Patient Information Sheet

Prospective UroLift Arm

Study Title: Prostatic Urethral Lift in Subjects with Acute Urinary Retention Study (PULSAR)

Sponsored by: NeoTract, Inc., Pleasanton, California, USA

We would like to invite you to participate in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. **One member of our team will go through the information sheet with you and answer any questions you have.** We'd estimate this taking about 30 minutes.

(Part 1 tells you the purpose of this study and what will happen to you if you participate.
Part 2 gives you more detailed information about the conduct of the study).

Ask us if there is anything that is not clear.

PART 1

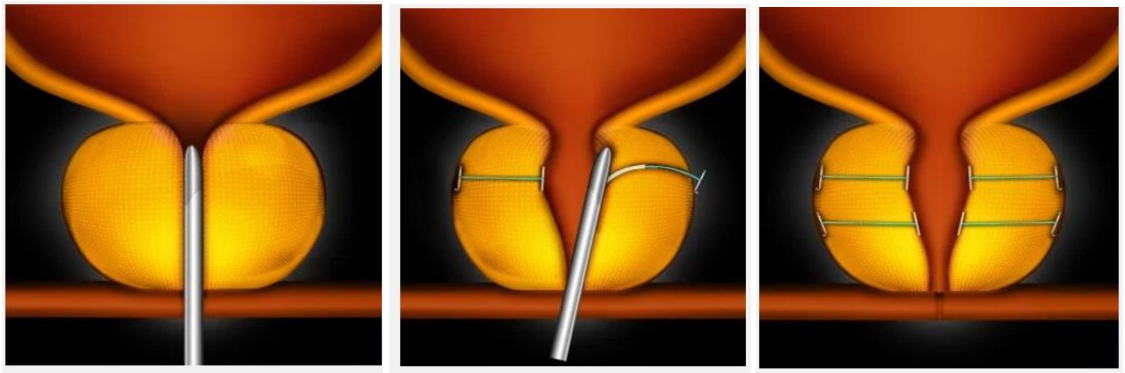
WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to determine if the UroLift® System procedure can allow patients in urinary retention (unable to urinate) to urinate without the use of a catheter compared to patients who had invasive surgery for their urinary retention.

Benign Prostatic Hyperplasia (BPH) is an enlarged prostate gland that can cause bothersome urinary symptoms because it blocks the normal flow of urine. Men with BPH often have a frequent and urgent need to urinate and symptoms can increase over time as the prostate continues to grow. After time, some men develop urinary retention. If medication does not restore the ability to urinate, men have a catheter (a tube placed in bladder to allow urine to drain) placed. In these cases, surgery is offered to relieve the urinary retention. Often the benefits of these surgeries come with negative side effects. Common side effects include loss of ability to perform sexually and urinary leakage. There may also be a long waiting period with catheter before a surgery can be scheduled.

THE UROLIFT® SYSTEM

The UroLift System, which received CE Marking in May 2010, is a device that delivers an implant into the prostate to open an overgrown prostate. The UroLift procedure is a minimally invasive approach that lifts or holds the enlarged prostate tissue out of the way so it no longer blocks the urethra. There is no cutting, heating or removal of prostate tissue.



Step 1 Step 2 Step 3

STEP 1: The UroLift delivery device is placed through the blocked urethra (tube that leads from the bladder and transports and discharges urine outside the body).

STEP 2: Small UroLift implants are permanently placed to lift or hold the enlarged prostate tissue out of the way. The implants are placed through a small needle that comes out of the delivery device and into the prostate.

STEP 3: The UroLift delivery device is removed, leaving an open urethra.

WHY HAVE I BEEN INVITED?

You are being invited to participate in this study because you have BPH and are not able to urinate without the use of a catheter. Your doctor has determined that the UroLift® System would be an appropriate treatment for your symptoms.

If you agree to participate, you will be one of approximately 55 men enroled into the study at up to 6 different hospitals in the United Kingdom.

DO I HAVE TO PARTICIPATE?

The decision to participate is yours, not your doctor's. It is up to you to decide to join the study. If you agree to participate, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. Choosing not to participate or withdrawing from the study will not affect the standard of care you receive.

WHAT WILL HAPPEN TO ME IF I PARTICIPATE?

- **BEFORE YOUR PROCEDURE**

Upon signing a consent form, tests will be conducted to make sure that you qualify. This is called "screening" and will be done before your study procedure. If at any point during these screening tests, the results do not qualify you, your doctor will discuss your future health care.

