

## ASX ANNOUNCEMENT

### Analytica Submission to Senate Committee Inquiry into Mesh Implants

**30 January 2018.** Analytica Ltd (ASX:ALT) presents the Company's submission to the Australian Senate Committee "Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters".

The submission has recently been published by the Committee and has been assigned number 481. It is attached for shareholder's convenience. Other submissions and the Inquiry terms of reference can be found at the Senate Committee website:

[http://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/Community\\_Affairs/MeshImplants/Submissions](http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Submissions)

For more information, please contact: [investorrelations@analyticamedical.com](mailto:investorrelations@analyticamedical.com)

For more information about the PeriCoach System, visit: [www.PeriCoach.com](http://www.PeriCoach.com)

For more information about Analytica, visit [www.AnalyticaMedical.com](http://www.AnalyticaMedical.com)

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#### About Analytica Limited

Analytica's lead product is the PeriCoach® System – an e-health treatment system for women who suffer Stress Urinary Incontinence. This affects 1 in 3 women worldwide and is mostly caused by trauma to the pelvic floor muscles as a result of pregnancy, childbirth and menopause.

PeriCoach comprises a device, web portal and smartphone app. The device evaluates activity in pelvic floor muscles. This information is transmitted to a smartphone app and can be loaded to a cloud database where physicians can monitor patient progress via web portal. This novel system enables physicians to remotely determine if a woman is performing her pelvic floor exercises and if these are improving her condition. Strengthening of the pelvic floor muscles can also potentially improve sexual sensation or satisfaction and orgasm potential in some women.

PeriCoach has regulatory clearance in Australia, and has CE mark and USFDA 510(k) clearance. The product is available for sale from [pericoach.com](http://pericoach.com) in Australia, New Zealand, UK and Ireland, and the USA.



## Submission to Senate Inquiry:

### “Number of women in Australia who have had transvaginal mesh implants and related matters”

Submitted 29<sup>th</sup> June 2017

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## Key Points

- **Pelvic floor exercise may obviate the need for surgical intervention.**
- **Many women may have undergone surgery unnecessarily.**
- Accepted clinical guidance recommends pelvic floor exercises as conservative treatment before considering mesh implant surgery.
- Pelvic floor exercises can be difficult to do correctly and are not done regularly.
- PeriCoach® overcomes these issues by providing the patient with motivation, biofeedback on strength improvements, and can tell the patient if she's performing her exercises correctly.
- The PeriCoach system provides independent compliance data and improvement results to the doctor to assist with the decision to proceed to surgical intervention.
- PeriCoach has Australian TGA, US FDA, and European regulatory clearances.
- PeriCoach is designed and manufactured in Australia, and exported to UK, Europe and USA.
- PeriCoach is a Class I (lowest risk) medical device in Australia and has a low risk of adverse events compared with surgery.
- PeriCoach is extremely affordable compared with total costs of surgery. One-off cost AUD\$299.



## Executive Summary

The existence of this inquiry shows that intravaginal implants carry significant risk. Clinical guidelines recommend that patients first undergo conservative treatment, including a pelvic floor exercise programme before proceeding to surgery.

Analytica believes that many women may have undergone surgery unnecessarily and may have been able to avoid that risk had conservative treatments been prescribed and enforced.

Analytica is an Australian company that has developed the PeriCoach system which provides real-time biofeedback to women doing their pelvic floor exercises, guiding them through their exercise sessions and assisting with technique.

The system can also provide independent evidence to a clinician regarding their patient's improvement and compliance with their prescribed exercise programme. The PeriCoach system was designed and is manufactured in Australia, and currently exported to UK, Europe and the USA. PeriCoach has patents pending and medical device regulatory clearances in major jurisdictions worldwide.

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Dear Senators,

The American College of Physicians (ACP)<sup>1</sup>, and the American Urologic Association (AUA) and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)<sup>2</sup> have released treatment guidelines for implant surgeries in recent years, which both include recommendations that the patient attempt conservative treatments before surgical interventions are considered. These conservative treatments include diet, general exercise, and **pelvic floor muscle exercises**.

Our submission relates to the Inquiry Terms of Reference 2, 3, and 4 regarding the information provided to women and doctors about possible complications and side effects of mesh implants, and the incentives to prescribe or undergo surgery. This submission will present a preventative solution using the company's PeriCoach® product which may reduce the number of women needing surgical procedures.

Analytica is an Australian Securities Exchange-listed medical device development company. Our main product is the PeriCoach® system, which is designed to assist women with their pelvic floor exercises.

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<sup>1</sup> <http://annals.org/aim/article/1905131/nonsurgical-management-urinary-incontinence-women-clinical-practice-guideline-from-american>

<sup>2</sup> [http://www.auanet.org/guidelines/stress-urinary-incontinence-\(sui\)](http://www.auanet.org/guidelines/stress-urinary-incontinence-(sui))



10 years ago, Analytica identified the gap in conservative treatment for urinary incontinence and other pelvic floor disorders. With little guidance or understanding of conservative treatments by generalist clinicians, women either “put up with it” at one extreme, or have pharmacological and surgical interventions at the other.

**Relevant to Terms of Reference 2 and 3** is the general lack of understanding by clinicians of the benefits of pelvic floor muscle exercises prior to surgery, and consequently the amount of information then passed to the patients. In the position of power that a clinician holds, offering better guidance and information to patients is paramount as complications carry a significant personal risk.

Pelvic floor muscle exercises (PFME's) were invented by Dr Arnold Kegel in the US in the 1940's and most Americans refer to pelvic floor muscle exercises as “Kegel” exercises. They have been in clinical practice for more than 70 years and have been proven to reduce the incidence of stress urinary incontinence, and in many cases, eliminate it completely<sup>3</sup>. They are also prescribed for conditions such as pelvic organ prolapse, and faecal incontinence. Pelvic floor muscle exercises have been observed to benefit patients with lower back pain, and improve sexual function.

