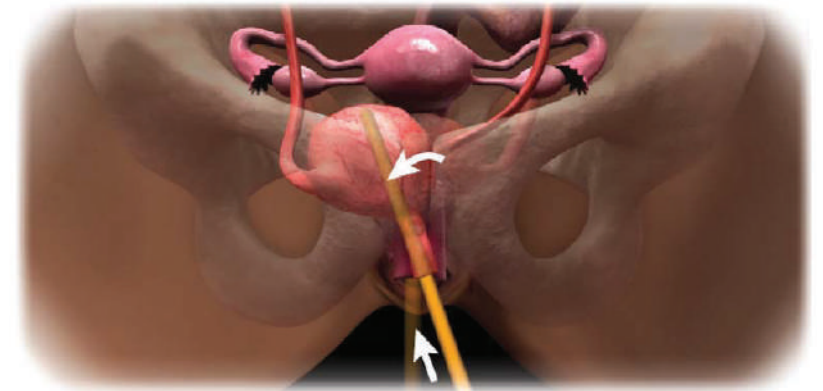
STEP 3: Perform retropubic hydrodissection

- If retropubic infiltration of local anesthesia is not performed then consider infiltrating the retropubic space with two injections of normal saline on either side of midline.
- Starting at the trocar exit sites, pass an 18-gauge needle along the back of the pubic bone until the tip of the needle touches the endopelvic fascia.
- As the needle is withdrawn, inject 30 to 50 mL.
Note: By so doing, it opens up the retropubic space to further minimize the risk of bladder puncture during retropubic Trocar passage.



STEP 4: Displace bladder and prepare product

- Confirm that all urine has been drained from the bladder.
- Once the bladder is empty, insert the GYNECARE TVT™ Reusable Rigid Catheter Guide (available separately) into the channel of the 18 French Foley catheter.
Note: The handle of the GYNECARE TVT™ Reusable Rigid Catheter Guide should be fixed around the catheter at its proximal end.
- Place the Trocar Shaft inside one of the two white Trocar Sheaths. Secure the Trocar Sheath to the Trocar Handle by hooking the Trocar Sheath Cut-out onto the Trocar Sheath Lock on the Trocar Handle
Note: Ensure that the Trocar Sheath Cut-out goes completely over the Trocar Sheath Lock and is holding the Trocar Sheath on the Trocar Shaft securely. Be careful not to manipulate the Trocar Sheath appendage hanging past the Trocar Sheath Lock during the procedure, as that may result in the unintended disengagement of the Trocar Sheath Lock.
- Using the Rigid Catheter Guide, gently push the tip of the 18 French Foley catheter toward the posterior lateral wall of the bladder opposite to the intended Trocar Sheath passage.

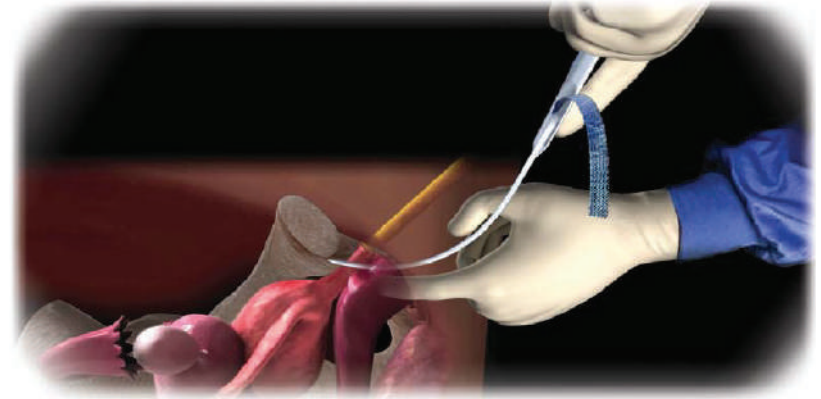


Needle Passage

Steps 5-7

STEP 5: Pass through dissected space

- Hold the Trocar Handle using your dominant hand. Pass the tip of the white Trocar Sheath that has been mounted on the Trocar Shaft para-urethrally through the urogenital diaphragm at the level of the mid-urethra.
- Initial insertion of the device is controlled by using the tip of the index finger of the non-dominant hand, which is placed in the vagina under the anterior vaginal wall, just lateral to the sub-urethral incision. The curved part of the Trocar Shaft should rest in the palm of the non-dominant hand.
- Pass the Trocar Sheath through the urogenital diaphragm into the retropubic space. During the initial placement into the para-urethral dissected space, the Trocar Sheath tip should be oriented horizontally, i.e., in the frontal plane.
- Pass the Tip of the Trocar Sheath until it reaches the end of the dissected space



