iTind
RESHAPING BPH TREATMENT

Medi-Tate iTind System

INSTRUCTIONS FOR USE

Manufacturer **Medi-Tate Ltd.**

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Made in Israel

⚠ CAUTION

Before using the Medi-Tate iTind System, read the entire instructions for use.

INTRODUCTION

INTENDED USE:
The Medi-Tate Temporary Implantable Nitinol Device (iTind) System is designed to treat male patients who suffer from lower urinary tract symptoms (LUTS) secondary to BPH.

The iTind System includes:

FOR INSERTION: 1 iTind device, supplied sterile (EO) by Medi-Tate.

FOR REMOVAL: 1 Retrieval Snare, supplied sterile (EO) by Medi-Tate.

BEFORE YOU BEGIN

Make sure that you have a suitable cystoscope so that proper device positioning can be visualized:

- **OPTION 1:** Rigid cystoscope – 19Fr and up.
- **OPTION 2:** Access Sheath or similar instrument – 12Fr (inner lumen) and up and Flexible cystoscope.

The iTind system is supplied sterile and is comprised of a device crimped inside an introducer sheath and pre-mounted on a dedicated guidewire and a retrieval snare.

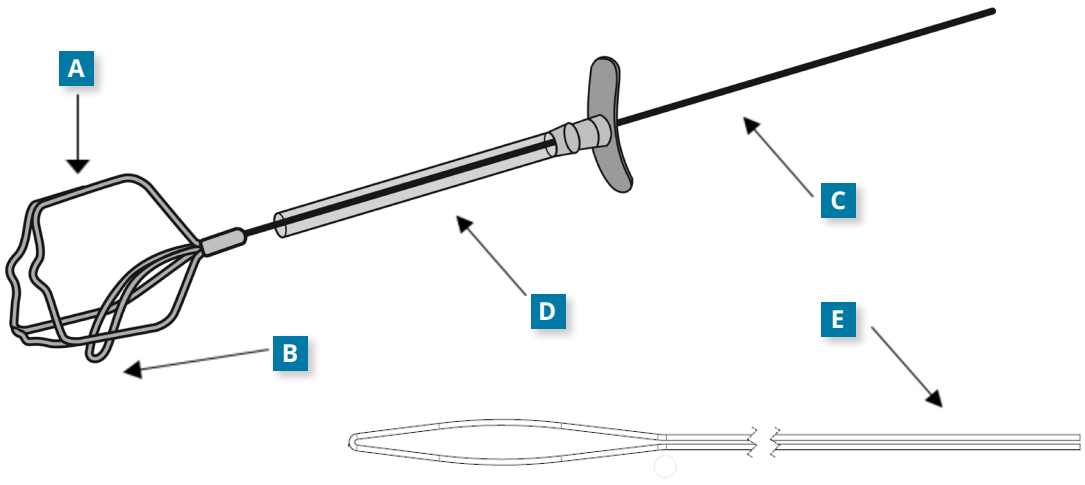
A. iTind device (shown here in expanded configuration)

B. Anchoring leaflet

C. Guidewire (inside protective cover)

D. Introducer sheath

E. Retrieval Snare



CONTRAINDICATIONS

- Active urinary tract infection.
- Artificial urinary sphincter or any implant (metallic or nonmetallic) within the urethra.
- Any patient condition which, to the implanting physician's opinion, may cause complications during the deployment of the device.

WARNINGS AND PRECAUTIONS

General Warnings and Precautions:

- The iTind System should only be used by a trained Urologist.
- The risks of implanting the iTind System in patients with blood coagulation disorders, compromised immune systems, or any other conditions that would compromise healing should be carefully considered against the possible benefits.
- The iTind system is for single use. Do not re-sterilize or reuse any part of the system.
- The iTind System components should be disposed safely after use according to local regulation.
- Non-functional items should not be used and should be returned to Medi-Tate.
- Do not use any part of the iTind System beyond the indicated expiration date.
- Do not use the iTind System if the package was opened or damaged.
- Do not use the iTind System if the patient has a known allergy to Nickel.
- Please contact your distribution/Medi-Tate for a hard copy of the IFU. It will be provided within 7 calendar days.

