UroCure

ADVANCING WOMEN'S HEALTH

PRODUCTS REVIEW FOR VALUE ANALYSIS COMMITTEES

- UROCURE: OUR STORY
- PRODUCT OVERVIEW
- REGULATORY INFORMATION
- INSTRUCTIONS FOR USE
- REIMBURSEMENT GUIDE
- ORDERING INFORMATION

A NEW WAY FORWARD FOR WOMEN'S HEALTH

UroCure was founded with one goal: to design medical device solutions tailored to address the needs of women and their surgeons.

Our comprehensive portfolio of sling systems—designed to address stress urinary incontinence (SUI) in women—introduces the next generation of devices patterned after the industry standard-bearer, AMS. Each of our products is the result of listening carefully to surgeons, considering the needs of women and designing solutions to deliver the highest quality patient outcomes.

Our sling systems are offered in three configurations to accommodate the surgeon's preferred technique—bottom-up, top-down, or outside-in. Each of our handle-needle designs are noted for their ergonomic design and are optimized for their intended surgical technique. All of our systems incorporate UroCure's best-in-class laser-cut **sling with integrated stabilizing suture**. This patented innovation helps our sling retain its shape and prevent deformation during placement, tensioning, and sheath removal.

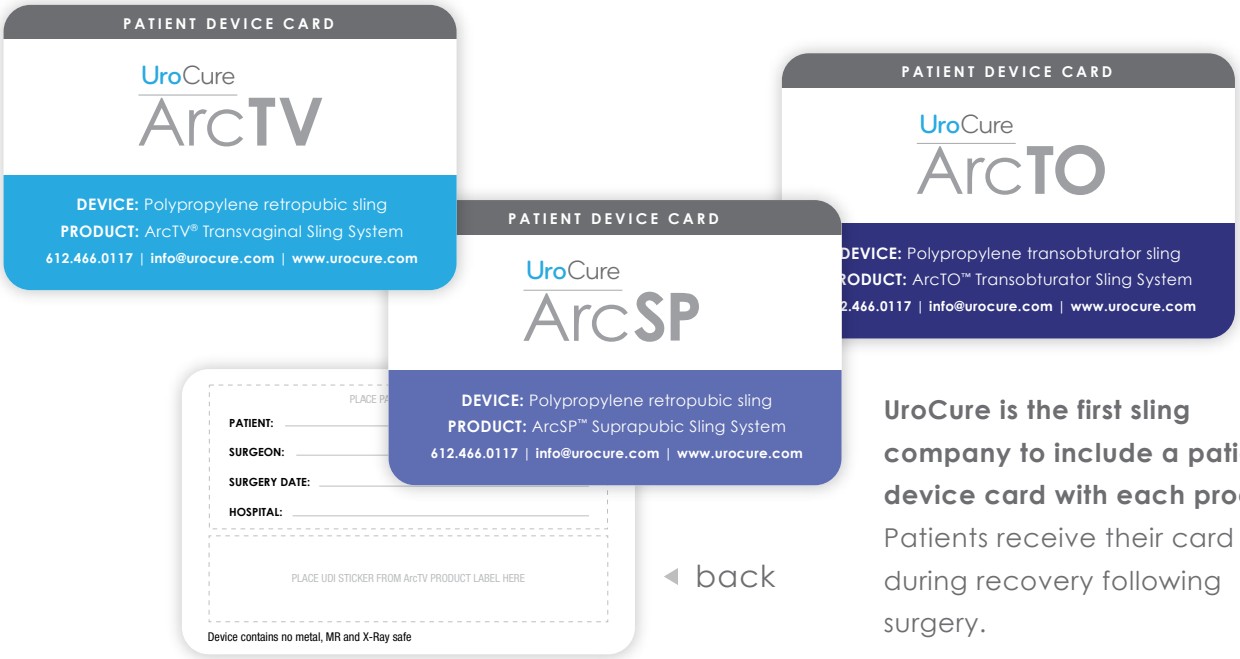
Patient outcomes are critical to our design process: What was her surgical experience? What was her outcome? What can we improve? That is why we are the first sling company to (1) impanel a Quality and Safety Oversight Committee to provide guidance on our commercial path forward, (2) to provide a patient device card with each sling and (3) to offer a means of instantaneous feedback from the OR-to-company via QR code on our product packaging. From start to finish, we are a user-centered company. That is why UroCure sits on the leading edge of women's health.

FOCUS ON PATIENT OUTCOMES: HOW WE STAND APART

QUALITY AND SAFETY OVERSIGHT

UroCure is the first sling company to impanel a Quality and Safety Oversight Committee (QSOC), comprised of leading academic physicians who monitor outcomes and provide guidance to UroCure moving forward.

PATIENT DEVICE CARD



UroCure is the first sling company to include a patient device card with each product. Patients receive their card during recovery following surgery.

