



## UroLift® 2 System Instructions for Use

The UroLift 2 System is comprised of two main components:

- UroLift 2 Delivery Handle with Scope Seal (UL2-H)
- UroLift 2 Implant Cartridge (UL2-C)

Each Implant Cartridge is pre-loaded with one (1) UroLift Implant.

Both components are required to use the UroLift 2 System.

Patient Implant Cards are provided with packaged Implant Cartridges.

Packaged quantities may vary.

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**R<sub>x</sub>** only

## 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® 2 System has been sterilized using gamma sterilization. The UroLift 2 Delivery Handle and Scope Seal are for SINGLE PATIENT USE only and must not be resterilized and must not be used after a maximum of eight (8) cartridges have been deployed. The UroLift 2 Implant Cartridge is SINGLE USE only.

Not made with natural rubber latex.

**⚠ WARNING:** The UroLift 2 Delivery Handle has not been validated for use in more than eight deployments or after resterilization. The UroLift 2 Delivery Handle may not perform according to specifications if used more than eight times or if additional sterilization is attempted. No part of the UroLift 2 System should be resterilized. Resterilization may result in device malfunction including incomplete needle deployment, failed suture delivery, or patient infection requiring further physician intervention. Using a UroLift 2 Delivery Handle, UroLift 2 Implant Cartridge, or Scope Seal on more than one patient may result in infection.

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

### STORAGE CONDITIONS

Store Delivery Handles and Implant Cartridges at room temperature.

### INDICATIONS FOR USE

The UroLift 2 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

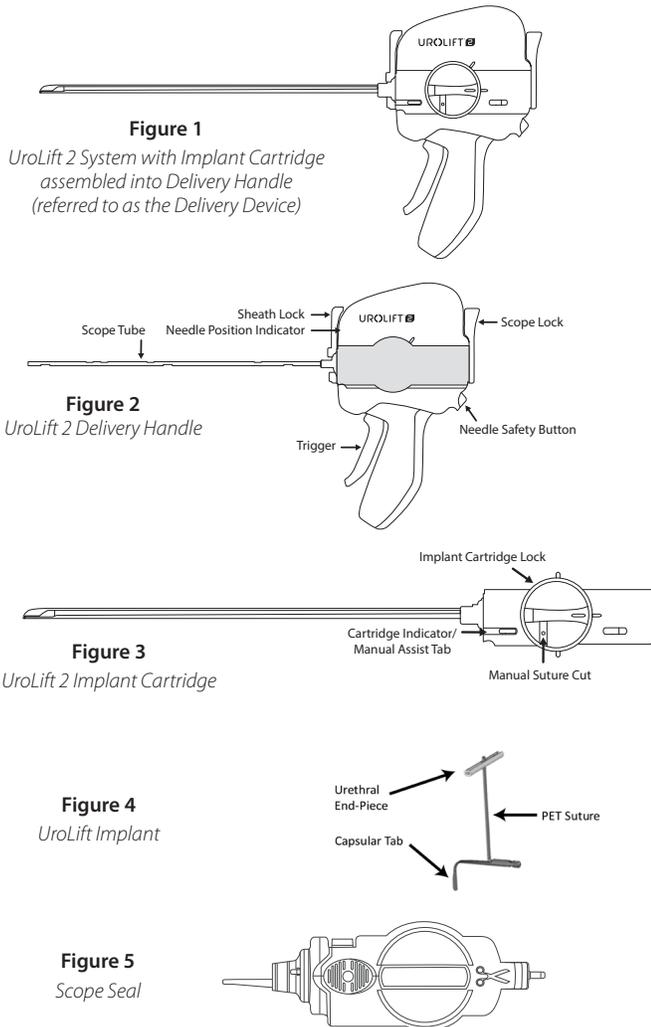
The UroLift 2 System should not be used if the patient has:

- 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

The UroLift® 2 System (**Figure 1**) is comprised of two main components:

- UroLift 2 Delivery Handle (**Figure 2**)
- UroLift 2 Implant Cartridge (**Figure 3**). Each Implant Cartridge is pre-loaded with one UroLift Implant (**Figure 4**).



The UroLift 2 System (**Figure 1**) is designed to access the prostatic urethra and deliver permanent UroLift Implants through the lobes of the prostate.

