UROLIFT®

UroLift® System UL400 Instructions for Use

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

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

Manufactured By:

NeoTract® Inc.

4473 Willow Rd, Suite 100

Pleasanton, CA USA 94588

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neotract®

RX ONLY.

CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

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.

Not made with natural rubber latex.

WARNING: Do not use if package is opened 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), including lateral and median lobe hyperplasia, in men 45 years of age or older.

CONTRAINDICATIONS

The UroLift System should not be used if the patient has:
- Prostate volume of >80 cc
- A urinary tract infection
- Urethra conditions that may prevent insertion of delivery system into bladder
- Urinary incontinence due to incompetent sphincter
- Current gross hematuria

PRODUCT DESCRIPTION

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

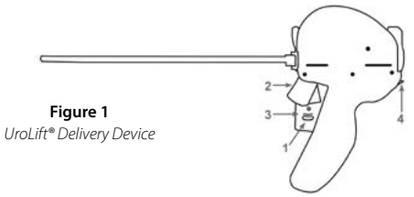


Figure 1
UroLift® Delivery Device

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

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

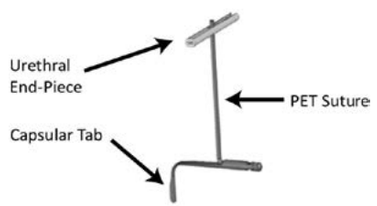


Figure 2
UroLift® Implant

Treatment with the UroLift System does not preclude follow up treatment with the UroLift System, transurethral resection of the prostate (TURP) or laser 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 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 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.
4. Users should be familiar with performing sterile transurethral surgical procedures and cystoscopic techniques. Patient should be placed in balanced lithotomy position.
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 (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 federal laws and regulations.

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

OPERATING INSTRUCTIONS

Read all instructions prior to using the UroLift System.

ANCILLARY EQUIPMENT

1. 2.9 mm 0° telescope (i.e. **NeoTract REF UL-SCOPE** or equivalent)
2. 20F sheath (i.e. **NeoTract REF UL-SHEATH** or equivalent)
3. Visual Obturator (i.e. **NeoTract REF UL-VO** or equivalent)
4. Cystoscopy camera, light box/cable and monitor
5. Standard fluid irrigation system including new, sterile fluid tubing
6. 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 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 sterilizable per the respective manufacturer's instructions and should be sterilized prior to use.

OPERATING INSTRUCTIONS

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 cover to access the sterile contents.

1.5. Remove lid of tray using sterile technique.

WARNING: 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 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: LATERAL LOBES

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 visualize the urethra and bladder by advancing it through the urethra and into the bladder.

2.3. Remove the telescope and bridge/visual obturator, leaving the sheath in the bladder.

2.4. To install the telescope, insert 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 the scope 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. When treating the prostate lateral lobes, 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, bleeding, pain, infection, damage to the gastrointestinal tract or fistula formation.

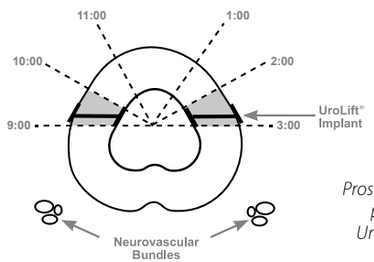


Figure 3
Prostatic schematic – placement of UroLift® Implants

2.7. Pre-determine treatment site by orienting the Delivery Device tip in a lateral direction, typically about 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.

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 and may need to be removed.

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

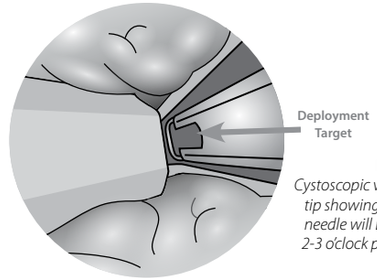


Figure 4
Cystoscopic view of Delivery Device tip showing Deployment Target, needle will Extend/Deploy in the 2-3 o'clock position in this image.