OPERATING INSTRUCTIONS

Patient Preparation:

Prior to the procedure and at the physician's discretion, the patient should receive anesthesia: spinal anesthesia is not recommended. Prophylactic antibiotics should be given per local hospital or clinic practice.

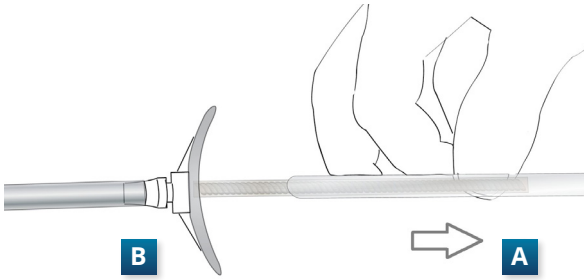
System Preparation:

1 Open the iTind system box and withdraw the iTind device from the pouch in a sterile environment.

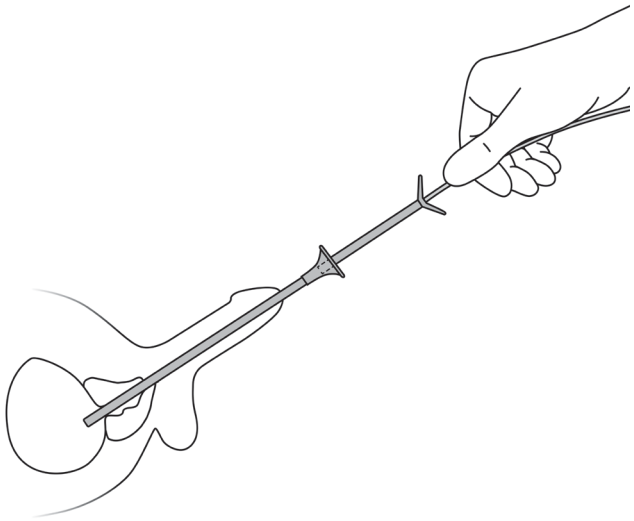
A. Protective cover

B. Introducer sheath

2 Carefully withdraw the iTind device from the protective cover without disconnecting or breaking the introducer sheath.



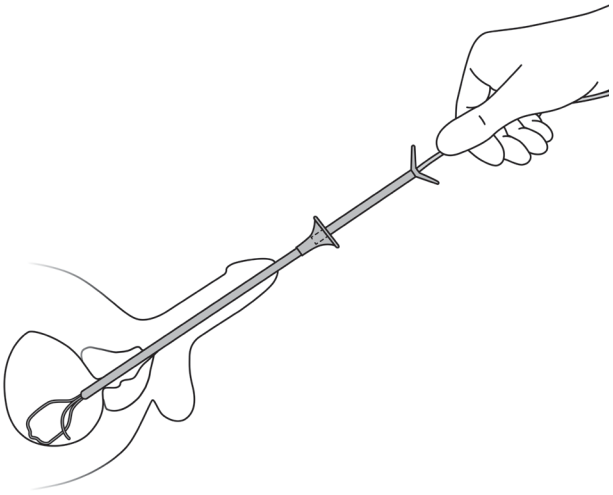
Placement of the iTind device in the bladder:



3 Insert a liberal amount of local anesthetic gel, into the urethra.

4 Instrument the patient with a sheath (access sheath, rigid cystoscope or similar) according to minimal size defined above.

5 Insert the crimped device into the sheath and advance it until opens up in the bladder.



! **Note: a slight pull may be felt as the iTind device expands upon entry to the bladder.**

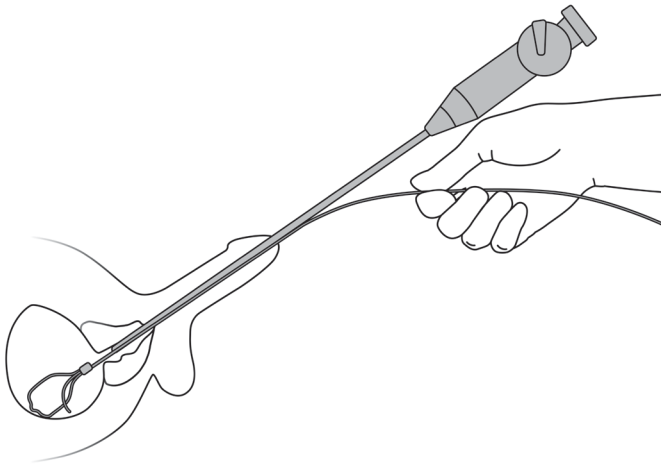
6 Remove the sheath used for insertion while leaving the device in the bladder.

