

# UROLIFT®

## UroLift® System UL400 and UroLift ATC™ System

### Instructions for Use

#### UroLift System UL400

##### Box Contents

Catalog No. REF UL400-4 (4 Trays)

##### Tray Contents

- 1 UroLift System UL400 Delivery Device
- 1 UroLift Handle Release Tool (HRT)

#### UroLift Advanced Tissue Control (ATC) System

##### Box Contents

Catalog No. REF UL400ATC (1Tray)

##### Tray Contents

- 1 UroLift ATC System Delivery Device
- 1 UroLift Handle Release Tool (HRT)



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### PRODUCT DIMENSIONS

DIMENSION	VALUE
Needle Diameter	19 Gauge (0.0372 in)
Deployed Needle Length	33 mm (1.299 in)
Suture Component Diameter	0.38 mm (0.015 in)

**STERILE:** The UroLift System has been sterilized using gamma sterilization. For single-use only and must not be resterilized. The UroLift System is inoperable after single use.

Not made with natural rubber latex.

**⚠ WARNING:** Do not use if package is opened or damaged. A non-sterile device may result in patient infection.

### STORAGE CONDITIONS

Store device at room temperature.

### INDICATIONS FOR USE

The UroLift System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral and median lobe hyperplasia, in men 45 years of age or older.

### CONTRAINDICATIONS

The UroLift System should not be used if the patient has:

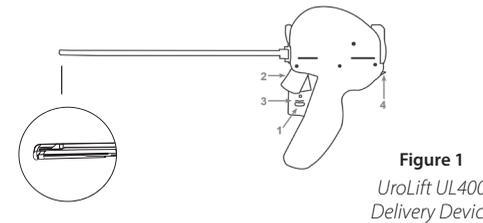
- Prostate volume of >100 cc
- A urinary tract infection
- Urethral conditions that may prevent insertion of delivery system into bladder
- Urinary incontinence due to incompetent sphincter
- Current gross hematuria

### PRODUCT DESCRIPTION

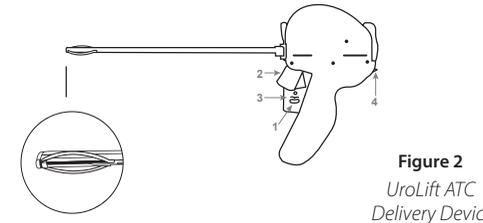
Each UroLift System (UL400 and ATC) is comprised of two main components: UroLift Delivery Device (UL400 or ATC) and UroLift Implant.

The UroLift System provides two types of Urolift Delivery Devices:

- UroLift UL400 Delivery Device (**Figure 1**)
- UroLift ATC Delivery Device (**Figure 2**)



**Figure 1**  
UroLift UL400  
Delivery Device



**Figure 2**  
UroLift ATC  
Delivery Device

Each UroLift Delivery Device also includes one UroLift Handle Release Tool (HRT) for use in troubleshooting steps.

Each Delivery Device (**Figure 1** and **Figure 2**) is designed to access the prostatic urethra and deliver one implant through the lobes of the prostate. The ATC Delivery Device has an enhanced tip design to mobilize challenging lateral and median lobe tissue.

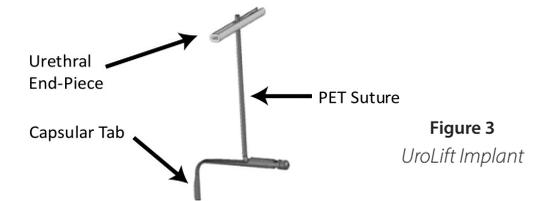
**Note:** You may use either UroLift Delivery Device to perform the implant procedure.

Using either Delivery Device, the implant is delivered in four basic steps (detailed in section 6, Implant Deployment):

1. Needle Safety Lock (**1**) is released.
2. Needle Trigger (**2**) is depressed, deploying the needle and Capsular Tab to the capsular side of the prostate. The needle extends 33 mm from the tip of the device.
3. Retraction Lever (**3**) is depressed, resulting in delivery of the Capsular Tab with suture under tension.
4. Urethral Release (**4**) is pressed, deploying the Urethral End-Piece and cutting excess suture.

