

FDA approves PeriCoach® pelvic floor trainer for sale over-the-counter in the United States

Clinician-trusted home pelvic floor trainer device and smart phone app
now available direct to consumers

Denver, CO – July 13, 2016 – Analytica (ASX: ALT) today announced that the U.S. Food and Drug Administration (FDA) has approved the PeriCoach® at-home pelvic floor trainer device and smartphone app as an over-the-counter (OTC) treatment for treatment of mild, moderate and stress urinary incontinence (UI) and urge incontinence. A strong pelvic floor is also associated with improved sexual function and satisfaction.

“Women can use pelvic floor exercises or “Kegels” to reduce or eliminate symptoms, and home training with PeriCoach, now available OTC, just got a lot more convenient,” 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. “It is critical that women put their trust in new technology for pelvic floor muscle training that has been medically tested and FDA-cleared, as these products have an internal component and are designed to treat a real medical condition.”

Pelvic floor muscle exercise (PFME) is recommended as first line non-pharmacologic treatment for the millions of women—estimated at one in three—who suffer from urinary incontinence.

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.

“As a physical therapist, I feel confident recommending to my patients, and using on myself, vaginal devices that were developed and evaluated first as medical products,” said Heather Jeffcoat, DPT, founder of Fusion Wellness & Physical Therapy and author of *Sex Without Pain: A Self-Treatment Guide To The Sex Life You Deserve*. “PeriCoach has a well-established profile as an easy-to-use, effective and affordable home pelvic floor trainer. Now, for women who will benefit from PFME, there are no more excuses!”

UI has both lifestyle and financial costs. For example:

- One in three women will experience UI at some point in their lives
- Half of the women who suffer from UI don't report it and try to manage the condition on their own for 6 years or more before speaking to a clinician
- In the USA alone, adults spend over \$20 billion dollars on "routine care" of UI including pads, protection and laundry
- The cost of pads for one woman in the USA for one year is approximately \$900

"This approval will bring PeriCoach, and the confidence that comes with it, to women in a convenient way," said Geoff Daly, CEO Analytica, LTD. "The OTC approval is also a significant milestone for our company in the U.S. We are committed to offering as many women as possible a simple, effective way to deal with a condition that is common but not normal. Over the counter availability of PeriCoach may mean the difference between a day lost to worrying about leaking, and a day confident in enjoying favorite activities."

For more information about pelvic floor muscle training, sign up for the Newsletter with updates, tips and special savings, women can visit www.pericoach.com. The website will be accepting PeriCoach orders without a prescription beginning Monday, July 18, 2016.

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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