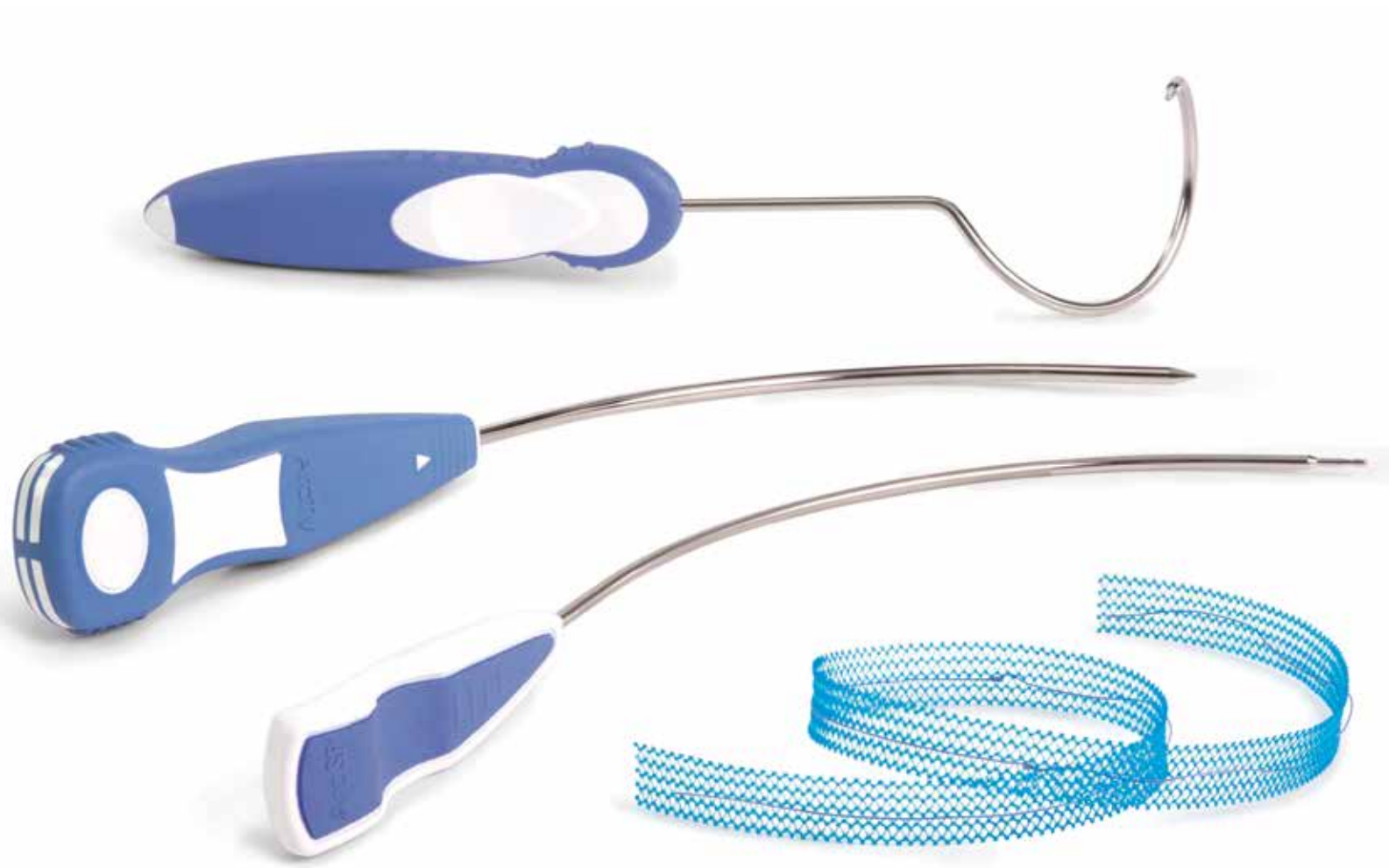
INSTANTANEOUS FEEDBACK

UroCure is the first sling company to offer an instantaneous feedback mechanism: using a QR code on the sling packaging, physicians or nurses in the operating room can provide direct feedback on their experience with UroCure's slings.