Positioning of the iTind device:

7 Advance a cystoscope (and optics) in parallel to the iTind device guidewire.

8 Inflate the bladder with saline to enable visibility and easy rotation of the iTind device.

9 Position the cystoscope so that the iTind device is visible in the bladder.

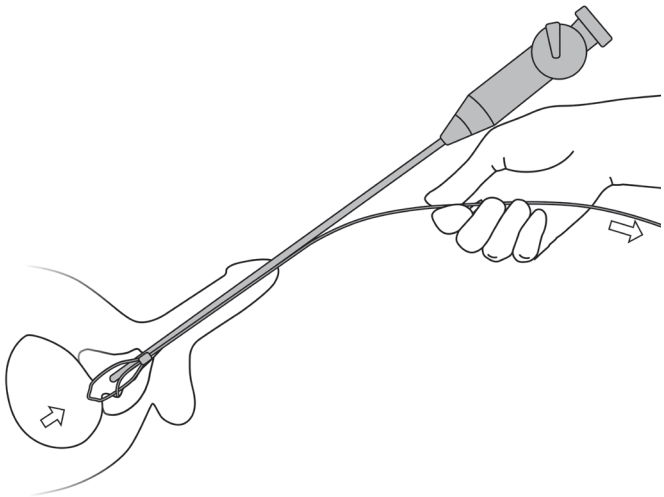


10 Rotate the iTind's guidewire in order to orient the anchoring leaflet down at the 6 o'clock position. In devices that have a blue line proximal to the device, ensure that the line is oriented at 12 o'clock position, that way the anchoring leaflet will be facing 6 o'clock.

11 Slowly pull the cystoscope optics back until the bladder neck is visible.

12 Carefully pull the iTind device into the prostatic urethra using the guidewire, until the anchoring leaflet slides snugly over the bladder neck.

13 While being careful not to displace the device, move the cystoscope optics past the external sphincter and ensure it is not being held open by the iTind device.



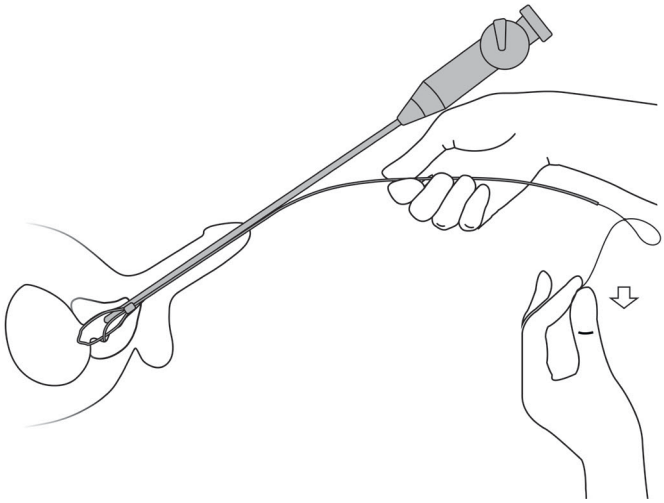
! **Accurate iTind device positioning must always be verified visually.**

NOTE: The iTind device can be repositioned if required as long as the guidewire has not been cut. Accurate iTind device positioning must always be verified visually.

- Option 1: push the iTind device back into the bladder with the help of the guidewire and repeat steps 9-13.
- Option 2: guide a sheath up the guidewire, re-crimp the iTind device into the sheath and repeat steps 5-13.
- Option 3: guide a sheath up the guidewire, re-crimp the iTind device into the sheath and remove device from the body. Re-crimp the iTind device into the introducer sheath and repeat steps 4-13.

14 To enable removal of the guidewire loosen the tied suture by pulling it gently. In case the knot can not be released or noticed, cut the guidewire at its proximal end with surgical scissors and carefully remove it from the urethra, exposing the retrieval suture. Empty the bladder of saline with the help of the scope. Remove the scope from the urethra.

