

PRESS RELEASE:
FOR IMMEDIATE RELEASE

**[PRACTICE NAME] OFFERS WOMEN AN INNOVATIVE, AT-HOME TREATMENT
FOR BLADDER LEAKAGE WITHOUT SURGERY OR MEDICATIONS**

[PRACTICE NAME] is proud to offer patients the *leva*® Digital Therapeutic System, an innovative treatment for urinary incontinence (UI), also known as bladder leakage, a medical condition experienced by many adult women in the U.S. This FDA-cleared treatment, developed by Renovia, is done at home and does not involve surgery, medications or referral to a specialist.

UI is often caused by a weakening of or injury to the muscles of the pelvic floor, an interconnected group of muscles that support the bladder and other pelvic structures. Normally, those muscles contract to compress the bladder outlet and prevent leakage. But pregnancy, childbirth or aging can weaken those muscles, resulting in leakage that can be bothersome as well as embarrassing.¹⁻³ That is one reason why relatively few of those affected seek care.^{4*,5†}

Pelvic floor muscle training, commonly referred to as Kegels, is the standard, first-line therapy for UI.⁶⁻⁸ Unfortunately, most women don't do these exercises – and of those who do, few perform them adequately. In one study of 325 women with pelvic floor disorders, 75% of women did not perform pelvic floor muscle exercises. Of those that did perform their exercises, fewer than 25% performed them adequately.^{9‡}

leva Digital Therapeutic System addresses this problem with the *leva* Motion Sensor powered by Accelerometer^{6™} Technology. It uses sensitive motion sensors that give patients real-time feedback to encourage consistent and more effective pelvic floor muscle training. The system also provides patients with personalized support from a Renovia Women's Center Coach, who assists them in setting goals and following the training.

"We are very excited to be able to provide our patients with this innovative treatment," said [Dr. Name of Practice Name]. "leva is an at-home, non-surgical solution to an bothersome condition that allows women to live more confidently. We encourage any woman dealing with bladder leakage to give our office a call."

For more information, call [XXX-XXX-XXXX]

*68587 US women ages 65 and older and enrolled in the Nurses' Health Study responded to the 2012 full-length questionnaire, answering questions about UI frequency, amount of leakage, and usual cause of leakage. 18576 respondents had prevalent UI. Their responses were matched to Medicare claims data, demonstrating that 16% (n=2963 of the 18576) had an outpatient evaluation for UI during the two-year study period.

†Of 1339 women who reported UI from baseline through visit 9 (data collected annually 1995-2005) and answered the treatment seeking questions, 814 (61%) reported they did not seek treatment for UI from a health care professional during follow up.

‡n=325 women, averaging 57.8 years of age. All patients were presenting for evaluation of pelvic floor complaint and had one or more pelvic floor disorders.

1. Wu JM, Vaughan CP, Goode PS, et al. Prevalence and trends of symptomatic pelvic floor disorders in U.S. women. *Obstet Gynecol.* 2014;123(1):141-148. 2. Lian WQ, Li FJ, Huang HX, Zheng YQ, Chen LH. Constipation and risk of urinary incontinence in women: a meta-analysis. *Int Urogynecol J.* 2019;30(10):1629-1634. 3. Subak, L. L., Richter, H. E., & Hunskaar, S. (2009). Obesity and urinary incontinence: epidemiology and clinical research update. *The Journal of urology*, 182(6 Suppl), S2–S7. 4. Erekson E, Hagan KA, Austin A, et al. Outpatient Evaluation and Management Visits for Urinary Incontinence in Older Women. *J Urol.* 2019;202(2):333-338. 5. Waetjen LE, Xing G, Johnson WO, Melnikow J, Gold EB; Study of Women's Health Across the Nation (SWAN). Factors associated with reasons incontinent midlife women report for not seeking urinary incontinence treatment over 9 years across the menopausal transition. *Menopause.* 2018;25(1):29-37. 6. Urinary Incontinence in Women. Practice Bulletin No. 155. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2015; 126:e66-81. 7. Qaseem A, Dallas P, Forciea MA, Starkey M, Denberg TD. Clinical Guideline Nonsurgical Management of Urinary Incontinence in Women : A Clinical Practice Guideline From the American College of Physicians. 2014;(September 2013). 8. Hersh L, Salzman B. Clinical Management of Urinary Incontinence In Women [published correction appears in *Am Fam Physician.* 2013 Oct 1;88(7):427]. *Am Fam Physician.* 2013;87(9):634-640. 8. Moen MD, Noone MB, Vassallo BJ, Elser DM. Pelvic floor muscle function in women presenting with pelvic floor disorders. *Int Urogynecol J.* 2009;20(7):843-846. doi:10.1007/s00192-009-0853-6.

The *leva* Digital Therapeutic System is intended for: (i) strengthening of the pelvic floor muscles; and (ii) rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed, and mild to moderate urgency urinary incontinence (including overactive bladder) in women. This product interacts with the user via smartphone technology.

Important Safety Information for *leva* Digital Therapeutic System: Do not share *leva*. *leva* is a single-user medical device. Do not use *leva* while pregnant, or if you think you may be pregnant, unless authorized by your doctor. Do not leave the probe in your body for longer than necessary to complete the training session. Remove the probe after each training session. Do not use *leva* in any other place in your body. Do not have sexual intercourse while the probe is inserted. If you experience odor, fever, vomiting, diarrhea, any signs of infections or any flu-like symptoms, contact your doctor immediately. If you experience redness or swelling near the insertion area, or signs of an allergic reaction, contact your doctor immediately. For a complete summary of the risks and instructions for the *leva* Digital Therapeutic System, see its Instructions for Use available at Renovia's website.

Treatment with *leva* Digital Therapeutic System is prescribed by your healthcare provider. This treatment is not for everyone. Please talk to your healthcare provider to see if it is right for you. Your healthcare provider should discuss all potential benefits and risks with you.