UroCure

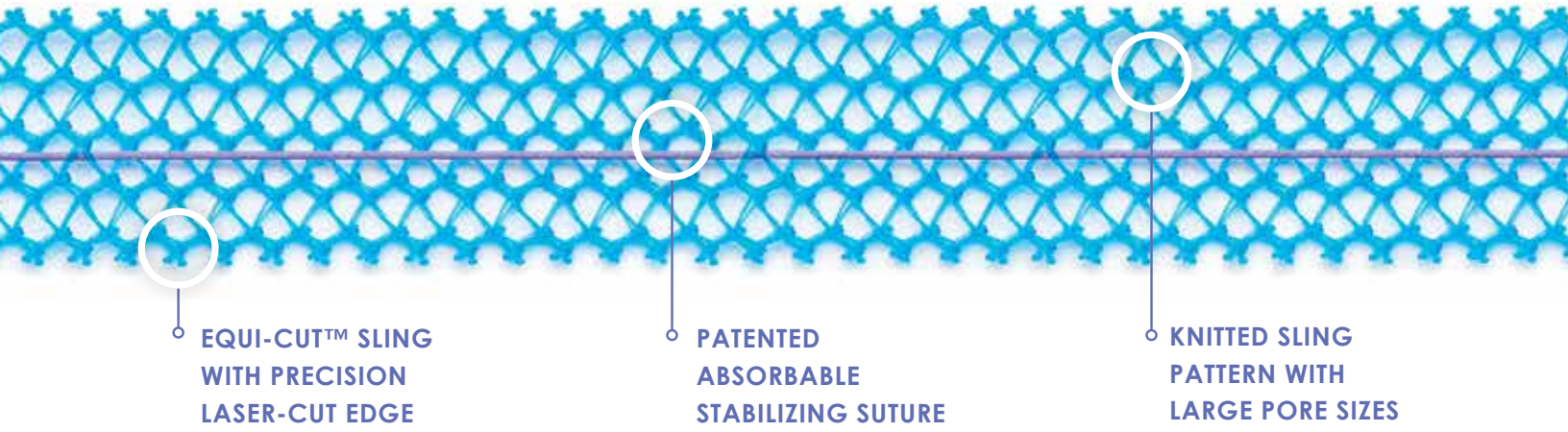
ADVANCING WOMEN'S HEALTH

A PORTFOLIO OF LEADING-EDGE SLING SOLUTIONS

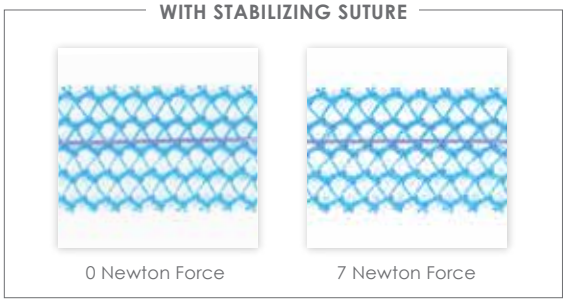


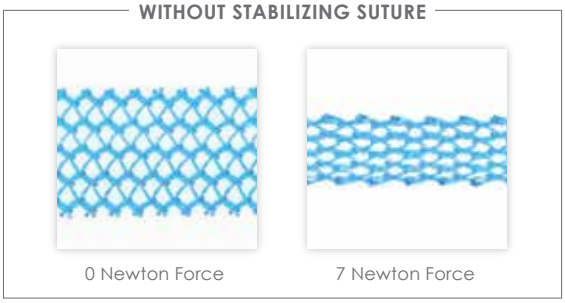
THE STABILIZING SUTURE SETS US APART

Our patented absorbable stabilizing suture was developed in collaboration with leading surgeons and is unique to all UroCure slings. Secured by strategically-placed knots, the suture helps the sling retain its shape—preventing deformation and pore collapse during placement, tensioning, and sheath removal.



The photos below show how a 7N force, applied to the sling outside the knots, affects the pore integrity of the sling. With the stabilizing suture, the sling experiences minimal stretch and maintains its open pore design. Without the stabilizing suture, the sling experiences severe stretch and pore collapse.





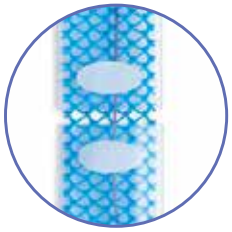
PATENTED SLING WITH STABILIZING SUTURE

Each of our sling systems incorporates UroCure's patented sling with stabilizing suture. Here is why this sling works seamlessly with each of our three needle designs:

"CLEAR-CLICK" RAPID CONNECTOR
simplifies needle-sling connection and is consistent across all UroCure slings.

ATRAUMATIC TAPERED SHEATHS
are designed to minimize tissue trauma and decrease the force required during sheath-sling passage.

EASILY-REMOVABLE SHEATHS
designed to maintain sling integrity during removal.



MIDLINE DOTS AND NON-OVERLAPPING SHEATHS
indicate the center of the sling for accurate placement and help with recognizing sling twisting.

ArcTV

TRANSVAGINAL SLING SYSTEM

Bottom-up delivery system:

- follows trajectory for transvaginal (bottom-up) needle passage
- maintains sufficient rigidity and minimizes needle deflection during passage

ArcTO

TRANSOBTURATOR SLING SYSTEM

Outside-in delivery system:

- follows trajectory for transobturator (outside-in) needle passage
- with unique helical needle, allows single, continuous handle rotation during needle passage until vaginal incision is reached.

ArcSP

SUPRAPUBIC SLING SYSTEM

Top-down delivery system:

- follows trajectory for suprapubic (top-down) needle passage
- remains palpable and atraumatic during vaginal tunnel passage

UroCure

ArcTV

March 20, 2019

Dear Valued Customer,

Thank you for your request for consideration for the ArcTV™ Transvaginal Sling System from UroCure.

The ArcTV Transvaginal Sling System is marketed in accordance with US Food and Drug Administration (FDA) regulations 21 CFR 878.3300. The 510(k) that supports this product was cleared by the FDA on February 7, 2019. Attached you will find a copy of the 510(k) clearance letter from the FDA and accompanying cleared Indications for Use.