The Delivery Device is then withdrawn. This process is intended to increase the luminal prostatic urethral opening thereby relieving lower urinary tract symptoms associated with BPH. On average, 4 to 6 implants are typically placed per patient. The maximum number recommended to be placed per patient is 10 implants.

The implant (**Figure 3**) consists of a Capsular Tab connected by monofilament suture to the Urethral End-Piece.



**Figure 3**  
UroLift Implant

The materials used in the implant are well established for use in medical device implants and elicit minimal acute inflammatory reaction in tissue. The suture is made from PET (Polyethylene Terephthalate), the Capsular Tab is made from nitinol (nickel titanium alloy), and the Urethral End-Piece is made from stainless steel. The implant is not absorbed, nor is any significant change in tensile strength known to occur in vivo.

Treatment with the UroLift System does not preclude follow up treatment with the UroLift System, transurethral resection of the prostate (TURP) or laser vaporization of the prostate. Retreatment via other therapies has not been studied.

### ⚠ WARNINGS AND PRECAUTIONS

- Read all instructions prior to using the UroLift System.
- Do not use if the patient has a known allergy to nickel, titanium, or stainless steel.
- The UroLift System is intended for Single Use Only – DO NOT RESTERILIZE. Resterilization may result in device malfunction including incomplete needle deployment or failed implant delivery requiring further physician intervention. The UroLift System is provided sterile. Sterility will be maintained only if package is unopened and undamaged. Always inspect packaging integrity prior to use. If damage is detected or sterile packaging compromised, do not use the product. Return the product to NeoTract, Inc.
- Store device at room temperature. Avoid exposure to prolonged elevated temperatures.
- Users should be familiar with performing sterile transurethral surgical procedures and cystoscopic techniques. Patient should be placed in balanced lithotomy position.
- Training is required prior to using the UroLift System. Physician and Staff Training Program entails a) a didactic session; b) clinical video review; and c) hands-on device use. The program focuses on patient selection, procedure preparation, device operation, and implantation technique. Please contact NeoTract Customer Service for UroLift System training information.

- Each device contains a needle. After use, the device may be a potential biohazard and should be handled accordingly. Dispose of device in accordance with accepted medical practice and applicable local and federal laws and regulations.

**Note:** Other relevant warnings and precautions are included with the associated section or process step for emphasis as described below.

#### ANCILLARY EQUIPMENT

- 2.9 mm 0° telescope (NeoTract REF UL-SCOPE or equivalent)
- 20F sheath (NeoTract REF UL-SHEATH or equivalent)
- Visual Obturator (NeoTract REF UL-VO or equivalent)
- Cystoscopy camera, light box/cable and monitor
- Standard fluid irrigation system including new, sterile fluid tubing
- Flexible cystoscope to inspect bladder and prostate after implant deployment
- Standard endoscopic grasper kit<sup>1</sup>

*It is recommended to have a grasper kit (or an equivalent standard urology instrument for foreign body retrieval) in the event that it is desired or necessary to retrieve or remove part of the implant during the procedure.*

All equipment compatibility should be verified prior to use.

The ancillary equipment, including the telescope, sheath, visual obturator, and grasper kit must be sterilized per the respective manufacturer's instructions, prior to use.

#### HANDLING COMPONENTS

Care must be taken to avoid mishandling components. Use caution when handling components to avoid inadvertent punctures. When surgical instruments and accessories from different manufacturers are employed together, ascertain their compatibility prior to the procedure.

#### OPERATING INSTRUCTIONS

Read and thoroughly understand all instructions prior to using the UroLift® System.

**IMPORTANT:** You may use either UroLift Delivery Device to perform the implant procedure. In steps where the procedure is different depending on the Delivery Device, the specific Delivery Device is underlined to highlight the difference (UL400 or ATC™). If there is no difference in which device you use to perform the step, the device is simply referred to as the Delivery Device or the UroLift System.

**WARNING:** Failure to maintain the sterility of the UroLift System and ancillary equipment could lead to infection.

### 1. PRE-PROCEDURE CYSTOSCOPY

- 1.1 Assemble the 2.9 mm 0° telescope (NeoTract REF UL-SCOPE or equivalent), visual obturator, and 20F sheath.
- 1.2 Advance the telescope assembly through the urethra and visualize both the urethra and bladder by advancing into the bladder.
- 1.3 Remove the telescope and visual obturator, leaving the sheath in the bladder.

