UroCure

ArcTV™

TRANSVAGINAL 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

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 transvaginal 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 ArcTV™ Transvaginal Sling System is a retropubic sling indicated for a transvaginal (TV) placement of a mid-urethral sling for the treatment of adult female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Contraindications

- Do not implant the ArcTV 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

- The ArcTV System 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 retropubic space for the placement of mid-urethral sling devices. The surgeon should be familiar with the specific steps for ArcTV implantation, including retropubic needle passage and the placement of polypropylene slings before placing the ArcTV System.

- 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 all or part of the 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 always 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 TV route.

- The risks and benefits of performing the ArcTV 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
- Vaginal or urinary tract infection should be treated and resolved prior to the ArcTV procedure. The procedure should not be performed in the presence of a urinary, vaginal or suprapubic infection.
- Acute inflammatory tissue reaction and transitory local irritation has been reported with the use of absorbable suture in the vagina or abdomen.
- ArcTV 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 ArcTV 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

- Do not use the ArcTV System with a suprapubic, "top-down" approach.
- Omitting the suprapubic incisions with the vaginal approach 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.
- 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 ArcTV 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 ArcTV 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 ArcTV 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 ArcTV sling.

NOTE: *The implanted ArcTV 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
- Denovo, persistent or worsening overactive bladder, with or without incontinence
- Perforation or laceration of vessels, nerves, bladder, urethra or bowel
- Pain (local or regional discomfort that may be transient or persistent)
- Pain, ongoing pain (pelvic, bladder, vaginal, groin, thigh, suprapubic, dyspareunia)
- Loss of sexual function
- Severe chronic pain
- Bleeding (routine surgical, hematoma, hemorrhage)
- Bruising, bleeding (vaginal, hematoma formation)
- 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 / tissue contraction of vagina or surrounding tissues
  - device migration
  - fistula formation and inflammation
- Temporary or permanent lower urinary tract obstruction and retention
- Like all foreign bodies, the polypropylene sling may potentiate an existing infection
- A foreign body inflammatory response or infection, which may result in systemic symptoms, pain,

damage to adjacent structures, scarring and adhesions.

- Infection (superficial, abscess, systemic sepsis)
- Local irritation at the wound site and/or a foreign body response may occur.
- Edema and erythema at the wound site
- Dehiscence of vaginal incision
- Vaginal discharge
- Allergic reaction to the polypropylene sling

The occurrence of adverse events from this procedure may require additional surgical interventions, including removal of the entire sling. Removal of 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

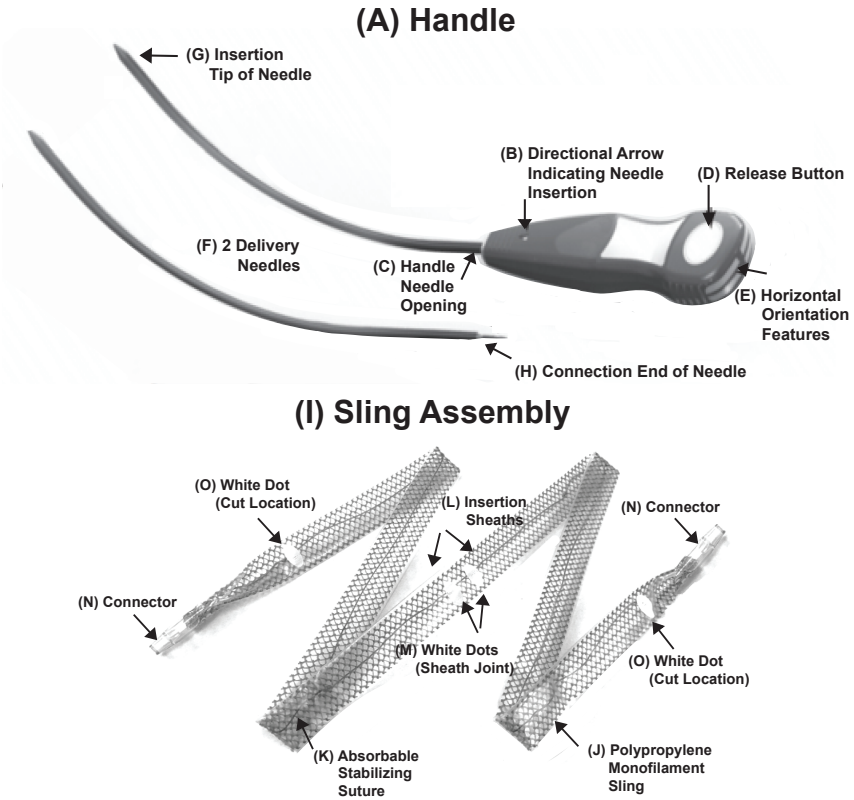

Figure 1: ArcTV Transvaginal Sling System Components

NOTE: *Natural rubber latex is not used in the manufacture of any ArcTV component.*

