UroCure

ArcTO™

TRANSOBTURATOR SLING SYSTEM

INSTRUCTIONS FOR USE

www.urocure.com/IFU

This IFU should be reviewed in its entirety by the physician user before performance of the procedure.

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1 INTENDED USE/INDICATIONS FOR USE

℞Only **CAUTION!** Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING! This product is intended for use only by physicians with adequate training and experience in the surgical treatment of stress urinary incontinence (SUI). The physician must be credentialed by the surgical facility for performance of this procedure. The physician is advised to know and understand the current FDA recommendations, the current AUGS and/or SUFU recommendations and the medical literature regarding indications, patient counseling and consent, technique, risks and benefits, complications and their management associated with the transobturator use of polypropylene surgical mesh and the mid-urethral sling procedure.

WARNING! Concerning Device Sterility
Contents supplied sterile using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, report the damage to UroCure and do not use.

This product is for single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury, illness, or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

After use of the device, dispose of all remaining product and packaging in accordance with applicable hospital, administrative and/or local government policy.

Indications for Use

The ArcTO Transobturator Sling System is indicated to be placed at the mid-urethra for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Contraindications

- Do not implant the ArcTO sling in patients with:
  - pre-existing conditions that pose an unacceptable surgical risk.
  - any anatomic abnormality or variation which would significantly compromise implant placement
  - any soft tissue pathology into which the implant is to be placed.
  - any pathology, such as vascular limitations or infections, or medications that would significantly compromise healing.
  - sub-urethral areas with active infection or signs of tissue necrosis.
  - conditions prone to excessive scarring such as keloids
  - urinary, vaginal or local skin infection
  - an untreated, clinically significant coagulopathy
  - a known sensitivity or allergy to polypropylene.
  - pediatric patients
  - pregnant patients or patients that are considering future pregnancies

2 GENERAL WARNINGS AND PRECAUTIONS

- It is the responsibility of the physician to advise prospective patients and their representatives, prior to surgery, of the warnings, precautions and adverse events associated with the use of this product.
  – A thorough assessment of each patient should be made to determine the suitability of a polypropylene sling procedure for that patient.
  – The patient should be counseled that alternative incontinence treatments may be appropriate, and the reason for choosing a polypropylene sling procedure should be explained.
  – Patient consent should be obtained prior to surgery and the physician should ensure that the patient understands the postoperative risks and adverse events associated with the placement of a polypropylene sling.

- The ArcTO sling should only be used by a physician trained in the clinical indications and limitations of slings, the use of polypropylene slings for the surgical treatment of stress urinary incontinence and detailed knowledge of the transobturator space for the placement of mid-urethral sling devices. The surgeon should be familiar with the specific steps for ArcTO sling implantation, including transobturator needle passage and the placement of polypropylene slings before placing the ArcTO sling.

- The use of a polypropylene sling in urogynecologic procedures such as the treatment of stress urinary incontinence, regardless of the route of delivery (transvaginal, suprapubic or transobturator), has been associated with cases of erosion. Mesh erosion into the bladder, urethra, ureter, and bowel has been reported. Mesh extrusion into the vagina has been reported. Treatment of the mesh erosion or mesh extrusion may require surgical removal.

- A polypropylene sling is considered a permanent implant. Adverse events from an implanted sling may require additional surgical interventions that may include removal of a portion of or the entire sling.

- Removal of a polypropylene sling or correction of sling related complications may involve multiple surgeries. Complete removal of the sling may not be possible and additional surgeries may not fully correct the complications.

- Regardless of the level of surgeon's experience or technique, the risks from adverse events and related complications caused by polypropylene slings cannot be eliminated.

- As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), prior pelvic procedures, or active infection in or near the surgical site. The above pathophysiologic conditions must be considered when determining whether the patient is an appropriate candidate for polypropylene sling implantation by a TO route.

