

NeoTract® UroLift® System Instructions for Use

Box Contents:

REF UL400-1 (1 Tray) or
UL400-4 (4 Trays)

Tray Contents:

- 1 UroLift® System
- 1 UroLift® Handle Release Tool



Manufacturer:

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neotract®

Device Dimensions

DIMENSION	VALUE
Needle Diameter	19 Gauge (0.042 in.)
Maximum Deployed Needle Depth	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.

All Components of the UroLift® System are latex-free.

DO NOT USE IF PACKAGE IS OPEN OR DAMAGED.

A non-sterile device may result in patient infection.

STORAGE CONDITIONS:

Store in a cool, dry, place.

INDICATIONS FOR USE

The UroLift® System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50.

CONTRAINDICATIONS

The UroLift® System should not be used if the prostate volume is >100 cc.

PRODUCT DESCRIPTION

The UroLift® System (REF UL400) is comprised of two main components: UroLift® Delivery Device and UroLift® Implant.

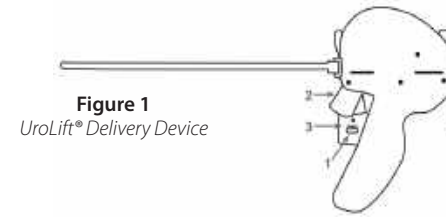


Figure 1
UroLift® Delivery Device

The UroLift® Delivery Device (**Figure 1**) is designed to access the prostatic urethra and deliver one UroLift® Implant through the lobe of the prostate.

Using the Delivery Device, the UroLift® Implant is delivered in 4 basic steps: Safety Lock (1) is released; Trigger (2) is depressed, deploying the needle and Capsular Tab to the capsular side of the prostate; Retraction Lever (3) is retracted, resulting in delivery of the Capsular Tab with suture under tension; Urethral Release (4) is pressed, deploying the Urethral End-Piece and cutting excess suture. The UroLift® Delivery Device is then withdrawn.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.

The UroLift® Implant (**Figure 2**) consists of a Capsular Tab connected by PET (Polyethylene Terephthalate) monofilament suture to the Urethral End-Piece.

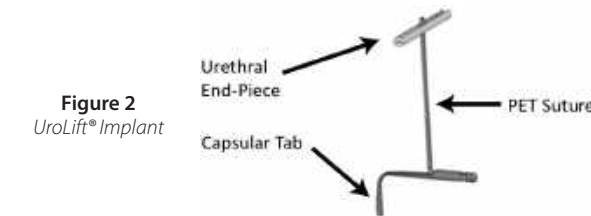


Figure 2
UroLift® Implant

Treatment with the UroLift® System does not preclude follow up treatment with the UroLift® System, TURP or Photoselective Vaporization of the Prostate. Retreatment via other therapies has not been studied.

ACTIONS

The materials used in the UroLift® Implant are well established for use in medical device implants and elicit minimal acute inflammatory reaction in tissue.

The UroLift® Implant is not absorbed, nor is any significant change in tensile strength known to occur in vivo.

WARNINGS

Do not use the UroLift® System in the presence of infection.

Do not use if patient has known allergy to Nickel.

The UroLift® System is intended for Single Patient Use Only – DO NOT RESTERILIZE. Resterilization may result in device malfunction including incomplete needle deployment or failed suture delivery requiring further physician intervention.

The UroLift® System is provided sterile. Sterility will be maintained only if package is unopened and undamaged. The user should inspect packaging integrity prior to use. If damage is detected or sterile packaging compromised, user should not use the product and should return it to NeoTract, Inc.

Users should be familiar with transurethral surgical procedures and cystoscopic techniques.

Training is required prior to using the UroLift® System. Please contact NeoTract Customer Service at +1 (925) 401.0700 for UroLift® System training information.

Store device at room temperature. Avoid exposure to prolonged elevated temperatures.

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.

PRECAUTIONS

Read all instructions prior to using the UroLift® System.

ADVERSE REACTIONS

Adverse reactions associated with the UroLift® System are comparable to other minimally invasive surgical therapies as well as standard cystoscopy. The majority of the adverse reactions are transient and resolved within 30 days following treatment. These include dysuria, hematuria, frequency, urgency, retention, pain-pelvic region pain/penile pain, nocturia, transient incontinence, bladder spasms, infection, incomplete void, weak stream hesitancy, erectile dysfunction, and prostatitis.