3.2 OPENING THE BOX AND PREPARING THE DEVICE FOR SURGERY

- Open the box and remove the tray containing the ArcTV 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 ArcTV 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 ArcTV System is intended for single use only. No portion of the ArcTV System is reusable.
- Do not use any part of the ArcTV System beyond the indicated expiration date.
- Do not use the ArcTV System if the package's sterile barrier is opened or damaged, as sterility may be compromised.

3.3 DEVICE DESCRIPTION (see Figure 1)

- The handle (A) has a directional arrow (B) indicating the needle opening (C) into which a stainless steel delivery needle (F) is inserted. The release button (D) is on the top side of the handle. The proximal end of the handle facing the user has horizontal orientation features (E) that are perpendicular to the needle. Each needle has a connection end (H) with flat sides that orient the needle to the handle. The needle is inserted into the handle so the tip (G) is upward.

- The sling assembly (I) is constructed of polypropylene monofilament sling (J) that is 1.1 cm wide by 50 cm long. An absorbable stabilizing suture (K) is threaded into the sling to allow for refined adjustment of the sling after placement in the patient. Two plastic sheaths (L) that come together in the center of the sling assembly, indicated by the white dot markings (M) on each sheath, cover and protect the sling during placement. The connectors (N) are attached to the connection ends of the delivery needles during the procedure. Two additional white dot markings (O) identify where to cut the sling assembly 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.

3.4 PROCEDURE STEPS

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

2. Patient should be placed in a 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 suprapubic 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.

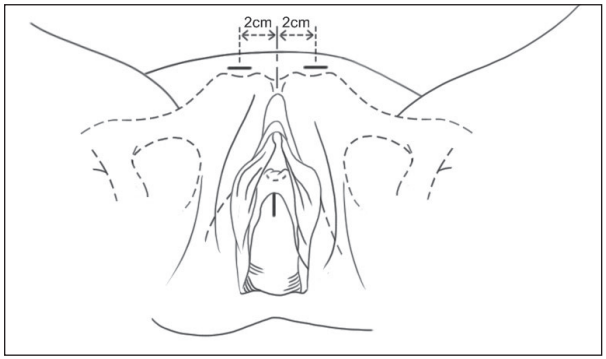

Figure 2: Incision locations

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 the two suprapubic exit points approximately 2 cm from the midline and 1 cm above the pubic symphysis (Figure 2). Create two small transverse incisions approximately 0.5 cm in length. The performance of these incisions may be deferred until step 18 per surgeon preference.

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).

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

13. The ArcTV Transvaginal Sling System package 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.

Placing the Sling

14. Insert a delivery needle into the needle opening of the handle indicated by the directional arrow. While loading the delivery needle to the handle, ensure that the release button and needle curvature is facing upward. An audible “click” should be heard indicating that the delivery needle is fully engaged in the handle.

NOTE: *A rigid catheter guide may be employed within the Foley per surgeon preference.*

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15. Retract the edge of the vaginal incision, then hold the delivery needle handle with one hand, and support the underside of the distal end of the needle with a finger of the other hand (Figure 4). Insert the tip of the delivery needle into the space created by the vaginal dissection. The delivery needle should be guided gently in close proximity to the pubic bone.

CAUTION! Do not use force on the handle to drive the needle trajectory; it should gently slide into the tunnel.

NOTE: *The horizontal orientation feature on the handle may be used as a visual cue to aid with alignment of the needle during passage through tissue.*

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16. Advance the needle tip and puncture through the endopelvic fascia at the junction of the symphysis pubis and inferior pubic ramus and into the retropubic space. Stop advancing the delivery needle when it punctures through the periurethral fascia. Confirm with an index finger that the needle tip is just past the inferior edge of the pubic bone (Figure 5). Do not advance further. The initial needle trajectory is towards the ipsilateral shoulder during perforation and after perforation immediately superiorly toward the ipsilateral suprapubic exit site.

