

Healthcare Company Watkins-Conti Announces Publication of Positive Clinical Trial Results for FDA-Cleared Yōni.Fit

Self-administered device for stress urinary incontinence is unique alternative to surgery or pads

EDMOND, OK, UNITED STATES, May 14, 2025 /EINPresswire.com/ -- Watkins-Conti Products, Inc. ("Watkins-Conti"), a company that develops innovative



solutions for women's pelvic health, today announced the peer-reviewed publication of clinical trial results evaluating <u>Yōni.Fit</u>[®] Bladder Support ("Yōni.Fit[®]"). Designed and manufactured in the United States, Yōni.Fit[®] obtained 510(k) clearance from the U.S. Food and Drug Administration (FDA) in 2024 for the temporary management of urine leakage caused by stress urinary incontinence (SUI) in women, 18 years and older.

The Study, "A Randomized Controlled Trial of a Novel Device for Stress Incontinence," was published in <u>Urogynecology</u>, the official journal of the American Urogynecologic Society. The peer-reviewed, multidisciplinary journal is dedicated to prevention, diagnosis and treatment of female pelvic floor disorders.

Darren Walter Goff, MD OB-GYN said, "Many of my post-partum patients develop SUI, but they're not necessarily ready for surgery, especially if they plan to have more children. With just one office or telehealth visit, I can prescribe Yōni.Fit® and bring immediate relief to these patients."

Participants were enrolled in a randomized, controlled, single blind, multi-center study of Yōni.Fit® in women with SUI. The study was conducted by urogynecologists at Stanford, NYU Langone, and Jefferson Health. Among study participants experiencing adverse events, the severity was mild to moderate; there were no serious adverse events related to Yōni.Fit®.

"Among participants who completed the evaluation phase, significantly more achieved a meaningful reduction in 12-hour pad weights spanning seven days with Yoni.Fit compared to the control device — highlighting Yoni.Fit's superior performance," said Karolynn T. Echols, MD, Director and Associate Professor of Female Pelvic Medicine and Reconstructive Surgery at Thomas Jefferson University, an investigator in the Yōni.Fit® clinical study, and an author on the paper.

Manufactured in the U.S. with 100% medical-grade silicone, Yōni.Fit[®] is a self-administered, soft vaginal insert that can be used during a specific activity or up to 12 hours for general control over symptoms.

"With multiple national distribution partners and the availability of self-sizing kits, we are focused on bringing Yōni.Fit® to women across the country as a convenient, easy and tariff-proof solution for SUI," said Allison L. Watkins, founder and CEO of Watkins-Conti. "The Very Important Provider (VIP) kit assists in integrating Yōni.Fit® seamlessly into primary care, OB-GYN, urology, or urogynecology practices."

SUI is the leaking of urine when pressure is applied to the bladder, as in exercising, laughing, or coughing. Urinary incontinence is a condition that is estimated to affect about 2 in 3 women in the United States at some point in their lives, negatively impacting their quality of life.

Yōni.Fit[®] is available by an in-person or telehealth prescription that may be filled by <u>Edgepark</u>, a business unit of Cardinal Health. It is covered by most major commercial and government insurance plans and is HSA-Eligible. Product and prescribing information is at Yōni.Fit.com.

About Watkins-Conti Products, Inc.

Founded by entrepreneur and inventor Allison L. Watkins, Watkins-Conti is an American healthcare company that develops innovative and accessible solutions for women's pelvic health.

Watkins-Conti is developing a pipeline of treatments and diagnostics with the goal of getting women everywhere the care they deserve. The company's flagship product, Yōni.Fit®, is the first patient-designed, non-surgical device designed to relieve the symptoms of stress urinary incontinence. Based in Edmond, Oklahoma, Watkins-Conti holds numerous utility patents, design patents, and trademarks in the U.S. and abroad. For more information, visit Watkins-Conti Products.com and LinkedIn.

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