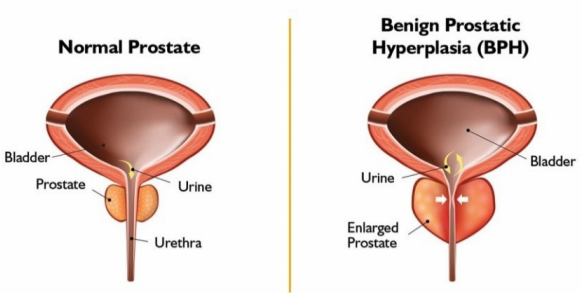
UROLIFT®
BPH Relief. In Sight.™

# UroLift® System - Patient Information

## What is BPH or an enlarged prostate?

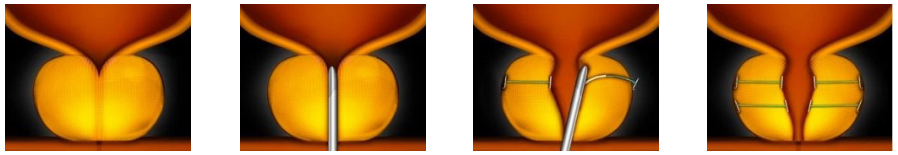
Benign Prostatic Hyperplasia, or BPH, is a common condition in which the prostate enlarges as men get older. Over 40% of men in their 50s and over 70% of men in their 60s have BPH.[1] While BPH is a benign condition and unrelated to prostate cancer, it can greatly affect a man's quality of life.

- As the prostate enlarges, it presses on and blocks the urethra, causing bothersome urinary symptoms such as:[2,3]
  - Frequent need to urinate both day and night
  - Weak or slow urinary stream
  - A sense that you cannot completely empty your bladder
  - Difficulty or delay in starting urination
  - Urgent feeling of needing to urinate
  - A urinary stream that stops and starts
- If you suffer from the above symptoms, you are not alone.




## How can BPH be treated with the UroLift® System?

- The UroLift® System is a proven approach to treating BPH that lifts and holds the enlarged prostate tissue out of the way so it no longer blocks the urethra.
- It is a proven option for patients looking for an alternative to medications or major surgery.[4]
- The UroLift System can provide rapid symptom relief and recovery from BPH symptoms. It can break the cycle of medications and how they make a person feel, all without the risks of more invasive surgery. The goal of the UroLift System treatment is to relieve symptoms so you can get back to your life and resume your daily activities. [5,6]
- It can be performed as a same-day outpatient procedure, including the office setting under local anesthesia.[6]
- Compared to medications, the UroLift System has demonstrated a larger positive reported effect on quality of life for patients.[1]
- The UroLift System is the only leading BPH procedure shown not to cause new and lasting sexual dysfunction.*[1,2,3]
- The only leading enlarged prostate procedure that does not require heating, cutting or destruction of prostate tissue.



**Enlarged Prostate**
An enlarged prostate can narrow or even block the urethra.

**Step 1**
The UroLift Delivery Device is placed through the obstructed urethra to access the enlarged prostate.

**Step 2**
Small UroLift Implants are permanently placed to lift and hold the enlarged prostate tissue out of the way and increase the opening of the urethra.

**Step 3**
The UroLift Delivery Device is removed, leaving an open urethra designed to provide symptom relief.

## What is the intended purpose, indications for use and contraindications?

The UroLift System is a prostatic implant intended to retract protate tissue. It 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.

### The UroLift System should not be used if you have:

- Prostate volume of >100 cc
- A urinary tract infection

**1** Berry J Urol 1984; **2** Rosenberg, Int J Clin Pract 2007; **3** Vuichoud, Can J Urol 2015

* No instances of new, sustained erectile or ejaculatory dysfunction in the LIFT pivotal study

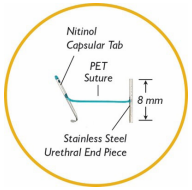
**1.** Roehrborn, Can J Urol 2017; **2.** Roehrborn, J Urology 2013; 3. Shore Can J Urol 2014; **4.** Roehrborn, Can J Urol 2017, Fwu, J Urol 2013; **5.** AUA BPH Guidelines 2003, 2020; **6.** McVary, J Sex Med 2016