- The risks and benefits of performing the ArcTO procedure should be carefully considered for patients:
  – with untreated coagulopathies or who are being treated with anticoagulants or antiplatelet agents.
  – with compromised immune systems or any other conditions that would compromise healing
  – with renal insufficiency or upper urinary tract obstruction
  – with hypertonic bladders or vesicoureteral reflux
  – with poor bladder emptying

  – who have had previous incontinence surgery
  – who have had prior pelvic radiation
  – with a pre-existing history of pelvic, bladder, vaginal, abdominal, groin or lower extremity pain
  – who are undergoing concomitant pelvic floor surgery
  – who have anatomical distortion caused by bladder prolapse
  – who have co-morbidities that may exacerbated by placement of patients in the dorsal lithotomy position.

- Prophylactic antibiotics should be administered according to the physician's usual practice for implant surgery.

- Local skin, vaginal or urinary tract infection should be treated and resolved prior to the ArcTO sling procedure. The procedure should not be performed in the presence of a urinary, vaginal or groin skin infection adjacent to and/or including the site of placement of the ArcTO introducer needle.

- Acute inflammatory tissue reaction and transitory local irritation has been reported with the use of absorbable suture in the vagina or abdomen.

- The ArcTO sling is not indicated for the treatment of overactive bladder, urinary retention or other voiding dysfunction.

- Urgency incontinence symptoms may appear de novo, worsen, remain unchanged, improve or resolve after sling placement.

- The surgical risks associated with the use of ArcTO sling require understanding by a qualified surgeon who is knowledgeable of this device and the mid-urethral sling procedure and the complications associated with the use of this device and the mid-urethral sling procedure.

2.1 PROCEDURAL WARNINGS

- The ArcTO sling should only be used with an "outside-in" transobturator approach. Do not use the ArcTO sling with any other surgical approach than the one described in this IFU.

- Omitting the skin incisions may require excessive force to perforate the skin with the delivery instruments and may cause device malfunction and injury to the patient.

- Take care to avoid perforation of blood vessels during needle placement. Observe patient for any signs of bleeding.

- Transobturator placement of midurethral slings are associated with a higher risk of long-term groin/thigh pain and dyspareunia in comparison with other mid-urethral slings placed by other methods.

- Take care to avoid damage to nerves, urethra, vaginal wall, bladder, pubic bone or bowel during needle placement.

- In the case of perforation of the urethra or organs adjacent to the bladder, the procedure should be terminated without sling implantation.

- Cystoscopy should be performed after needle placement to confirm bladder and urethral integrity and to detect if bladder or urethral perforation has occurred.

- The ArcTO sling should be placed tension-free under the mid-urethra. Verify mid-urethral and tension-free placement prior to vaginal closure. Improper placement or excessive tension may cause temporary or permanent urinary obstruction and retention. Improper placement may also lead to continued incontinence due to incomplete support.
- Do not remove the plastic sheaths until the ArcTO sling is in its desired position. Once the sheaths are removed, major adjustments of the sling are difficult.
- The plastic sheaths must be removed fully from the patient prior to completion of the procedure.
- Avoid excessive tension on the sling during handling.
- Do not allow the ArcTO sling to contact any staples, clips or other instruments as they may damage the sling.

2.2 POST PROCEDURE WARNINGS

- Duration of urinary catheter usage for bladder drainage should be based on physician preference and morbidity of the procedure including bladder perforation and patient co-morbidities.
- Bleeding occurs. Check carefully that the patient is not bleeding before releasing the patient from the hospital.
- The patient should be instructed to contact the physician immediately should she experience fever, dizziness, dysuria, bleeding, any severe pain, and specifically pain in the abdomen, pelvis or lower extremities.
- The patient should be instructed to contact the physician for any symptoms of urinary retention or abnormal voiding patterns.
- The patient can return to normal daily activities at the physician's discretion.
- The physician should instruct the patient about when to safely resume heavy lifting, exercise and sexual intercourse.
- Standard post-surgical practice should be followed for management of infected wounds, with attention to the possibility of sling infection potentially requiring the removal or revision of the ArcTO sling.

