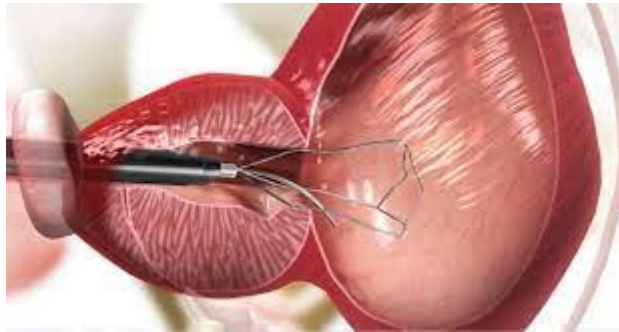


iTIND Prostate Surgery

This leaflet contains evidence-based information about your proposed urological procedure - iTIND (Temporary Inserted Nitinol Device) stent prostate surgery



What does this procedure involve?

With the patient under sedation, the surgeon places the iTIND device through a cystoscope, which offers direct vision of the patient's urethra. The nitinol stent is then unfurled and positioned over the bladder neck at prostatic urethra in an expanded state (see picture opposite).

The cystoscope is then removed and the device is held in position by its struts and connected to a long piece of thin string brought out via the meatus (eye of penis). While the expanded stent is in place, the pressure of the nitinol struts causes ischaemia and creates longitudinal slits/channels. After 5-7 days, the device is removed using an open-ended catheter under sedation/local anaesthesia.

The main benefits of this procedure are that it allows minimally invasive insertion of a temporary prostatic stent to treat patients with tight bladder neck and enlarged prostate in a day surgery procedure under sedation, with no sexual side effects.

Important points

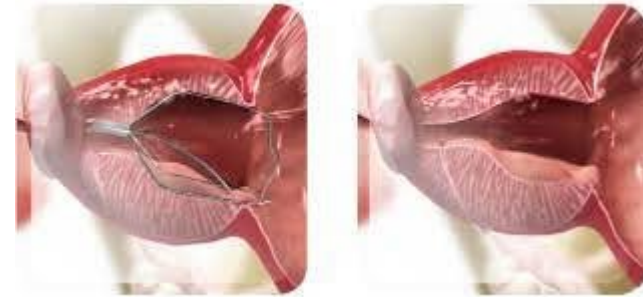
- A temporary prostatic urethral stent is inserted at the prostate and bladder neck using a telescope; and subsequently removed after 5-7 days under light sedation.
- While the iTIND device is in place, pressure applied by struts in the expanding stent creates slits in the prostatic urethra and bladder neck. Upon removal of device, these longitudinal channels/slits created will improve the urine flow through bladder neck and prostate.
- It is designed to improve symptoms of bladder outflow obstruction due to a tight bladder neck and enlarged prostatic tissue; however currently, it is registered as experimental on NICE guidelines (IP 1701 [IPG641]; limited data from clinical

trials).

- There may be minor discomfort and urinary frequency/urgency whilst the device is in place.
- It is a day surgery procedure both for the insertion and, 5-7 days later, removal of device; and you will be discharged without a catheter.
- There are no reported sexual side-effects such as retrograde (dry) ejaculation or erectile dysfunction (impotence).

What are the alternatives?

- Conservative treatment - restricting your fluid or caffeine intake, pelvic floor exercises, bladder training regimes - to improve your urinary symptoms and help you avoid surgery
- Drug treatment - there are drugs which shrink your prostate or others which relax the muscles in the prostate to improve urine flow
- Transurethral resection of the prostate (TURP) / transurethral incision of prostate(TUIP) / Bladder neck incision (BNI) - cutting/removing the portion of bladder neck and central, obstructing part of your prostate with electric current, using a telescope passed along your urethra
- Bladder neck incision using laser energy (Photo-selective vapourisation of the prostate) using greenlight laser to cut the bladder neck via a telescope passed along your urethra
- Aquablation of prostate which involves high velocity waterjet removal of prostate tissue to improve the flow of urine
- Other minimally invasive surgical procedures, which include urolift with mini bladder neck incision, REZUM (steam) and prostatic artery embolization



Before the procedure

We will invite you to come to a Pre-op Assessment Clinic before your operation. The purpose of this appointment with our pre-operative nurse is to organise any more tests that may be needed and ensure you are fit for surgery.

Please bring in a list of any medicines that you normally take at home and let us of know any drug allergies you may have. Depending on what medicines you take, you may be asked to have your normal medicine regime or some may be withheld and given to you after the operation. Taking medicines before the operation is safe and will not put you at risk.

It is important to let us know if you are on any drugs that thin the blood, e.g., aspirin, warfarin, clopidogrel, dipyridamole, endoxaban, apixaban, etc., as you may have to stop taking these for a short time before the operation.

If you are taking warfarin, we may need to bring you into hospital a few days before your operation or to change the warfarin to an injection that can be given at home.