## What materials are in the UroLift® Implant?

The implant is made up of standard surgical implantable materials: a nitinol (nickel and titanium) capsular tab, a stainless steel urethral end piece, and polyethylene suture that holds the two tabs together. The following lists the substance concentration of each component in the UroLift® Implant:

| Component | Material Description | Substances in Material | Substances Concentration | Material Concentration Range (% w/w) |
|---|---|---|---|---|
| Urethral End Piece | 316L stainless steel | Chromium | 17.00-19.00 | 56-58% |
| | | Nickel | 13.00-15.00 | |
| | | Molybdenum | 2.25-3.00 | |
| | | Manganese | 2.00 maximum | |
| | | Silicon | 0.75 maximum | |
| | | Copper | 0.50 maximum | |
| | | Nitrogen | 0.10 maximum | |
| | | Carbon | 0.030 maximum | |
| | | Phosphorus | 0.025 maximum | |
| | | Sulfur | 0.010 maximum | |
| | | Iron | Balance | |
| Capsular Anchor | Nickel Titanium (nitinol) | Nickel | 54.5-57.0 | 28-29% |
| | | Cobalt | 0.050 maximum | |
| | | Iron | 0.050 maximum | |
| | | Carbon | 0.040 maximum | |
| | | Oxygen | 0.040 maximum | |
| | | Niobium | 0.025 maximum | |
| | | Copper | 0.010 maximum | |
| | | Chromium | 0.010 maximum | |
| | | Hydrogen | 0.005 maximum | |
| | | Nitrogen | 0.005 maximum | |
| | | Titanium | Balance | |
| PET Monofilament | Polyethylene terephthalate | Polyethylene terephthalate | 99.94-99.96 | 13-16% |
| | | D&C Green #6 | 0.04-0.06 | |

**Warning:** This device contains stainless steel and nitinol (an alloy of nickel and titanium). Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, discuss anyallergy/hypersensitivity to these materials with your physician.




## What are the residual risks with the UroLift® System?

As with any urological procedure, side effects may occur. Most common adverse events are temporary and can include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence.[1] Rare side effects, including bleeding and infection, may lead to a serious outcome and may require intervention. Individual results may vary.

Having the UroLift System procedure does not preclude future treatment of the prostate, if needed.[2]

For details on the UroLift Implant and MRI, see **Can I have an MRI after the UroLift System procedure**?

**1.** Roehrborn, J Urology 2013; **2.** Roehrborn, Can J Urol 2017

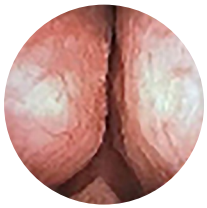
## How do I know if the UroLift® System is right for me?

The examination performed will be determined by your doctor. The doctor will likely ask you to fill out a questionnaire to assess your symptoms, otherwise known as IPSS (International Prostate Symptom Score). Additionally, some of the common examinations include Digital Rectal Exam (DRE), Transrectal Ultrasonography (TRUS), Bladder Ultrasound, Uroflow test, Cystoscopy, and Urinalysis.

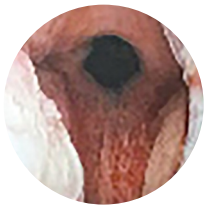
After the exam(s) and IPSS, talk to your provider about what treatments are available and ask about the UroLift® System

## What to expect during and after the UroLift System procedure?

If you and your doctor decide that the UroLift® System treatment is right for you, your doctor will provide you with more detailed information relating to the treatment. In general, the UroLift System is a minimally invasive treatment that entails minimal downtime.[1,2] Your doctor will use the UroLift Delivery Device to deploy permanent implants to relieve obstruction caused by the enlarged prostate that is pressing on your urethra. The procedure can be performed as a same-day outpatient procedure, including the office setting under local anesthesia. The length of the procedure varies based on the patient's anatomy and number of prostatic implants required.[2] You may be given medication to feel comfortable during the treatment. This typically helps minimize discomfort during the procedure, though everyone's definition for pain and discomfort varies greatly. Typically, no catheter and no overnight stay is required post-treatment. [1,2]



*Urologist's view of obstructed prostate*



*Unblocked urethra after UroLift System procedure**

**1.** Roehrborn, J Urology 2013; **2.** Shore, Can J Urol 2014

## What you need to do post procedure?

### How quickly can I expect to have symptom relief?

Most patients experience minimal downtime post-treatment and symptom relief as early as two weeks. Results may vary.[1,2]

### When can I resume my usual activities?

Many men experience recovery in days, not months.[1] Your doctor will discuss any restrictions and your specific situation after your procedure.