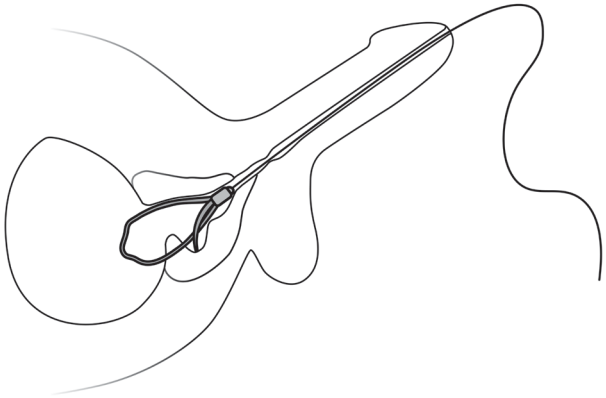
! **NOTE: At this point iTind device implantation is complete and repositioning is no longer possible. If repositioning is required, a new iTind device must be used.**



15 Fold the retrieval suture into a loop and loosely fasten it to the patient's penis using adhesive tape.

! **Make sure to leave enough slack when fastening the suture to avoid irritation of the meatus. Instruct the patient not to pull or cut the suture while the iTind device is implanted.**

! **NOTE: The iTind device should remain in place for 5-7 days before it is removed.**



iTind Device Removal:

BEFORE YOU BEGIN

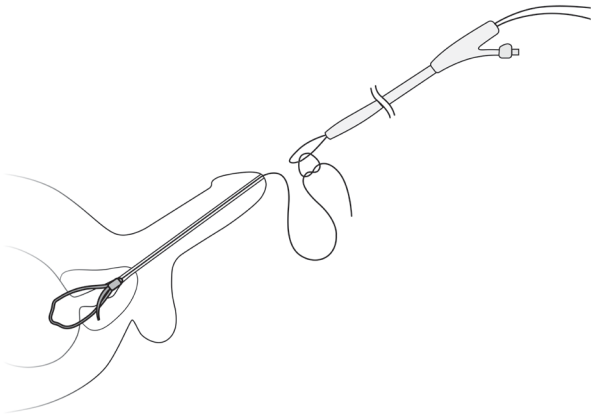
Make sure that you have a suitable removal sheath:

- Open ended Foley catheter – 22Fr
- Access Sheath or similar instrument – 12Fr (inner lumen) and up

1 Liberally insert anesthetic gel into the meatus and into both ends of the Foley catheter.

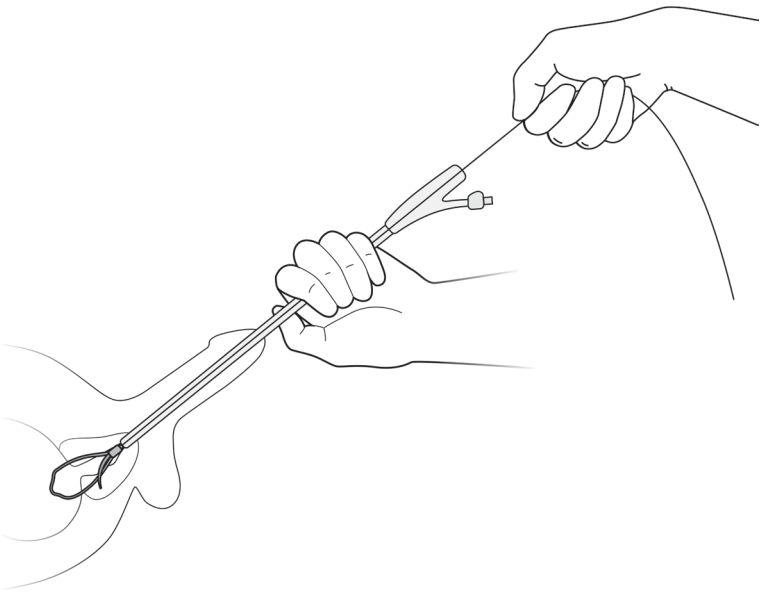
2 Open the sterile retrieval snare package.

