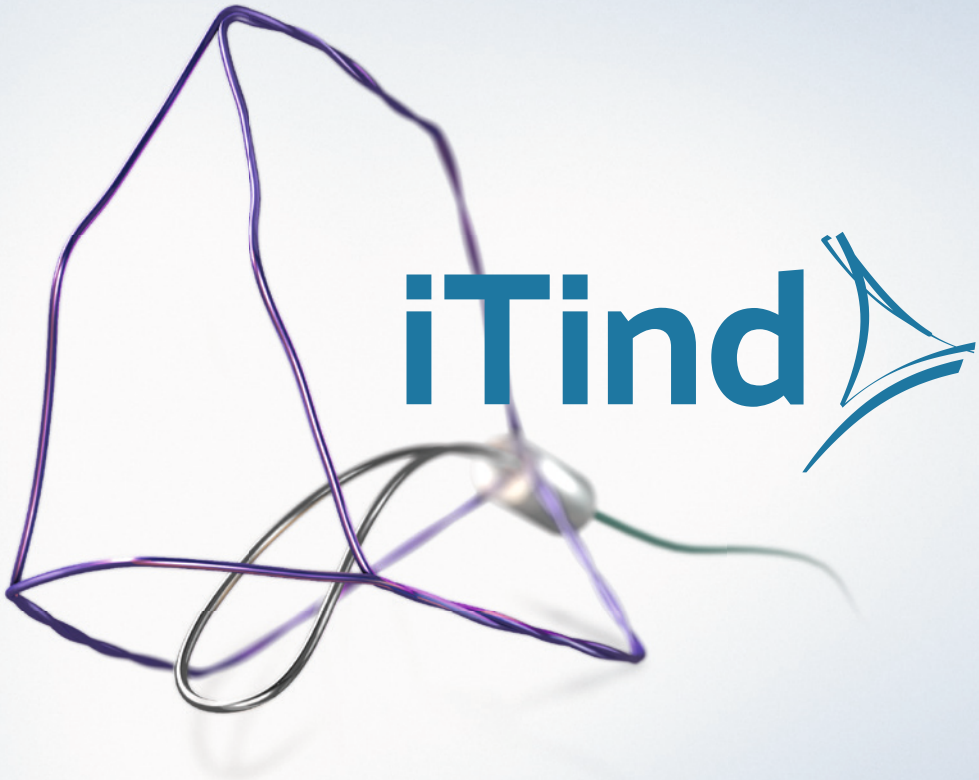
OLYMPUS

iTind

Minimally Invasive BPH Treatment



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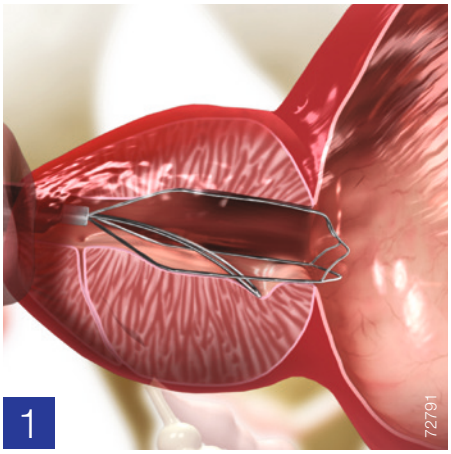
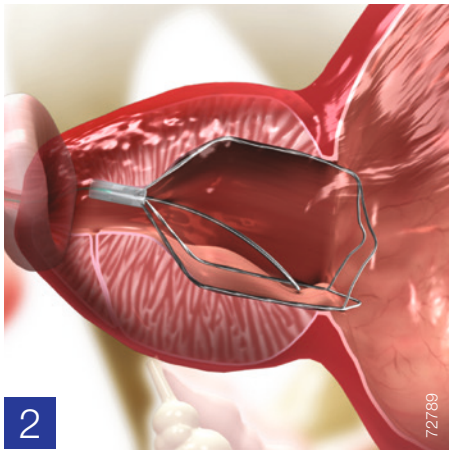
The Mechanism of Action

