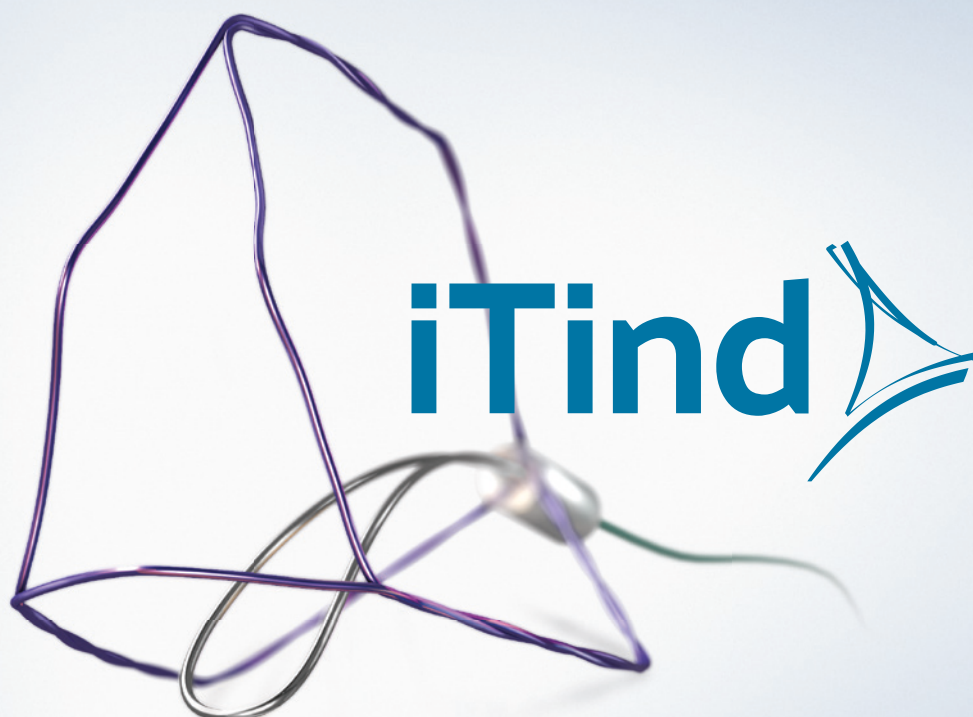


PROCEDURE GUIDE

iTind

Minimally Invasive BPH Treatment



iTind

Improving Minimally Invasive BPH Treatment

Introducing iTind

iTind: Minimally Invasive Treatment for Relieving the Symptoms of Benign Prostatic Hyperplasia (BPH)

iTind is placed into the prostate in a folded configuration, where it expands and exerts localized ischemic pressure on the tissue. This pressure aims to reshape the tissue of the prostatic urethra and the bladder neck, creating three longitudinal channels through which urine can flow.

Patients are able to return home during the 5-7 day treatment, at the end of which the device is entirely removed, while the newly created channels aim to provide long-lasting¹ relief of BPH symptoms.

Benefits

- 1

Rapid and Effective Symptomatic Relief
Designed for BPH symptom relief within days or weeks.
- 2

Lower Risk Profile Than More Invasive Procedures
No long-term complications observed in clinical studies.^{2,3,4}
- 3

Routinely Catheter Free Procedure
Patients are routinely discharged without catheter following the procedure.
- 4

Preserves Sexual and Ejaculatory Function
Designed to preserve the integrity of the verumontanum by ischemic remodelling.
- 5

No Permanent Implant Resulting From the Procedure
iTind is removed entirely after 5-7 days.
- 6

Straightforward Procedure
Efficient procedure with short learning curve.

¹ BPH symptom relief of up to 3 years is clinically proven.

² Porpiglia F, Fiori C, Bertolo R et al. 3-Year follow-up of temporary implantable nitinol device implantation for the treatment of benign prostatic obstruction. BJU Int. 2018 Jul;122(1):106-112.

³ Porpiglia F, Fiori C, Amparore D et al. Second-generation of temporary implantable nitinol device for the relief of lower urinary tract symptoms due to benign prostatic hyperplasia: results of a prospective, multicentre study at 1 year of follow-up. BJU Int. 2019; 123: 1061-1069.

