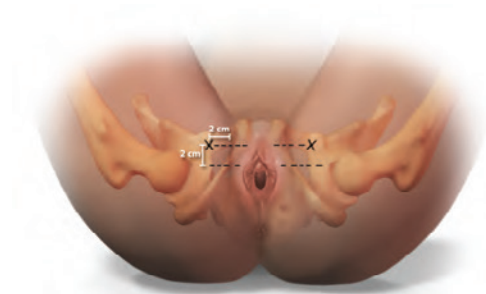


# GYNECARE TVT™ Obturator System

Tension-free Support for Incontinence

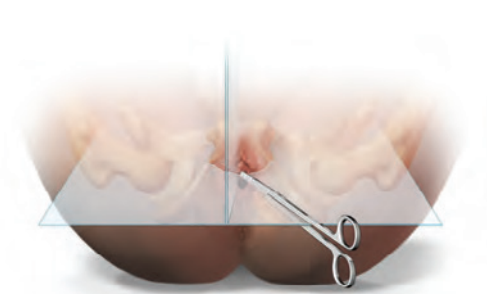
## Key Steps

The goal is to keep the point of the needle as close to the bone as possible using the “Pop, Stop, Drop, Rotate, and Hug the Bone” Key Steps



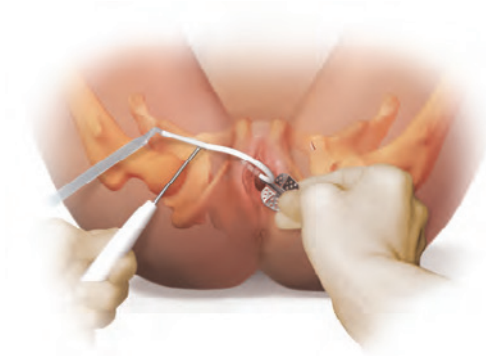
### STEP 1: Position Patient, Mark Exit Points, and make Vaginal Incision

- Place patient in dorsal lithotomy with hips hyperflexed to patient's comfort with the coccyx flush to the edge of the table. Insert a urethral catheter into the bladder and empty the bladder.  
**Note:** This positioning ensures proper clearance to allow the handle to drop.
- Locate the reference exit points first by tracing a horizontal line at the level of the urethral meatus, and a second line parallel and 2 cm above the first line.
- Mark the reference skin exit points on this second line, 2 cm lateral to the folds of the thigh. Do not make incisions at this point.
- Using Allis clamps for traction, make a 1 cm midline vaginal incision starting at 1 cm proximal to the urethral meatus.



### STEP 2: Dissect

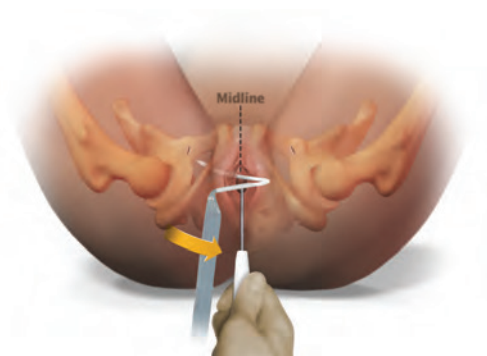
- Initiate using sharp dissection.
- With the scissors oriented on the horizontal plane, dissect from the vaginal incision using a “push-spread” technique to the inferior pubic ramus.
- Stop dissection after the obturator membrane has been perforated.



### Pop and Stop

### STEP 3: Insert the Safety Winged Guide and Helical Passer

- Insert the Safety Winged Guide into the dissected track and just through the obturator membrane.
- Insert the Helical Passer inward along the Winged Guide until you just **Pop** through the obturator membrane with the Helical Passer. Immediately **Stop** insertion of the Helical Passer once tactile feel confirms the membrane has been penetrated.
- Once in this position, remove the Safety Winged Guide.