### 2. PREPARATION

- 2.1 Confirm that packaging components are unopened and undamaged.

**WARNING:** Do not use if package is damaged or opened.

- 2.2 Inspect all components for any damage that may have occurred during shipment or other handling.

**CAUTION:** Do not use if device is damaged.

- 2.3 While holding the handle end (heavy end) of tray, peel back the cover to access the sterile contents.

- 2.4 Using sterile technique, remove the lid of the tray.

- 2.5 Using sterile technique, remove the device from the packaging by grasping the handle and lifting the device from the tray.

**CAUTION:** Do not lift the device by the steel shaft.

- 2.6 Inspect the device tip and confirm that the needle is not visible. Inspect the Needle Safety Lock and confirm that it is in the locked (forward) position.

**CAUTION:** Do not use if the needle is exposed or if the Needle Safety Lock is in the unlocked (rear) position.

### 3. DEVICE INSERTION AND POSITIONING

- 3.1 Insert 2.9 mm 0° telescope (NeoTract REF UL-SCOPE or equivalent) into device with the telescope lightpost at 12 o'clock. Keep forward pressure on the telescope, hold telescope lightpost at 12 o'clock, and secure the scope lock by rotating clockwise until finger tight. Do not overtighten.

**CAUTION:** Overtightening the scope lock may result in damage to the Delivery Device.

- 3.2 Insert the Delivery Device (with 2.9 mm telescope installed) into the sheath and lock the sheath lock.

**WARNING:** To avoid inadvertent needle advancement, do not place fingers on Needle Safety Lock or Trigger when positioning Delivery System.

**WARNING:** Use caution when inserting the device so as not to put excessive force on the back wall of the bladder.

**WARNING: ATC** When using the UroLift ATC Delivery Device, do not manually compress the wing components at the device's distal tip prior to insertion into the sheath.

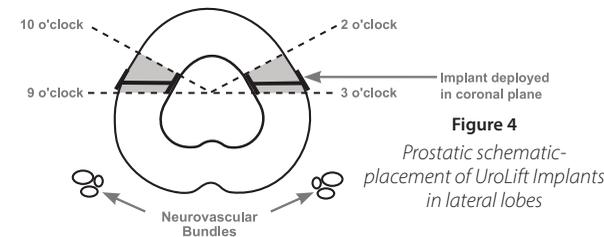
**CAUTION:** Avoid placing pressure on the camera head to position the Delivery Device. Image should be round on the video monitor. A dark crescent or a portion of image missing is evidence of excessive pressure on the camera head. Excess pressure could compromise device performance or damage telescope.

### 4. DELIVERY DEVICE POSITIONING: LATERAL LOBE

**WARNING: ATC** When using the UroLift ATC Delivery Device, use caution to prevent excessive tissue manipulation during compression, rotation, and retraction.

- 4.1 Locate the treatment site by visualizing the prostatic fossa from the bladder neck to the verumontanum.

- 4.2 To avoid external prostatic structures (e.g. neurovascular bundles), position the Delivery Device tip in the anterior aspect of the prostate in either the 2-3 or 9-10 o'clock position (**Figure 4**). Orient the tip to ensure the needle deploys laterally (needle deploys in line with the Delivery Device handle).



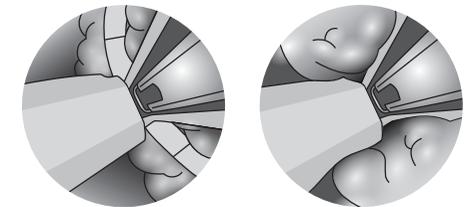
As with cystoscopy, keep device parallel to the prostatic fossa and avoid excessive instrument movement throughout positioning and deployment.

To obtain the desired urethral opening, place implants throughout the length of both lateral prostate lobes at approximately 1 cm intervals starting 1.5 cm distal to the bladder neck with implants generally paired on the left and right sides.