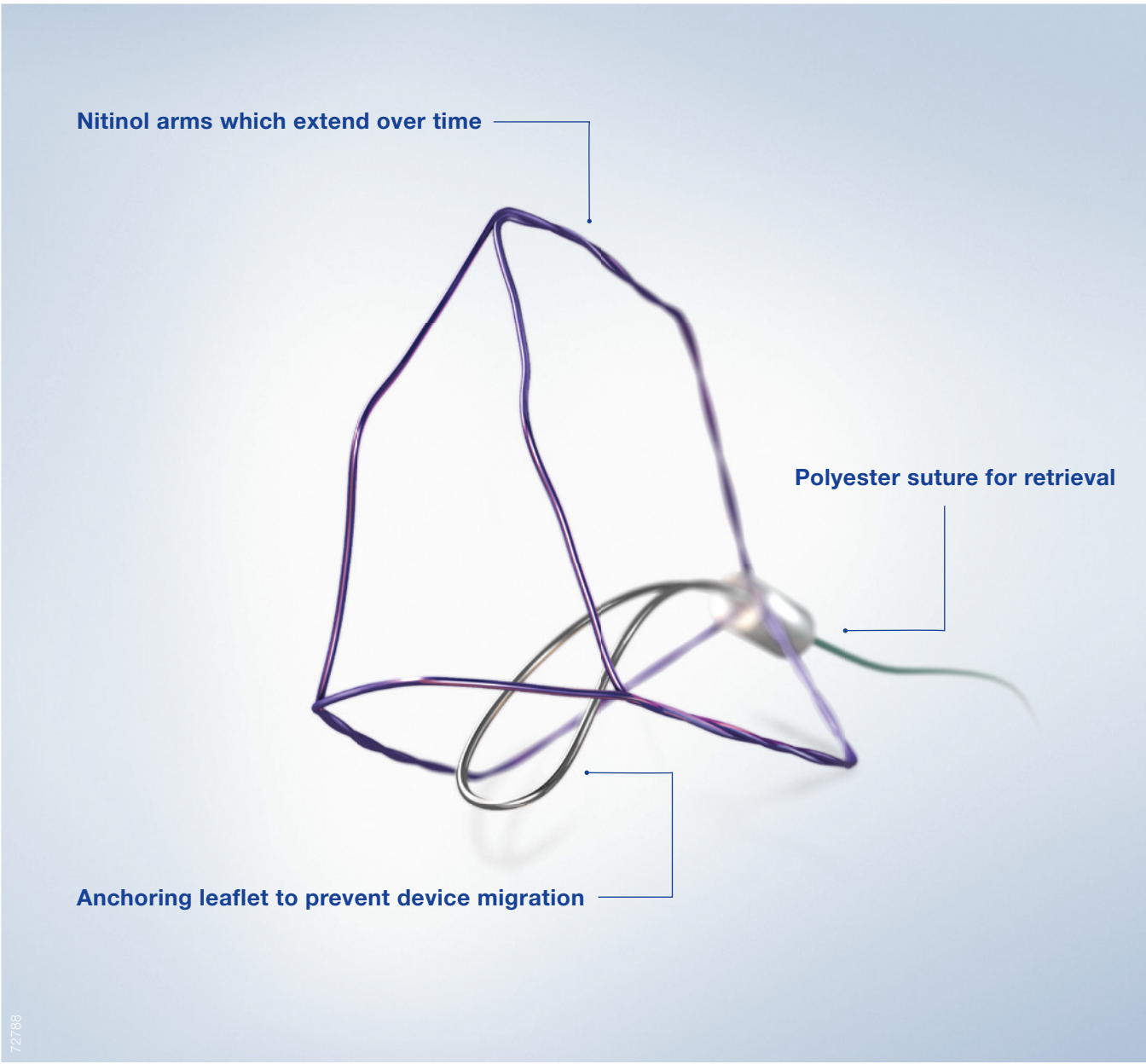
⁴ Kadner G, Valerio M et al. Second generation of temporary implantable nitinol device (iTind) in men with LUTS: 2 year results of the MT-02-study, World Journal of Urology, 2020 Mar.

The Device

Introducing iTind

Specifications

The iTind device is made of nitinol and is 5 cm in length and 3.5 cm in height. It is delivered crimped inside an introducer sheath and pre-mounted on a dedicated guidewire.



