

ENGLISH

UROLIFT®

UroLift® System Instructions for Use

Box Contents:

Catalog No. REF UL400-4 (4 Trays)

Tray Contents:

- 1 UroLift® System
- 1 UroLift Handle Release Tool



Manufactured By:
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STERILE R



RX ONLY

CAUTION:
Federal law restricts this device to use by or on the order of a physician

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 sterilised using gamma sterilisation. For single-use only and must not be resterilised. The UroLift System is inoperable after single use.

Not made with natural rubber latex.

WARNING:

DO NOT USE IF PACKAGE IS OPEN 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) in men 50 years of age or older.

CONTRAINDICATIONS

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

- Prostate volume is >100 cc.
- A urinary tract infection.

PRODUCT DESCRIPTION

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

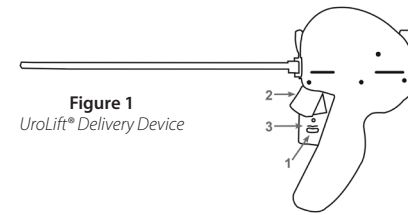


Figure 1
UroLift® Delivery Device

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

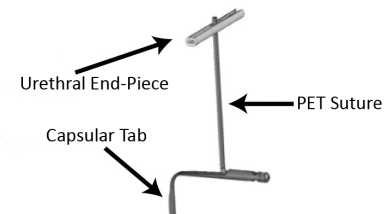
Using the Delivery Device, the UroLift Implant is delivered in 4 basic steps:

- Needle Safety Lock (1) is released.
- 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.
- 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 Vaporisation 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 AND PRECAUTIONS

1. Read all instructions prior to using the UroLift System.
2. Do not use if patient has known allergy to nickel, titanium, or stainless steel.
3. The UroLift System is intended for Single Patient Use Only – DO NOT RESTERILISE. Resterilisation 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.
4. Users should be familiar with transurethral surgical procedures and cystoscopic techniques.
5. 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 at +1 (925) 401.0700 for UroLift System training information.
6. Store device at room temperature. Avoid exposure to prolonged elevated temperatures.
7. 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 national laws and regulations.

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

SAFETY

The UroLift System was evaluated in a prospective, multicenter, multinational, randomized, blinded controlled clinical study called the L.I.F.T. Study (NCT012941450). Safety was assessed via post-operative catheter use, de novo chronic sexual dysfunction, and adverse events over a 12 month period. Mean postoperative catheterisation was 0.9 days and mean return to preoperative activity was 8.6 days. Post-operative catheterisation >7 days was 1.4% (2/140). The proportion of UroLift subjects who experienced de novo sustained sexual dysfunction (sustained erectile dysfunction or anejaculation) was assessed as a safety endpoint. None (0.0%) of the 140 UroLift subjects experienced de novo sustained sexual dysfunction (erectile dysfunction or anejaculation).

Adverse reactions associated with UroLift System Treatment were comparable to other minimally invasive surgical therapies as well as standard cystoscopy. The majority of the adverse events in the UroLift group occurred within 7 days of treatment. Most were mild to moderate and resolved within 30 days following treatment. The device related events reported through one year included dysuria (35.0% of subjects), hematuria (26.4%), pelvic pain (19.3%), micturition urgency (9.3%), urinary incontinence (7.9%, no reported stress incontinence), calculus urinary (6.4%), retention (5.7%), constipation (5%), nocturia (5.0%), and bladder spasm (4.3%) and prostatic specific antigen increase (4.3%).

Other adverse events noted at 4% or less in the 12 month data on the L.I.F.T. study for regulatory clearance include pollakiuria, abdominal pain, urinary tract infection, ejaculation disorder, erectile dysfunction, capsular tab in bladder, haematospermia, urinary hesitation, urine flow decrease, hemorrhoids, hypertonic bladder, penile pain, proctalgia, pyrexia, and residual urine.

The following can occur as a result of pelvic or urological procedures including but not limited to adhesion formation, adverse tissue reaction, bleeding, contracture, epididymitis, gastrointestinal complications, injury to the urinary tract or adjacent organs, migration of foreign body, nerve damage, prostatitis, orchitis, sepsis, sphincter injury, and stricture that could lead to serious outcomes.

OPERATING INSTRUCTIONS

Read all instructions prior to using the UroLift® System.