A single Delivery Handle can be used to deliver up to eight implants by employing eight UroLift 2 Implant Cartridges (**Figure 3**), each containing a single UroLift Implant. On average, 4 to 6 UroLift Implants are typically placed. The maximum number recommended to be placed per patient is 10 UroLift Implants.

The materials used in the UroLift Implant (**Figure 4**) 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.

The Scope Seal (**Figure 5**) is an accessory that is provided with the UroLift 2 Delivery Handle. It can be used for troubleshooting steps and to perform cystoscopy when inserted in the UroLift 2 Delivery Handle with an installed Telescope.

This procedure is intended to increase the luminal prostatic urethral opening thereby relieving lower urinary tract symptoms associated with BPH. Treatment with the UroLift 2 System does not preclude follow up treatment with the UroLift 2 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 2 System.
- Do not use if the patient has a known allergy to nickel, titanium, or stainless steel.
- The UroLift 2 System is comprised of the UroLift 2 Delivery Handle and the UroLift 2 Implant Cartridge. Both are provided sterile. Sterility will be maintained only if packaging is unopened and undamaged. Always inspect packaging integrity prior to use. If damage is detected or sterile packaging is compromised, do not use the product. Return the product to NeoTract, Inc.
- Store 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 recommended prior to using the UroLift 2 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 2 System training information.
- The UroLift 2 Delivery Handle and Scope Seal are SINGLE PATIENT USE only and should not be used after a maximum of eight (8) UroLift Implant Cartridges have been deployed. Each UroLift 2 Implant Cartridge is SINGLE USE only, in that it contains only one implant, and is inoperable after one use.
- Each Implant Cartridge contains a needle. After use, the Delivery Handle, Implant Cartridge, and Scope Seal may be a potential biohazard and should be handled accordingly and disposed of in accordance with accepted medical practice and applicable local and federal laws and regulations.
- During the deployment, the needle may come in contact with pelvic bone (bone strike) and may cause needle fragmentation or breakage. This is a known procedural risk. The user is instructed to ensure that all implant components are properly placed. If needle fragment or residual material is present, user is instructed to remove prior to completing the procedure. A final cystoscopy of the urethra and bladder should be performed to confirm the desired effect has been achieved and that implant components are properly placed. Refer to Section 4.

**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
- Standard endoscopic grasper kit<sup>†</sup>

<sup>†</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 UroLift 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 all instructions prior to using the UroLift® 2 System.

### 1. PRE-PROCEDURE CYSTOSCOPY

- 1.1 Assemble the 2.9 mm 0° telescope (NeoTract REF UL-SCOPE or equivalent), Visual Obturator (NeoTract REF UL-VO or equivalent), and 20F sheath (NeoTract REF UL-SHEATH or equivalent).
- 1.2 Conduct cystoscopy, noting possible locations for UroLift Implants.
- 1.3 While leaving the sheath in the bladder, remove the telescope/visual obturator assembly.

### 2. UroLift 2 SYSTEM PREPARATION

Read and thoroughly understand all instructions.

**⚠ WARNING:** Failure to maintain the sterility of the UroLift 2 System and ancillary equipment could lead to infection.

- 2.1 Confirm that packaging components are unopened and undamaged.
  - ⚠ WARNING:** Do not use if package is damaged or opened.
- 2.2 While holding the Delivery Handle end (heavy end) of the tray, peel back the cover to access the sterile contents.
- 2.3 Using sterile technique, remove the lid of the Delivery Handle tray.
- 2.4 Using sterile technique, remove the device from packaging by grasping the Delivery Handle and lifting it from tray.
  - ⚠ CAUTION:** Do not lift Delivery Handle by the steel shaft.
- 2.5 Inspect the blue Needle Safety Button (**Figure 2**) and confirm that it is NOT depressed.
  - ⚠ CAUTION:** Do not use if the blue Needle Safety button is in the depressed (unlocked) position.
- 2.6 While holding the Implant Cartridge end (heavy end) of the tray, peel back the cover to access the sterile contents.
- 2.7 Using sterile technique, lift the Implant Cartridge from the packaging by grasping the Implant Cartridge Lock.
  - ⚠ CAUTION:** Do not lift Implant Cartridge by the steel shaft or tamper with internal components.
- 2.8 Inspect the Implant Cartridge tip and confirm that the needle is not protruding past the protective film.