STEP 6: Perforate urogenital diaphragm

- During passage through the urogenital diaphragm, lower the Trocar Handle to ensure that the Trocar Sheath Tip passes vertically while staying in close contact to the back of the pubic symphysis.
- 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

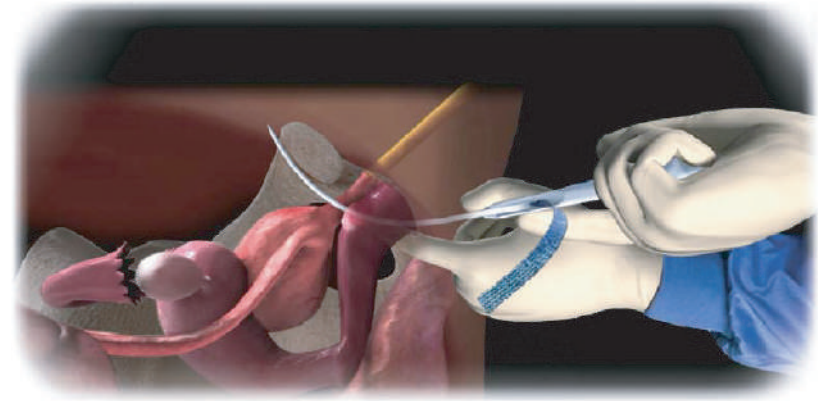


Needle Passage

Steps 5-7

STEP 7: Pass through retropubic space

- Move the non-dominant hand from the vagina to the suprapubic exit point
- Guide the Trocar Sheath tip through the retropubic space staying as close to the back of the pubic symphysis as possible. This is achieved by lowering the Trocar Handle, thereby pressing the Trocar Sheath tip against the back of the pubic bone.
- During passage through the retropubic space, aim the Trocar Sheath tip towards the pre-marked abdominal exit site

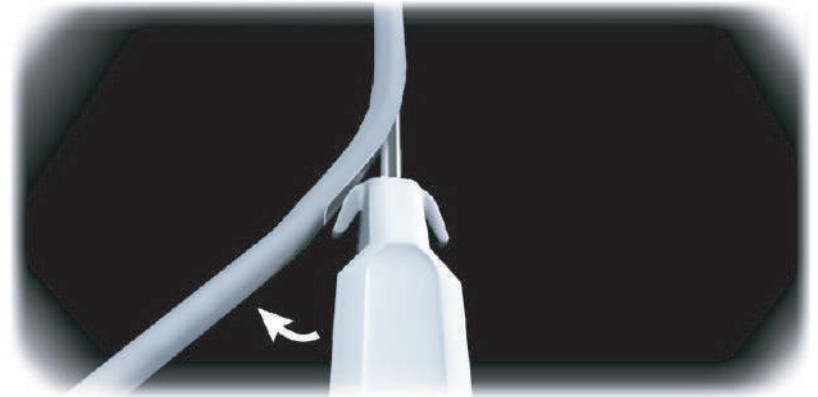


Complete Procedure

Steps 8-11

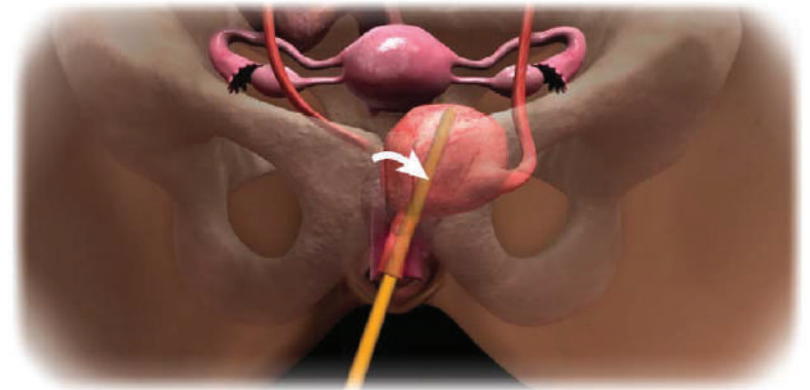
STEP 8: Complete passage and release trocar sheath