Many of the tests in this study are "standard of care." This means that the tests are medically necessary even if you do not participate in this study. They include:

- A physical exam, including digital rectal exam
- A sample of urine for a laboratory urine analysis
- An ultrasound scan of your prostate. This is done by putting a lubricated probe into the back passage of your body (your rectum).
- The following procedures may not be "standard of care" in every hospital. Urodynamics will be done at qualified sites only, you should ask the research staff if your site is qualified and if

the procedure will be done as part of the research study. The cystoscopy will be done at all sites if you participate.

- A procedure (Urodynamics) that measures how severe your urine flow is blocked. A small catheter will be placed through your urethra and another into your rectum. The procedure may last up to two hours.
- A procedure (Cystoscopy) that allows the doctor to view your prostate. This procedure involves inserting a flexible tube with a camera on it into your urine tract. It will help your doctor to see if your prostate shape can be treated with the UroLift.

You will also answer questions about your health status, including sexual function.

- **THE UROLIFT PROCEDURE**

If your doctor confirms that you meet all the study requirements you will be scheduled for a UroLift procedure. The procedure will be performed under anaesthesia. Typically, your doctor will place at least 4 implants, but the number will depend on the size and shape of your prostate. On average, the procedure takes less than 1 hour. You will be placed on a catheter at the end of the procedure. Your doctor will determine how soon after treatment you can go home

You should know that a representative of NeoTract, Inc. (the study Sponsor) may be present during the procedure to help answer any questions about the collection of procedure data for the study. The Sponsor representative will not be allowed to discuss the study with you.

- **POST-OPERATIVE VISIT**

You will return to the clinic 2-4 days after your procedure to test if you can urinate without a catheter. During this visit, you will:

- Answer questions about your health, medication use and symptoms associated with your enlarged prostate.
- Urinate into a special toilet to measure your urine flow rate and after undergo an ultrasound of your bladder to determine if all urine exited. This is standard of care. You will be asked to come in with a full bladder.

If you are not able to urinate without a catheter, you will return for another clinic visit as directed by your doctor to re-test your ability to urinate without a catheter. This is standard of care.

- **FOLLOW-UP VISITS**

You will be asked to return to your doctor's office at 6 weeks, 3 months and 12 months after your procedure. At 6 months after your procedure, you will be asked to either come in for a visit or have a telephone call with the study personnel. Below is an outline of what to expect during your follow-up visits.

- At each visit you will need to answer questions about your symptoms, your procedure recovery, and your health status.

- At your 6 week visit you will:
  - Urinate into a cup for a laboratory urine analysis.

- Urinate into a special toilet to measure your urine flow rate and afterward undergo an ultrasound of your bladder to determine if all urine exited. This is standard of care. You will be asked to come in with a full bladder.
- Answer questionnaires

- At your 3 month visit you will:
  - Urinate into a cup for a laboratory urine analysis.
  - Urinate into a special toilet to measure your urine flow rate and after undergo ultrasound of your bladder to determine if all urine exited. This is standard of care. You will be asked to come in with a full bladder.
  - Undergo a digital rectal exam. This is standard of care for patients after undergoing this type of procedure.
  - Answer questionnaires

- At your 6 month visit you will:
  - Be asked to either come in for a visit or have a telephone call with the study personnel to discuss your health status.
  - Answer questionnaires

- At your 12 month visit you will:
  - Urinate into a cup for a laboratory urine analysis.
  - Urinate into a special toilet to measure your urine flow rate and after undergo an ultrasound of your bladder to determine if all urine exited. This is standard of care. You will be asked to come in with a full bladder.
  - Undergo a digital rectal exam. This is standard of care for patients after undergoing this type of procedure.
  - Undergo a cystoscopy. This involves inserting a flexible tube with a camera on it into your bladder to take pictures of your urinary system. Cystoscopy may not be standard of care in every hospital.
  - Undergo a Urodynamics Study procedure that measures your bladder health and the extent your prostate is blocking the normal flow of urine. Urodynamics will be done at qualified sites only, you should ask the research staff if your site is qualified and if the procedure will be done as part of the research study.
  - Answer questionnaires.

It is possible that your symptoms may not get better, may get worse, or may return at a later time. If this happens, your doctor may decide to treat you with the same procedure again, or with a different procedure. The decision will be made by you and your doctor together. Any further procedure will be performed in a standard manner and has not been shown to have additional risk associated with the UroLift devices. If you undergo a second procedure for your symptoms, you will be asked to remain in the study and will only complete a 12 month follow-up visit. If you undergo another UroLift procedure, you will continue to come in for study follow-up visits as originally scheduled.

