

PRESS INFORMATION

Abstract of Durability Study Results for iTind Procedure Presented at 2022 American Urological Association Annual Meeting

STUDY RESULTS SHOW LONG-TERM EFFICACY OF ITIND PROCEDURE

Hamburg/Center Valley, 05/18/2022 – Olympus, a leading global medtech company providing innovative solutions for medical and surgical procedures, announced today the summary results of a follow-up study to measure the durability of the iTind™ procedure for treating the lower urinary tract symptoms caused by BPH (benign prostatic hyperplasia). [The abstract](#) was presented at the American Urological Association Annual Meeting (AUA) on May 15, 2022.ⁱ

Study results show the long-term efficacy of the iTind procedure for IPSS (*International Prostate Symptom Score*) and QoL (*Quality of Life*) with durability up to 6.6 years. Two out of 50 patients required subsequent surgical intervention during the study period from 36 to 79 months after initial treatment with the iTind procedure. No late post-operative complications were reported, and no patients returned to BPH medication.

“Our long-term follow-up with patients was hampered by the global pandemic. Still, we were able to report on IPSS, QoL and durability up to 6.6 years,” said Professor Francesco Porpiglia, MD, Chair of the Urology Division at San Luigi Gonzaga Hospital, University of Turin in Torino, Italy, and primary investigator of the study. “The data demonstrate that the iTind procedure is a safe and effective treatment for BPH symptoms that is durable over time.”

“These study results are highly anticipated by urologists, which was confirmed by the high interest in the iTind device at the Olympus booth at the 2022 AUA meeting,” said Vanessa Malka, Executive Director and iTind Commercial Head for Olympus Corporation. “The results demonstrate that the iTind procedure is an alternative to current BPH therapies. It contributes to positive patient outcomes because it is durable and, as a temporary implant, does not preclude future treatment options.”

BPH is a noncancerous enlargement of the prostate and one of the most common diseases in aging men. BPH affects approximately 50% of men between the ages of 51 and 60 and up to 90% of men over the age of 80.ⁱⁱ BPH symptoms include frequent urination with a sense of urgency and a weak urinary stream, and excessive urination at night.ⁱⁱⁱ Suffered over time, these symptoms can have a negative impact on overall quality of life.^{iv} With

most men facing BPH in their lifetimes, there is a need for more minimally invasive treatment options beyond drugs and surgery.

The iTind procedure involves the placement of a temporary nitinol device that reshapes the prostatic urethra without burning or cutting out tissue. The device remains in place for five to seven days while the patient is at home. Clinical trials have demonstrated that, upon removal, patients experience immediate relief of their symptoms without any effect on their sexual function.^v

As with any medical procedure, implantation of the iTind device comes with the possibility of side effects, including pelvic discomfort, blood in urine, painful or urgent urination. In rare cases, the iTind device may cause urinary tract infection or a sudden difficulty to urinate.

The international multicenter prospective study was funded by Medi-Tate, a wholly owned subsidiary of Olympus Corporation. Publication of the study results is pending review.

More information about the iTind procedure in the U.S. is available at BPHTherapy.com/iTind and in the EMEA region at olympus-europa.com/medical/en/Products-and-Solutions/Products/Product/iTind.html.

About Olympus

A leading medical technology company, Olympus uses innovative capabilities in medical technology, therapeutic intervention, and precision manufacturing to help healthcare professionals deliver diagnostic, therapeutic, and minimally invasive procedures to improve clinical outcomes, reduce overall costs, and enhance the quality of life for patients. Olympus' portfolio includes endoscopes, laparoscopes, and video imaging systems, as well as surgical energy devices, system integration solutions, medical services, and a wide range of endotherapy instruments. For more information, visit Olympus-Global.com.

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ⁱ Amparore D, De Cillis S, Fiori C, Kadner G, Schulman C, Porpiglia F. Long term Follow Up of an International Multicenter Prospective Study in Application of Temporary Implantable Nitinol Device (iTind) in Men with Lower Urinary Tract Symptoms for BPH. *Urology*. 2022;207(5):e1307. doi.org/10.1097/JU.0000000000002669.06

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- ⁱⁱ What is Benign Prostatic Hyperplasia (BPH)? UrologyHealth.org. [https://www.urologyhealth.org/urology-a-z/b/benign-prostatic-hyperplasia-\(bph\)](https://www.urologyhealth.org/urology-a-z/b/benign-prostatic-hyperplasia-(bph)). Updated September 2021. Accessed March 8, 2022.
- ⁱⁱⁱ Benign prostatic hyperplasia (BPH). Urology Care Foundation. Accessed November 12, 2021. [https://www.urologyhealth.org/urology-a-z/b/benign-prostatic-hyperplasia-\(bph\)](https://www.urologyhealth.org/urology-a-z/b/benign-prostatic-hyperplasia-(bph))
- ^{iv} 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
- ^v 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