For further information or questions, please contact UroCure directly at customerservice@urocure.com or UroCure's local representative.

Sincerely,

Regulatory Affairs

The regulatory information provided confirms ArcTV regulatory status and may not be used for any other purposes without the expressed written consent or permission of UroCure.

701 North 3rd Street, Suite 110 | Minneapolis, MN 55401 | 1 612-466-0117

ArcTV

February 7, 2019

UroCure LLC
% Ming-Cheng Chew
Regulatory Consultant
Libra Medical, Inc.
8401 73rd Ave No., Suite 63
Brooklyn Park, MN 55428

Re: K183134
Trade/Device Name: ArcTV Transvaginal Sling System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OTN
Dated: January 9, 2019
Received: January 11, 2019

Dear Ming-Cheng Chew:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Glenn B. Bell -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

ArcTV

510(k) Number *(if known)*

K183134

Device Name
ArcTV Transvaginal Sling System

Indications for Use *(Describe)*
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).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

UroCure

ArcTO

September 26, 2022

Dear Valued Customer,

Thank you for your request for consideration for the ArcTO™ Transobturator Sling System from UroCure.

The ArcTO Transobturator Sling System is marketed in accordance with US Food and Drug Administration (FDA) regulations 21 CFR 878.3300. The 510(k) that supports this product was cleared by the FDA on September 15, 2022. Attached you will find a copy of the 510(k) clearance letter from the FDA and accompanying cleared Indications for Use.

For further information or questions, please contact UroCure directly at info@Urocure.com or UroCure's local representative.

Sincerely,

Regulatory Affairs

The regulatory information provided confirms ArcTO regulatory status and may not be used for any other purposes without the expressed written consent or permission of UroCure.

ArcTO

September 15, 2022

UroCure LLC
Denise Lenz
Regulatory Consultant
Libra Medical, Inc.
8401 73rd Avenue North, Suite 63
Brooklyn Park, MN 55428

Re: K222468
Trade/Device Name: ArcTO Transobturator Sling System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OTN
Dated: August 15, 2022
Received: August 16, 2022

Dear Denise Lenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Angel A. Soler-garcia -S

for
Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222468

Device Name
ArcTO Transobturator Sling System

Indications for Use *(Describe)*
The polypropylene sling is indicated to be placed mid-urethra for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FORM FDA 3881 (6/20) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

UroCure

ArcSP

September 26, 2022

Dear Valued Customer,

Thank you for your request for consideration for the ArcSP™ Suprapubic Sling System from UroCure.

The ArcSP Suprapubic Sling System is marketed in accordance with US Food and Drug Administration (FDA) regulations 21 CFR 878.3300. The 510(k) that supports this product was cleared by the FDA on September 22, 2022. Attached you will find a copy of the 510(k) clearance letter from the FDA and accompanying cleared Indications for Use.

For further information or questions, please contact UroCure directly at info@Urocure.com or UroCure's local representative.

Sincerely,

Regulatory Affairs

The regulatory information provided confirms ArcSP regulatory status and may not be used for any other purposes without the expressed written consent or permission of UroCure.

ArcSP

September 21, 2022

UroCure LLC
% Denise Lenz
Regulatory Consultant
Libra Medial, Inc.
8401 73rd Ave N, Suite 63
Brooklyn Park, MN 55428

Re: K222293
Trade/Device Name: ArcSP Suprapubic Sling System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OTN
Dated: August 31, 2022
Received: September 6, 2022

Dear Denise Lenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

ArcSP

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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Sincerely,

Jessica K. Nguyen -S

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222293

Device Name
ArcSP Suprapubic Sling System

Indications for Use *(Describe)*
The ArcSP Suprapubic 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).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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ArcTV

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.

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 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 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 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.
  - pregnant patients or patients that are considering future pregnancies
  - pediatric patients

UroCure IFUs are supplied in electronic format. For the most current revision, please refer to www.urocure.com/IFU.

ArcTV

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 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 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 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.
- Local skin, vaginal or urinary tract infection should be treated and resolved prior to the ArcTV sling procedure. The procedure should not be performed in the presence of a urinary, vaginal or suprapubic skin 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.

ArcTV

- 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
- 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.

