PRESS INFORMATION

Study Proves iTind Treatment for Enlarged Prostate Lasts More than Four Years

Published Data Shows Long-Lasting Positive Impact of iTind™ Treatment for Those Suffering from Benign Prostatic Hyperplasia (BPH)

Center Valley, Pa. / Hamburg, July 12, 2023 – Olympus Corporation, a global medical technology company, announced publication of study data demonstrating that the minimally invasive iTind™ treatment provides long-lasting relief of more than four years for people suffering from the symptoms of an enlarged prostate, also known as BPH.

The **long-term study** data demonstrates that the iTind procedure leads to significant and durable reduction of BPH-related LUTS (lower urinary tract symptoms) and improved IPSS (International Prostate Symptom Score) and QoL (Quality of Life) for over 50 months and up to 79 months (6.6 years) following treatment.[1]

“This evidence of clinical durability is important to physicians considering surgical options for BPH symptom treatment,” said Daniele Amparore, MD, Division of Urology, San Luigi Hospital, Orbassano, Italy, who is a co-leading author of the study. “We now have published study data showing iTind device treatment is a reliable minimally invasive surgical option with minimal safety concerns for extended time periods.”

Due to the COVID-19 pandemic, patients could not be examined in-person for functional testing at the >48-month follow-up. Hence, the protocol was adapted so that data regarding long-term symptoms’ relief (IPSS, QoL improvement and the need for re-treatment) could be gathered telephonically.

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[1] Amparore D, De Cillis S, Schulman C, Kadner G, Fiori C, Porpiglia F. Temporary implantable nitinol device for benign prostatic hyperplasia-related lower urinary tract symptoms: over 48-month results [published online ahead of print, 2023 Jun 23]. *Minerva Urol Nephrol*. 2023;10.23736/S2724-6051.23.05322-3. doi:10.23736/S2724-6051.23.05322-3

Summary of Long-term Study Results

> Fifty patients pursued the prospective, single-arm, multicenter study beyond 36 months following treatment. The study analyzes results for 41 of the 50 patients 50-79 months following treatment. Nine of the 50 were unavailable for follow-up: five patients were lost to follow-up; two patients died unrelated to iTind placement; and two patients (36-48 months follow-up) required surgical re-treatments (one transurethral resection of prostate, and one thulium laser enucleation of prostate).

> iTind device treatment showed significant improvement in symptoms, with IPSS reduction of 45.3% and IPSS-QoL reduction of 45.1% from baseline up to 79 months post-procedure (both P<0.0001)

> No late post-operative complications were reported beyond 36 months of follow-up, and no patients required additional medication.

> The surgical re-treatment rate after 36 months was 4%, and the total cumulative re-treatment rate from baseline up to 79 months was 11.1%.

“We are very excited to see positive results from the study follow-up showing that treatment with the iTind procedure is safe, effective and long lasting,” said Vanessa Malka, Executive Director and iTind Commercial Head for Olympus Corporation. “This is very important evidence for urologists and their male patients who are considering treatment with the iTind procedure as an alternative to current BPH therapies, as it proves the iTind procedure contributes to positive patient outcomes over a long period of time.”

BPH is a common health problem for men as they age, affecting approximately 50% of men between the ages of 51 and 60 and up to 90% of men over the age of 80.[2] Symptoms of BPH include frequent urination with a sense of urgency and a weak urinary stream, and excessive urination at night.[3] Suffered over time, these symptoms can have a detrimental effect on quality of life for men and their families.[4]

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[2] What is Benign Prostatic Hyperplasia (BPH)? UrologyHealth.org. https://www.urologyhealth.org/urology-a-z/b/benign-prostatic-hyperplasia-(bph). Updated September 2021. Accessed March 8, 2022.

[3] Benign prostatic hyperplasia (BPH). Urology Care Foundation. Accessed November 12, 2021. https://www.urologyhealth.org/urology-a-z/b/benign-prostatic-hyperplasia-(bph)

[4] Alcaraz A, Carballido-Rodríguez J, Unda-Urzaiz M, et al. Quality of life in patients with lower urinary tract symptoms associated with BPH: change over time in real-life practice according to treatment--the QUALIPROST study. *Int Urol Nephrol*. 2016;48(5):645-656. doi:10.1007/s11255-015-1206-7

About the iTind procedure

Evidence shows the iTind procedure is an effective alternative to pharmaceutical therapy, as well as an alternative to surgeries and permanent implants, and is proven to relieve symptoms without affecting sexual and ejaculatory function[5,6,7] or urinary continence.[6]

The iTind procedure involves the placement of a temporary implanted nitinol device that reshapes the prostatic urethra without burning or cutting out the prostate. The device can be placed in an outpatient setting or physician office. It remains in place for five to seven days while the patient is at home. Upon removal, patients experience rapid and effective relief of their symptoms.[5,6,8,9]

The iTind procedure may not be for everyone. Please consult with a doctor to see if the iTind procedure is right for you. As with any medical procedure, implantation of the iTind device comes with the possibility of side effects, including pelvic discomfort, blood in urine, and/or painful or urgent urination. In rare cases, the iTind device may cause urinary tract infection or a sudden difficulty to urinate.

The study was funded by Medi-Tate, a wholly owned subsidiary of Olympus Corporation.

More information about the iTind procedure is available at **www.olympus-europa.com/medical**.

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[5] 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

[6] 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

[7] Elterman D, Alshak M, Martinez Diaz S, et al. An Evaluation of Sexual Function in the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia in Men Treated with the Temporarily Implanted Nitinol Device [published online ahead of print, 2022 Sep 7]. *J Endourol*. 2022; doi:10.1089/end.2022.0226

[8] 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

[9] 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

About Olympus

At Olympus, we are committed to Our Purpose of making people's lives healthier, safer and more fulfilling. As a global medical technology company, we partner with healthcare professionals to provide best-in-class solutions and services for early detection, diagnosis and minimally invasive treatment, aiming to improve patient outcomes by elevating the standard of care in targeted disease states.

For more than 100 years, Olympus has pursued a goal of contributing to society by producing products designed with the purpose of delivering optimal outcomes for its customers around the world.

For more information, visit **www.olympus-europa.com** and follow our LinkedIn account: **linkedin.com/company/OlympusMedEMEA**.

For questions or additional information, please contact:

Matthias Gengenbach
Olympus Europa SE & Co. KG
Mobile: +49 151 4236 9420
E-mail: **matthias.gengenbach@olympus.com**