NOTE: *The implanted ArcTO sling is MR safe.*

2.3 ADVERSE EVENTS

The following adverse events have been reported due to polypropylene mid-urethral sling placement, but are not limited to:

- Complete failure of the procedure, including worsening of incontinence
- Partial failure resulting in mild to moderate incontinence

- De novo, persistent or worsening overactive bladder and/or detrusor overactivity symptoms, with or without urge incontinence
- Temporary or permanent lower urinary tract obstruction and retention
- Tissue responses to the sling implant include:
  - erosion / exposure / extrusion of the mesh through the vaginal or urethral mucosa, bladder wall or other surrounding tissue and/or other organs
  - scarring / scar contracture / mesh contracture / tissue contraction of vagina or surrounding tissues
  - device migration
  - fistula formation and inflammation
  - dehiscence of vaginal incision
  - vaginal discharge
- An acute or chronic foreign body inflammatory response or infection, which may result in systemic symptoms, pain, damage to adjacent structures, scarring and adhesions.
- Local irritation at the wound site and/or a foreign body response.
- Like all foreign bodies, the polypropylene sling may potentiate an existing infection
- Allergic reaction to the polypropylene sling
- Edema and erythema at the wound site
- Infection (superficial, abscess, systemic sepsis)
- Bleeding (routine surgical, hematoma, hemorrhage)
- Bruising, bleeding, hematoma formation (vaginal, retropubic, abdominal, or thigh)
- Perforation or laceration of vessels, nerves, bladder, urethra or bowel
- Pain (local or regional) that may be acute or chronic
- Pain, ongoing pain (pelvic, bladder, vaginal, groin, thigh, suprapubic, dyspareunia, with voiding)
- Severe chronic pain
- Vaginal shortening or stenosis, which may result in dyspareunia and/or sexual dysfunction
- Loss of sexual function, temporary or permanent, secondary to pain and/or mesh contracture, tissue contracture or scarring; including inability to have intercourse which may not resolve
- Pain or discomfort to the patient's partner during intercourse caused by exposed mesh

If an adverse event from this procedure occurs, report it to UroCure and begin treatment per standard practice. The occurrence of adverse events from this procedure may require additional surgical interventions, including removal of the entire sling. The adverse events may persist as a permanent condition after the surgical intervention(s) or treatment(s). Removal of a portion of or the entire sling and/or attempts to correct the sling or procedure related adverse events may involve multiple surgeries. Complete removal of sling may not be possible and additional surgeries may not always fully correct the adverse events and/or associated symptoms. These additional surgeries are associated with their own unique adverse events.

3 DIRECTIONS FOR USE

3.1 CONTENTS OF THIS BOX AND LABELS

The ArcTO™ Transobturator Sling System is a sterile, single use system consisting of the following:

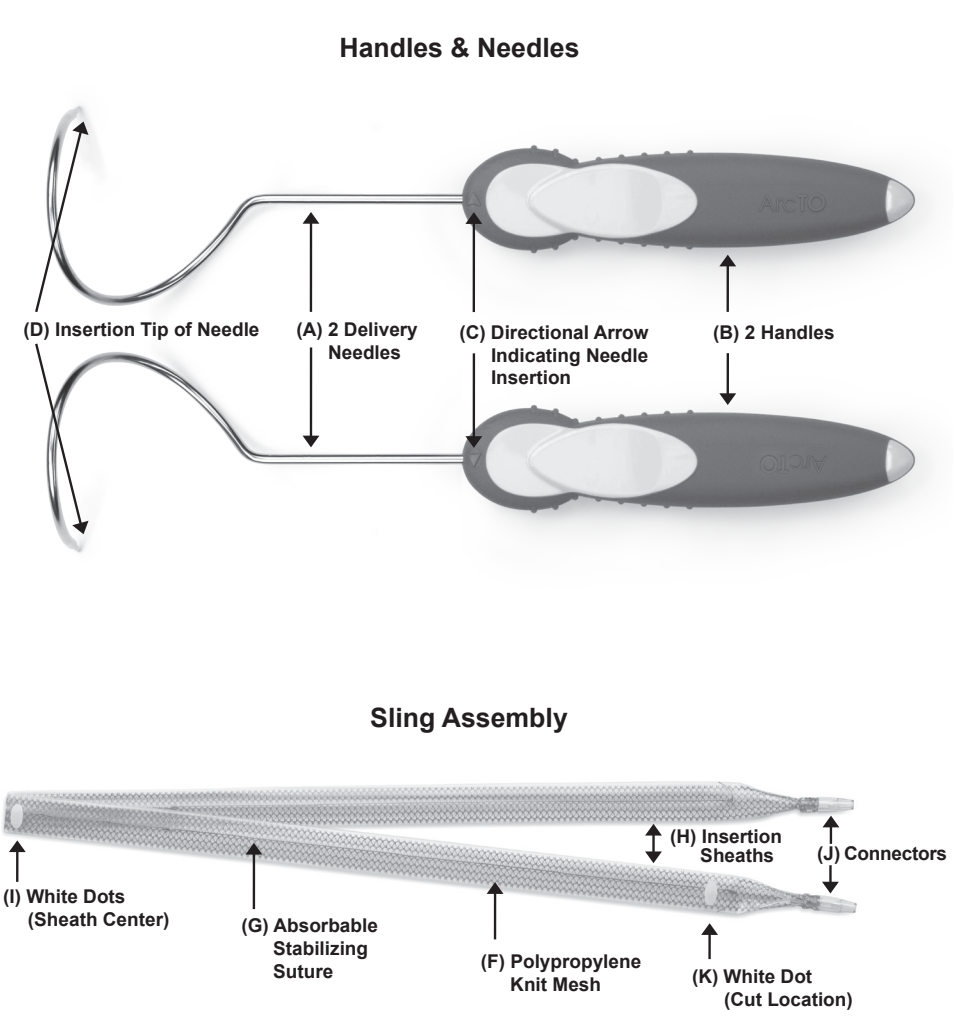

Figure 1: ArcTO Transobturator Sling System Components

NOTE: *Natural rubber latex is not used in the manufacture of any ArcTO sling components.*

3.2 DEVICE DESCRIPTION (see Figure 1)

- Each system contains two delivery needles (A) with integrated handles (B) designed for an outside-in, transobturator needle pass. The needles are specific to placement on the patient's right and left side. The handle has a directional arrow (C) indicating direction of needle passage. Each needle has a connection end at its tip (D) to allow the sling assembly to be securely attached after needle passage.

- The sling is constructed of a polypropylene knit mesh (F) that is 1.1 cm wide by 50 cm long. An absorbable stabilizing suture (G) is threaded into the sling to minimize sling distortion during insertion, placement and tensioning. The two insertion sheaths (H) cover and protect the sling during placement and abut each other in the center, indicated by white dots (I) on each sheath. The connectors (J) are attached to the ends of the delivery needles during the procedure. Two additional white dots (K) identify where to cut the sling after placement to allow the sheaths to be removed.

- The polypropylene sling is intended to remain in the body as a permanent implant. The polypropylene sling is not absorbed or degraded by tissue ingrowth or tissue enzymes. The stabilizing suture is intended for intra-operative purposes only and is absorbed by tissue enzymes.

3.3 OPENING THE BOX AND PREPARING THE DEVICE FOR SURGERY

- Open the box and remove the tray containing the ArcTO Sling System.

- Carefully remove the foil pouch from the top of the tray. Open the foil pouch and remove the clear pouch containing the sterile sling.

WARNINGS – Relating to the Device Prior to Intraoperative Use

- Inspect each component of the ArcTO sling system prior to use. Non-functional or damaged delivery instruments or sling assembly components should not be used and should be returned to UroCure.
- Do not place the foil pouch in the sterile field. Do not open the foil pouch and deposit the contents (non-sterile drying agent and clear package containing the sterile sling) in the sterile field. Do not put clear package in the sterile field. Note: The clear package is opened to deposit the sterile sling into the surgical field
- Do not open the foil pouch until ready for use. The foil pouch and enclosed drying agent are protecting the sling and absorbable suture from moisture.
- Do not re-sterilize or reuse this device. The ArcTO sling system is intended for single use only. No portion of the ArcTO sling system is reusable.
- Do not use any part of the ArcTO sling system beyond the indicated expiration date.
- Do not use the ArcTO sling system if the package's sterile barrier is opened or damaged, as sterility may be compromised.