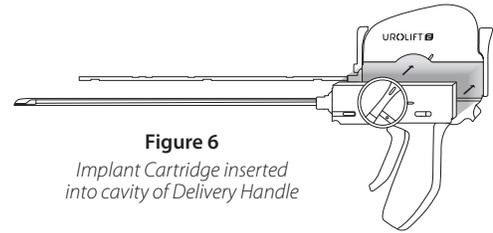
**⚠ CAUTION:** Do not use if the needle is exposed. Use caution when handling components to avoid inadvertent punctures.

**⚠ CAUTION:** Inspect the Cartridge Indicator/Manual Assist Tab on the Implant Cartridge and verify that it is in the unused position (green bar is visible) (**Figure 3**). If the green bar is not fully visible, discard and use a different cartridge.

### 3. DEVICE INSERTION AND POSITIONING: LATERAL LOBES

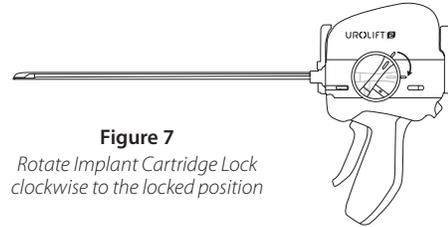
- 3.1 Insert the 2.9 mm 0° telescope into the Delivery Handle with the telescope light post at 12 o'clock. Keep forward pressure on the telescope, hold the telescope with light post at 12 o'clock position, and secure the Scope Lock (**Figure 2**) by rotating clockwise until finger tight. Do not overtighten.
  - ⚠ CAUTION:** Overtightening the Scope Lock may result in damage to the Delivery Handle.

- 3.2 Push and hold the Implant Cartridge into the cavity on the Delivery Handle (**Figure 6**) and rotate the Implant Cartridge Lock clockwise to the horizontal dashed line at 3 o'clock, locking the Implant Cartridge into the Delivery Handle (**Figure 7**). The Delivery Handle with the Implant Cartridge installed is referred to as the *Delivery Device*.



**Figure 6**

*Implant Cartridge inserted into cavity of Delivery Handle*



**Figure 7**

*Rotate Implant Cartridge Lock clockwise to the locked position*

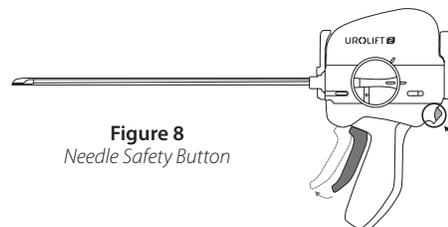
- 3.3 Once again, inspect the blue Needle Safety Button and confirm it is NOT depressed before proceeding (**Figure 2**).
- 3.4 Insert the Delivery Device (with 2.9 mm telescope installed) into the sheath with the Delivery Handle oriented in the anterior-posterior position and lock the Sheath Lock by fully rotating the Sheath Lock (~90 degrees).

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

**⚠ 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 portion of image missing is evidence of excessive load on the camera head. Excess pressure could compromise device performance or damage the telescope.

**NOTE:** If the sheath is not completely locked, it may affect the field of view and may increase leakage.

- 3.5 Press down on the blue Needle Safety Button (**Figure 8**), which automatically releases the Trigger.

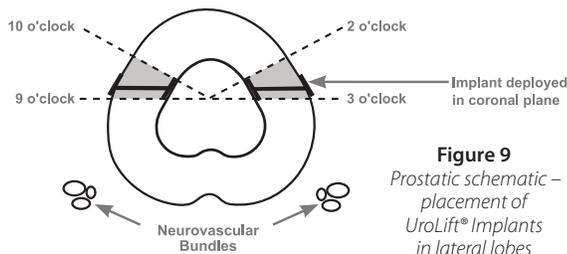


**Figure 8**

*Needle Safety Button*

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

- 3.6 Locate the treatment site by visualizing the prostatic fossa from the bladder neck to the verumontanum.
- 3.7 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 o'clock or 9-10 o'clock position (**Figure 9**). Orient the tip to ensure the needle deploys laterally (needle deploys in line with the Delivery Handle).



**Figure 9**  
Prostatic schematic –  
placement of  
UroLift® Implants  
in lateral lobes

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 UroLift Implants generally paired on the left and right sides.

**⚠ WARNING:** Failure to deploy the implant in the locations 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.

- 3.8** Position the Delivery Device such that the keyhole is against the target prostatic lobe in the lateral direction.