**WARNING:** Failure to deploy the implant as described above could lead to nerve damage, bleeding, pain, infection, damage to the gastrointestinal tract or fistula formation.

**WARNING:** Deploying too close (<1 cm) to the bladder neck may result in implants that are exposed to the bladder vesicle. Improperly placed implants could lead to encrustation and may need to be removed.

- 4.3 Position the Delivery Device such that the keyhole (**Figure 5**) is against the target prostatic lobe in the lateral direction.



**Figure 5**

UroLift ATC Delivery Device tip (left) and UroLift UL400 Delivery Device tip (right) showing keyhole position

- 4.4 To achieve desired amount of urethral opening, angle the Delivery Device laterally (against the target lobe), applying slight pressure to the Delivery Device tip via Delivery Device handle.

**CAUTION:** Do not use the cystoscopy camera head to apply pressure to the prostate tissue as this could compromise UroLift System performance.

- 4.5 For instructions on deploying the implant(s) in the lateral lobe, see section 6, Implant Deployment.

### 5. DELIVERY DEVICE POSITIONING: MEDIAN LOBE

**WARNING: ATC** When using the UroLift ATC Delivery Device, use caution to prevent excessive tissue manipulation during compression, rotation, and retraction.

- 5.1 Once the lateral lobes are secured out of the anterior aspect of the urethra from bladder neck to verumontanum, and if obstruction persists due to a median lobe, place additional implant(s) as follows.

- 5.2 Do either of the following, depending on which Delivery Device you are using:

- **ATC** With the ATC Delivery Device in the sulcus, align the black lines on the wings with the bladder neck.
- **UL400** Align the keyhole with the bladder neck.

- 5.3 Rotate the Delivery Device tip so that the keyhole is pointing to either the 3-4 o'clock or 8-9 o'clock position, toward the median lobe.

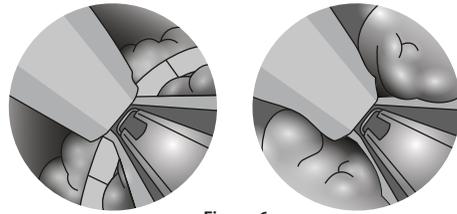


Figure 6

UroLift® ATC™ Delivery Device tip (left) and UroLift UL400 Delivery Device tip (right) shown in 3-4 o'clock position

- 5.4 Begin compressing the median lobe posterior-laterally towards 3-4 or 8-9 o'clock by raising the handle of the Delivery Device in the opposite direction, while simultaneously retracting the median lobe into the prostatic urethra.
- 5.5 Ensure the tip of the Delivery Device is within the prostatic urethra and that the median lobe tissue does not slip from under the tip of the Delivery Device during retraction. If the median lobe tissue does slip from under the tip, relax compression, advance the Delivery Device tip back into the bladder, and begin again at step 5.2.
- 5.6 Once the median lobe has been retracted and the tip of the Delivery Device is in the prostatic urethra, maintain compression and slowly begin to rotate the tip into a more lateral trajectory (towards 3 o'clock or 9 o'clock), then slowly lower hands more parallel to the floor.
- 5.7 If required, additional implants can be placed. For instructions on deploying additional implants, see section 6, Implant Deployment.

**⚠ WARNING:** Failure to deploy the implant as described above could lead to nerve damage, bleeding, pain, infection, damage to the gastrointestinal tract or fistula formation.

**⚠ WARNING:** When treating the prostate median lobe, the Capsular Tab of the implant should not be implanted posterior to the 4 and 8 o'clock positions on the prostatic capsule (**Figure 7**) to avoid external prostatic structures (e.g., neurovascular bundles, gastrointestinal tract).

**⚠ CAUTION:** If no portion of the intravesical tissue can be manipulated into the prostatic fossa, no implant should be deployed.