3.4 PROCEDURE STEPS

1. Anesthesia should be administered after consultation between anesthesia, surgeon, and patient.

2. Patient should be placed in a relaxed dorsal lithotomy position as tolerated with hips flexed, legs elevated in stirrups and buttocks even with the edge of the table to permit proper exposure of the surgical field.

3. Use of compression boots and/or anti-clotting prophylaxis for the distal extremities should be determined by physician preference.

4. Prep and drape to allow access to surgical field in both the groin and vaginal areas.

5. Insert a Foley catheter, empty the bladder and leave catheter for drainage of bladder.

6. If desired, place a weighted vaginal retractor or utilize other suitable retraction for vaginal exposure.

Incision and Dissection

7. Identify the mid-urethra. This is accomplished by gently withdrawing the catheter balloon to the level of the bladder neck and by palpating the proximal border of the balloon at the level of the urethral-vesical junction. The mid-urethra is normally located halfway between the proximal border of the Foley balloon and urethral meatus.

8. If desired, hydro-dissect with injectable saline at the level of the mid-urethra between the vaginal mucosa and the periurethral fascia. This solution may contain a local anesthetic and/or vasoconstrictive agent per surgeon preference.

9. Identify and mark two needle entrance locations in the groin along the lateral edge of the ishiopubic ramus below the inferior edge of the adductor longus tendon attachment. Create a small longitudinal incisions approximately 0.5 cm in length over the marked locations (Figure 2). Repeat on the patient's contralateral side.

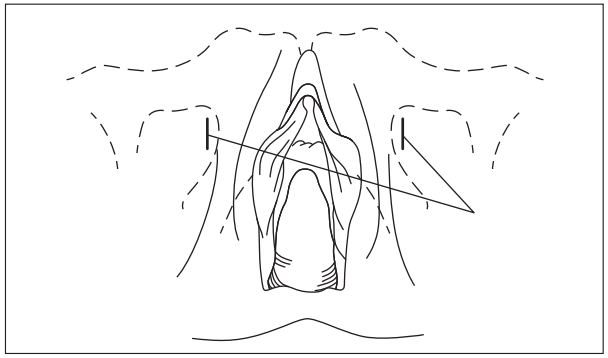

Figure 2: Incision locations

10. Create a full thickness longitudinal incision through the vaginal epithelium/mucosa and submucosa centered at the level of the mid-urethra. The incision should be at least 1.5 cm to permit the sling to lay flat after the dissection is complete.

11. Utilizing Metzenbaum scissors, dissect tunnels laterally between the periurethral fascia and full-thickness vaginal flaps to the edge of the inferior ramus of the pubic bone. The dissection should create a tunnel of at least 1.5 cm width in each direction in order to afford access for the delivery of the needles and sling assembly and allow the sling to lay flat within the dissection tunnel (Figure 3).

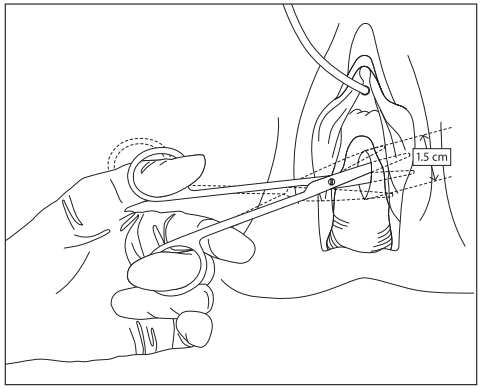

Figure 3: Dissect to create a tunnel of 1.5 cm width in each direction

12. Ensure that the bladder is empty prior to proceeding.

13. The ArcTO sling system box can now be opened. Be certain that the integrity of the sterile barrier has not been compromised in shipment or storage and verify that the expiration date is valid relative to the date of surgery.

NOTE: *The sling is enclosed within a sterile, clear package. This package is enclosed along with a desiccant in a larger foil envelope. Open the foil package away from the sterile field. The clear package can now be opened to deposit the sling onto the sterile field.*

WARNING! Do not use the device if there is any damage that has compromised the sterile barrier or if device is outside the expiration date.