#### 4. IMPLANT DEPLOYMENT

**Summary of procedure:** Deploying each implant consists of four (4) pulls of the Trigger. To summarize:

- **Pull #1** deploys the needle and Capsular Tab.
- **Pull #2** partially retracts the needle and unsheathes the Capsular Tab.
- **Pull #3** fully retracts the needle and applies tension to the suture, holding the Capsular Tab in place.
- **Pull #4** seats the Urethral End-Piece into the suture, cuts the suture from the Implant Cartridge, and resets the Delivery Handle.

#### IMPORTANT:

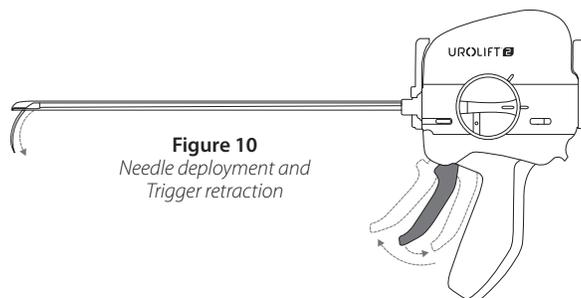
- When performing each pull, make sure to fully squeeze the Trigger to meet the Delivery Handle and then fully release the Trigger. Failure to fully release the Trigger may prevent the Trigger from fully returning to its released (out) position. If the Trigger is prevented from moving to the released position, move fingers away from the Delivery Handle and Trigger. If needed, use fingers to push the Trigger to the released position.
- All four Trigger pulls must be completed to allow for removal of the Implant Cartridge. If you remove the device from the patient prior to completing all four Trigger pulls, complete the remaining pulls outside of the patient to fully reset the Delivery Handle and to allow removal of the Implant Cartridge. For more information, see section 7, *TROUBLESHOOTING*.

- 4.1** 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 Handle.

**⚠ CAUTION:** Do not use the cystoscopy camera head to apply pressure to the prostate tissue as this could compromise the UroLift 2 System or telescope performance.

- 4.2** Squeeze the Trigger to meet the Delivery Handle (**Pull #1**), which deploys the needle and Capsular Tab to the capsular side of the prostate. The needle extends 33 mm from the tip of the device (**Figure 10**). The needle is visible in the cystoscope view.

**Note:** A Needle Position Indicator (**Figure 2**) is provided on the Delivery Handle for use in verifying that the needle deployed completely. In the event of bone contact, decrease the compression angle to successfully deploy the implant. For more information about bone contact, see section 7, *TROUBLESHOOTING*.



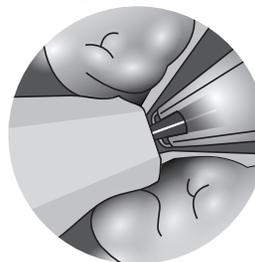
**Figure 10**  
Needle deployment and  
Trigger retraction

- 4.3** Squeeze the Trigger to meet the Delivery Handle (**Pull #2**). This action retracts the needle part-way and unsheathes the Capsular Tab.

- 4.4** Squeeze the Trigger to meet the Delivery Handle again to fully retract the needle and tension suture (**Pull #3**). The suture is visible in the cystoscope view.

- 4.5** While maintaining the 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.

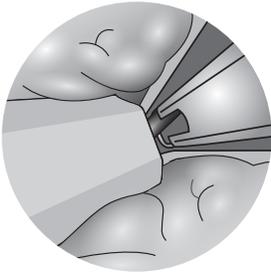
The suture is now tensioned and the tension is maintained by the Delivery Device. After confirming that the needle is fully retracted and that the suture is visible, slowly move the Delivery Device proximally towards the bladder to ensure the suture is aligned within the keyhole (side-to-side). Continue advancing until the white lines that appear on the suture and the opposing metal surface nearly converge (**Figure 11**).



**Figure 11**  
Delivery Device tip showing correct  
suture position

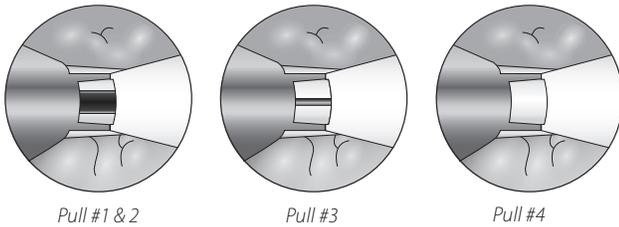
If the suture is not visible in the keyhole, slightly advance the Delivery Handle toward the bladder and check again. If the suture is still not visible and no resistance is felt while slowly advancing towards the bladder, the Capsular Tab may have deployed inside the prostate and the implant will not be formed correctly. In this case, fully advance the Delivery Device tip into the bladder (ensuring the suture does not appear), remove the device from the patient prior to Pull #4, and discard. Use a new device and increase the compression angle to avoid recurrence of this issue.