3 Feed the Snare through the Foley catheter.



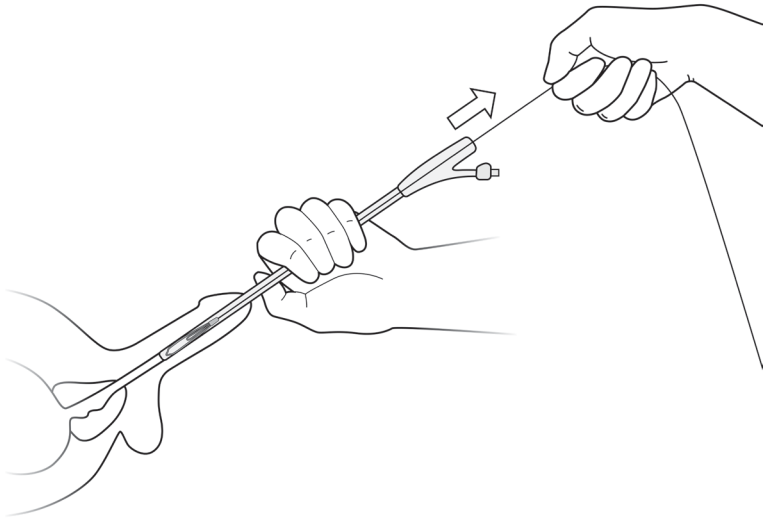
4 Tie the retrieval suture to the loop of the snare and pull the suture through the Foley catheter all the way out. If required, use a polyester suture USP 1 to extend the iTind device retrieval suture.

5 While holding the retrieval suture taut, insert the Foley catheter into the meatus and guide it up the urethra until it meets the iTind device.



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

7 Dispose of the iTind device safely according to local regulation.



! **NOTE: If the iTind device does not collapse easily, the end of the Foley catheter may have passed the device. Pull the catheter back 2-3 centimeters, tighten the grip on the suture, and re-advance the Foley catheter to meet the device. If it still hard to collapse, make sure that the suture was threaded through the main opening of the Foley catheter and not a side hole.**

! **NOTE: If the retrieval suture has been broken and cannot be extended, instrument the patient with a rigid cystoscope (19Fr and more) and use a grasper to grasp the proximal end of the device. Pull the iTind device out through the cystoscope sheath.**

ADVERSE SIDE EFFECTS

(a complete list of side effects is on file with the manufacturer)

The cystoscopy procedure, and/or the presence of the iTind device in the prostatic urethra or the deployment/retrieval procedure may lead to the following adverse side effects:

- Fever, bleeding, pain, UTI, false route of the urethra, dysuria, difficult urination, frequency and urgency, urinary retention and related symptoms, blood in urine (hematuria), urinary incontinence, urethrorrhagia, blood in semen (hemospermia), bladder perforation, urethral and/ or bladder neck strictures, prolonged erection and retrograde ejaculation.
- Local irritation and foreign body response.

REPROCESSING INFORMATION

The iTind system is NOT reusable in any way. For this reason, no handling instructions are required.

STORAGE AND TRANSPORTATION

- Storage temperature: +10 to +40 °C. The iTind System should be stored in dry and away from sunlight environment.
- Transportation conditions: temperature -35°C to +60°C; Humidity 15% to 90%.

USE OF ORIGINAL PRODUCTS

The components of the Medi-Tate iTind System are designed for specific use and complement each other.

System components cannot be replaced by a product from another manufacturer, even if the other product or part is comparable or identical to the original product in appearance and dimensions. For instance, materials used from other manufacturers and any structural alterations resulting from the use of products from another source can lead to impurities to the material as well as minor differences in adjustment between the instruments. This introduces unforeseen risks to the patient and user.

SYMBOLS and their **DEFINITIONS**

LOT	Batch code.		Keep away from sunlight.
	Use by date.	EC REP	Authorized representative in the European community.
	Do not re-use.	REF	Catalogue number.
STERILIZE	Do not re-sterilize.		Humidity limitation.
	Do not use if package is damaged.		Temperature limitation.
STERILE EO	Sterilized using ethylene oxide.	Distributed By	Local distributor address.
eIFU	Consult instructions for use.		Transportation conditions.
	Caution, consult accompanying documents.		Storage conditions.
	Manufacturer.	CE 0344	Marking of conformity to European Medical Device Directive, plus a 4-digit number signifying the notified body.
	Keep Dry.		

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Year of Authorization 2011

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