CAUTION! Verify the presence of each component and inspect for any damage. Do not use the device if a component cannot be identified or is damaged

Passing the needles and placing the Sling

14. Prepare to pass the right hand needle on the patient's left side. The right hand needle and handle – identified by the arrow on the handle pointing to the right (Figure 4) – should be held in the surgeon's right hand and be positioned at a 45 degree angle to the midline, prior to and during the entire needle passage (Figure 5). For improved control during needle passage, place the thumb from the left hand on the outside curve of the needle with the right hand on the handle.

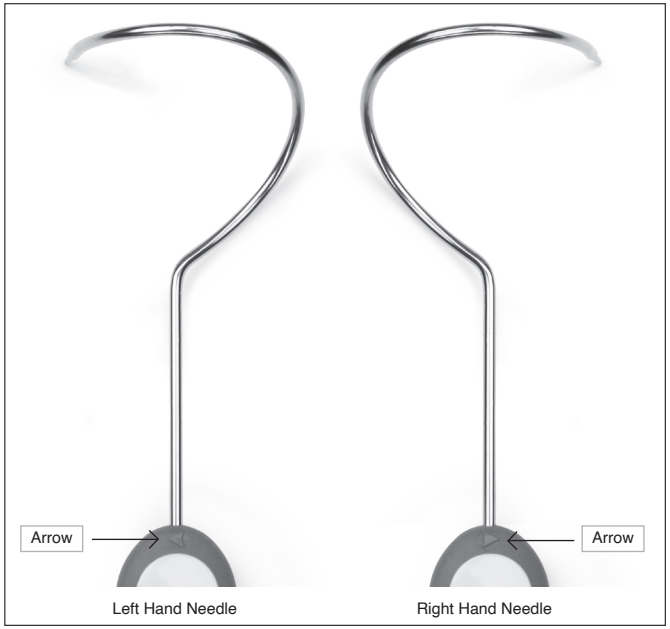

Figure 4: Identification of right and left hand needle

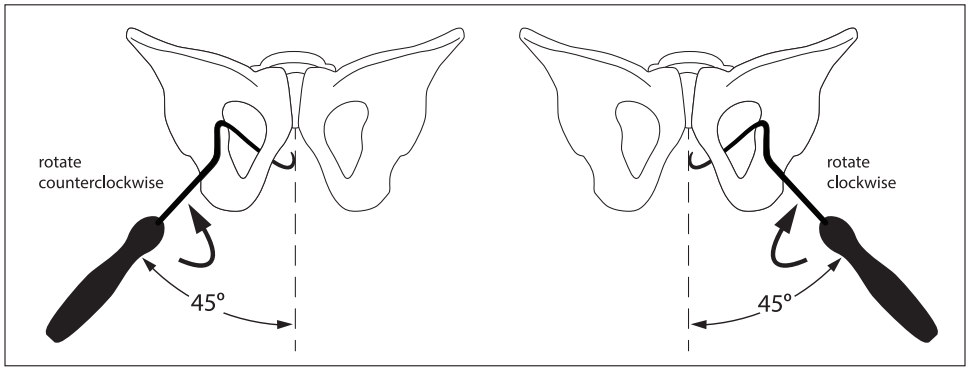

Figure 5: Needle positioning and passage

NOTE: *Step 14 describes initiating the procedure with the right hand needle pass. Per surgeon preference, the surgeon can make the initial needle pass with the left hand needle (on the patient's right side) and perform the second needle pass with the right hand needle (on the patient's left side).*

CAUTION! As the needle tip is advanced during the preceding steps, ensure there is not a puncture or "buttonhole" through the vaginal wall into the vaginal sulcus.

15. Pass the first needle straight in through the groin incisions on the surgeon's right at the point of the junction below adductor longus tendon insertion and lateral to the edge of the ishiopubic ramus. A gentle clockwise rotational motion should be employed to assess the needle depth necessary to circumvent the ishiopubic ramus (Figure 5).