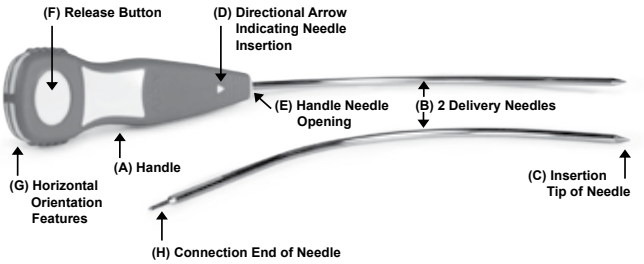
ArcTV

3 DIRECTIONS FOR USE

3.1 CONTENTS OF THIS BOX AND LABELS

The ArcTV® Transvaginal Sling System is a sterile, single use system consisting of the following:

Handle & Needles



Sling Assembly

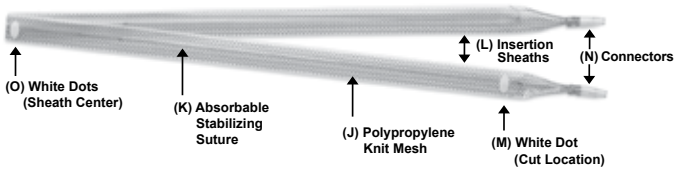


Figure 1: ArcTV Transvaginal Sling System Components

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

3.2 DEVICE DESCRIPTION (see Figure 1)

- Each system contains one handle (A) and two delivery needles (B) designed for transvaginal needle passage. The needle is inserted into the handle so the tip (C) is upward. The handle has a directional arrow (D) indicating the opening (E) into which the delivery needles (B) should be inserted. The release button (F), on the top side of the handle, allows the handle to be removed after needle passage. The proximal end of the handle facing the user has horizontal lines (G) that provide orientation guidance during needle passage. Each needle has a connection end (H) that serves a dual purpose: (i) to enable the handle-to-needle connection to facilitate needle passage and (ii) after needle passage, to enable the sling assembly-to-needle connection to facilitate sling placement.
- The sling is constructed of a polypropylene knit mesh (J) that is 1.1 cm wide by 50 cm long. An absorbable stabilizing suture (K) is threaded into the sling to minimize sling distortion during insertion, placement and tensioning. The two insertion sheaths (L) cover and protect the sling during placement and abut each other in the center, indicated by white dots (M) on each sheath. The connectors (N) are attached to the connection ends of the delivery needles during the procedure. Two additional white dots (O) 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 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.

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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.

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.

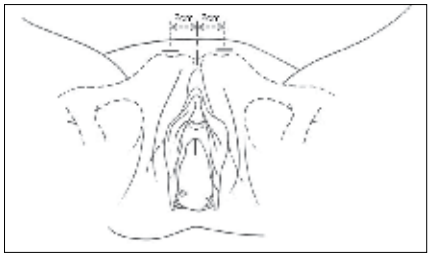

Figure 2: Incision locations

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).

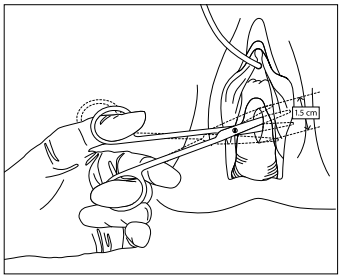

Figure 3: Dissect to create a tunnel of 1.5 cm width in each direction

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

13. The 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.

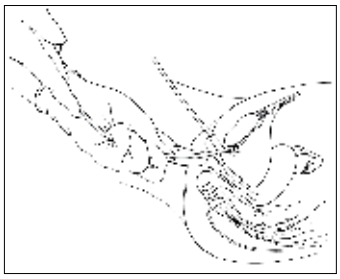

Figure 4: Support the tip of the delivery needle with one hand

⚠ **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.*

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.

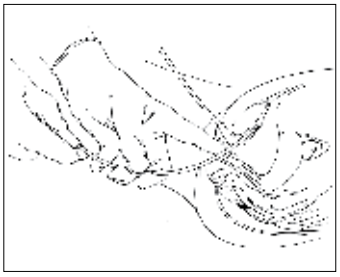

Figure 5: Confirm needle placement through endopelvic fascia

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 exits through the suprapubic incision exit point (Figure 6) or 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.

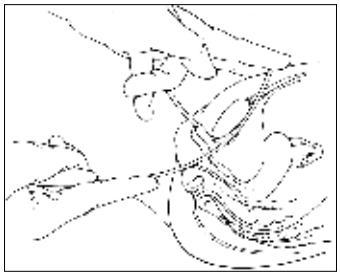

Figure 6: Needle tip exiting through the suprapubic incision

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

⚠ **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.

ArcTV

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.

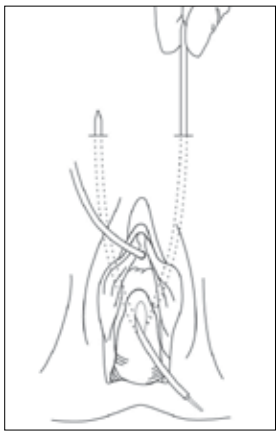

Figure 7: Needle positioning

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 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 14-19. 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 the sling assembly exits the suprapubic region, a clamp may be placed on the ends to secure the sling and sheaths.

27. The sling and sheaths are then cut just below the level of the white dot on the 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.*

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 per surgeon preference.