ANCILLARY EQUIPMENT

- 2.9 mm 0° telescope (i.e. **NeoTract REF UL-SCOPE, Storz REF 27324AA** or equivalent)
- 20F sheath (i.e. **NeoTract REF UL-SHEATH, Storz REF 27026C** or equivalent)
- Visual Obturator (i.e. **NeoTract REF UL-VO, Storz REF 27028CN** or equivalent)
- Cystoscopy camera, light box/cable and monitor
- Standard fluid irrigation system including new, sterile fluid tubing
- 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.

All equipment compatibility should be verified prior to use.

The ancillary equipment, including the telescope, sheath, visual obturator, bridge and graspers must be sterilisable per the respective manufacturer's instructions and should be sterilised prior to use.

HANDLING COMPONENTS

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.

1. PREPARATION

- 1.1 Read and thoroughly understand all instructions.
- 1.2 Confirm that packaging components are unopened and undamaged.

WARNING: 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.

CAUTION: 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.

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

1.6 Remove device from packaging using sterile technique by lifting device from tray by grasping handle.

CAUTION: Do not lift device by the steel shaft.

1.7 Inspect device tip and confirm that needle is not visible. Inspect Needle Safety Lock (**Figure 1**) and confirm that it is in the locked (forward) position.

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

2. DEVICE POSITIONING

CAUTION: Avoid placing pressure on the camera head to position the UroLift Delivery Device. 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. Excess pressure could compromise device performance or damage telescope.

2.1 Assemble the 2.9 mm 0° telescope (NeoTract REF UL-SCOPE or equivalent), visual obturator, and 20F sheath.

2.2 Insert the telescope assembly in the urethra and visualise 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.

2.4 To install the telescope insert 2.9 mm 0° telescope (NeoTract REF UL-SCOPE) 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 scope lock may result in damage to the UroLift Delivery Device.

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

2.6 To avoid external prostatic structures (e.g. neurovascular bundle), UroLift Implants should be implanted in the anterior aspect of the prostate, in between the 2-3 and 9-10 o'clock positions (**Figure 3**).

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

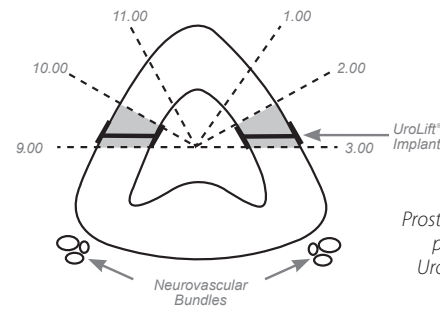


Figure 3
Prostatic schematic – placement of UroLift® Implants

2.7 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 visualise the prostatic fossa from the bladder neck to the verumontanum.

Delivery device tip should be approximately 1.5 cm distal from the bladder neck for delivery of the most proximal implant.

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

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

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.

2.8 Position the UroLift Delivery Device such that the Deployment Target (**Figure 4**) is against the target prostatic lobe in the lateral direction.

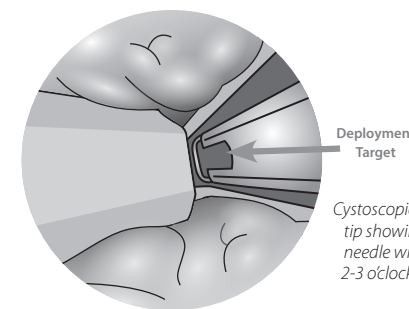


Figure 4
Cystoscopic view of Delivery Device tip showing Deployment Target, needle will Extend/Deploy in the 2-3 o'clock position in this image.

2.9 To achieve desired amount of urethral opening, angle delivery device laterally (pivot about external urinary sphincter), 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 Needle Safety Lock 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 5**).

3.2 Lightly depress the Trigger to deploy the needle (**Step 2, Figure 5**), then release Trigger.

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

WARNING: When the Needle Trigger is in the pulled (rear) position, the needle is extended.

3.3 After a brief pause, depress the Retraction Lever (**Step 3, Figure 5**) fully to retract needle and deploy Capsular Tab. Squeeze the Retraction Lever again to ensure completion of retract stroke.

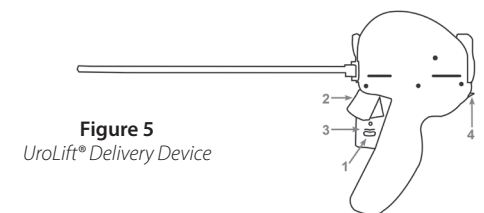


Figure 5
UroLift® Delivery Device

3.4 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.