Implantation Procedure

Disclaimer

This procedure guide will take you through the steps required to implant and remove iTind. This technique has been adopted by Mr. Neil Barber of the Frimley Benign Prostate Clinical Research Centre at Frimley Health NHS Foundation Trust (UK).

Olympus as distributor does not practice medicine. Therefore, the information on the products and procedures contained in this document is of a general nature and does not represent medical advice or recommendations. This information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case. Each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

This procedure guide is a voluntary service of Olympus, compiled with the greatest possible care. The guide is not meant to replace the instructions for use. Any user of the iTind must at all times observe all mandatory information for the iTind, in particular contained on the labels and the instructions for use.



Mr. Neil Barber
Consultant Urological Surgeon

Implantation Procedure

Procedure Steps with iTind

00 | Equipment and Patient Preparation

The following is required for the implantation procedure using a rigid cystoscope:

- iTind device.
- Rigid cystoscope with
 - min. 19 Fr. sheath (e.g. 19.8 or 22.5 Fr. Olympus sheath).
 - 12° or 30° telescope.
- Scissors or scalpel.
- Surgical tape.

Recommended patient preparation for the implantation of iTind (not obligatory):

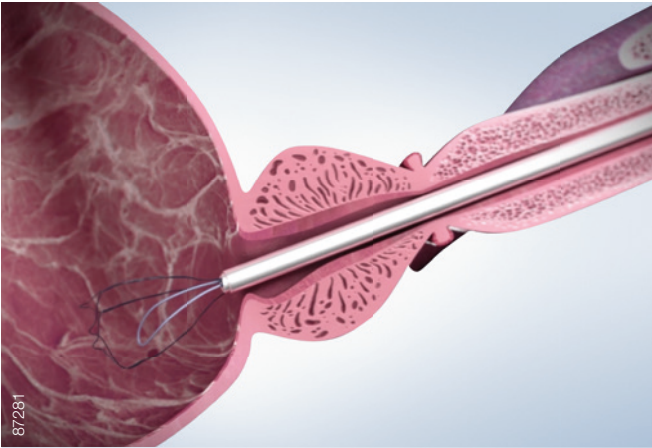
- Light intravenous sedation / IV Propofol.
- Anesthetic gel.
- Prophylactic antibiotics.

01 | Patient Instrumentation

- Open the pouch and prepare the iTind so that it is ready for deployment.
- Pass the cystoscope into the bladder.
- Fill the bladder with sterile saline.
- Observe the urethra and bladder to rule out any contraindications, such as obstructive median lobe (IPP > 1) or bladder pathology.
- Remove any bladder stones or blood clots, if present.

02 | Device Insertion

- Hold the sheath of the rigid cystoscope in the bladder, and withdraw the telescope.
- Insert the iTind, folded within the introducer sheath, into the cystoscope sheath.
- Advance the iTind until you feel the device release into the bladder.
- Withdraw the introducer sheath and set aside.



Troubleshooting — The iTind Does Not Fit into the Cystoscope Sheath

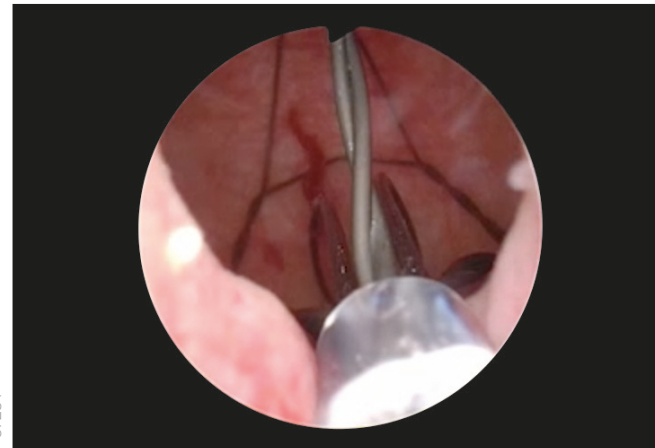
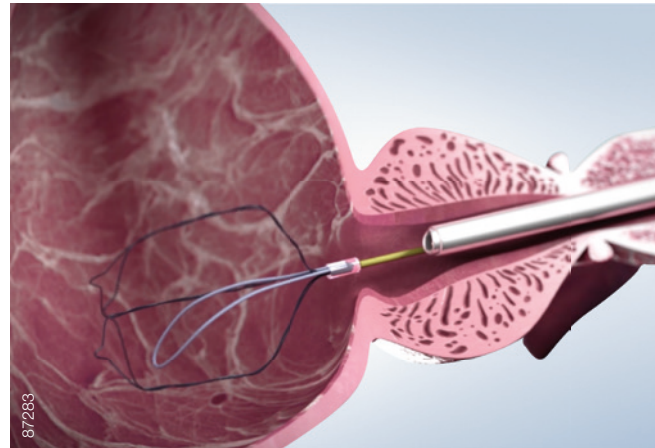
- Make sure the rigid cystoscope is at least 19 Fr.
- Make sure the iTind is fully folded inside the introducer sheath.