**⚠ CAUTION:** Failure to position the suture within the keyhole (**Figure 12**) may result in Urethral End-Piece misdeployment or an incomplete suture cut.



**Figure 12**  
Delivery Device tip showing suture NOT within the keyhole

- 4.6** Squeeze the Trigger to meet the Delivery Handle (**Pull #4**). The first half of the stroke cuts the suture and deploys the tensioned implant. Neither the suture nor the needle will be visible in the cystoscope view after the first half of the stroke. Make sure to fully complete Pull #4 to completely reset the Delivery Handle.



Pull #1 & 2

Pull #3

Pull #4

**⚠ WARNING:** Do not press down on the Needle Safety Button during Pull #4 as it will prevent proper resetting of the Needle Safety Button and may lead to a non-reset of the Delivery Handle and an inadvertent subsequent needle advancement.

**⚠ CAUTION:** If the UroLift® 2 System is unable to successfully complete the implant delivery sequences, the UroLift 2 System should be removed. All four Trigger pulls must be completed to allow for removal of the Implant Cartridge. If you remove the device from the patient prior to completing all four Trigger pulls, complete the remaining pulls outside of the patient to fully reset the Delivery Handle and to allow removal of the Implant Cartridge. For more information, see section 7, *TROUBLESHOOTING*.

- 4.7** 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-deployed angle of either the 9 or 3 o'clock orientation.
- 4.8** 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. It can then be removed from the cystoscopy sheath. Rotate the Sheath Lock counterclockwise and into the unlocked position and remove the Delivery Device from the sheath.
- 4.9** The Implant Cartridge is SINGLE-USE only. If additional UroLift Implants are needed, unlock the used Implant Cartridge from the Delivery Handle by rotating the Implant Cartridge Lock counterclockwise to the unlocked position.
- 4.10** Lift the used Implant Cartridge out of the Delivery Handle and discard.
- 4.11** To repeat the implant deployment procedure, insert a new Implant Cartridge into the Delivery Handle as described in step 3.2 and shown **Figure 6** and **Figure 7**.

**⚠ CAUTION:** Inspect Cartridge Indicator/Manual Assist Tab on the Implant Cartridge and verify that it is in the unused position (green bar is visible) (**Figure 3**). If the green bar is not fully visible, discard and use a different cartridge.

**⚠ WARNING:** Each UroLift® 2 Implant Cartridge is SINGLE-USE only. The Delivery Handle is a single patient device. Once the Delivery Handle has been used with up to eight (8) Implant Cartridges, the Delivery Handle should no longer be used. The UroLift 2 Delivery Handle has not been validated for use in more than eight deployments nor after resterilization. The UroLift 2 Delivery Handle may not perform according to specifications if used more than eight times nor if resterilization is attempted.

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

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

- 4.12** 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 3, *DEVICE INSERTION AND POSITIONING: LATERAL LOBES*. If an obstruction persists due to the median lobe, see section 5, *DEVICE POSITIONING: MEDIAN LOBE*. If no obstruction persists, continue to section 6, *CYSTOSCOPY*.

## 5. DEVICE POSITIONING: MEDIAN LOBE

- 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** Insert a new Implant Cartridge into the Delivery Handle as described in step 3.2, and shown **Figure 6** and **Figure 7**.
- ⚠ CAUTION:** Inspect the Cartridge Indicator/Manual Assist Tab on the Implant Cartridge and verify that it is in the unused position (green bar is visible) (**Figure 3**). If the green bar is not fully visible, discard and use a different cartridge.
- 5.3** With the Delivery Device tip in the sulcus, align the keyhole with the bladder neck.
- 5.4** Rotate the Delivery Device tip so that the keyhole is pointing to either the 3-4 o'clock or 8-9 o'clock position, towards the median lobe.
- 5.5** Begin compressing the median lobe posterior-laterally towards 3-4 o'clock or 8-9 o'clock by raising the Delivery Handle in the opposite direction, while simultaneously retracting the median lobe into the prostatic urethra.
- 5.6** 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 5.3.
- 5.7** Press down the blue Needle Safety Button which automatically releases the Trigger.