REQUIRED ANCILLARY EQUIPMENT

1. 2.9 mm 0° Telescope [Storz REF 10324AA or equivalent]
2. 20F Sheath [Storz REF 27026C or equivalent]
3. Visual Obturator [Storz REF 27028CN or equivalent]
4. Cystoscopy camera and monitoring equipment
5. Fluid irrigation system
6. Standard endoscopic grasper kit†

† It is recommended to have 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.

AVOID APPLYING A LOAD ON CAMERA HEAD

- Placing pressure on the camera head to position the UroLift® Delivery Device may cause an incomplete suture deployment.
- Avoid placing pressure on the camera head to position the UroLift® Delivery Device or as a lever point to compress the lobe.
- Image should be round on the video monitor. A dark crescent or a portion of image missing is evidence of excessive load on the camera head.

Care must be taken to avoid mishandling components.

Users should be cautious when handling components to avoid inadvertent punctures.

When surgical instruments and accessories from different manufacturers are employed together, first ascertain their compatibility prior to commencing with the procedure.

APPROXIMATION PROCESS

1. PREPARATION

- 1.1. Read and thoroughly understand all instructions.
- 1.2. Confirm that packaging components are unopened and undamaged. Do not use if package is damaged or opened.
- 1.3. Inspect all components for any damage that may have occurred during shipment or other handling. Do not use if device is damaged.
- 1.4. While holding the handle end (heavy end) of tray, peel back the Tyvek lid to access the sterile contents.
- 1.5. Remove lid of tray using sterile technique.
- 1.6. Remove device from packaging using sterile technique by lifting device from tray by grasping handle. Do not lift device by the steel shaft.
- 1.7. Inspect device tip and confirm that needle is not visible. Inspect Safety Lock (**Figure 1**) and confirm that it is in the locked (forward) position. Do not use if needle is exposed or Safety Lock is in the unlocked (rear) position.
- 1.8. To install the telescope insert Storz 2.9 mm 0° telescope (REF 10324AA) 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 telescope bayonet lock by rotating clockwise until finger tight. Do not overtighten.

CAUTION: Overtightening the telescope bayonet lock may result in breaking the telescope bayonet lock, inadvertent removal of telescope bayonet lock, and/or a non-functional telescope bayonet lock.

2. POSITIONING

- 2.1. Assemble the cystoscopy telescope, visual obturator and sheath listed above in Ancillary Equipment.
- 2.2. Using standard cystoscopic technique, insert the sheath/scope/visual obturator assembly in the urethra and visualize the urethra and bladder by advancing it through the urethra and into the bladder.
- 2.3. Remove the telescope and visual obturator, leaving the sheath in the bladder. Insert the UroLift® Delivery Device (with 2.9 mm telescope installed) into the sheath and lock the sheath lock.
- 2.4. To avoid external prostatic structures (e.g., neurovascular bundle), UroLift® Implants should be implanted anterior to the 3 and 9 o'clock positions (**Figure 3**).
- 2.5. Pre-determine treatment site by orienting the delivery device tip in a lateral direction, typically either 2-3 o'clock or 9-10 o'clock, (**Figure 3**) in the bladder then slowly moving the device distally to visualize the prostatic fossa from the bladder neck to the verumontanum.

Note: The needle deployment direction is in line with the Delivery Device handle.

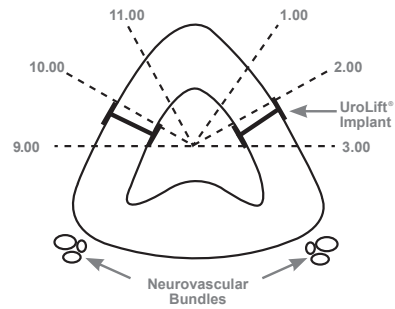


Figure 3
Prostatic schematic – placement of UroLift® Implants

- 2.6. Delivery device tip should be more than 1 cm distal from the bladder neck for delivery of the most proximal implant.

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

CAUTION: 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.

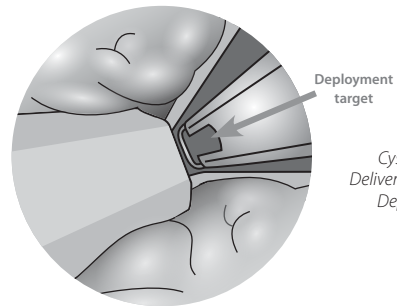


Figure 4
Cystoscopic view of Delivery Device tip showing Deployment Target.