How iTind Works

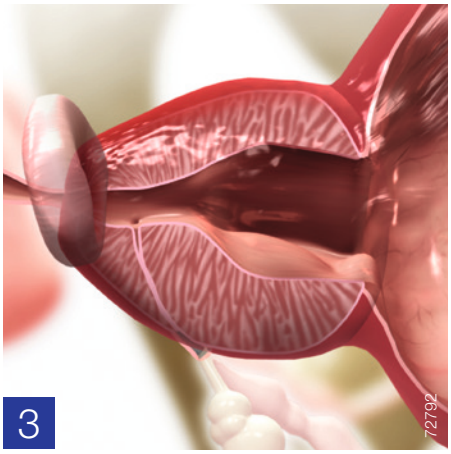
Procedural Steps



The Insertion of iTind

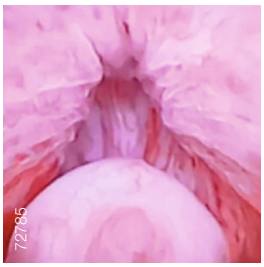


The Implantation Period



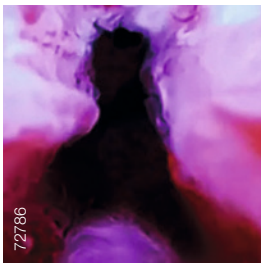
The Removal of iTind

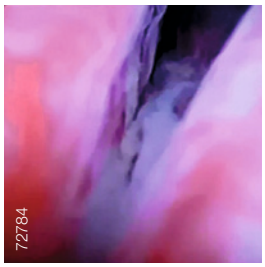
Before



7 o'clock

After





7 o'clock

12 o'clock

The iTind is a temporarily implanted nitinol device which delivers rapid and effective relief from BPH symptoms through a minimally invasive treatment.

The iTind device is inserted into the prostatic urethra under vision using a cystoscope and held in the right position through the anchoring leaflet. The device is designed to ensure easy and precise positioning. Once in place, the iTind expands and exerts continuous pressure on the prostatic urethra and the bladder neck at the 5, 7 and 12 o'clock positions.

Over the next five to seven days, the iTind remodels the tissue by creating three deep longitudinal channels through a localized ischemic response. These three channels then allow urine to flow better. Patients are able to return home during the 5-7 day treatment. After the implantation period of 5-7 days, the device is completely removed.

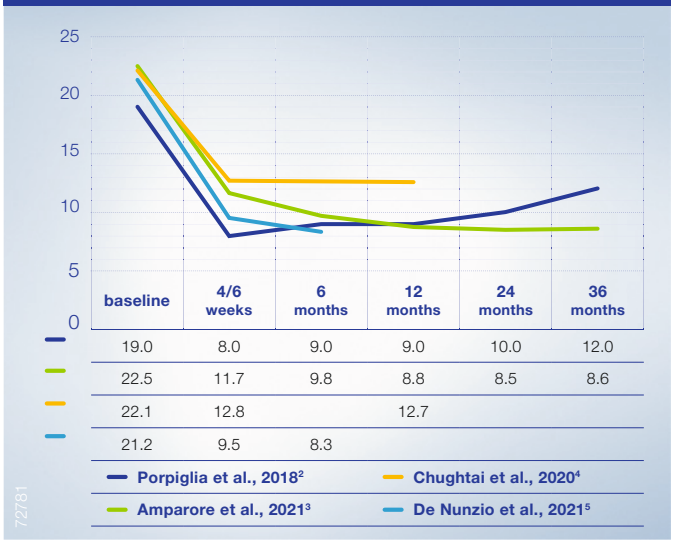
Clinical Evidence

Scientific Publications[1]

Clinical data demonstrate that the first generation TIND boasts a durability of three years, and powerful efficacy at 36 months is also demonstrated by the second-generation and commercially available iTind.