### STEP 4: Drop the handle towards Midline

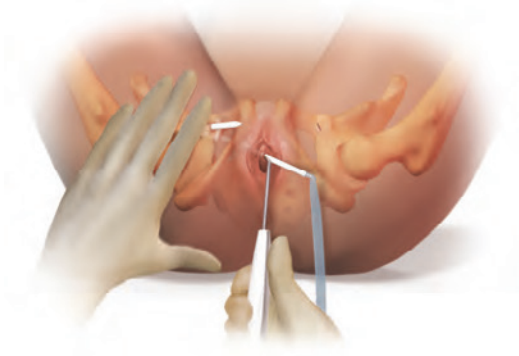
- Take care not to advance the needle tip.
- Reposition the handle of the Helical Passer by **Dropping** it towards the midline until the handle is nearly vertical to the floor.



## Rotate and hug the bone

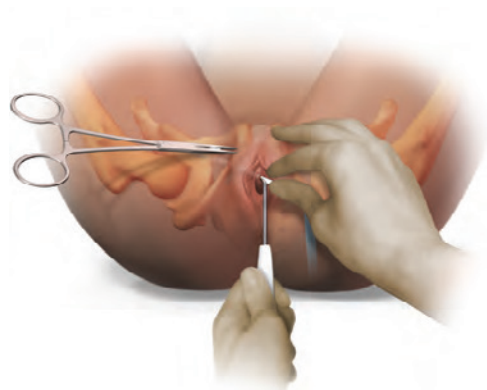
### STEP 5: Rotate the Helical Passer

- **Rotate** the Helical Passer and **Hug the Bone** (ischo-pubic ramus), until the skin is tented.  
**Note:** Hugging the ischo-pubic ramus will aid in reproducible passage through the obturator foramen.



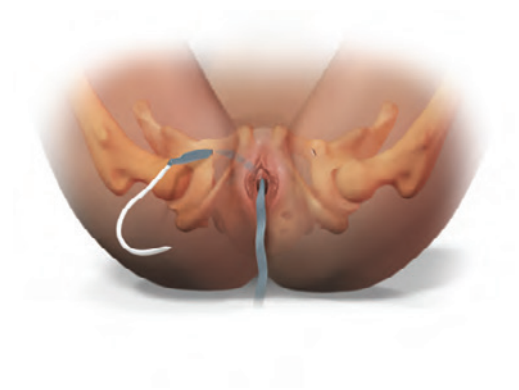
### STEP 6: Pass through Skin

- Stabilize the skin.  
**Note:** The point of the Helical Passer may exit medially to the previously marked reference exit points. Under no circumstances should the Helical Passer exit laterally to the previously marked reference skin exit points.
- Make skin incision at the point where the tip of the helical passer tents the skin.
- Fully rotate the helical passer until the tip of the plastic tube appears at the skin.



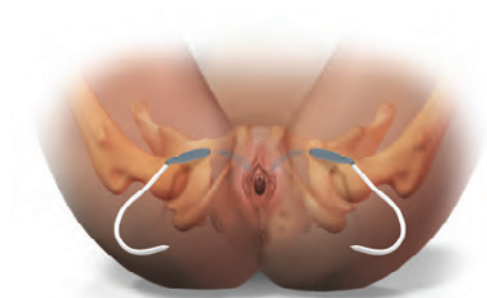
### STEP 7: Removal of the Helical Passer

- Grasp the extreme point of the exposed tip with a clamp.
- Stabilize the tube near the urethra and remove the Helical Passer with a reverse rotation of the handle.



### STEP 8: Pull Plastic Tube

- Pull the plastic tube completely through the skin until the tape appears.



### STEP 9: Repeat Steps 2-8 on Patient's Other Side

- Repeat the technique on the patient's other side.
- Ensure that the mesh lies flat under the urethra.



### STEP 10: Remove Sheath, Adjust Tension, Close

- Place a suitable blunt instrument (eg, scissors or forceps) between the urethra and the mesh or other suitable means to avoid positioning the mesh with tension.
- Sequentially remove each plastic sheath carefully.
- Make final mesh adjustment.
- Cut the ends of the tape at skin level.
- Close vaginal and skin incisions.

**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 the GYNECARE TVT™ Obturator System.**