Implantation Procedure

Procedure Steps with iTind

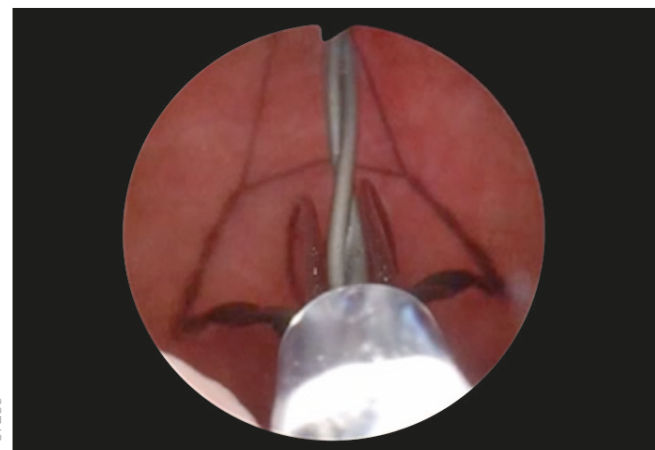
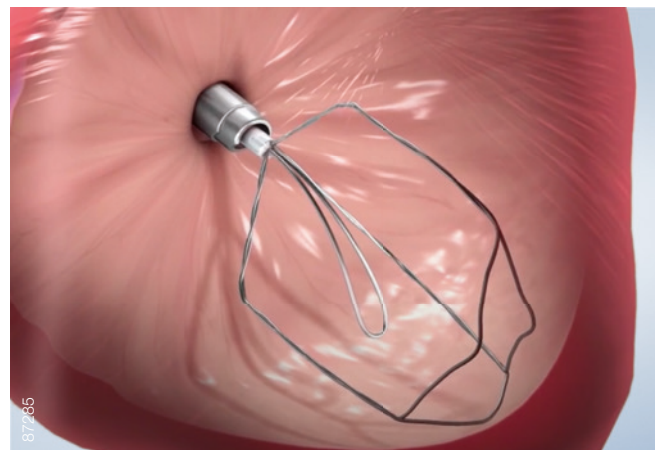
03 | Visualization

- Remove the sheath of the rigid cystoscope, ensuring that the iTind remains in the bladder.
- Under vision, reinsert the rigid cystoscope alongside the guidewire into the bladder.
- Advance the rigid cystoscope until the iTind is visualized inside the bladder.



04 | Orientation

- Fill the bladder with saline to enable visibility and easy rotation of the iTind.
- Differentiate between the double intertwined struts and the smooth anchoring leaflet.
- Maneuver the iTind so that the anchoring leaflet is oriented at the 6 o'clock position.

