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

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

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.

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

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:

1. Needle Safety Lock (1) is released.
2. Needle Trigger (2) is depressed, deploying the needle and Capsular Tab to the capsular side of the prostate. The needle extends 3.3 mm from the tip of the device.
3. Retraction Lever (3) is retracted, resulting in delivery of the Capsular Tab with suture under tension.
4. Urethral Release (4) is pressed, deploying the Urethral End-Piece and cutting excess suture.

The UroLift Delivery Device is then withdrawn.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 with PET (Polyethylene Terephthalate) monofilament suture to the Urethral End-Piece.

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

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 (55.0% 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%).
1. While holding the handle end (heavy end) of tray, peel back the Tyvek lid to access the sterile contents.
2. Remove lid of tray using sterile technique.

**CAUTION:** Failure to maintain the sterility of the Urolift System and ancillary equipment could lead to infection.
3. Remove device from packaging using sterile technique by lifting device from tray by grasping handle.
4. Do not lift device by the steel shaft.
5. 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.
6. 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.

1. Assemble the 2.9 mm 0° telescope (NeoTract REF UL-SCOPE or equivalent), visual obturator, and 20° sheath.
2. Insert the telescope assembly into the urethra and visualise the urethra and bladder by advancing it through the urethra and into the bladder.
3. Remove the telescope and visual obturator, leaving the sheath in the bladder.
4. To install the telescope insert 2.9 mm 0° telescope (NeoTract REF UL-SCOPE or equivalent), visual obturator, and 20° sheath.

**CAUTION:** While holding the Urolift Delivery Device distal tip showing Deployment Target, needle will Extend/Display in the 2-3 o'clock position in this image.

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

1. To achieve desired amount of urethral opening, angle delivery device laterally (pivoting about external urinary sphincter), applying slight pressure to the prostate tissue as this could compromise Urolift System performance.
2. CAUTION: Do not use the cystoscopy camera head to apply pressure to the prostate tissue as this could compromise Urolift System performance.
3. WARNING: To avoid inadvertent needle advancement, do not place finger on trigger when positioning Delivery Device once Needle Safety Lock is unlocked.
4. To install the implant 2.9 mm 0° telescope (NeoTract REF UL-SCOPE or equivalent) into device with the telescope lightpost at 12 o'clock. Keep forward pressure on the telescope, hold telescope lightpost at 12 o'clock and secure 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.

**3. IMPLANT DEPLOYMENT**

**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.

**3.1 Unlock the Needle Safety Lock (Step 1, Figure 5).**

**3.2 Lightly depress the Trigger to deploy the needle (Step 2, Figure 3), 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.

**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 while 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 cystoscope view (Figure 6).
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.

5. 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.

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).

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).

CAUTION: Failure to remove implants inserted to bladder urin will cause to entrapment, urinaria symptom and possible subsequent intervention for removal.

Magnetic 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 4.4 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 MR 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

**SPECIAL PATENTS**

US Patents: 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; 8,902,552; 8,936,609; 8,999,986; 9,250,511; 9,548,739

DISCLAIMER AND PATENTS

Patents

Although the UroLift System and its components (the “Product”) has been manufactured under careful controlled conditions, Neotrac, Inc., and its affiliates (hereinafter “Neotrac”) has no control over the conditions under which this product is used. Neotrac 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. Neotrac 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 Neotrac to any representation or warranty with regard to the System.

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).

NeoTract, Inc., 4115 Hoppy Road Pleasanton, CA 94588 USA
Tel: +1 925-401-0700
Fax: +1 925-401-0699
www.neotrac.com
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