CAUTION: Failure to pull the Retraction Lever completely may result in needle redeployment, poor suture tension, Urethral End-Piece misdeployment, or incomplete suture cut.

CAUTION: 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.

3.5 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 cystoscopy view (**Figure 6**).

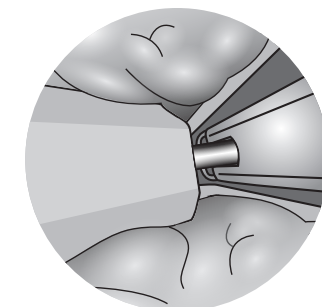


Figure 6
Image of Delivery Device tip showing suture against closest edge of keyhole.

- 3.6 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 colour, showing reflection of the cystoscopy light.

CAUTION: Failure to position suture against closest edge of keyhole (example shown in **Figure 7**, below) may result in Urethral End-Piece misdeployment or incomplete suture cut.

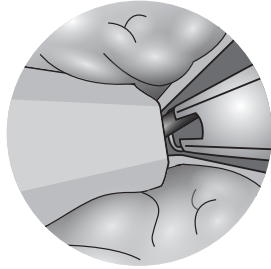


Figure 7
Image of Delivery Device tip showing suture **not** against closest edge of keyhole.

- 3.7 Press the Urethral Release button toward the telescope (**Step 4, Figure 5**) to deploy Urethral End-Piece and cut the excess suture. 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.

- 3.8 Angle the Delivery Device towards the midline and advance into the bladder. As with cystoscopy, keep device parallel to prostatic fossa.

When advancing the Delivery Device proximally into the bladder, ensure the handle remains horizontal either at the 9-10 or 2-3 o'clock orientation.

- 3.9 Once positioned in bladder, the Delivery Device can be safely removed from the cystoscopy sheath. If procedure is complete, remove the Delivery Device and Sheath from the patient.

- 3.10 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.

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 to 6 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.

4. FINAL CYSTOSCOPY

- 4.1 Perform a cystoscopy of the urethra and bladder to confirm the desired effect has been achieved.
- 4.2 Confirm that all implant components are well apposed to mucosal tissue within the prostatic urethra. Ensure Implants are not present in the bladder or extending into the bladder vesicle. If present, remove implant using graspers.

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

5.1 Retract Lever Release

- 5.1.1 If needle does not retract, insert Tip 2 of Handle Release Tool (**Figure 8**) into hole on right side of case (**Figure 9**). Tip 3 should point towards Retraction Lever. While still inserted, turn and hold Handle Release Tool clockwise with light finger pressure, approximately 5-10 degrees, and gently squeeze the Retraction Lever.

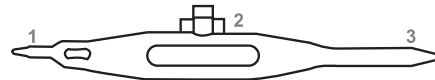


Figure 8
Handle Release Tool with Tip Numbering

- 5.1.2 Finish retracting the Needle as normal.



Figure 9
Retraction Lever Release

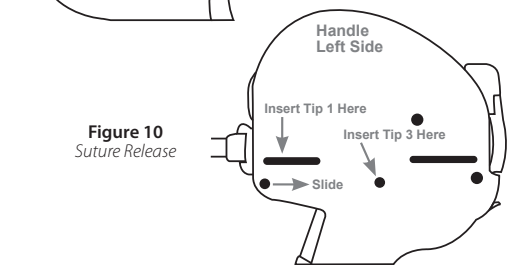


Figure 10
Suture Release

5.2 Monofilament Suture Release

- 5.2.1 If it is desired to cut the monofilament suture without delivering Urethral End-Piece, Insert Tip 3 of Handle Release Tool (**Figure 8**) into hole on left side of case (**Figure 10**).

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

- 5.2.2 If the suture is not fully cut in Step 5.2.1, insert Tip 1 of Handle Release Tool (**Figure 8**) into the groove on the front left side of the case and slide the tool from front to back (**Figure 10**).

MRI SAFETY INFORMATION

Non-clinical testing 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)
- 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 UroLift Implant 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.

SYMBOLS

SYMBOL	DEFINITION
	Manufacturer
	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
	Catalogue Number/Part Number
	Do Not Use if Package is Damaged
	Sterile (radiation)
	Manufacturing Lot Number
	Use By Date
	Authorised Representative
	MR Conditional

DISCLAIMER AND PATENTS

PATENTS

US 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; 8,663,243; 8,715,239; 8,715,298; 8,900,252; 8,936,609; 8,939,996; 9,320,511; 9,549,739

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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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