17. Lower the handle so the distal end of the delivery needle contacts the posterior surface of the pubic ramus before advancing the needle superiorly. The trajectory of the needle tip is redirected vertically along the posterior surface of the pubic bone to the ipsilateral suprapubic exit point incision.

18. Continue advancing the delivery needle along the posterior surface of the pubic bone until the needle tip (A) exits through the suprapubic incision exit point (Figure 6) or (B) perforates the rectus fascia at which time skin incisions can be performed over the tip of the needle.

    The needle tip should protrude through the suprapubic incision allowing sufficient length to grasp the needle. Pull up on the delivery needle until the trailing end of the needle is protruding approximately 2-3 cm out of the vaginal incision. This will ensure that the first delivery needle does not interfere with the second delivery needle pass.

> ⚠ **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.

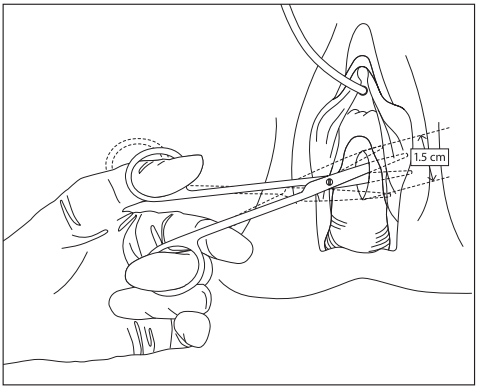

Figure 3: Dissect to create a tunnel of 1.5 cm width in each direction

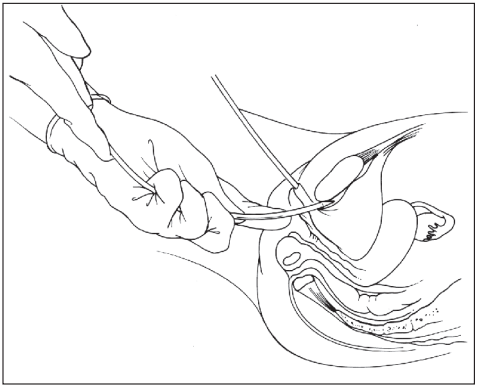

Figure 4: Support the tip of the delivery needle with one hand

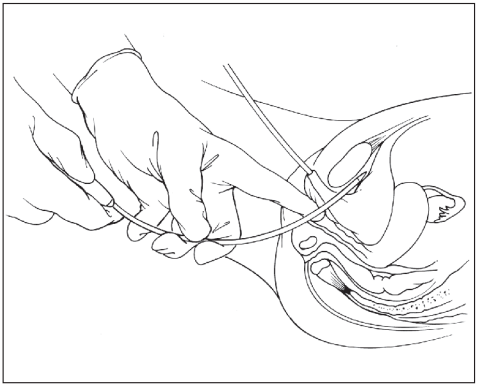

Figure 5: Confirm needle placement through endopelvic fascia

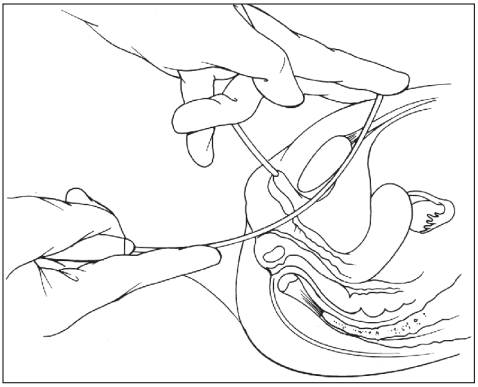

Figure 6: Needle tip exiting through the suprapubic incision

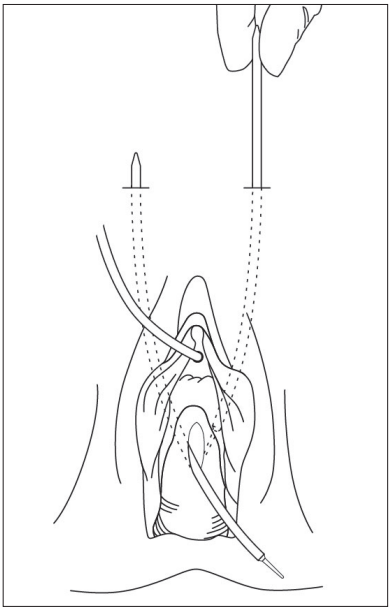

Figure 7: Needle positioning

19. Disconnect the handle from the delivery needle by pressing the release button.

20. Repeat steps 14 to 19 for the second delivery needle on the contralateral side. The previously placed needle can be positioned within vaginal incision to facilitate access for contralateral needle placement (Figure 7).