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3.5 IMMEDIATE POST-OPERATIVE CARE

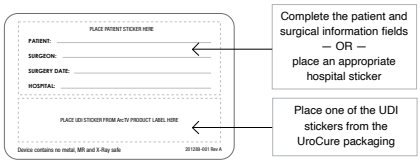
1. A vaginal pack can be used at the discretion of the physician. Remove prior to discharge.
2. Bleeding occurs. Check carefully that the patient is not bleeding before releasing the patient from the hospital
3. The ability of the patient to empty the bladder should be confirmed post-procedure. Catheterization 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 (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 8: 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.
LOT	Batch code (5.1.5)	ISO 15223-1:2021	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	Catalogue number (5.1.6)	ISO 15223-1:2021	Indicates the manufacturer's catalogue number so that the medical device can be identified.
STERILE EO	Sterilized using ethylene oxide (5.2.3)	ISO 15223-1:2021	Indicates a medical device that has been sterilized using ethylene oxide.
2 STERILE	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.
MD	Medical Device (5.7.7)	ISO 15223-1:2021	Indicates the item is a medical device.
MR	MR Safe (7.2.1)	ASTM F2503-20	Indicates that the implanted medical device is safe to be used in an MR environment
℞ Only	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

UroCure, LLC

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www.urocure.com

UroCure IFUs are supplied in electronic format. For the most current revision, please refer to www.urocure.com/IFU.

ArcTO

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.

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

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ArcTO

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.

ArcTO

- 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.

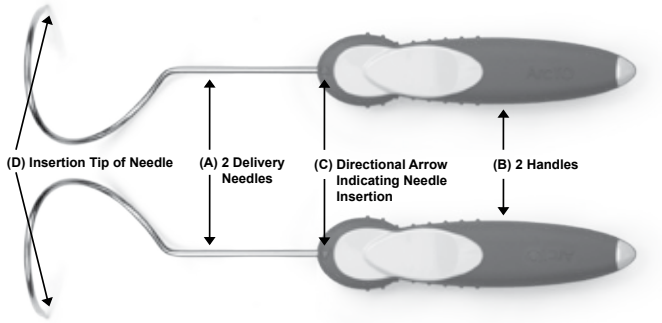
ArcTO

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:

Handles & Needles



Sling Assembly

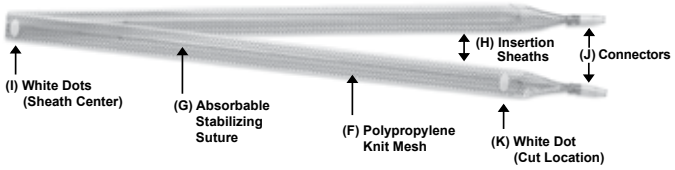


Figure 1: ArcTO Transobturator Sling System Components

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.

ArcTO

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.

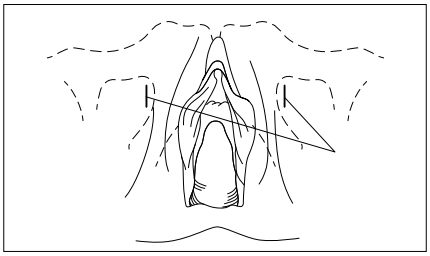


Figure 2: Incision locations

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).

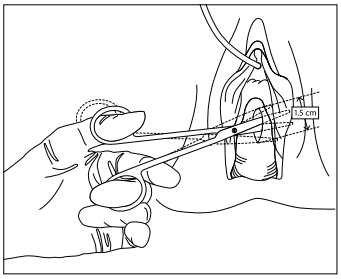


Figure 3: Dissect to create a tunnel of 1.5 cm width in each direction

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

ArcTO

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.

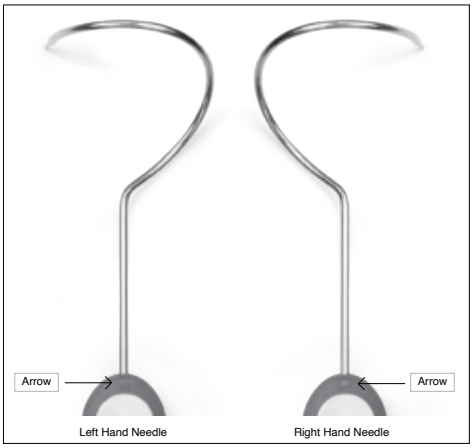


Figure 4: Identification of right and left hand needle

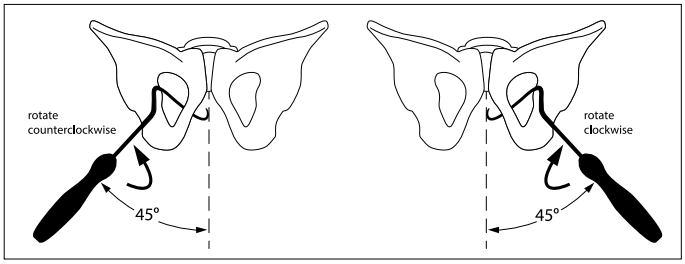


Figure 5: Needle positioning and passage

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.

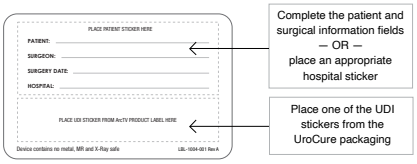
1. Remove UroCure ArcTO PDC insert from the ArcTO box. The patient device card should be removed from the insert after the procedure.