- 2.7. Position the UroLift® Delivery Device such that the Deployment Target (**Figure 4**) is against the target prostatic lobe in the anterolateral direction.
- 2.8. To achieve desired amount of urethral opening, angle delivery device laterally (pivot about pubic symphysis), applying slight pressure to the Delivery Device tip via Delivery Device handle.

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

WARNING: To avoid inadvertent needle advancement, do not place finger on trigger when positioning Delivery Device once Safety is unlocked.

3. IMPLANT DEPLOYMENT

While holding the UroLift® Delivery Device distal tip stable against the target tissue:

- 3.1. Unlock the Needle Safety Lock. (**Step 1, Figure 1**).
- 3.2. Lightly depress the Trigger to deploy the needle (**Step 2, Figure 1**), then release Trigger.

CAUTION: Do not pull on the Retraction Lever during the Trigger pull.

WARNING: When the Trigger is in the pulled (rear) position, the needle is extended.
- 3.3. After a brief pause, depress the Retraction Lever (**Step 3, Figure 1**) fully to retract needle and deploy Capsular Tab. Squeeze the Retraction Lever again to ensure completion of retract stroke.

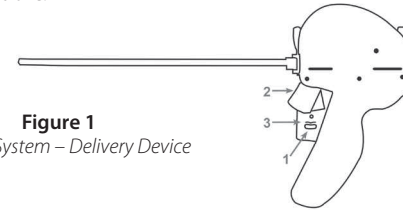


Figure 1
UroLift® System – Delivery Device

- CAUTION:** Depress the Retraction Lever completely until it locks into the handle. Once the Retraction Lever is locked into the handle, the needle is in the retracted (not exposed) position and is contained within the Delivery Device. Failure to pull the Retraction Lever completely may result in needle redeployment, poor suture tension, Urethral End-piece misdeployment, or incomplete suture cut.
- Avoid contact with the Urethral Release button when pulling the Retraction Lever. Contact with the Urethral Release button while pulling the Retraction Lever may result in inadvertent deployment of the Urethral End-Piece and unintentionally cutting the suture.

- 3.4. Release the Retraction Lever and release the compression applied to the prostatic lobe.

Note: Suture tension is now maintained by the delivery device. The suture will be against the edge of the keyhole that is closest in the cystoscope view, (**Figure 5**).

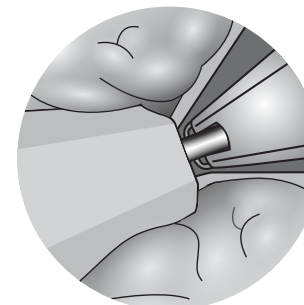


Figure 5
Image of Delivery Device tip showing suture against closest edge of keyhole.

- 3.5. If the suture is not against the closest edge of the keyhole, slowly move the device proximally toward the bladder to get the suture against the closest edge of the keyhole. Often the suture becomes visibly brighter in color, showing reflection of the cystoscopy light.

CAUTION: Failure to position suture against closest edge of keyhole (example shown in **Figure 6**, below) may result in Urethral End-Piece misdeployment or incomplete suture cut.

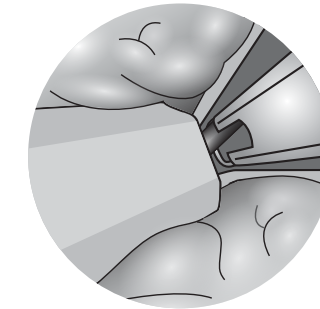


Figure 6
Image of Delivery Device tip showing suture **not** against closest edge of keyhole.

- 3.6. Press the Urethral Release button toward the telescope (**Step 4, Figure 1**) to deploy Urethral End-Piece and cut the excess suture.

WARNING: After the Urethral Release button is pressed the complete UroLift® Implant has been deployed. No further Implants can be delivered using the same Delivery Device.
- 3.7. Delivery Device should be pivoted medially away from the prostatic lobe and parallel to prostatic fossa before advancing sheath into bladder.

Note: When advancing the Delivery Device proximally into the bladder, ensure the handle remains horizontal either at the 9 or 3 o'clock orientation.

4. DELIVERY DEVICE REMOVAL

- 4.1. Angle the Delivery Device towards the midline and advance into the bladder.

Note: As with cystoscopy, keep device parallel to prostatic fossa.
- 4.2. Once positioned in bladder, the Delivery Device can be safely removed.
- 4.3. If procedure is complete, remove the Delivery Device and Sheath from the patient.

