ENGLISH

UROLIFT®

UroLift® System Instructions for Use

Box Contents:
Catalog No. REF UL400-AP (4 Trays)

Tray Contents:
- 1 UroLift® System
- 1 UroLift Handle Release Tool

CE
0050

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EC REP

STERILE R

Rx only

Device Dimensions

DIMENSION	VALUE
Needle Diameter	19 Gauge (0.945mm)
Deployed Needle Length	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.

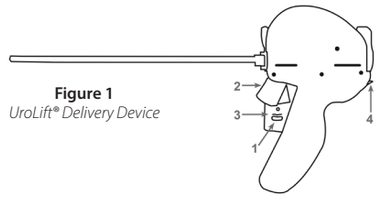

Figure 1
UroLift® Delivery Device

Each UroLift Delivery Device also includes one UroLift Handle Release Tool (HRT) for use in Manual Release Instructions (Section 5).

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

Using the Delivery Device, the 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 depressed, 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The Delivery Device is then withdrawn.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 implant **(Figure 2)** consists of a Capsular Tab connected by monofilament suture to the Urethral End-Piece.

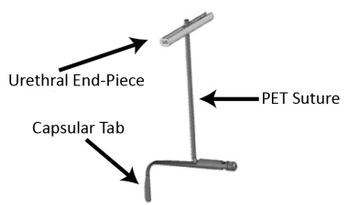

Figure 2
UroLift® Implant

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.

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

⚠ WARNINGS AND PRECAUTIONS

- Read all instructions prior to using the UroLift System.
- Do not use if patient has known allergy to nickel, titanium, or stainless steel.
- 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 implant 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 urological procedures and assessment techniques. Physician should use their medical discretion when assessing relevant prostate characteristics; techniques for assessment may include but are not limited to digital rectal exam, transurethral ultrasound (TRUS), or cystoscopy.
- 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.
- During the deployment, the needle may come into 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 a 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.
- Store device at room temperature. Avoid exposure to prolonged elevated temperatures.
- 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 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. 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. Only1.4% (2/140) in the L.I.F.T. study required extended post-operative catheterization. Mean postoperative catheterisation was 0.9 days and mean return to preoperative activity was 8.6 days.

The proportion of UroLift subjects who experienced de novo sustained sexual dysfunction (sustained erectile dysfunction or anejaculation) was assessed as a safety endpoint in L.I.F.T. None (0.0%) of the 140 UroLift System 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 System 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 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%).

Other adverse events included but were not limited to PSA elevation, urinary tract infection, abdominal pain, constipation, ejaculation disorder, erectile dysfunction, improperly placed implant, encrustation/stone formation, haematospermia, urinary hesitation, splitting of urinary stream, urine flow decrease, hemorrhoids, hypertonic bladder, penile pain, proctalgia, pyrexia/chills, and residual urine.

The following can lead to serious outcomes as a result of pelvic or urological procedures and includes but not limited to adhesion formation, adverse tissue reaction, inflammation, pain, bleeding, contracture, epididymitis, gastrointestinal complications, changes in heart rate, blood pressure or chemistry, dizziness/syncope, changes in sexual function, drug withdrawal syndrome, injury to the urinary tract or adjacent organs, foreign body presence, sensation, migration or unintentional placement (i.e. broken needle), device failure, need for additional intervention, nerve damage, prostatitis, orchitis, balanitis, thrombophlebitis, infection, sphincter injury, and stricture.

OPERATING INSTRUCTIONS

Read all instructions prior to using the UroLift® System.

ANCILLARY EQUIPMENT

- 2.9 mm 0° telescope (**REF UL-SCOPE**, or equivalent)
- 20F sheath (**REF UL-SHEATH**, or equivalent)
- Visual Obturator (**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†

† 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 sterilised per the respective manufacturer's instructions, 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 INSERTION AND POSITIONING:

⚠ **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 load on the camera head. Excess pressure could compromise device performance or damage telescope.

2.1 Delivery Device insertion

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

2.1.2 Insert the telescope assembly in the urethra and visualise the urethra and bladder by advancing it through the urethra and into the bladder.

2.1.3 Remove the telescope and visual obturator, leaving the sheath in the bladder.

2.1.4 To install the telescope insert 2.9 mm 0° telescope (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 Delivery Device.

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

2.2 Delivery Device positioning:

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

2.2.2 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 3)**. Orient the tip to ensure the needle deploys laterally (needle deploys in line with the Delivery Device handle).

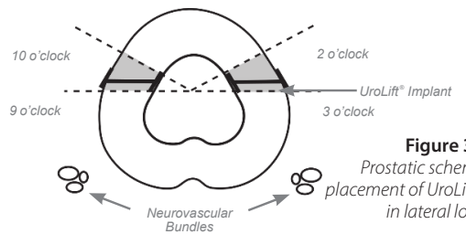

Figure 3
Prostatic schematic – placement of UroLift® Implants in lateral lobes

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

⚠ **WARNING:** Failure to deploy the implant as described above could lead to nerve damage, 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.