EXPENSES AND PAYMENTS

You will not receive any payment for partaking in this study however you, and your caregiver, may be reimbursed for reasonable refreshments and travel costs associated with required study visits. You will not be reimbursed for expenses of other family members. Receipts for refreshments and travel expenses incurred may be requested.

WHAT WILL I HAVE TO DO?

After you undergo the procedure, you will be in the study for 1 year. In order to be in the study, you must be willing to be available and agree to have all the required tests and activities done before and after the procedure. However, you have the right to withdraw your consent at any time during the course of the study.

WHAT ARE THE ALTERNATIVES FOR TREATMENT?

You do not need to participate in this study to receive treatment for your urinary symptoms. Other standard treatments may include removal or destruction of some of the prostate gland. Medications can also be used to decrease urinary symptoms. Your doctor will explain available standard treatments for your symptoms.

WHAT ARE THE POSSIBLE RISKS OF TAKING PART?

All medical procedures involve some risk of injury. Your doctor will review these risks with you before. Be sure to ask any questions so that you thoroughly understand the risks.

Filling out questionnaires and answering questions about your health status may cause inconvenience or distress. There are also other standard inconveniences of participating in a research study such as possible repeat procedures or visit wait times.

The cystoscopy may cause temporary swelling of the urethra, which may make it difficult to urinate. Difficulty with urination may lead to retention of urine and catheter placement (a catheter is a tube that is inserted into the bladder to allow urine to be drained). Cystoscopy may cause pain that that requires painkillers. Dysuria (a burning sensation when urinating) and bleeding may occur. These symptoms are mild and generally resolve within the first 2 days. A urinary tract infection may develop in a small percentage of patients.

The urodynamic testing may cause discomfort when passing urine, urgency, frequency, bladder spasms, lower urinary tract symptoms, blood in your urine, and urinary tract infection.

There are different types of catheters that are used after urological procedures. One type is inserted through the urethra and left in the bladder for a short or long time (called “indwelling”) and attached to a drainage bag. To prevent clogging, you will need to irrigate the catheter periodically. Your study doctor or a qualified staff member will provide instructions of how to properly care for your catheter. If the catheter becomes clogged, painful, or infected, it may need to be replaced right away. Risks include, but are not limited to:

- Catheter Misplacement
- Urinary Tract Infection (UTI)
- Bladder spasm
- Bladder/Abdominal pain
- Catheter blockage leading to increased heart rate, high blood pressure, kidney damage

The risks of undergoing the UroLift® System procedure are the same as having procedure done without being in the study. Because UroLift has not been studied in patients with urinary retention, the frequency of risks and side effects are not known. The anticipated risks associated with the UroLift system procedure are provided below.

- Allergic reactions
- Bleeding associated with the urinary tract, gastrointestinal tract, pelvic region or abdomen
- Change in muscle function (urine control or bladder) or narrowing of the urine path
- Changes in ejaculation such as semen going into the bladder rather than out the end of the penis, inability to ejaculate, reduced ejaculation volume, delayed ejaculation, change in ejaculate characteristics, blood in semen, and pain with ejaculation
- Cloudy urine, discharge and bleeding in urine, or blood clots in urine that may require a catheterisation with or without fluid irrigation of the bladder and urethra
- Equipment malfunction or device failure such as a broken needle
- Elevated PSA
- Foreign body (part of implant) associated problems including foreign body sensation, erosion, inflammation, or irritation
- Formation of blood clot
- Gastrointestinal (GI) damage or changes including rectal damage, hemorrhoid, bleeding, constipation, diarrhea, vomiting, inability to control bowel movements, and additional procedure.
- Improperly placed implant, including those that are not removable
- Inability to urinate post-procedure requiring a catheter to be put inErectile dysfunction
- Requirement for delayed, aborted, changed or additional procedure

Dependent on the study doctor's preference, you will be offered some form of medication or anaesthesia, such as general anaesthesia, to allow you to be comfortable throughout the procedure. Some of the known effects associated with these medications include, but are not limited to:

- Allergic reactions
- Brain damage
- Bruising of swelling at site of IV Cardiac arrest
- Confusion
- Constipation
- Death
- Fainting, dizziness, or blurred vision
- Fatigue
- Low blood pressure
- Memory loss
- Nausea and/or vomiting
- Other medication problems and anesthesia problems, as listed in medication labeling.
- Poor breathing requiring intervention
- Respiratory arrest
- Respiratory difficulties
- Sleepiness

The use of an antibiotic for any surgical procedure is routine. There are risks associated with the use of any antibiotic. Risks may vary depending on the antibiotic prescribed. The study doctor will explain to you the risks associated with your antibiotic.