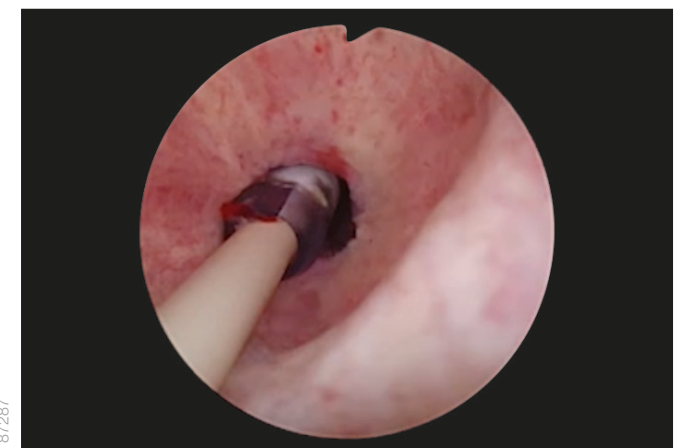
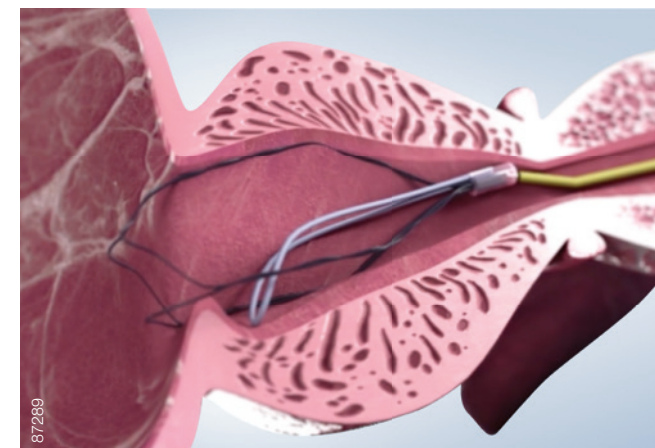
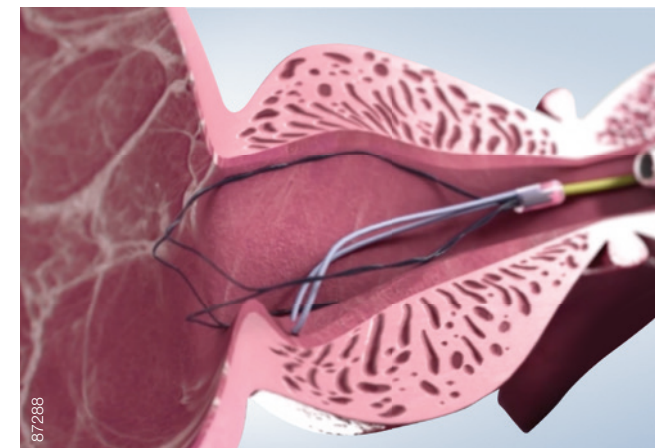


Troubleshooting — The iTind Is Not Clearly Visible Because of Bleeding or Oozing

- Flush the bladder with additional saline.
- Do not attempt to implant the iTind until good visibility has been restored.

05 | Positioning

- While holding the device in position, slowly pull the cystoscope back until the bladder neck is visible.
- Pull the iTind back into the prostatic urethra until the anchoring leaflet passes over the bladder neck and falls into the base of the bladder neck, just before the verumontanum.
- Advance the optics toward the bladder neck to ensure that the distal end of the device is protruding slightly into the bladder.
- If needed, use the guidewire to advance the distal end of the device over the bladder neck.
- Ensure that both the anchoring leaflet and distal end are correctly positioned before continuing.



Troubleshooting — Repositioning Is Required

- If the iTind is not correctly positioned and the anchoring leaflet has not yet been pulled over the verumontanum, push the iTind back into the bladder with the aid of the guidewire and restart the positioning.
- If the iTind is not correctly positioned and the anchoring leaflet has been pulled up to or past the verumontanum:
 - Remove the rigid cystoscope and telescope.
 - Reinsert the cystoscope sheath over the guidewire and re-crimp the iTind into the sheath.
 - Push the iTind back into the bladder. Restart the positioning according to the previous procedure steps.

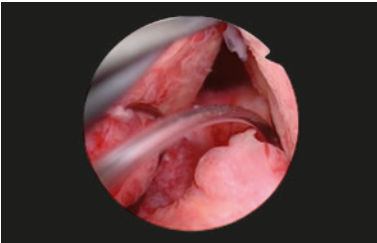
Implantation Procedure

Procedure Steps with iTind

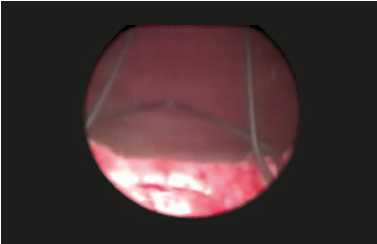
Correct Positioning ✓



Anchoring leaflet resting at the bottom of bladder neck.