### Will I need to continue taking my BPH medications after the procedure?

A benefit to getting the UroLift® System procedure is that you may be able to discontinue BPH medications afterwards.[3] You and your doctor will decide if continued use of BPH medication is necessary.

### Will my sexual function be affected by the UroLift System procedure?

Clinical studies have shown the UroLift® System procedure is the only leading enlarged prostate procedure shown to not cause new and permanent sexual disfunction.*[3,4,5] Other BPH therapies such as TURP, laser, and even medication may affect erectile or ejaculatory function.

### What happens if the implants need to be removed?

The implants are intended to be permanent. The implant is made up of standard surgical implantable materials: a nitinol capsular tab, a stainless steel urethral tab, and a polyethylene terephthalate suture that holds the two tabs together. If needed, your urologist can remove the urethral tab. The capsular tab and part of the suture will remain in place inside the body. For details about the materials in the implant, see "**What materials are in the UroLift® Implant?**"

### I have read that many men don't need a catheter after the UroLift System procedure. Is this true?

Typically, no catheter is required after having the UroLift System procedure.1,2 Your doctor will determine if you need a catheter at the time of the procedure.

## Can I have an MRI after the UroLift System procedure?

The UroLift Implant is Magnetic Resonance Imaging (MRI) "Conditional" which means you can be scanned at any time after the procedure in an MRI system which meets the following conditions. Please share the following information with your radiology technician:

- Static magnetic field of 3.0 Tesla or less
- Maximum spatial field gradient 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 continuous 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.

## What to look for post-procedure and when to contact your doctor?

The UroLift® System procedure is intended to be a minimally invasive, durable solution for BPH/LUTS that utilizes a permanently placed implant.1 Clinical studies have proven durability out to five years.1 Individual results may vary.

As with any urological procedure, side effects may occur. Most common adverse events are temporary and can include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence.[2] Rare side effects, including bleeding and infection, may lead to a serious outcome and may require intervention. Individual results may vary.

Report all complaints and adverse events to your doctor (for Australia, see also www.tga.gov.au). Any serious incident that occurs in relation to the device should be reported to the manufacturer (NeoTract Inc.).

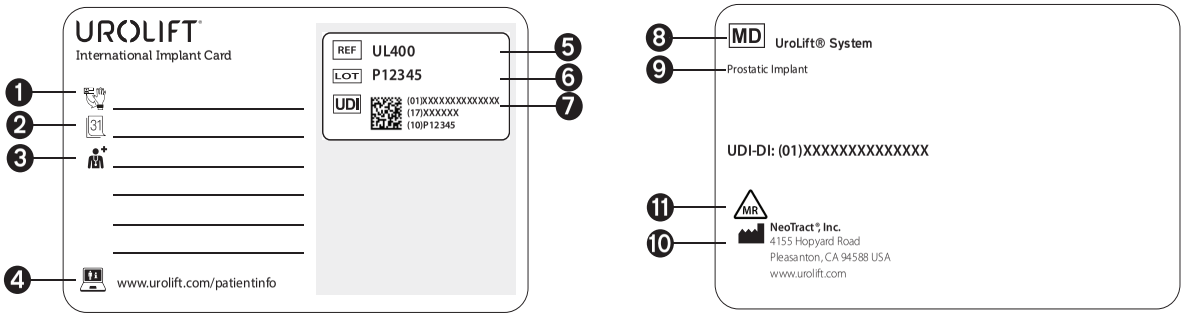
***** No instances of new, sustained erectile or ejaculatory dysfunction in the L.I.F.T. pivotal study

**1.** Shore, Can J Urol 2014; **2.** Roehrborn, J Urology 2013; **3.** Roehrborn, Can J Urol 2017; **4**. AUA BPH Guidelines 2003, 2020; **5.** McVary, J Sex Med 2016

**1.** Roehrborn, Can J Urol 2017; **2.** Roehrborn, J Urology 2013

# How to read and interpret your implant card?

## Your International Implant Card includes the following information:




| Item | Symbol | Description | Item | Symbol | Description |
|---|---|---|---|---|---|
| ❶ | | Patient Name | ❻ | LOT | Batch code |
| ❷ | 31 | Implant Date | ❼ | UDI | Unique Device Identifier |
| ❸ | | Name/Address Health care centre or doctor | ❽ | MD | Device Name |
| ❹ | | Patient information website | ❾ | – – | Device Type |
| ❺ | REF | Catalogue Number/Part Number | ❿ | | Manufacturer |
| ⓫ | MR | MR Conditional (See Instructions for Use for MRI Safety Information) | | | |

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