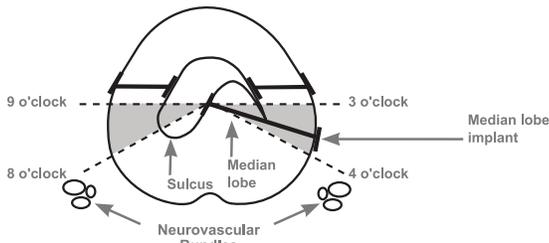
**⚠ WARNING:** To avoid inadvertent needle advancement, do not place fingers on the Trigger when positioning the Delivery Device once Needle Safety is unlocked.

- 5.8 Maintaining compression, rotate the Delivery Device into a more lateral trajectory (towards 3 o'clock or 9 o'clock), then slowly lower hands more parallel to the floor.
- 5.9 Place the implant as described in section 4, *IMPLANT DEPLOYMENT*.
- 5.10 If required, additional implants can be placed at 3-4 o'clock or at 8-9 o'clock positions (**Figure 13**).

**⚠ 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.

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

**⚠ WARNING:** When treating the prostatic median lobe, the Capsular Tab of the UroLift Implant should not be implanted posterior to the 4 and 8 o'clock positions on the prostatic capsule (**Figure 13**) to avoid external prostatic structures (e.g., neurovascular bundle, gastrointestinal tract).



**Figure 13**  
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. CYSTOSCOPY

Cystoscopy can be performed by using either the Scope Seal (provided with the UroLift 2 Delivery Handle) or a Visual Obturator.

Between and after implant deployment, 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.

- 6.1 If using the Scope Seal, follow the instructions below.
- 6.2 Insert the Scope Seal into the cavity on the Delivery Handle and press the oval ribbed section of the Scope Seal to secure.

- 6.3 Insert the Delivery Handle and Scope Seal assembly (with 2.9 mm telescope installed) into the sheath and lock the Sheath Lock.

**Note:** More force is required to install and lock the Delivery Handle with the Scope Seal in place compared to locking the Delivery Handle with the Implant Cartridge in place. If the sheath is not completely locked, it may affect the field of view.

- 6.4 Conduct cystoscopy. When advancing the Delivery Handle and Scope Seal assembly towards the bladder, take care to minimize tissue contact with the tip of the assembly.

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

- 6.5 Unlock the Sheath Lock, leave the sheath in the bladder, and remove the Delivery Handle and Scope Seal assembly.
- 6.6 Remove the Scope Seal from the Delivery Handle.

## 7. TROUBLESHOOTING

### IMPORTANT:

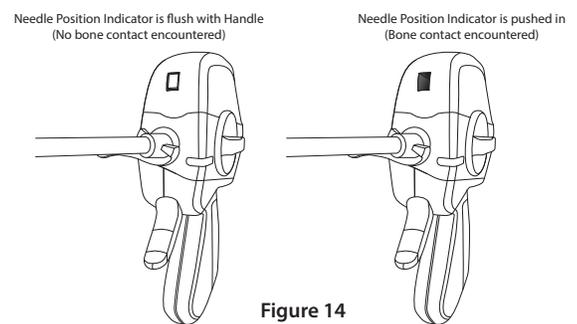
- When performing each pull, make sure to fully squeeze the Trigger to meet the Delivery Handle and to fully release the Trigger. Failure to fully release the Trigger may prevent the Trigger from fully returning to its released (out) position. If the Trigger is prevented from moving to the released position, move fingers away from the Delivery Handle and Trigger. If needed, use fingers to push the Trigger to the released position.
- All four Trigger pulls must be completed to allow for removal of the Implant Cartridge. If you remove the device from the patient prior to completing all four Trigger pulls, complete the remaining pulls outside of the patient to fully reset the Delivery Handle and to allow removal of the Implant Cartridge.

**⚠ WARNING:** When completing Pull #4 outside of the patient, use caution when aiming the tip of the Delivery Device as the Urethral End-Piece may eject from the tip of the Delivery Device.