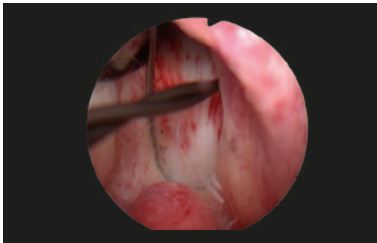


Natural curvature of leaflet can be seen.

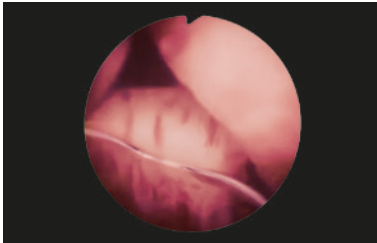


Distal end of the device not visible; protruding into the bladder.

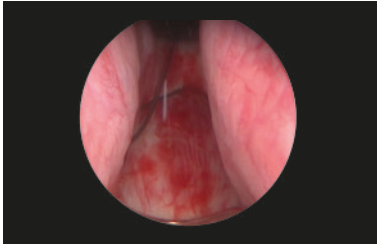
Incorrect Positioning ✗



Anchoring leaflet pushed against bladder neck. "Floating" struts at 3 o'clock.



Anchoring leaflet only pulled back halfway and not resting at bottom of bladder neck.



Distal end of the device is over the bladder neck.

Troubleshooting — The Anchoring Leaflet Cannot Be Seen Sliding Over the Bladder Neck

- Ensure that the iTind and the cystoscope are not being maneuvered together:
 - Position the cystoscope so that the camera is as close to the bladder neck as possible. This will ensure that the lateral lobes do not obstruct the view.
 - Maintain the position of the cystoscope with one hand while pulling the iTind back into the prostatic urethra with the other hand until the anchoring leaflet can be seen gliding over the bladder neck.

Troubleshooting — No Clear Differentiation between the Bladder Neck and Verumontanum OR Asymmetrical Prostate

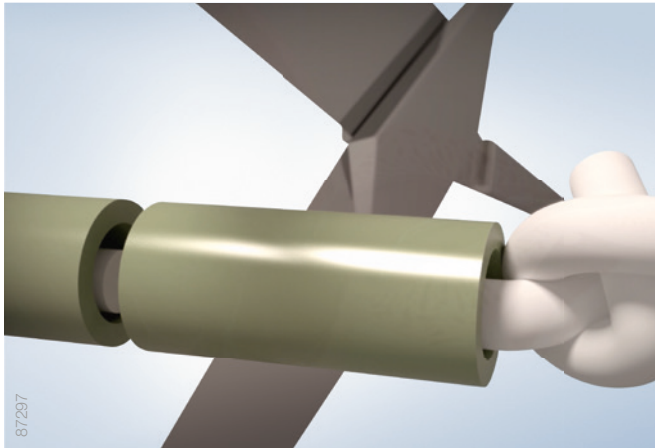
- Ensure the anchoring leaflet is positioned as snugly as possible over the bladder neck, while maintaining the positioning of the struts at the bladder neck.

06 | Deployment

- Empty the bladder through the cystoscope sheath.
- Withdraw the cystoscope until the external sphincter is visible and ensure that it is not being held open by the device.
- Loosen the slipknot at the proximal end of the guidewire and slide it off, exposing the retrieval suture.
- Remove the cystoscope from the urethra.

Troubleshooting — The iTind Guidewire Cannot Be Released

- Cut the proximal end of the guidewire with scissors.
- If the problem remains, use a new device.



07 | Dressing

- Loop the retrieval suture and loosely fasten it to the patient's penis with surgical tape.
- Leave enough slack to allow for an erection and to minimize irritation of the meatus while the device is in situ.
- Instruct the patient not to pull, cut or damage the retrieval suture during the implantation period (5-7 days).

08 | Patient Discharge

- Patients should be discharged only after a successful voiding trial.

Troubleshooting — The Patient Cannot Void

Empty the bladder through a 12 Fr. Tiemann or Foley catheter:

- When inserting the catheter, be sure to hold the suture very taught to avoid displacing the iTind.
- The catheter can typically be removed either directly after emptying the bladder or left for a few hours until another voiding trial is performed.
- If a catheter was placed, it is recommended to perform an abdominal ultrasound to verify that the iTind was not displaced during the catheterization.