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 Needle 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 Needle Trigger to deploy the needle **(Step 2, Figure 5)**, then release the Needle Trigger. The UroLift System needle extends 33 mm, which is sufficient to reliably access the prostatic capsule based on cadaver and clinical studies. The Capsular Tab is delivered from the tip of the extended needle and is tensioned back towards the prostatic capsule until it seats on the capsular surface.

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

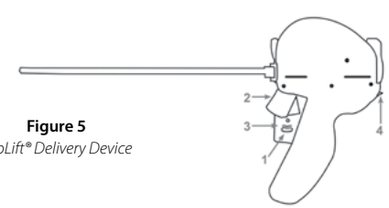


Figure 5
UroLift® Delivery Device

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, Urethral End-Piece misdeployment, loose Urethral End-Piece, 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.

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)**.

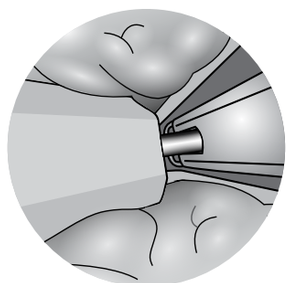


Figure 6
Image of Delivery Device tip showing suture against closest edge of keyhole.

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 color, showing reflection of the cystoscopy light.

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

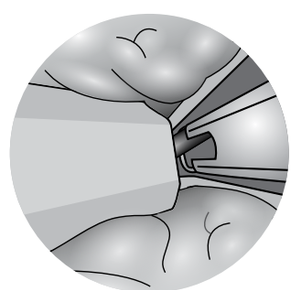


Figure 7
*Image of Delivery Device tip showing suture **not** against closest edge of keyhole .*

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, maintain the handle horizontal either at about the 9-10 or 2-3 o'clock orientation.

3.9. Once positioned in bladder, the Delivery Device should be oriented in the anterior-posterior orientation and can be removed from the cystoscopy sheath.

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 starting 1.5 cm distal to the bladder neck with UroLift Implants 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. DEVICE POSITIONING: MEDIAN LOBE

4.1 If the lateral lobes are secured out of the anterior aspect of the urethra from bladder neck to veru montanum and obstruction persists due to a median lobe, place additional implant(s) as follows.

4.1.1 Using the UroLift Delivery Device tip at sulcus, slowly compress the median lobe posteriorly until it enters the prostatic fossa.

4.1.2 Once the median lobe is within the prostatic fossa, angle the UroLift Delivery Device tip between 3 to 4 o'clock or 8 to 9 o'clock, and place the implant as described in Section 3. Lower the UroLift Delivery Device handle such that it is parallel to the midline prior to deploying needle.

4.1.3 If required, additional implants can be placed at 3 to 4 o'clock or at 8 to 9 o'clock **(Figure 8)**.

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

CAUTION: When treating the prostate 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 8)** to avoid external prostatic structures (e.g., neurovascular bundle, gastrointestinal tract).

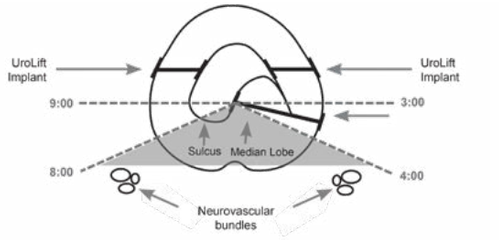


Figure 8
Prostatic schematic-placement of UroLift® Implants in median lobe

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: 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.

5. FINAL CYSTOSCOPY

5.1. 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.

5.2. Ensure implants are not present in the bladder or extending into the bladder vesicle. If present, remove implant using graspers. Also cystoscopically assess the trigone and ureter orifices for any damage. Remove implants that may compromise a ureteral orifice.

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

6. MANUAL RELEASE INSTRUCTIONS FOR USE

6.1. Retract Lever Release

6.1.1. If needle does not retract, insert Tip 2 of Handle Release Tool **(Figure 9)** into hole on right side of case **(Figure 10)**. 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.