16. Continue to rotate the handle and needle allowing the curved portion of the needle to traverse the musculature, the obturator membrane, and the endopelvic/periurethral fascial plane. Using the index finger of the surgeon's left hand to meet the tip of the needle, guide the needle tip through these structures into the vaginal tunnel and out through the vaginal incision.

NOTE: *If the needle tip hits the pubic bone during needle insertion, retract the needle and re-pass taking care to penetrate beyond the initial insertion depth. If the needle tip can not be located by the index finger, retract the needle and repeat steps 14-16.*

NOTE: *Placing the fingertip into the incision is per surgeon preference.*

17. When the right hand needle is in place, pass the left hand needle – identified by the arrow on the handle pointing to the left (Figure 4) – rotating counterclockwise (Figure 5), in the same manner on the contralateral side, repeating steps 14 to 16.

18. With the delivery needles now in place, perform a cystoscopy to confirm bladder and urethral integrity. Inspect the entire bladder and urethra for potential perforations. Each needle can be gently manipulated with the needle handles to aid exclusion of bladder and urethral perforation during the cystoscopy.

CAUTION! If the urethra is entered by sharp or blunt dissection or perforated with a delivery needle, do not proceed further. Remove any device components and treat according to standard practice.

CAUTION! If bladder perforation is detected, remove the delivery needle, reinsert the Foley catheter and ensure the bladder is empty. Repeat procedure Steps 14-18. Reconfirm bladder and urethral integrity with another cystoscopy.

19. Once bladder and urethral integrity is confirmed, attach the sling assembly to each needle connection end protruding from the vagina. The connector is properly attached when an audible "click" is heard.

CAUTION! If the audible click is not heard, confirm secure connection between needle and sling assembly by pulling on needle and connector. If secure connection is not verified, replace with a new ArcTO sling system and return the existing system to UroCure.

20. Orient the white dots on the sheaths facing outward, away from the urethra. Ensure that the sling assembly lies flat and is not twisted. The connectors can be rotated but cannot be removed once they are snapped into place.

21. Verify that the connectors are attached securely to the delivery needles to ensure that they do not disconnect when they are pulled up through the groin incisions.

22. When the sling assembly is properly attached, rotate the delivery needles and sling assembly up through the groin incisions one at a time. Allow the needle handles to rotate while the connectors and sling traverse the dissection tunnel and perforate the endopelvic/periurethral fascia. Pushing the connector with the index finger can help to facilitate this maneuver.

23. When the sling assembly exits the groin region , a clamp may be placed on the ends to secure the sling and sheaths.

24. The sling and sheaths are then cut just below the level of the white dots on the sheaths.

25. Pull on the cut ends of the sling and sheath to position it under the mid-urethra in a tension-free manner.

NOTE: *To avoid over-tensioning, keep a forceps or other blunt instrument between the sling and the periurethral fascia.*

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26. Once the desired sling position is achieved, remove the plastic sheaths by carefully securing the groin end of the sheath with a clamp. Avoid including the sling and stabilizing suture in the clamp. The separate arms of the sheath are pre-divided in the center of vaginal portion of the sling and can be removed with minimal traction. Keep the forceps or other blunt instrument in place beneath the periurethral fascia to maintain the desired sling position. Remove the sheaths by pulling up on the sheath arms. Confirm that the sling is lying flat within the vaginal space and tunnels.

27. Further refined adjustment of the sling can be done after the sheaths have been removed:

    To loosen the sling after sheath removal:
    Place a blunt instrument such as a clamp between the sling and the periurethral fascia. Ensure that both the sling and stabilizing suture are located beneath the clamp. Use the clamp or instrument to pull down and loosen the sling as desired.

    To tighten the sling after sheath removal:
    Place a clamp, across either end of the sling as they exit the groin incisions. Ensure that both the stabilizing suture and the sling are captured within the clamp. The sling may be rolled around the clamp to improve the grip. Pull up on either or both clamps to tighten the sling as desired.

28. Once optimal placement is achieved, cut the sling arms at the level of the skin after applying gentle traction on the sling arms. This results in the sling withdrawing within the subcutaneous obturator tissue bilaterally.