If additional UroLift® Implants are desired, remove UroLift® Delivery Device from the Sheath and replace with a new UroLift® System. Follow the referenced Instructions for Use.

Note: To obtain the desired urethral opening, place implants throughout the length of both lateral prostate lobes at approximately 1 cm. intervals with UroLift® Implants paired on the left and right sides. On average, 4 UroLift® Implants are typically placed per patient. The maximum number recommended to be placed per patient is 10 UroLift® Implants.

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

APPROXIMATION PROCESS

continued

5. FINAL CYSTOSCOPY

- 5.1 Perform a cystoscopy of the urethra and bladder to confirm the desired effect has been achieved.
- 5.2 Confirm that all implants are well apposed to mucosal tissue within the prostatic urethra. Remove any implants that are exposed to bladder urine.

CAUTION: Failure to remove implants exposed to bladder urine could lead to encrustation, urinary symptoms and possible subsequent intervention for removal.

MANUAL RELEASE INSTRUCTIONS FOR USE

6. Retract Lever Release

- 6.1 If needle does not retract, insert Tip 2 of Handle Release Tool (Figure 7) into hole on right side of case (Figure 8). Tip 3 should point towards Retraction Lever. While still inserted, turn Handle Release Tool clockwise approximately 45 degrees.
- 6.2 Remove Handle Release Tool and retract the needle as normal by retracting the Retraction Lever.

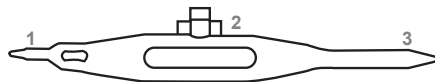


Figure 7
Handle Release Tool with Tip Numbering

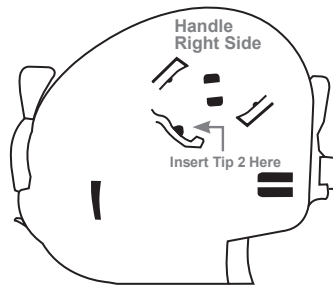


Figure 8
Retraction Lever Release

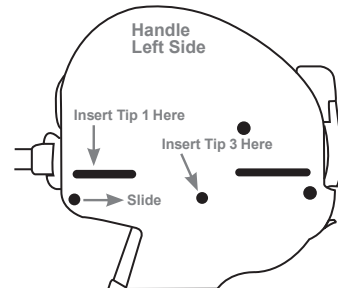


Figure 9
Suture Release

7. Monofilament Suture Release

- 7.1 If it is desired to cut the monofilament suture without delivering Urethral End-Piece, Insert Tip 3 of Handle Release Tool (Figure 7) into hole on left side of case (Figure 9).

Note: In the event that an unattached Urethral End Piece is in the urinary tract it should be flushed out.

- 7.2 If the suture is not fully cut in Step 1, insert Tip 1 of Handle Release Tool (Figure 7) into the groove on the front left side of the case and slide the tool from front to back (Figure 9).

MRI SAFETY AND COMPATIBILITY



The UroLift® Implant is MR conditional. Non-clinical testing demonstrated that the UroLift® Implant is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm 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 of operation for the MR system

MRI-Related Heating

In non-clinical testing, the UroLift® Implant produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change +1.6°C

Therefore, the MRI-related heating experiments for the UroLift® Implant at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 -W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the UroLift® Implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 15-mm relative to the size and shape of the UroLift® Implant.

SYMBOLS

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

DISCLAIMER AND PATENTS

PATENTS

U. S. Patent 7,645,286; 7,766,923; 7,758,594; 7,905,889; 7,951,158; 8,007,503; 8,157,815; 8,216,254; 8,333,776; 8,343,187; 8,394,110, 8,425,535

DISCLAIMER OF WARRANTY

ALTHOUGH THE UroLift® SYSTEM AND ITS COMPONENTS (THE "PRODUCT") HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, NEOTRACT, INC., AND ITS AFFILIATES (HEREINAFTER "NEOTRACT") HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. NEOTRACT THEREFORE DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NEOTRACT SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE, OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT, OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND NEOTRACT TO ANY REPRESENTATION OR WARRANTY WITH REGARD TO THE SYSTEM.

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NeoTract, Inc. is dedicated to developing innovative medical device solutions for urologists and their patients. Our first product, the UroLift® System, is designed to treat urinary symptoms in men who have an enlarged prostate due to benign prostatic hyperplasia (BPH).

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