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

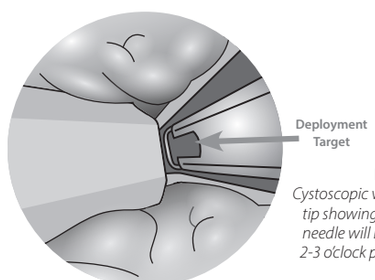

Figure 4
Cystoscopic view of Delivery Device tip showing Deployment Target, needle will Extend/Deploy in the 2-3 o'clock position in this image.

2.2.4 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.

⚠ **CAUTION:** 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 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 Needle Trigger to deploy the needle **(Step 2, Figure 5)**.

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

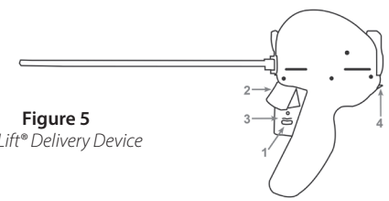

Figure 5
UroLift® Delivery Device

3.3 After the needle is fully deployed, depress the Retraction Lever **(Step 3, Figure 5)** 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 5.1 to manually release the Retraction Lever.

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

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

⚠ **CAUTION:** Avoid contact with the Urethral Release button when depressing the Retraction Lever. Contact with the Urethral Release button **(Step 4, Figure 5)** while depressing the Retraction Lever may result in inadvertent deployment of the Urethral End-Piece and unintentionally cutting the suture.

3.4 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 6)**.

If it is desired to cut the suture without delivering the Urethral End-Piece which will result in an incomplete implant, follow Step 5.2 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). If the suture still does not appear, then remove the device from the patient and discard. Use a new device and increase the compression angle to avoid recurrence of this issue.

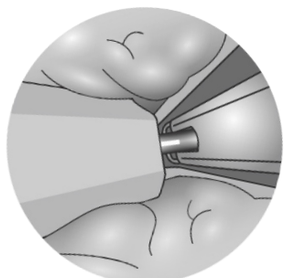

Figure 6
Image of Delivery Device tip showing suture against closest edge of keyhole.

⚠ **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.

3.5 Press the Urethral Release button toward the telescope **(Step 4, Figure 7)** 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 5.3 to manually cut the suture. No further implants can be delivered using the same Delivery Device.

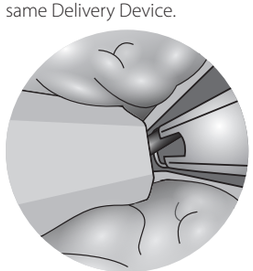

Figure 7
*Image of Delivery Device tip showing suture **not** against closest edge of keyhole .*

3.6 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 in the 9-10 or 2-3 o'clock orientation.

3.7 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.

3.8 If additional UroLift Implants are desired, 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 1 cm intervals starting 1.5 cm distal to the bladder neck 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 implants, be careful not to disrupt previously deployed 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.

⚠ **WARNING:** Failure to remove implants exposed to bladder urine could lead to encrustation, 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.

MANUAL RELEASE INSTRUCTIONS FOR USE

5.1 Retract Lever Release

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

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

Finish retracting the needle.

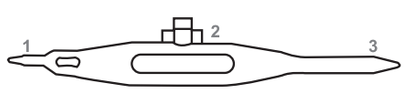

Figure 8
Handle Release Tool with Tip Numbering

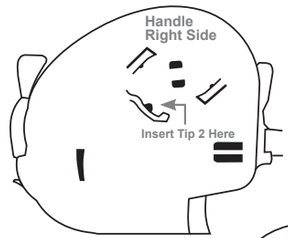

Figure 9
Retraction Lever Release

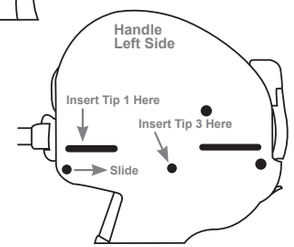

Figure 10
Suture Release

5.2 Monofilament Suture Release

If it is desired to cut the monofilament suture without delivering Urethral End-Piece, insert **Tip 3** of HRT **(Figure 8)** into hole on left side of handle **(Figure 10)**. The Capsular Tab and the suture will remain in the patient.

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

5.3 Manual Suture Cut

If the suture was not cut after pressing the Urethral Release Button, insert **Tip 3** of HRT **(Figure 8)** into hole on left side of handle **(Figure 10)**.

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.

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 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 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
Rx only	Prescription Only: Federal law restricts this device to use by or on the order of a physician
STERILIZE	Do Not Resterilise
	Do Not Reuse
REF	Catalogue Number/ Part Number
	Do Not Use if Package is Damaged
STERILE R	Sterile (radiation)
LOT	Manufacturing Lot Number
QTY	Quantity in Package
YYYY-MM-DD	Use By Date
EC REP	Authorised Representative
MR	MR Conditional
⚠	Warning/Caution

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