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

ArcTO

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.

UroCure
ADVANCING WOMEN'S HEALTH

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www.urocure.com

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ArcSP

UroCure

ArcSP™

SUPRAPUBIC 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.

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 retropubic 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 ArcSP Suprapubic 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 ArcSP 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

UroCure IFUs are supplied in electronic format. For the most current revision, please refer to www.urocure.com/IFU.

ArcSP

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 ArcSP 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 ArcSP implantation, including suprapubic needle passage and the placement of polypropylene slings before placing the ArcSP 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 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 suprapubic route.

- The risks and benefits of performing the ArcSP 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 ArcSP sling procedure. The procedure should not be performed in the presence of a urinary, vaginal or suprapubic skin infection adjacent to and/or including the site of placement of the ArcSP introducer needle.

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

- ArcSP 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 ArcSP 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 ArcSP should only be used in a "top-down" suprapubic approach. Do not use the ArcSP System 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.

- 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 ArcSP 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.

ArcSP

- Do not remove the plastic sheaths until the ArcSP 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 ArcSP 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 ArcSP sling.

NOTE: *The implanted ArcSP 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.

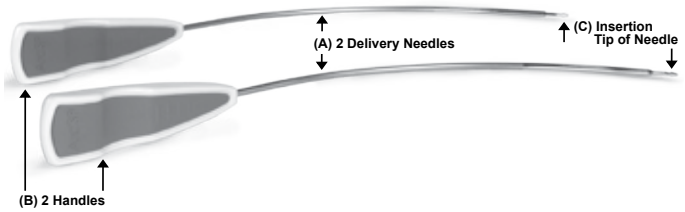
ArcSP

3 DIRECTIONS FOR USE

3.1 CONTENTS OF THIS BOX AND LABELS

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

Handles & Needles



Sling Assembly

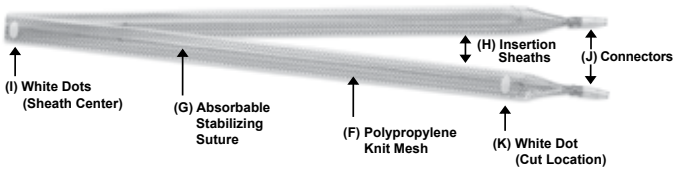


Figure 1: ArcSP Suprapubic Sling System Components

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

3.2 DEVICE DESCRIPTION (see Figure 1)

- Each system contains two delivery needles (A) with integrated handles (B) designed for a suprapubic (top-down) needle pass. Each needle has a connection end at its tip (C) 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 ArcSP 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 ArcSP 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 ArcSP System is intended for single use only. No portion of the ArcSP System is reusable.
- Do not use any part of the ArcSP System beyond the indicated expiration date.
- Do not use the ArcSP System if the package's sterile barrier is opened or damaged, as sterility may be compromised.

ArcSP

3.4 PROCEDURE STEPS

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

2. Patient should be placed in a modified 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.

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 entry 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.

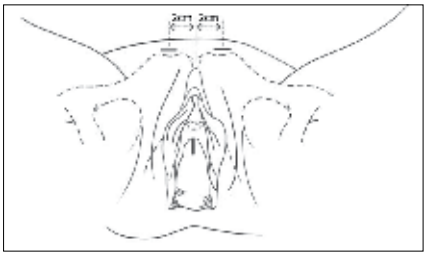


Figure 2: Incision locations

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).

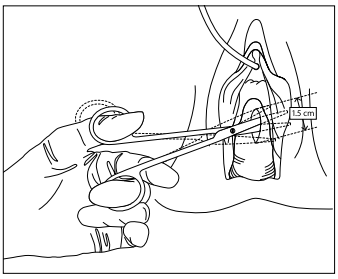


Figure 3: Dissect to create a tunnel of 1.5 cm width in each direction

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

13. The ArcSP Suprapubic 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.

Passing the needles and placing the Sling

14. Pass the needle through one of the suprapubic incisions. The superior surface of the pubic symphysis can be located, and the needle tip can be advanced superior to this location. After perforation of the rectus fascia/musculature with the tip of the needle, the needle handle should immediately rotate superiorly as the needle is advanced.

NOTE: *Surgeon may elect to hold the needle shaft rather than the handle for enhanced control during needle passage.*

ArcSP

15. Using the posterior surface of the pubic bone as a guide, advance the needle tip downward toward the distal ipsilateral vaginal sulcus where the junction of the inferior portion of the symphysis joins the inferior border of the pubic ramus.

16. Using the index finger to meet the tip of the needle, guide the needle tip through the endopelvic fascia and periurethral fascia, into the vaginal tunnel, and then out of the vaginal incision.

17. When the first needle is in place, pass the second needle in the same manner on the contralateral side (repeating steps14 through 16), following the posterior surface of the pubic bone, perforating the endopelvic/periurethral fascia and exiting via the vaginal dissection tunnel (Figure 4). vertically along the posterior surface of the pubic bone to the ipsilateral suprapubic exit point incision.