Removal Procedure

Procedure Steps with iTind

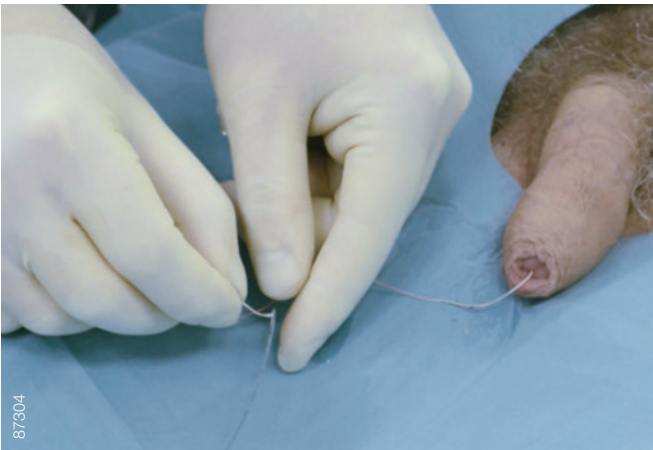
00 | Equipment and Patient Preparation

The following is required for the removal procedure:

- Snare.
- Open ended, 22 Fr. silicone Foley catheter.
- Anesthetic gel.

Equipment preparation for the removal of iTind:

- Lubricate both tips of the silicone catheter and the meatus with anesthetic gel.
- Feed the snare through the catheter.
- Use the snare to thread the retrieval suture through the catheter.



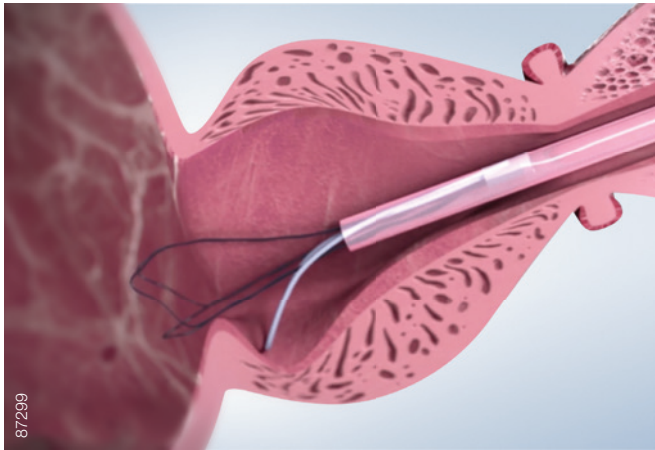
01 | Insert the Catheter

- Insert the catheter into the meatus while holding the retrieval suture taut.
- Guide the catheter up the retrieval suture until it meets the device.



02 | Device Retrieval

- Once the iTind has been reached, pull back the retrieval suture firmly and retract the iTind device into the catheter.
- When the iTind has been folded completely inside the catheter, remove the catheter from the urethra.



Troubleshooting — The Retrieval Suture Breaks or Is Cut

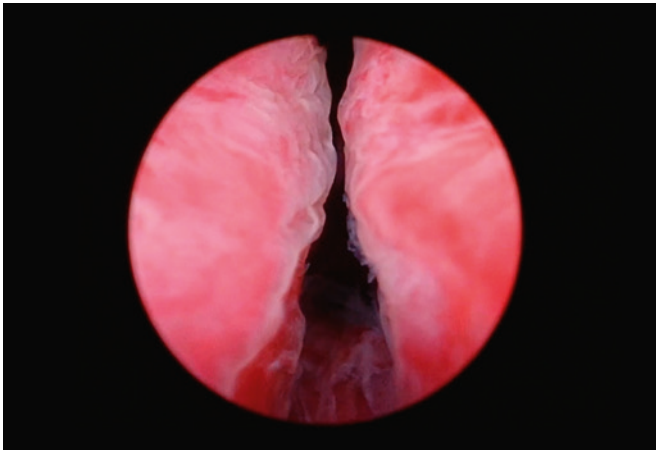
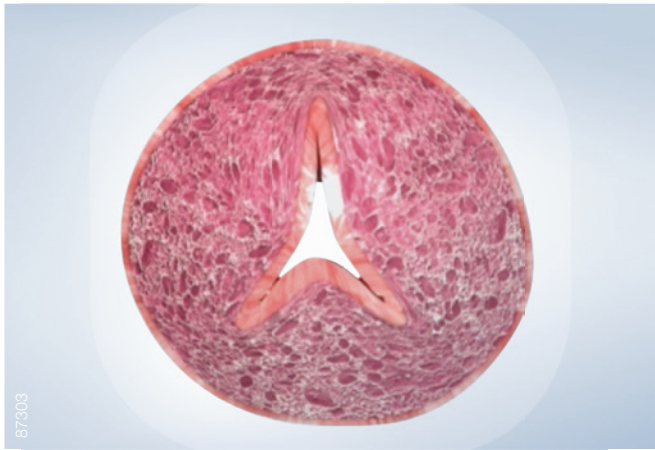
Option 1:

- Attach a #1 Ethibond® type suture using a surgical knot to extend the retrieval suture.
- Continue removal according to standard procedure steps.

Option 2:

- Insert surgical graspers or forceps through a rigid cystoscope.
- Grasp the proximal end of the device to re-crimp it into the scope.

- Through the iTind device, three new channels are meant to be created at the 5, 7 and 12 o'clock positions by ischemic response.
- These channels allow urine to flow better immediately.
- Patients are generally discharged a few hours after the iTind has been removed.



Patient Management: Symptoms and Expectations

During the Implantation Period

Patients should be advised that they may experience some of the symptoms listed below during the implantation period. These are the recommendations for managing patient symptoms, should they occur:

Dysuria, Pain in the Area of the Perineum, or the Feeling of Pressure

- We recommend sending patients home with analgesics such as acetaminophen and/or NSAIDs for the reduction of pain and inflammation.
- Either intravenous or oral steroids may be given to reduce swelling and inflammation and speed recovery.

Urinary Frequency and Urgency

- We recommend encouraging patients to drink little and often. The distal end of the device should protrude slightly into the bladder. If the bladder is empty, the bladder walls may rub against the device, causing further irritation.
- In severe cases anticholinergics may be given. However, this may increase the possibility of acute urinary retention (AUR) upon removal of the iTind device.

Hematuria

- Hematuria is usually mild and self-resolving, but it is recommended to inform patients that they may have some blood in their urine, particularly during the first 48 hours of having the iTind implanted.

Irritation of the Meatus

- The retrieval suture can cause irritation to the patient's meatus, particularly toward the end of the implantation period.
- It is recommended to leave ample slack when fastening the retrieval suture to minimize chaffing.
- Be sure to instruct the patient not to cut or tamper with the retrieval suture.

Dampness

- The retrieval suture can become damp after voiding. It is recommended to provide the patient with absorbent pads in case he decides to use them.

Acute Urinary Retention (AUR)

- The incidence of AUR after the patient has been discharged is very rare.
- We recommend providing the patient with a medical contact person who is familiar with the procedure to contact in case of need.

NOTE: Most of the symptoms above, if experienced, are most common during the first 2-3 days of the iTind being implanted, after which they usually begin to subside.

After Removal

After the removal of the iTind device, patients can expect rapid and effective relief as well as rapid return to daily life:

- Most patients feel an immediate relief of symptoms upon removal of the device and experience a good urinary stream, although symptoms typically continue to improve for up to three, and sometimes even six months.
- Usually, patients may return to normal activities 1-2 days after the iTind has been removed.

Patients should be prepared that they might experience some of the following symptoms:

Mild Episodes of Blood in Urine

- Light blood in the urine may occur for a few days to one week after the procedure.
- This will resolve on its own.

Acute Urinary Retention (AUR)

- Should AUR occur, a standard Tiemann or Foley catheter may be temporarily placed to empty the bladder.
- Routinely, patients can be discharged without a catheter after they have passed urine satisfactorily.

The treatment with iTind avoids many of the complications associated with prescription medication, surgery or permanent implants.

Notes

Place to Write Down Notes

 www.olympus.eu/itind

As medical knowledge is constantly growing, technical modifications or changes of the product design, product specifications and accessories may be required.

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