



Promising Clinical Study Results of the Zenflow Spring System Featured at the AUA 2021 Meeting

-- 12-Month Interim Results from Multicenter, Prospective Clinical Study Highlighted --

SOUTH SAN FRANCISCO, Calif., September 11, 2021 – Study results from the Spring® System from [Zenflow, Inc.](#), a medical device company developing a minimally invasive treatment for urinary obstruction caused by enlarged prostate, or benign prostatic hyperplasia (BPH), were featured at the [American Urological Association](#) 2021 annual meeting.

The Spring System was designed with the patient experience in mind and relies on a small spring-like coil to gently prop open the urethra, restoring its normal function while preserving the natural anatomy. Over 40 million patients suffer from BPH in the U.S.

Impressive Study Results Highlighted at Conference

Presentations at the preeminent AUA conference conveyed both the evolutionary path of this innovative technology, as well as the clinical evidence collected along the way. To date, over 100 patients have been treated with the Spring System in a collection of studies that have demonstrated promising safety, effectiveness, and long-term durability.

Presentation 1: 12-Month Interim Results of the Multicenter, Prospective, Single-Arm Study with the Zenflow Spring System

In Zenflow's two recent pilot studies (ZEST 2 and ZEST EU), which consisted of 76 patients, there was a 95% procedural success rate with no unanticipated adverse events. Of these patients, 38 completed their 12-month follow up and showed statistically significant improvements in symptoms, including the following, which were all compared to baseline:

- 50% improvement in mean [International Prostate Symptom Score](#) (IPSS)
- 64% improvement in mean quality of life (QoL) score
- 60% improvement in mean maximum urinary flow rate (Qmax).

The presentation, titled "12-Month Interim Results of the Multicenter, Prospective, Single-Arm Study with the Zenflow Spring System: A Novel Minimally-Invasive Treatment for LUTS Associated with BPH," was presented by Peter Gilling, M.D., Professor of Surgery, University of Auckland, Head of Bay of Plenty District Health Board Clinical Campus in Tauranga, New Zealand.

"Contributing to the advancement of urologic care has been our practice's focus. I am impressed with how quickly patients experience benefit from the Spring System and the durability we've seen 12 months out. Patients treated with this minimally-invasive treatment have been very satisfied with the procedure and the relief of their symptoms," said Professor Gilling.

Presentation 2: Evolution of the Zenflow Spring System: A Novel Nitinol Implant for Benign Prostatic Hyperplasia (BPH)

In this session, Peter Chin, M.D., Associate Professor, University of Wollongong, Wollongong, Australia, reviewed the engineering advancements that led to today's Spring design along with an overview of Zenflow's first feasibility study (ZEST) of 11 patients. This study demonstrated



successful implant delivery, no unanticipated adverse events and improvement in symptoms out to three years.

“Early clinical experience in this first-in-human study showed encouraging results with successful treatment and durable symptom improvement. It is exciting to see the development, evolution and ongoing evaluation of this new technology that has potential to offer a simple, intuitive, and minimally invasive procedure for LUTS secondary to BPH,” said Dr. Chin.

Next Clinical Trial Announced

To build on its foundation of clinical evidence, Zenflow is preparing to initiate its BREEZE™ clinical trial, a prospective, multinational and multicenter randomized controlled study that will continue to assess the safety and effectiveness of the Spring System and was designed to support FDA clearance.

About Zenflow

[Zenflow, Inc.](#) is a privately held medical device company dedicated to improving treatment for patients suffering from urinary obstruction caused by enlarged prostate. The company was founded by Stanford University Biodesign Fellows working in collaboration with top global urologists who, after witnessing patients' frustration with existing treatment options, made it their mission to find a better solution. The innovative Spring® technology was designed with the patient experience in mind and relies on a small spring-like coil that gently props open the urethra, restoring its normal function while preserving the natural anatomy. The Zenflow Spring System is an investigational device and is not approved for commercial sale.

For more information, visit www.zenflow.com

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