

FDA expands use of PeriCoach at-home pelvic floor trainer device and smartphone app for sexual health

DENVER, Co, August 2, 2016 – Analytica announced that the U.S. Food and Drug Administration (FDA) clarified use for PeriCoach to potentially improve sexual sensation or satisfaction and orgasm potential in women.

“This clarification for PeriCoach provides a critical level of certainty when women and clinicians consider PeriCoach to improve sexual function and satisfaction,” said Megan Henken, Vice President Marketing for Analytica. “While it is empowering for women to self-manage pelvic floor related issues from bladder leakage to sexual function, the product they use has to be reliable.”

Last month, FDA approved PeriCoach as an over-the-counter (OTC) treatment for treatment of mild, moderate and stress urinary incontinence (UI) and urge incontinence.

Studies have found that that sexual complaints, from low libido to problems with sexual arousal to inability to achieve orgasm, are common among women with pelvic floor disorders.¹

“Unfortunately, many women feel that decreased sexual function is an inevitable part of aging,” said Leslie Rickey, MPH, MD, Associate Professor of Urology and of Obstetrics, Gynecology and Reproductive Sciences; Fellowship Director, Female Pelvic Medicine and Reconstructive Surgery, Yale School of Medicine. “But women should know there are self-help strategies, and now home pelvic floor training support with PeriCoach can help improve pelvic floor muscle strength and sexual function at ANY age. Sexual function can also be affected by psychological, biological or interpersonal factors and may require a multi-modal treatment approach in addition to pelvic floor muscle rehabilitation. It is important to note that women who experience pain with sexual activity should first be evaluated by their gynecologist or PCP.”

Since its introduction in 2015 as a prescription product, PeriCoach, designed by a woman engineer, has been studied and clinically evaluated by clinicians including women's health physical therapists, urogynecologists, OBGYNs and urogynecological nurses. Data and case reports have been presented and published in peer-reviewed forums.

Analytica intends to pursue further pelvic floor indications where pelvic floor exercise is an effective conservative treatment option, such as; mild pelvic organ prolapse and fecal incontinence.

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For more information please visit the PeriCoach website (www.pericoach.com) for pelvic floor muscle training support, updates, tips and special savings.

PeriCoach has regulatory clearance in Australia, and has CE mark and USFDA 510(k) clearance. The product is available for sale in Australia and New Zealand, UK and Ireland, and in the USA.

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Reference

Handa, VL, Cundiff G, Chang H, Helzlsouer KJ, Female sexual function and pelvic floor disorders, Obstet Gynecol, 2008 May 111 (5): 1045-1052 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2746737/>

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