Please inform the nurse if you have an implanted foreign body (pacemaker, prosthetic heart *valve*, stents or joint replacements); and if you have at present or have previously had MRSA infection.

What happens on the day of the procedure?

Please bring a supply of your usual medicines to take whilst you are in hospital. Please report to Day Surgery reception when you arrive.

If there are any more tests that we have not already carried out before admission, we will perform them before your operation.

You may eat a light meal and drink normally up to 6 hours before your operation. From that point, you will need to starve (nil by mouth) to reduce the risk of problems during the anaesthetic.

We will ask you to put on a theatre gown and to wear some special TED stockings during and after the operation. These stockings aim to reduce the risk of developing blood clots (DVT) in your lower legs. Your surgeon or member of the surgical team will see you to discuss the procedure and obtain informed consent from you.

An anaesthetist will see you to discuss the options of anaesthesia and also discuss pain relief after the procedure with you.

You will be taken from the ward to the operating theatre on your trolley.

Details of the procedure

For the procedure, we normally use a general anaesthetic (where you are asleep) or heavy sedation. You will be given an injection of antibiotics before the procedure, after you have been checked for any allergies.

The telescope, together with the iTIND device, will be passed through the urethra using plenty of anesthetic gel. After inspecting the bladder, the surgeon will insert the iTIND device via the telescope, which enables the surgeon to place it precisely at the bladder neck and prostate junction.

After you return to the ward, the nurses will check your blood pressure, pulse and temperature regularly and, as soon as you feel able, you will be allowed to drink and eat. You may feel some sensation of urinary urgency and frequency, and mild discomfort.

The nurse will ask you to pass urine and the quantity you are able to pass will be noted. If you are unable to pass urine, the nurse may insert a small catheter to help you urinate while the swelling subsides.

You will be able to return home the same day and we will tell you when you need to return to have the catheter removed.

After your procedure, a member of the urology team will review you and discuss the operation, any specific requirements for you at home and a plan for your aftercare.

We will ask you to return in 5-7 days time to have the iTIND device removed under sedation.

It is normal to have some pain or discomfort after operations, and we will prescribe you painkillers to help keep it under control.

You can return to work when you feel comfortable, which will depend on your job. If in doubt, please check with your surgeon and obtain a sick note before you are discharged.

Are there any side effects?

The common possible after-effects following this procedure and your risk of getting them are shown below.

- Temporary burning and stinging when you pass urine - 7%
- Temporary bleeding in your urine (may last up to 1 week) - 12%
- Mild pain or discomfort in your pelvic area - 10%
- Urinary tract infection - 3-6%
- Inability to pass urine (urinary retention) following removal of catheter - 4%
- Urinary frequency and urgency - 11%
- Erection or ejaculation issues (retrograde or dry) - 0%
- Possible need for retreatment at later date due to regrowth of prostate - unknown
- Anaesthetic or cardiovascular problems possibly requiring intensive care (including chest infection, pulmonary embolus, stroke, deep vein thrombosis, heart attack and death) - 0.4% - 2%

Before you go home

We will explain to you how the procedure went and advise you what symptoms you should expect and what you can (or cannot) do at home. Your surgeon or nurse will also give you details of who to contact, and how to contact them, in the event of problems.

We will advise you when to restart your drugs that thin your blood (e.g., aspirin, warfarin, apixaban, etc) following the procedure.

We will give you a copy of your discharge summary and send a copy to your GP.

We will give you medications to take at home from the hospital

pharmacy.

We will also give you an appointment to return in 5-7 days' time at the same place to have the iTIND removed under sedation. (This will have been confirmed by our secretaries when the insertion date is booked).

What can I expect when I get home?

You should drink enough fluids for first 2 days to flush out the residual bleeding and reduce any risk of infection.

If there is heavy bleeding or you have fevers/feel unwell, you should see your GP or go to the Emergency department.

If you are unable to pass urine, then you need to go to Emergency department and a catheter may be inserted.

Within a few days you will be able to resume normal activities and should notice improvements within 2 weeks, although it may be 3 months before the full benefit is evident.

You may see blood in your urine and ejaculation fluid for a few weeks. A mild burning sensation, frequency and urgency may persist up to a week or two after insertion and/or removal of the iTIND device.

There are a few sensible precautions to take when at home and we would advise you not to

- do any strenuous activities/ exercise for 2-3 weeks
- have sexual intercourse for 1-2 weeks
- drive for 2 days after the procedure

If you would like to discuss issues after your operation, please call the ward.

Disclaimer

The information provided here in this leaflet have been generated to provide an accurate and up to date information as possible. However, there may still be errors in this leaflet. Please discuss any concerns you may have with your doctor.

Legal Notice

Please remember that this leaflet is intended as general information only. We aim to make the information as up to date and accurate as possible. Please therefore always check specific advice or any concerns you may have with your doctor.