There is a risk that a complication might occur as a result of the procedure requiring need for further treatment, including the need for surgery. Your study doctor will monitor you to see if you

have complications. The risks of lower abdominal procedures/surgery include, but are not limited to:

- Abdominal pain
- Abscess
- Bleeding requiring transfusion
- Blood and body chemistry abnormalities
- Blood clot in the lung or elsewhere
- Constipation
- Damage to a major blood vessel
- Damage to the abdominal muscles
- Heart attack or decreased blood flow to the heart
- Ileus
- Local infection
- Other complications described by your doctor as related to your specific situation
- Perforation of or damage to the gastrointestinal tract
- Pneumonia
- Puncture or blockage of or damage to the vascular system
- Rectal damage
- Scarring
- Stroke or temporary loss of normal blood flow to the brain
- Swelling or bruising
- Systemic infection (sepsis)
- Trauma or injury to abdominal organs
- Trauma or injury to reproductive organs
- Trauma or injury to the urinary system
- Weakness or numbness

It is possible in any medical research study that harmful things can happen that are not known at this time.

WHAT ARE THE POSSIBLE BENEFITS IF YOU PARTICIPATE?

We cannot promise the study will help you but the information we get from this study will help improve the treatment of people with symptoms of BPH in urinary retention.

This completes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decisions.

PART 2

WHAT IF RELEVENT NEW INFORMENTION BECOMES AVAILABLE?

Sometimes we get new information about the treatment being studied. If this happens, your research doctor will tell you and discuss whether you should continue in the study. If you decide not to carry on, your research doctor will make arrangements for your care to continue. If you decide to continue in the study he may ask you to sign a document outlining the discussion.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

You can withdraw at any time but keep in contact with us to let us know your progress. Information collected may still be used.

STUDY TERMINATION

This research may be suspended or stopped at any time for a variety of reasons without your consent such as if the Sponsor feels it's in the best interest of the study participants to stop the study, if required by a regulatory authority, etc.

The doctor may remove you from the study at any time, and this does not require your consent. This may be done for any reason such as if you do not follow the study instructions, your medical condition changes and your doctor feels it is in your best interest to stop the study, etc.

WHAT IF THERE IS A PROBLEM?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions at [contact number]. If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Liaison Group at [contact number] or [email].

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against [Trust Institution] but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

In the event you lose the capacity to consent, you will be withdrawn from the study. Data collected within your consent will be retained and used in the study. No further data will be collected or any other research procedures carried out on or in relation to you.

WHAT IF I AM HURT OR GET SICK DURING THE STUDY?

Please contact your study doctor for medical treatment if you believe you are injured or become ill as a result of this study. If your injury is caused only by the UroLift system procedure, the study sponsor has agreed to pay the study center its fair costs for the short-term treatment of your injuries, medical procedures to diagnosis your injury. The sponsor has not agreed to make any payments directly to you. The Sponsor has not agreed to pay for injury or illness that occurs as a result of negligence, malpractice or other wrongful acts on the part of the study doctor or the study staff. The sponsor has not agreed to pay for injuries or illnesses that are the result of a pre-existing condition or the normal progression of your disease, because you have not followed the directions of the study doctor, standard of care medical procedures or medications prescribed or delivered

during the study, or any other reason. The sponsor has not agreed to pay you for any pain, worry, lost income, or non-medical care costs that occur from taking part in the study. If you have an injury that is not caused only by the UroLift system procedure, you may be responsible for paying for the diagnosis and treatment. You are not giving up any of your legal rights by signing this consent.

WILL MY TAKING PART BE KEPT CONFIDENTIAL?

There are standard risks of participating in a research study which include the loss of confidentiality. Every attempt will be made to ensure that your personal information remains confidential.

NeoTract Inc. is the sponsor for this study based in the United States. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. NeoTract Inc. will retain only fully anonymized data (no personally identifiable information) after the study finishes.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by emailing privacyofficial@teleflex.com.

We use personally-identifiable information to conduct research to improve health and care. As a medical device company we have a legitimate interest in using information relating to your health and care when you agree to take part in a research study. This means that we will use your data collected in the course of a research study in the ways needed to conduct and analyse the research study.

If you join the study, your medical records and the data collected for the study will be reviewed by authorised persons from NeoTract, Inc. , or its designees. The only people in NeoTract, Inc. who will have access to information that identifies you will be people who need to review or audit the data collection process. The people who analyse the information will not be able to identify you. Personally identifiable may be reviewed but will never be collected/retained by NeoTract or its designees. Personal data could be reviewed by representatives of government agencies and the Ethics Committee of the facility where your procedure was performed. Inspection could be necessary in order to maintain the reliability and quality of the study. Every effort will be made to protect your confidentially as a research participant.