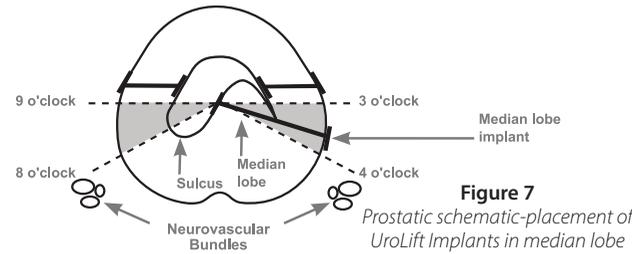


Figure 7

Prostatic schematic-placement of UroLift Implants in median lobe

**⚠ WARNING:** Deploying too close (<1 cm) to the bladder neck may result in implants that are exposed to the bladder vesicle. Improperly placed implants could lead to encrustation and may need to be removed.

## 6. IMPLANT DEPLOYMENT

While holding the Delivery Device distal tip stable against the target tissue, perform the following steps:

- 6.1 Unlock the Needle Safety Lock (**Step 1, Figure 8**).

**⚠ WARNING:** To avoid inadvertent needle advancement, do not place finger on Needle Trigger when positioning Delivery Device once Needle Safety Lock is unlocked.

- 6.2 Lightly depress *only* the Needle Trigger to deploy the needle (**Step 2, Figure 8**). The UroLift System needle extends 33 mm, which is sufficient to reliably access the prostatic capsule based on cadaver and clinical studies.

**⚠ CAUTION:** Do not depress the Retraction Lever during the Needle Trigger pull.

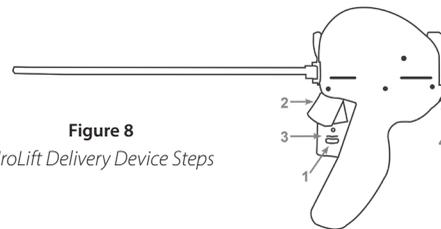


Figure 8

UroLift Delivery Device Steps

- 6.3 After the needle is fully deployed, depress the Retraction Lever (**Step 3, Figure 8**) fully to retract needle and deploy Capsular Tab. Squeeze the Retraction Lever again to ensure complete retraction. By this action, the Capsular Tab is delivered from the tip of the extended needle and is then tensioned back towards the prostatic capsule until it seats on the capsular surface. The needle is now in the retracted (not exposed) position and is contained within the Delivery Device. If complete retraction is not achieved, follow Step 8.1 to manually release the Retraction Lever.

**⚠ CAUTION:** Failure to depress the Retraction Lever completely may result in incomplete needle retraction, Urethral End-Piece misdeployment, loose Urethral End-Piece, or incomplete suture cut.

**⚠ CAUTION:** Avoid contact with the Urethral Release (**Step 4, Figure 8**) button when depressing the Retraction Lever. Contact with the Urethral Release button while depressing the Retraction Lever may result in inadvertent deployment of the Urethral End-Piece and unintentionally cutting the suture.

- 6.4 While maintaining angle of Delivery Device, slightly reduce the compression applied to the prostatic lobe to avoid interference of tissue with suture cutting, but still maintain contact with tissue.

The suture is now tensioned and the tension is maintained by the Delivery Device. Slowly move the Delivery Device proximally towards the bladder to ensure the suture is against the edge of the keyhole (closest to the operator) and also aligned within the keyhole (side-to-side). Continue advancing until a white line appears half-way across the suture, showing a reflection of the cystoscopy light (**Figure 9**). If desired, to cut the suture without delivering the Urethral End-Piece resulting in an incomplete implant, follow Step 8.2 to manually cut the suture.

If the suture is not visible in the keyhole, slightly advance the Delivery Handle toward the bladder and check again. If the suture is still not visible, the Capsular Tab may have been deployed inside the prostate and the implant will not be formed correctly. In this case, fully advance the Delivery Device tip into the bladder (ensuring the suture does not appear), and remove the device from the patient and discard. Use a new device and increase the compression angle to avoid recurrence of this issue.

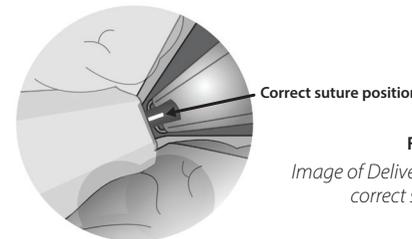


Figure 9

Image of Delivery Device tip showing correct suture position

**⚠ CAUTION:** Failure to position suture against closest edge of keyhole (**Figure 10**) may result in Urethral End-Piece misdeployment or an incomplete suture cut.