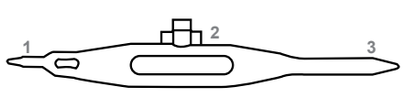


Figure 9
Handle Release Tool with Tip Numbering

6.1.2. Finish retracting the Needle as normal

6.2. Monofilament Suture Release

6.2.1. If it is desired to cut the monofilament suture without delivering Urethral End-Piece, insert Tip 3 of Handle Release Tool **(Figure 9)** into hole on left side of case **(Figure 11)**.

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

6.2.2. If the suture is not fully cut in Step 6.2.1, insert Tip 1 of Handle Release Tool **(Figure 9)** into the groove on the front left side of the case and slide the Handle Release Tool from front to back **(Figure 11)**.

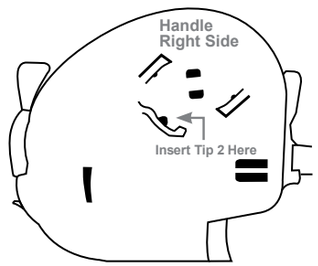


Figure 10
Retraction Lever Release

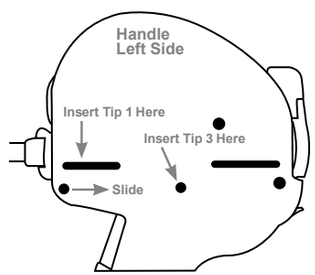


Figure 11
Suture Release
(Step 5.2.1 and 5.2.2)

SUMMARY OF CLINICAL STUDY RESULTS

The L.I.F.T. study enrolled a total of 206 subjects randomized 2:1 (140 UroLift®: 66 Control) at 19 investigational sites. The 3 month ITT primary endpoint was met: reduction in IPSS was 88% greater in the UroLift arm as compared to the Control arm (IPSS reduction of 11.1±7.7 UroLift vs. 5.9±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 subjects experienced symptom relief by 2 weeks, additional improvement to 3 months and sustained improvement at 12 months **(Figure 12)**.

All ITT secondary endpoints were met. For the UroLift 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).

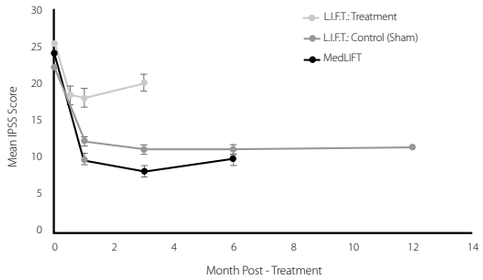


Figure 12
Mean IPSS at each follow-up interval – Active and Control arms.
Note: Mean +/- standard error

The MedLift (subjects with obstructive median lobe) study enrolled 45 subjects at 9 US Investigational sites. The 6 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 50.8%.

SAFETY

The primary safety endpoint in the L.I.F.T. and MedLift studies 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 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. A majority (86%) of MedLift subjects had ≥ 70% recovery per VAS by one month.

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 subjects experienced de novo sustained sexual dysfunction (erectile or ejaculatory dysfunction).

Adverse events 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 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 (7.1%), 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, improperly placed implant, hematospermia, urinary hesitation, urine flow decrease, hemorrhoids, hypertonic bladder, penile pain, proctalgia, pyrexia, and residual urine.

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, injury to the urinary tract or adjacent organs, foreign body sensation or migration, device failure, need for additional procedure, nerve damage, prostatitis, orchitis, sepsis, sphincter injury, and stricture that could lead to serious outcomes.

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)
- 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)

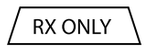
Under the scan conditions defined above, the UroLift Implant is expected to produce a maximum temperature rise of 2.4°C after 15 minutes of continuous scanning (i.e., per pulse sequence).

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.

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
	MR Conditional

DISCLAIMER AND PATENTS

PATENTS

U.S. 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; 8,715,298; 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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