29. Close the groin and vaginal incisions per surgeon preference.

3.5 IMMEDIATE POST-OPERATIVE CARE

1. A vaginal pack can be used at the discretion of the physician. Remove prior to discharge.

2. Bleeding occurs. Check carefully that the patient is not bleeding before releasing the patient from the hospital

3. The ability of the patient to empty the bladder should be confirmed post-procedure. Catheterization can be used at the discretion of the physician.

4. The patient can return to normal daily activities at the physician's discretion.

5. The physician should also instruct the patient about when to resume heavy lifting, exercise and sexual intercourse.

6. The patient should be instructed to call the physician immediately if fever, dizziness, dysuria, bleeding, severe pain or other problems occur (see Section 2.3 Adverse Events).

3.6 PATIENT DEVICE CARD

A patient device card is included on the PDC insert included with the ArcTO Sling System.

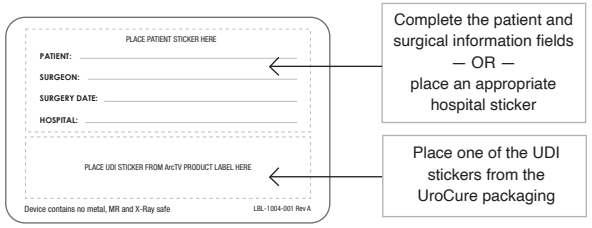
1. Remove UroCure ArcTO PDC insert from the ArcTO box. The patient device card should be removed from the insert after the procedure.

2. On the back of the card, there are two areas requiring completion. For the top half of the card, either complete the patient and surgical information fields or place an appropriate hospital sticker.

3. For the bottom half, place one of the UDI (unique device identifier) stickers from the UroCure foil pouch package which provides the unique lot number identification for the patient's implanted sling.

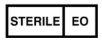
4. Once the back side of the patient device card is completed, it should be provided to the patient after their surgery in an appropriate setting.

Figure 6: Front of card



Back of card

GLOSSARY OF SYMBOLS USED ON LABELING

Symbol	Title of symbol and reference number	Standard	Description of Symbol
	Manufacturer (5.1.1)	ISO 15223-1:2021	Indicates the medical device manufacturer.
	Use-by date (5.1.4)	ISO 15223-1:2021	Indicates the date after which the medical device is not to be used.
	Batch code (5.1.5)	ISO 15223-1:2021	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number (5.1.6)	ISO 15223-1:2021	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Sterilized using ethylene oxide (5.2.3)	ISO 15223-1:2021	Indicates a medical device that has been sterilized using ethylene oxide.
	Do not resterilize (5.2.6)	ISO 15223-1:2021	Indicates a medical device that is not to be resterilized.
	Do not use if package is damaged and consult instructions for use (5.2.8)	ISO 15223-1:2021	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	Single sterile barrier system (5.2.11)	ISO 15223-1:2021	Indicates a single sterile barrier system.
	Single sterile barrier system with protective packaging outside (5.2.14)	ISO 15223-1:2021	Indicates a single sterile barrier system with protective packaging outside.
	Keep away from sunlight (5.3.2)	ISO 15223-1:2021	Indicates a medical device that needs protection from light sources.
	Keep dry (5.3.4)	ISO 15223-1:2021	Indicates a medical device that needs to be protected from moisture.
	Do not reuse (5.4.2)	ISO 15223-1:2021	Indicates a medical device that is intended for one use only.
 www.urocure.com/IFU	Consult electronic instructions for use (5.4.3)	ISO 15223-1:2021	Indicates the need for a user to consult the electronic instructions for use at the listed website.
	Caution (5.4.4)	ISO 15223-1:2021	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situaion needs operator awareness or operator action in order to avoid undesirable consequences.
	Medical Device (5.7.7)	ISO 15223-1:2021	Indicates the item is a medical device.
	MR Safe (7.2.1)	ASTM F2503-20	Indicates that the implanted medical device is safe to be used in an MR environment
	Prescription use only	21 CFR 801.109(b)(1)	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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UroCure

ADVANCING WOMEN'S HEALTH

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