21. With the delivery needles now in position, perform cystoscopy to confirm bladder and urethral integrity. Inspect the entire bladder and urethra for potential perforations. Each needle end that exits the suprapubic incision can be gently manipulated to help with visualization during the cystoscopy.

NOTE: *Both needles can be positioned within the vaginal incision in the fashion shown (Figure 7) to facilitate ease of cystoscopy. After cystoscopy, the connection end of the needles should be repositioned outside of the incision to attach the sling assembly.*

CAUTION! If urethral perforation is detected 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 14-19. Reconfirm bladder and urethral integrity with another cystoscopy.

22. Once bladder and urethral integrity are confirmed, position the needles to 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 ArcTV system and return the existing system to UroCure.

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

24. Verify that the connectors are attached securely to the delivery needles to ensure that they do not disconnect as they are pulled up through the suprapubic incisions.

25. When the sling assembly is properly attached, pull the delivery needles and sling assembly up through the suprapubic incisions one at a time.

26. When sling assembly exits the suprapubic region, the ends can be cut just below the level of the white dot on the sheaths.

27. A clamp may be placed on the ends to secure the sling and sheaths.

28. Pull up 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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29. Once the desired sling position is achieved, remove the plastic sheaths by carefully securing the edge of the suprapubic 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.

30. 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 suprapubic 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.

31. 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 suprapubic tissue bilaterally.

32. Close the suprapubic and vaginal incisions.

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 ArcTV Sling System.

1. Remove UroCure ArcTV PDC insert from the ArcTV 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 stickers from the UroCure packaging with provides unique lot number identification for the patient's implanted device.

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.

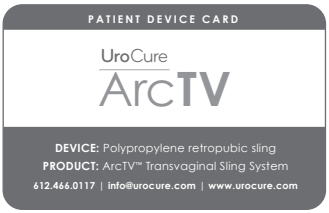

Figure 6: Front of card

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 15223-1:2016 Third Edition 2016-11-01	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Do not reuse (5.4.2)	ISO 15223-1:2016 Third Edition 2016-11-01	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do not use if package is damaged (5.2.8)	ISO 15223-1:2016 Third Edition 2016-11-01	Indicates a medical device that should not be used if the package has been damaged or opened.
	Use-by date (5.1.4)	ISO 15223-1:2016 Third Edition 2016-11-01	Indicates the date after which the medical device is not to be used.
	Batch code (5.1.5)	ISO 15223-1:2016 Third Edition 2016-11-01	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Caution (5.4.4)	ISO 15223-1:2016 Third Edition 2016-11-01	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Sterilized using ethylene oxide (5.2.2)	ISO 15223-1:2016 Third Edition 2016-11-01	Indicates a medical device that has been sterilized using ethylene oxide.
	Keep dry (5.3.4)	ISO 15223-1:2016 Third Edition 2016-11-01	Indicates a medical device that needs to be protected from moisture.
	Do not resterilize (5.4.2)	ISO 15223-1:2016 Third Edition 2016-11-01	Indicates a medical device that is not to be resterilized.
 www.urocure.com/IFU	Consult instructions for use (5.4.3)	ISO 15223-1:2016 Third Edition 2016-11-01	Indicates the need for the user to consult the electronic instructions for use at the listed website.
	Keep away from sunlight (5.3.2) (5.1.1)	ISO 15223-1:2016 Third Edition 2016-11-01	Indicates a medical device that needs protection from light sources.
	Catalogue number (5.1.6)	ISO 15223-1:2016	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Prescription use only	21 CFR 801 Title 21 FDA Medical Devices Part 801 Labeling	801.109(b)(1)
	MR Safe (7.2.1)	ASTM F2503-13	Indicates that the implanted medical device is safe to be used in an MR environment

UroCure

ADVANCING WOMEN'S HEALTH

UroCure, LLC

701 N 3rd St, Suite 110
Minneapolis, MN 55401 | USA

Customer Service: 1.612.466.0117

www.urocure.com