

Three-Year Data of Zenflow's Spring System Demonstrate Durability of Clinical Benefits for Patients Suffering from BPH

Data Presented at the AUA Meeting Reflect Longest-Term Data among FIT Interventions

SOUTH SAN FRANCISCO, Calif., April 26, 2025 – Zenflow, Inc. announced today the results of long-term data demonstrating that the investigational Zenflow Spring® System offers significant and durable benefits three years after placement. The Zenflow Spring is leading the way in establishing a new category of treatment, First-Line Interventional Therapy or "FIT", for patients suffering from benign prostatic hyperplasia (BPH) or enlarged prostate. The goal of FIT is to provide clinicians with minimally invasive therapies that offer distinct safety advantages such as the ability to reverse treatment if desired, more like a medication. The research was presented at the <u>2025 Annual Meeting of the American Urological Association</u> in Las Vegas.

Subjects treated with the Zenflow Spring showed statistically significant and sustained reduction in their International Prostate Symptom Score (IPSS) from baseline at all assessment time points. Highlights from the ZEST pilot studies include:

- At 36 months, IPSS was 46% improved relative to baseline (11.8 vs. 22.0).
- The negative impact of BPH symptoms on quality of life was half that at baseline (IPSS-QOL 2.23 vs. 4.49), and Qmax increased to 13.9 mL/s from 10.6 mL/s at baseline.
- The responder rate, calculated as the proportion of subjects with ≥ 30% improvement in IPSS, was 74% at 36 months, similar to 75% at 12 months and 70% at 24 months.
- No deterioration in erectile or ejaculatory function was seen over time through 36 months.

Dean Elterman, M.D., Associate Professor at the University of Toronto and an attending urologist at the University Health Network, in Toronto, and investigator in the ZEST studies presented the research. "It's exciting to see the front-runner in the FIT category continue to deliver consistent, long-term results for men living with BPH. Zenflow is the first to demonstrate this level of durability, and the only device offering a range of lengths and diameters to provide a truly tailored therapy. This new data reinforces earlier findings on durability and chronic safety, particularly the absence of implant encrustation or migration – making Zenflow a standout innovation in the field, and one to watch," he said.

"We're encouraged to see the three-year data build upon the strong efficacy and durability results we saw at two years, further underscoring the Zenflow Spring as a promising, much-needed alternative for BPH patients and urologists seeking FIT options. We look forward to

sharing developments with the urology community as we move toward FDA approval and commercial launch," said Shreya Mehta, CEO.

The ZEST pilot studies included 72 subjects who received the Zenflow Spring device. Symptom improvement was measured using IPSS and IPSS-QOL; functional improvement was measured by peak urinary flow rate (Qmax). Overall effectiveness measures were calculated using a mixed model repeated measures (MMRM) analysis, which incorporates within-patient correlations and missing data, and equally weighs results from each study. Sexual health was monitored using the Sexual Health Inventory for Men (SHIM) and the Male Sexual Health Questionnaire –Ejaculatory Domain (MSHQ-EjD).

The safety and effectiveness of the Zenflow Spring System is currently being evaluated through BREEZE™, a large, multi-center, prospective randomized study in the United States and Canada.

About Zenflow

Zenflow, Inc. is a medical device company dedicated to improving treatment for patients suffering from urinary obstruction caused by enlarged prostate. 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 <u>www.zenflow.com</u>, and for the latest updates, follow Zenflow on LinkedIn.

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