NOTE: *If the needle tip cannot be located by the index finger, retract the needle and pass again*

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

⚠ **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

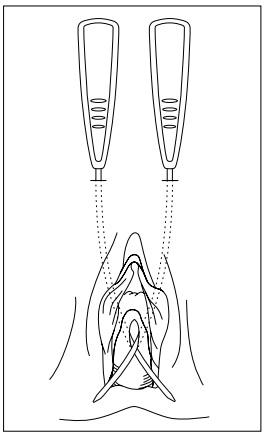


Figure 4: Needle passage and positioning

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 handles to aid exclusion of bladder 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 14-16. Reconfirm bladder and urethral integrity with another cystoscopy.

19. Once bladder and urethral integrity is confirmed, attach one end of the sling assembly to the needle 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 ArcSP 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 prior to attaching the second connector. The connectors can be rotated but cannot be removed once they are snapped into place.

21. Attach the other end of the sling assembly to the other needle. The connector is properly attached when an audible "click" is heard.

22. 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.

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

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

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

26. 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.*

ArcSP

27. 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.

28. 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.

29. 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.

30. Close the suprapubic 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. A type of 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 ArcSP Sling System

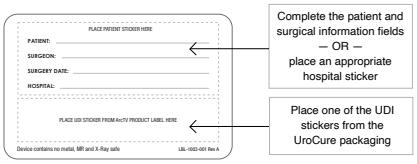
1. Remove UroCure PDC insert from the ArcSP box. The patient device card should be removed from the insert after the procedure.

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 surgery in an appropriate setting.

Figure 5: Front of card



Back of card

ArcSP

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.

UroCure
ADVANCING WOMEN'S HEALTH

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2022 FEMALE INCONTINENCE CODING & PAYMENT

SLING PROCEDURE FOR FEMALE STRESS INCONTINENCE

Current Procedural Terminology (CPT®)[1] codes identify procedures or services being performed and are not specific to the device being used. It is the provider's responsibility to choose codes that accurately describe the patient diagnosis and the services performed.

COMMONLY BILLED CPT CODES:

- 57288: Sling operation for stress incontinence (eg, fascia or synthetic)
- 57287: Removal or revision of sling for stress incontinence (eg, fascia or synthetic)

PHYSICIAN PAYMENT IN THE FACILITY SETTING[2]

CPT CODE	FACILITY RVU TOTAL	2022 PHYSICIAN MEDICARE NATIONAL AVERAGE	GLOBAL PERIOD
57288	22.08	$764	90
57287	22.14	$766	90

HOSPITAL OUTPATIENT CODING & REIMBURSEMENT[3]

CPT CODE	2022 APC	2022 HOPD MEDICARE NATIONAL AVERAGE
57288	5415	$4,503
57287	5414	$2,680

AMBULATORY SURGERY CENTER (ASC) PAYMENT[3]

CPT CODE	2022 ASC MEDICARE NATIONAL AVERAGE
57288	$2,586
57287	$1,331

DISCLAIMER:
The information contained in this document is for informational purposes only, is current as of January 1, 2022. It is always the responsibility of the provider to determine if the services actually provided are accurately described by any specific code(s) and to report services consistent with specific payer requirements. This information is subject to change at any time, and UroCure strongly recommends that you consult your payer organization with regard to its reimbursement policies. In all cases, services billed must be medically necessary, actually performed as reported and appropriately documented.

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[1] Current Procedural Terminology (CPT) Copyright 2021 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association. Applicable FARS/DFARS Restrictions apply to government use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.
[2] 2022 Medicare Physician Fee Schedule November 2021 release, CMS-1734-F, Addendum B
[3] 2022 Medicare OPPS and ASC November 2021 release, CMS-1736-FC, Addendum B and AA.

UroCure

Reimbursement Guide LBL-1001-003 Rev D

LiNA®

UroCure slings are distributed exclusively by LiNA Medical USA.

For Customer Service, please call (855) 546-2633 or email info@linamed.com.

Ordering Information:

PART NUMBER:	PRODUCT:	UOM*:
A-TV-1001	UROCURE ArcTV TRANSVAGINAL SLING SYSTEM	INCLUDES ONE (1) ArcTV SLING SYSTEM
A-SP-1001	UROCURE ArcSP SUPRAPUBIC SLING SYSTEM	INCLUDES ONE (1) ArcSP SLING SYSTEM
A-TO-1001	UROCURE ArcTO TRANSOBTURATOR SLING SYSTEM	INCLUDES ONE (1) ArcTO SLING SYSTEM

* Product can only be ordered and shipped in quantities of two

CAUTION: US Federal law restricts this device to sale by or on the order of a physician. This device is intended for use only by physicians with adequate training and experience in the use of polypropylene slings for stress urinary incontinence.

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 adhesion; 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.

For further information on indications, contraindications, warnings and precautions, and adverse events refer to the product instructions for use at www.urocure.com/ifu.

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