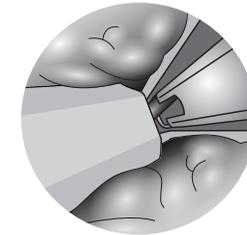


Figure 10

Image of Delivery Device tip showing suture not against closest edge of keyhole

- 6.5 Press the Urethral Release button toward the telescope (**Step 4, Figure 8**) to deploy Urethral End-Piece and cut the excess suture. After the Urethral Release button is pressed, the complete implant has been deployed. If the suture is not fully cut after pressing the Urethral Release button, follow Step 8.2 to manually cut the suture. No further implants can be delivered using the same Delivery Device.

- 6.6 After the implant deployment is complete, fully relax the angle of the device tip back to midline, and advance the tip of the device into the bladder. As with cystoscopy, keep the device parallel to prostatic fossa. When advancing the Delivery Device proximally into the bladder, maintain the Delivery Handle and keyhole laterally, toward the just-treated side, in either the 9 or 3 o'clock orientation.

**⚠ CAUTION:** At this point in the procedure, make sure the suture is cut.

- 6.7 Once positioned in bladder, the Delivery Device should be oriented in the anterior-posterior orientation with the Delivery Handle and keyhole pointing towards the floor. The Delivery Device can then be removed from the cystoscopy sheath.

**⚠ WARNING: ATC** If using the UroLift ATC Delivery Device, remove it from the sheath slowly to ensure the tip's wings collapse for removal.

- 6.8 To deploy more implants, remove Delivery Device from the sheath and replace with a new UroLift System.

To obtain the desired urethral opening, place implants throughout the length of both lateral prostate lobes at approximately 1cm intervals with UroLift Implants generally paired on the left and right sides.

**⚠ CAUTION:** When advancing ancillary equipment and/or devices and when deploying additional implants, be careful not to disrupt previously deployed implants.

**6.9** Cystoscopy may be performed in between implant deployments to cystoscopically address if any additional implants are needed. If additional implants in lateral lobes are needed, see section 4, Delivery Device Positioning: Lateral Lobe. If an obstruction persists due to the median lobe, see section 5, Delivery Device Positioning: Median Lobe. If no obstruction persists, continue to section 7, Cystoscopy.

## 7. CYSTOSCOPY

Between and after implant deployments, perform a cystoscopy of the urethra and bladder to:

- Confirm the desired effect has been achieved.
- Confirm that all implant components are well apposed to mucosal tissue within the prostatic urethra.
- Ensure implants are not present in the bladder or at the bladder neck extending into the bladder vesicle.
- Assess the trigone and bladder for any damage.

If required, using a foreign body retrieval grasper or other applicable instrument, remove:

- Improperly placed implants (i.e. implants placed within the bladder or exposed to stagnant urine)
- Implants not well apposed to tissue (i.e. untensioned implants or any loose implant components/device components)

**⚠ WARNING:** Failure to remove improperly placed implants could lead to encrustation, stone formation, urinary symptoms, and possible subsequent intervention for removal.

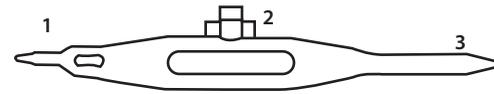
**⚠ CAUTION:** When advancing ancillary equipment and/or devices, be careful not to disrupt previously deployed UroLift® Implants.

## 8. MANUAL RELEASE INSTRUCTIONS FOR USE

### 8.1 Retract Lever Release

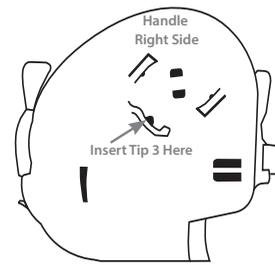
If the needle does not retract, insert **Tip 3** of Handle Release Tool (HRT) (Figure 11) into hole on right side of Delivery Device handle (Figure 12). Gently press **Tip 3** to displace the white tab while gently squeezing the Needle Trigger and Retraction Lever together to finish retracting the needle. Remove **Tip 3** from the Delivery Device handle.