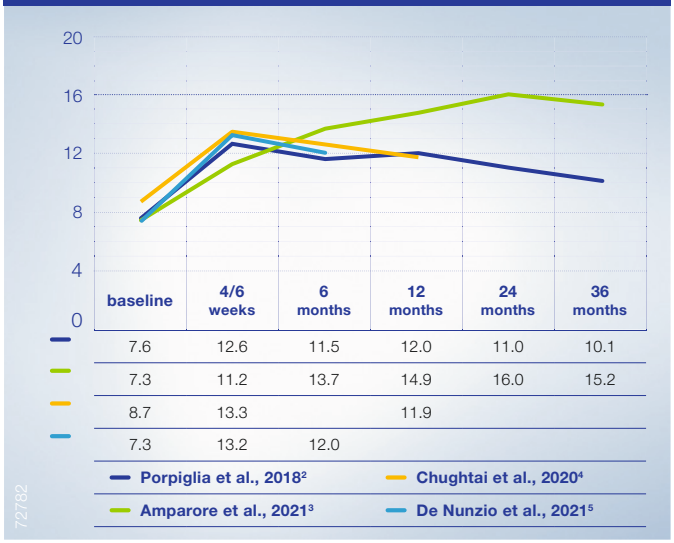
- Rapid and effective relief from BPH symptoms.[2-5]
- Lower risk profile than more invasive procedures.[3-5]
- Routinely catheter free procedure.[3,4]
- Preserves sexual and ejaculatory function.[4,5]
- No permanent implant resulting from the procedure.[2-5]
- Straightforward procedure.

IPSS (in points)



	baseline	4/6 weeks	6 months	12 months	24 months	36 months
Porpiglia et al., 2018[2]	19.0	8.0	9.0	9.0	10.0	12.0
Amparore et al., 2021[3]	22.5	11.7	9.8	8.8	8.5	8.6
Chughtai et al., 2020[4]	22.1	12.8		12.7		
De Nunzio et al., 2021[5]	21.2	9.5	8.3			

Q_{max} (in ml/s)



	baseline	4/6 weeks	6 months	12 months	24 months	36 months
Porpiglia et al., 2018[2]	7.6	12.6	11.5	12.0	11.0	10.1
Amparore et al., 2021[3]	7.3	11.2	13.7	14.9	16.0	15.2
Chughtai et al., 2020[4]	8.7	13.3		11.9		
De Nunzio et al., 2021[5]	7.3	13.2	12.0			

Porpiglia et al., 2018[2]
- Single-center prospective pilot study on first generation TIND.
- Study site: Turin, Italy.
- Number of patients: 32.
- Inclusion criteria: Age: > 50 years; PV < 60 ml; IPSS ≥ 10; Qmax ≤ 12 ml/s.

Amparore et al., 2021[3]
- Multicenter prospective study on second generation iTind.
- Study sites: Italy, UK, Switzerland, Belgium, Hong Kong, Spain.
- Number of patients: 81.
- Inclusion criteria: No age restriction; PV < 75 ml; IPSS ≥ 10; Qmax < 12 ml/s.

Chughtai et al., 2020[4]
- Multicenter randomized, controlled trial on second generation iTind.
- Study sites: USA, Canada.
- Number of patients: 175 (randomized 2:1 between iTind and sham)
- Inclusion criteria: Age: ≥ 50 years; PV < 75 ml, IPSS ≥ 10; Qmax ≤12 ml/s.

De Nunzio et al., 2021[5] — An Interim Analysis after 6 Months
- Multicenter prospective study on second generation iTind.
- Study sites: Italy, Spain.
- Number of patients: 70
- Inclusion criteria: No age restriction; PV < 120 ml; IPSS ≥ 10; Qmax < 12 ml/s.

[1] Company sponsored trials under the responsibility of Medi-Tate.

[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;122(1):106-112. doi:10.1111/bju.14141.
Note: Results are for predecessor device (not FDA approved in US).

[3] Amparore D, Fiori C, Valerio M, et al. 3-Year results following treatment with the second generation of the temporary implantable nitinol device in men with LUTS secondary to benign prostatic obstruction. Prostate Cancer Prostatic Dis. 2021;24(2):349-357. doi:10.1038/s41391-020-00281-5.
Note: Results shown were derived by per protocol analysis.

[4] Chughtai B, Elterman D, Shore N, et al. The iTind Temporarily Implanted Nitinol Device for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: A Multicenter, Randomized, Controlled Trial [published online ahead of print, 2020 Dec 26]. Urology. 2020;S0090-4295(20)31520-X. doi:10.1016/j.urology.2020.12.022.

[5] De Nunzio C, Cantiello F, Fiori C, et al. Urinary and sexual function after treatment with temporary implantable nitinol device (iTind) in men with LUTS: 6-month interim results of the MT-06-study. World J Urol. 2021;39(6):2037-2042. doi:10.1007/s00345-020-03418-2.

iTind

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