- Move the Trocar Sheath tip upwards toward the abdominal skin exit sites, keeping in close contact with the pubic bone until exiting the skin.
- Once the Trocar Sheath tip exits the skin, grasp the exposed Trocar Sheath tip with a clamp
- Release the Trocar Sheath from the Trocar Sheath Lock on the Trocar Handle by pushing the Trocar Sheath appendage 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.
Note: IN ORDER TO MINIMIZE THE RISK OF BLADDER INJURY, IT IS IMPORTANT THAT THE BLADDER NOW BE DISPLACED TO THE CONTRALATERAL SIDE USING THE MANEUVERS OUTLINED IN STEP 4.
- Repeat the technique on the contralateral side

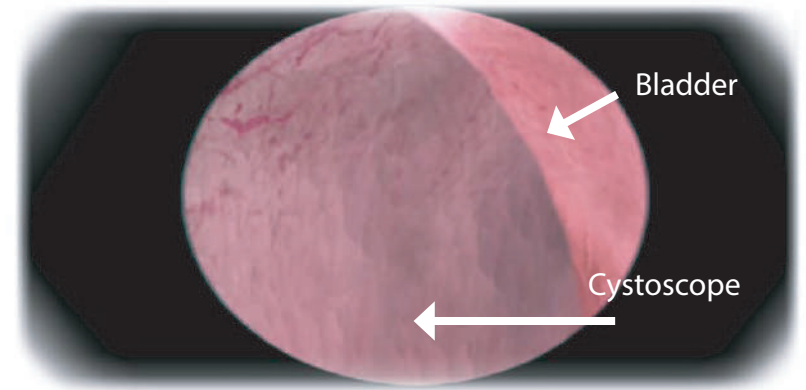


Complete Procedure

Steps 8-11

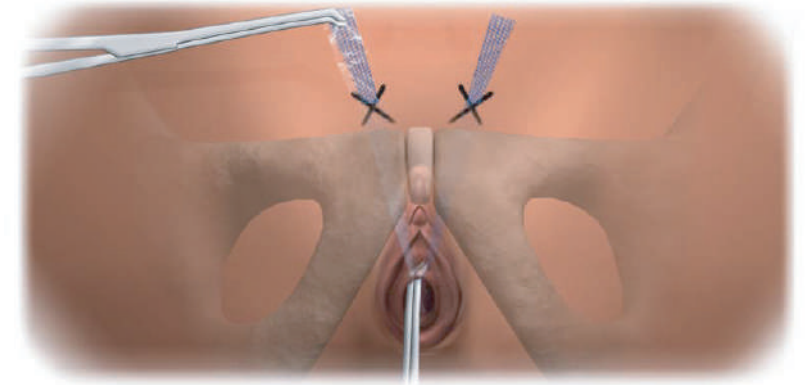
STEP 10: Perform cystoscopy

- Once both white Trocar Sheaths have been passed and before the Implant is pulled into place, remove the 18 French Foley catheter and perform a cystoscopy (70 degree lens recommended).
- Perform a cystoscopy to confirm bladder integrity



STEP 11: Complete implant placement & close

- Gently pull the Trocar Sheaths upward to bring the Implant loosely (i.e., without tension) 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. In case of general anesthesia, verify tension of the tape exerting manual pressure on the suprapubic area with a full bladder (approximately 300 mL).
- Grasp the Implant Sheaths that surround the Implant with clamps, taking care not to grasp the Implant. Then individually remove the Implant Sheaths by gently pulling up on the clamps, away from the abdomen, one at a time.
- To avoid putting tension on the Implant, a blunt instrument (scissors or forceps) should be placed between the urethra and the Implant during removal of the Implant Sheaths.
NOTE: Premature removal of the Sheaths may make subsequent adjustments difficult.
- After proper adjustment of the Implant, close the vaginal incision. The abdominal ends of the Implant are then cut and left in the subcutis; do not suture the Implant.
- Close the skin incisions with suture or surgical skin adhesive.



For indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

Please refer always to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.

Reference: 1. Gynecare TVT Exact. Instructions for Use.