**Note:** Likely, no implant will have been deployed. The needle may have been prevented from retracting because of bone contact. Therefore, for the next deployment, slightly decrease tissue compression.



**Figure 11**

Handle Release Tool with Tip Numbering



**Figure 12**

Retraction Lever Release (right side of Handle)

### 8.2 Monofilament Suture Release

If it is desired to cut the monofilament suture without delivering Urethral End-Piece, insert **Tip 3** of HRT (Figure 11) into hole on left side of handle (Figure 13).

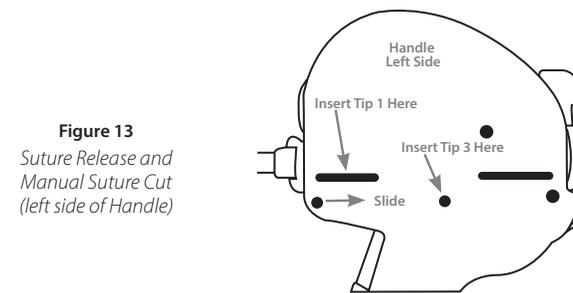
The Capsular Tab and suture will remain in the patient.

**⚠ CAUTION:** If an unattached Urethral End-Piece is in the urinary tract, remove it.

### 8.3 Manual Suture Cut

If the suture was not cut after pressing the Urethral Release Button, insert **Tip 3** of HRT (Figure 11) into hole on left side of handle (Figure 13).

If the suture is still not cut, insert **Tip 1** of the HRT into the slot on the front left side of the handle and slide the HRT from front to back.

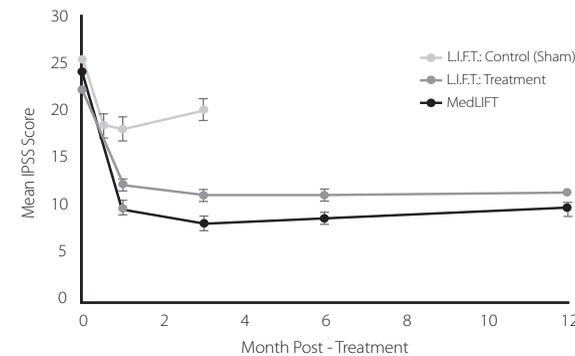


**Figure 13**

Suture Release and Manual Suture Cut (left side of Handle)

## SUMMARY OF CLINICAL STUDY RESULTS (UroLift System (UL400))

The L.I.F.T. study enrolled a total of 206 subjects randomized 2:1 (140 UroLift System: 66 Control) at 19 investigational sites. The 3-month Intent To Treat (ITT) primary endpoint was met: reduction in IPSS was 88% greater in the UroLift System arm as compared to the Control arm (IPSS reduction of  $11.1 \pm 7.7$  UroLift System vs.  $5.9 \pm 7.7$  Control,  $p=0.003$ ). The 12-month ITT primary endpoint was also met: UroLift subjects experienced a 45.5% IPSS reduction (97.5% CI lower bound of 38.3%) from baseline. UroLift System subjects experienced symptom relief by 2 weeks, additional improvement to 3 months and sustained improvement at 12 months (Figure 14).



**Figure 14**

Mean IPSS at each follow-up interval—Active and Control arms. Note: Mean  $\pm$  standard error

All ITT secondary endpoints were met. For the UroLift System subjects, Qmax was improved 63.5% at 3 months and sustained to 54.8% at 12 months,  $p<0.001$ ; QoL was improved 47.8% at 3 months and sustained to 48.1% at 12 months,  $p<0.001$ ; and BPHII was improved 56.5% at 3 months and sustained to 55.0% at 12 months,  $p<0.001$ . All endpoints were statistically superior to Control at the 3-month comparison (Qmax, QoL, BPHII p-values of 0.005,  $<0.001$ ,  $<0.001$ , respectively).

Improvement of IPSS, QoL, BPHII, and Qmax were durable through 5 years with improvements of 36%, 50%, 52%, and 44% respectively.

The MedLift (subjects with obstructive median lobe) study enrolled 45 subjects at 9 US investigational sites. The 12-month endpoint was met; the lower bound of the 95% lower confidence limit of the mean percent improvement in IPSS over baseline for the UroLift System was 55.1%.

