

## General FAQs

### BPH

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#### 1. Is BPH a type of cancer?

- a. No, BPH is Benign Prostatic Hyperplasia, a benign condition and unrelated to prostate cancer; however, it can greatly affect a man's quality of life. BPH is NOT a type of cancer.

#### 2. What happens when BPH is left untreated? Are there any long-term risks?

- a. If left untreated, BPH can lead to permanent bladder damage.<sup>1</sup> When the bladder does not empty completely, the risk of developing urinary tract infections (UTIs) may increase.<sup>2</sup> Other serious problems can also develop over time, including bladder stones, blood in the urine, incontinence, or urinary retention.<sup>2</sup>

#### 3. When should I seek BPH treatment?

- a. You may want to seek BPH treatment if you experience BPH symptoms such as urgent need to urinate, difficulty starting your urine stream, need to push or strain when urinating, dribbling, the sensation that the bladder is not empty after urinating, weak urine flow, increased frequency of urination, frequent nighttime urination, burning or pain during urination.<sup>3</sup>

### The UroLift® System

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#### 1. What is the UroLift® Delivery Device?

- a. The UroLift® Delivery Device is a single-use, sterile medical device that contains one UroLift Implant. Patients typically require 4-6 implants during a UroLift System treatment. The Delivery Device is inserted transurethral through a rigid sheath under cystoscopic visualization in order to reach the targeted area of obstruction. See Procedures and Device for more information.

#### 2. What is the UroLift Implant?

- a. The UroLift Implants are small permanent implants that hold the obstructing prostatic lobes apart. They are deployed through a needle that comes out of the delivery device. Each implant is made with common implantable materials: nitinol, stainless steel, and suture. Typically, 4-6 implants are placed into the prostate.

## Procedure

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### I. Who is a good candidate for the UroLift® System treatment?

- a. You may be a good candidate if you are a male, 45 years of age or older, and have symptoms relating to BPH. Speak with your urologist to see if the UroLift® System procedure is right for you.<sup>4</sup> If you have a known allergy to nickel, titanium or stainless steel, talk to your doctor about your allergy before getting a UroLift System treatment.

### 2. What is the UroLift System treatment?

- a. The FDA-cleared UroLift System is the only treatment that uses the Prostatic Urethral Lift (PUL) procedure. UroLift System is a proven, minimally invasive approach for treating lower urinary tract symptoms due to benign prostatic hyperplasia (BPH) that can get men off BPH medications and avoid major surgery. The UroLift System's permanent implants, delivered during a minimally invasive outpatient procedure, relieve prostate obstruction and open the urethra directly without cutting, heating, or removing prostate tissue.
- b. As with any medical procedure, individual results may vary. Speak with your urologist to see if the UroLift System treatment is right for you. Most common side effects are mild to moderate and include pain or burning with urination, blood in the urine, pelvic pain, urgent need to urinate and/or the inability to control the urge. Most symptoms resolve within two to four weeks after the procedure.

### 3. How does the UroLift System work?

- a. The UroLift System consists of a delivery device and tiny permanent implants.
  - The UroLift Delivery Device is placed through the obstructed urethra.
  - Small UroLift Implants are placed to lift or hold the enlarged prostate tissue out of the way. The Implants are delivered through a small needle that comes out of the delivery device and into the prostate.
  - The UroLift Delivery Device is removed, leaving an open urethra that provides symptom relief.

One unique aspect of the UroLift System is that it does not preclude retreatment or other BPH treatments, should it be required in the future.

### 4. Is the treatment permanent or can it be removed?

- a. The Implants are intended to be permanent. If for some reason the implant needs to be removed, your physician can use traditional cystoscopic technique that will simply remove and replace the implant as needed.

### 5. Who performs the UroLift System treatment?

- a. A urologist, a doctor who specializes in the treatment of diseases of the urinary system and sex organs, uses the UroLift System to treat urinary symptoms due to BPH. The urologist completes comprehensive training prior to using the UroLift System.

## What to Expect

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### 1. What examinations do I need prior to the UroLift® System treatment?

- a. The examination performed will be determined by your physician. The physician 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, and Urinalysis.

### 2. What should I expect during the treatment? Is it painful? How long does it take?

- a. 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. 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, which usually takes less than an hour, may be performed under local or general anesthesia and 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.<sup>4</sup>

### 3. What happens post-treatment, during the recovery period? Are meds required?

- a. After the treatment, patients typically go home the same day without a catheter. There is minimal downtime post-treatment and many patients experience symptom relief in as early as 2 weeks.<sup>4</sup> Patients may experience some urinary discomfort during the recovery period. The most common side effects may include blood in the urine, some pain or discomfort when urinating, some increased urge to go and discomfort in the pelvis that typically resolve within two to four weeks after the procedure.<sup>4</sup>

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

- a. The implant is made up of standard surgical implantable materials: a nitinol tab, a stainless-steel tab, and polyester suture that holds the two tabs together. Your doctor can remove the implant from the urethra, if needed.

### 5. Does the treatment affect my sexual function?

- a. Clinical studies have shown the UroLift System treatment does not cause new, sustained instances of sexual dysfunction.<sup>4</sup> The same cannot always be said of other BPH therapies such as TURP, laser, and even medication.

### 6. Will the UroLift Implants affect a digital rectal exam (DRE)?

- a. The implants are not expected to interfere with a DRE. The implants are placed on the anterior (front) side of the prostate, and a DRE is conducted on the posterior (back) side of the prostate.

## Clinical

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### 1. How does the UroLift® System treatment compare to other treatment options?

- a. The UroLift® System treatment has been found to be a safe and effective treatment for symptoms related to BPH. Its risk profile is better than most traditional surgical options, and patients report symptom relief better than reported with medications.<sup>5,6</sup> In clinical studies, there have been no instances of new, sustained erectile dysfunction or ejaculatory dysfunction.<sup>4</sup>

### 2. What clinical data is available?

- a. We have over 25 peer-reviewed publications demonstrating the UroLift System is safe and effective. Improvement in urinary symptoms, as seen through reduction in IPSS (International Prostate Symptom Score), has been consistent across the various studies, showing rapid relief in as early as two weeks and sustained effect to five years.<sup>5</sup>

### 3. What are the side effects?

- a. In our clinical studies, the most common side effects reported were mild to moderate and include pain or burning with urination, blood in the urine, pelvic pain, urgent need to urinate and/or the inability to control the urge. Most symptoms resolved within two to four weeks after the procedure.<sup>4</sup>

## Insurance

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### 1. Does my insurance cover the treatment?

- a. The UroLift System treatment is covered by Medicare and many private insurers. Contact your insurance provider for your specific coverage information.

1. Tubaro et al. 2003 Drugs Aging  
2. Lieber et al. Prostate volume and prostate-specific antigen in the absence of prostate cancer: a review of the relationship and prediction of long-term outcomes, Prostate 2001  
3. Barry M, Roehrborn C. Management of benign prostatic hyperplasia. Annu Rev Med.1997  
4. Abrams, et al., Neurourology and Urodynamics 2002; Maximilian, et al., BJU Intl 2012  
5. Roehrborn et al. Journal of Urology 2013 LIFT Study  
6. Sonksen, EU Urol, 2015 BPH6 Study  
7. Roehrborn et al. Can J Urol 2017