### 7.1 Bone Contact

During Pull #1, the needle may contact/impact against the pelvic bone. If you hear a dull sound or feel a kick-back during Pull #1, check the Needle Position Indicator (**Figure 14**) to determine whether the needle fully deployed. If the Needle Position Indicator is not flush with the outside of the Delivery Handle, the needle has not fully deployed. Lessen compression, by relaxing the angle, to allow the Needle to fully advance and the Needle Position Indicator to become flush with the handle, indicating that the needle is fully deployed.

**⚠ WARNING:** Use caution when feeling for the Needle Position Indicator to avoid pinching your finger or tearing your glove.



**Figure 14**  
Needle Position Indicator

## 7.2 Needle is Deployed But Does Not Retract

This may occur during Pull #2 or Pull #3 and may be detected by a higher Trigger retraction force or the needle remaining visible in the cystoscopic view following Pull #3. While keeping the sheath stationary, rotate the Sheath Lock to the unlocked position and carefully withdraw the device through the sheath.

**⚠ WARNING:** The needle will be exposed and may recoil. It will take more force to remove the device from the sheath with the needle exposed. Use caution when handling components to avoid inadvertent punctures. After device removal, assess for needle fracture and remove any needle remnant from the patient.

**⚠ WARNING:** After utilizing this troubleshooting step, remove and dispose of the Delivery Handle and Implant Cartridge. Use a new Delivery Handle and Implant Cartridge to resume the procedure.

## 7.3 Cutting the Suture Without Delivering the Urethral End-Piece

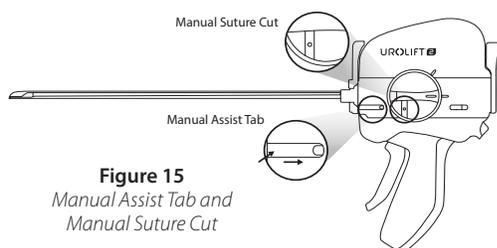
The need to cut the suture without delivering the Urethral End-Piece may occur after tensioning the suture (Pull #3). If you do not want to form an implant, you can cut the suture without proceeding to Pull #4. (Pull #4 seats the Urethral End-Piece and cuts the suture.) The Capsular Tab and suture remain in the patient.

Use pressure to insert the Scope Seal tab (the end marked with scissors (Figure 5)) into the Manual Suture Cut hole on the Implant Cartridge Lock (Figure 15). This step attempts to manually cut the suture without delivering the Urethral End-Piece. Repeat if necessary.

## 7.4 Device Tethered to Prostate After Pull #4

If the suture does not cut and is still cystoscopically visible after Pull #4, use pressure to insert the Scope Seal tab (the end marked with scissors (Figure 5)) into the Manual Suture Cut hole on the Cartridge Implant Lock (Figure 15). This action attempts to manually cut the suture, seat the Urethral End-Piece, and complete the deployment. Repeat if necessary.

If the suture still does not cut, insert the Scope Seal tab into the start of the slot at the front of the Delivery Handle. While maintaining pressure on the Scope Seal tab, move the Scope Seal in the direction away from the patient, pulling the Manual Assist Tab (Figure 15) to the end of the slot. This action attempts to manually cut the suture, seat the Urethral End-Piece, and complete the deployment. Repeat if necessary.



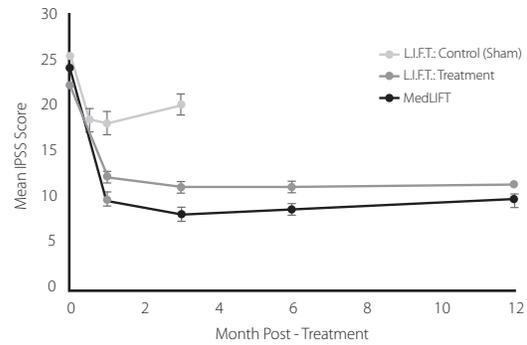
**Figure 15**  
Manual Assist Tab and  
Manual Suture Cut

If the implant deployment remains incomplete, while keeping the sheath stationary, rotate the Sheath Lock to the unlock position and carefully withdraw the device and implant through the sheath.

## SUMMARY OF CLINICAL STUDY RESULTS

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 16).



**Figure 16**

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.

## 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 Resterilize
	Do Not Reuse
	Catalog Number/Part Number
	Do Not Use if Package is Damaged
	Sterile (radiation)
	Manufacturing Lot Number
	Quantity in Package
 YYYY-MM-DD	Use By Date
	MR Conditional

## 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.

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### U.S. PATENTS

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