The Real-World Retrospective Study examined a cohort of 39 subjects with large prostates ( $\geq 80$ cc) and found no significant difference in symptom response or overall adverse event rate as compared to patients with  $<80$ cc.

## SAFETY

The primary safety endpoint in the L.I.F.T. study was achieved if  $<10\%$  of patients required post-operative catheterization for more than 7 days. Only 1.4% (2/140) in the L.I.F.T. study and 2.2% (1/45) in the MedLift study required extended post-operative catheterization. The mean postoperative catheter duration averaged over the entire population was 0.9 days in the L.I.F.T. study and 1.2 days in the MedLift study. Mean return to preoperative activity was 8.6 days in the L.I.F.T. study.

The proportion of UroLift System subjects who experienced de novo sustained sexual dysfunction (sustained erectile dysfunction or anejaculation) was assessed independently in the L.I.F.T. and MedLift studies and it was determined that none (0.0%) of the UroLift System subjects experienced de novo sustained sexual dysfunction (erectile or ejaculatory dysfunction).

The majority of the adverse events in the UroLift System group occurred in L.I.F.T. within 7 days of treatment. Most were mild to moderate and resolved within 2-4 weeks following treatment. The device related events reported through one year in the L.I.F.T. study included dysuria (35.7% of subjects), hematuria (27.1%), pelvic pain (18.6%), micturition urgency (10.0%), urinary incontinence (7.9%), calculus urinary (7.9%), retention (5.7%), nocturia (5.0%), pollakiuria (5.0%), and bladder spasm (4.3%). Adverse events most observed through 6 months in the MedLift study were blood clot in urine (57.8%), dysuria (48.9%), hematuria (24.4%), micturition urgency (8.9%) urinary retention (6.7%), urge incontinence (6.7%) and painful ejaculation (6.7%).

Other adverse events included, but were not limited to, PSA elevation, urinary tract infection, hypotension, residual urine, urine flow decrease, abdominal pain, constipation, ejaculation disorder, erectile dysfunction, hematospermia, urinary hesitation, splitting of urinary stream, hemorrhoids, hypertonic bladder, penile pain, proctalgia, and pyrexia.

The following can potentially occur as a result of pelvic or urological procedures including, but not limited to, adhesion formation, adverse tissue reaction, bleeding, contracture, epididymitis, gastrointestinal complications, changes in heart rate or blood chemistry, dizziness, drug withdrawal syndrome, injury to the urinary tract or adjacent organs, foreign body sensation or migration, need for additional procedure, nerve damage, prostatitis, orchitis, balanitis, thrombophlebitis, sepsis, sphincter injury, and stricture that could lead to serious outcomes.

## MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the UroLift® Implant is MR Conditional. A patient with this device can be safely scanned in an MR system immediately after placement meeting the following conditions:

- Static magnetic field of 3.0 Tesla or less
- Maximum spatial gradient magnetic field of 1,500 Gauss/cm (15 T/m) (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of scanning (i.e. per pulse sequence)(First Level Controlled Operating Mode)

Under the scan conditions defined above, the UroLift Implant is expected to produce a maximum temperature rise of 2.4°C after 15 minutes of continuous scanning (i.e. per pulse sequence).

In non-clinical testing, the image artifact caused by the device extends approximately 15 mm from the UroLift Implant when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

The safety of the delivery system has not been evaluated in the MR environment, and therefore, the delivery system should not be used within the MR environment. Patient implant cards are provided to inform the patient that the UroLift Implant is MR Conditional and can safely be scanned only under specific MR conditions.

## Symbols

SYMBOL	DEFINITION
	Manufacturer
	Attention, see Instructions for Use
	Warning/Caution
	Prescription Only: Federal law restricts this device to use by or on the order of a physician
	Do Not Rest sterilize
	Do Not Reuse
	Catalog Number/Part Number
	Do Not Use if Package is Damaged
	Sterile (radiation)
	Manufacturing Lot Number
	Quantity in Package
	Use By Date
	MR Conditional

## PATENTS, TRADEMARKS, AND DISCLAIMER

### U.S. PATENTS

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### U.S. TRADEMARKS

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