As a part of this study, personal information about you will be gathered and recorded on paper and in electronic form. This information collected will include your age, medical history, your response to questions during the study, cystoscopy videos/images, urodynamics testing, uroflow/PVR, prostate size and images, lab data, procedure details and results, information about any worsening or improving symptoms and your continued follow-up a year after your index procedure and other study requested data. You will <u>not</u> be identified in the Sponsor database by name, address, telephone number, or any other personal identifier. The Sponsor electronic database will generate a unique identification number assigned to you.

The anonymized data will be accessible for review to the principal research physician outside of your institution and may be transmitted for scientific analysis to the sponsor of the study, or to a research organisation assigned by the sponsor to assist with the study. This means that anonymized

data will be sent outside of United Kingdom (UK) to countries where UK data protection laws do not apply, including but not limited to the United States. The data transferred will include information collected from the study. The study data may be used to prepare for publications or presentations about the study, for regulatory purposes, for future research purposes including a larger study, and for other general business purposes. The data may also be transmitted to regulatory authorities in this country or in other countries of the world for the purpose of filing applications for marketing approvals, or to the research ethics committee.

The study records will be kept in secure storage until the completion of the study by the hospital department that oversees your care. At the end of the study these records along with all other study documentation will be stored securely for a minimum of two years or as required by local and national regulations.

INVOLVEMENT OF THE GENERAL PRACTITIONER/FAMILY DOCTOR

With your consent, your GP will be informed of your involvement in the study.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

It is intended that once the study is complete a report will be written and the results published making them available to the public and medical community.

A description of this study and the results will be available on http://www.ClinicalTrials.gov. You can search this Web site at any time.

WHO IS ORGANISING AND FUNDING THE RESEARCH STUDY?

NeoTract, Inc. will pay the hospital for the procedures that are not standard of care, the devices, and the time of your doctor to include you in this study.

NeoTract, Inc. has not agreed to pay you or anyone else for any other costs related to your participation in the study. This includes, but is not limited to, any prescriptions you may be given, medical equipment, standard of care tests or procedures, etc. These other costs may be your responsibility. Please ask your doctor if you are unsure about whether a specific test or procedure is required for the study.

WHO HAS REVIEWED THE STUDY?

All research in the NHS is looked at by the Health Research Authority (HRA), and an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by Wales Research Ethics Committee 6.

FURTHER INFORMATION AND CONTACT DETAILS?

If you have a question at any time about this research study, the procedures, or the use of your personal information, please ask. You should contact:

Study Doctor:	**Full Name**
Address:	**Institution Name**
	Address 1
	City

Phone: **Phone**

If you have any questions or complaints about your rights as a research participant, you should contact the Patient Advice and Liaison Service (PALS):

Address: **Institution Name**
Address 1
City
Phone: **Phone**
Email: **Email**

Site number: _____ Principal Investigator: _____ Study ID: _____

CONSENT FORM

Study Title: Prostatic Urethral Lift in Subjects with Acute Urinary Retention Study (PULSAR)

You are making a decision to voluntarily participate in this research project. Your signature indicates that you have read and understood the information provided, have discussed the study with your study doctor and had a chance to ask questions. Your signature also indicates that you consent to the procedures and treatment described, agree that your personal information may be used for the purposes of this research study, and agree to comply with study instructions. A copy of this informed consent document will be given to you.

	Please initial box
1. I confirm that I have read and understand the information sheet dated 14 Dec 2018 (version 5) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	☐
3. I understand that relevant sections of my medical notes and data collected during the study, including cystoscopy videos and images, may be looked at by individuals from NeoTract, Inc., from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. I understand that NeoTract representative may be present during the UroLift procedure. I give permission for NeoTract representatives to be present during the UroLift procedure.	☐
4. I agree to my GP being informed of my participation in the study.	☐
5. I agree to participate in the above study.	☐

Study Participant: **Person Obtaining Consent:**

Signature of Study Participant	Signature of Person Obtaining Consent
(Please PRINT name)	(Please PRINT name)
Date of Study Participant's Signature	Date of Person Obtaining Consents' Signature

Investigator:

I, the undersigned, have fully and carefully explained the study to this patient and certify that to the best of my knowledge, the patient named above clearly understands the nature, risks, and benefits of his participation in this study.

_____	_____
Signature(s) of Investigator	Date of Investigator's Signature

_____

(Please PRINT Name)

When completed: 1 copy for participant; 1 copy for researcher site file; 1 original to be kept in medical notes.