It is now well accepted in the urogynaecological field that pelvic floor muscle exercises are beneficial for several disorders *provided* they are done regularly and correctly. With 37% of Australian women having urinary incontinence and a staggering 70% not speaking to their clinicians<sup>4</sup> about their condition, personalised solutions are necessary to mitigate the growing prevalence and economic burden as the population ages.

A problem with pelvic floor muscle exercises, and the cause of some scepticism amongst clinicians, is that most women *don't* do their pelvic floor muscle exercises regularly or properly. Half of all women do not correctly contract their pelvic floor muscles with verbal or written instructions<sup>5</sup>. Limited GP time with patients, and women waiting years before speaking to a clinician about their urinary incontinence<sup>2</sup> results in a serious gap in clinical treatment guidance. Many women at most only ever receive a brochure describing how to do their exercises, or read about it in women's magazines and blogs. Very few receive supervised training. This patient management approach is a direct contributing factor to the growing health system expenditure for urinary incontinence which is projected to rise to \$450 million by 2020<sup>2</sup>. Women are also confused by a range of claimed Kegel exercise aids that simply don't work.

Pelvic floor physiotherapists are the standard of care, and highly trained to assess and rehabilitate the symptoms of incontinence and pelvic organ prolapse through pelvic floor muscle therapy. Globally, Australia leads the way in advocating for clinical referral and utilization of these

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<sup>3</sup> Qaseem A, Dallas P, Forciea MA, Starkey M, Denberg TD, Shekelle P, et al. Nonsurgical Management of Urinary Incontinence in Women: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med.* 2014;161:429-440. doi: 10.7326/M13-2410

<sup>4</sup> <http://www.continence.org.au/pages/key-statistics.html>

<sup>5</sup> <http://www.pelvicfloorfirst.org.au/pages/common-myths.html>



specialists. Numerous studies have shown up to 70% improvement in symptoms of incontinence across all age groups following appropriately performed pelvic floor exercise<sup>6</sup>. This conservative approach is further supported in studies like those from Hagen and colleagues<sup>7</sup>, which demonstrated that intensive pelvic floor muscle exercise does have a positive improvement in symptoms and quality of life effects for women with grade I/II pelvic organ prolapse cases. Most importantly, pelvic floor muscle exercises have far lower risk of adverse events which have unfortunately become commonplace with surgery and can be devastating for women.

Moreover, women who have been guided into mesh surgical interventions often end up with urinary incontinence, requiring additional surgery. While this outcome isn't viewed clinically as an adverse event, further surgery places the patient at unnecessary risk since the original procedure didn't address the underlying issue of weakened or stretched pelvic floor muscles. A comprehensive management approach, with physiotherapy or an approved medical device, such as PeriCoach, as a prophylactic measure to guide proper pelvic floor rehabilitation would result in improved patient outcomes.

The challenge with pelvic floor physiotherapy resides in availability and cost to cover the 'intensive' training with a pelvic floor physiotherapist, which can reach upwards of \$2000. Furthermore, compliance with a physiotherapy program requiring weekly visits is a hurdle while the nature of the training is also perceived as intrusive for some women. PeriCoach, is effectively a fitness tracker for pelvic health. Just as products like Fitbit® have revolutionized and motivated millions, healthcare apps and devices are changing expectations for clinical engagement as well as providing real-time data accessibility.

PeriCoach, developed and manufactured in Australia over the last 10 years at a cost of \$20m with globally held patents, offers clinicians and women a solution to fill the expanding gap in this women's healthcare epidemic.

The system is comprised of a device which measures the pelvic floor muscle contractions and movements, a smartphone app to record the exercise activity and provide real-time feedback to the patient, and an online database account through which the patient can voluntarily share her data with her nominated clinician. Refer Figure 1.

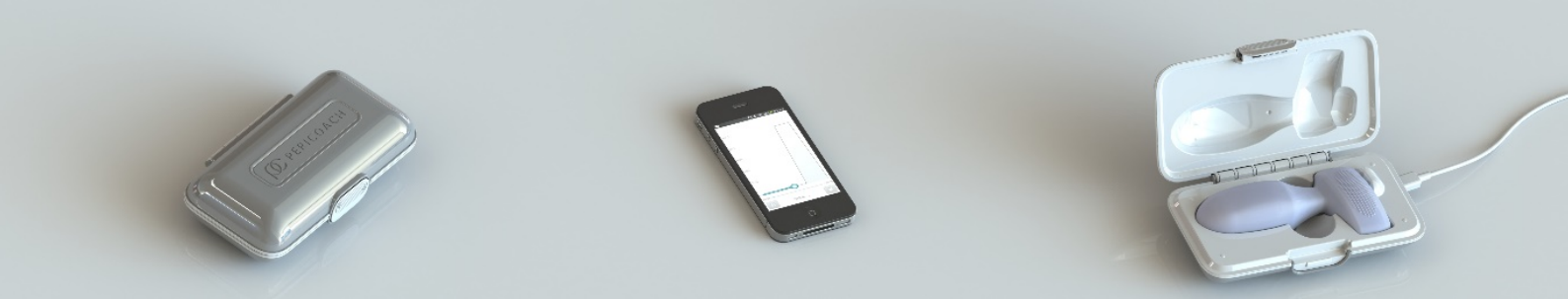
It is widely accepted that physical activity has immediate and long-term health benefits, pelvic floor exercises are no different. PeriCoach has the capacity to drive compliance along with proper technique, offering the intensive training the data has noted to be optimal for Urinary Incontinence and prolapse conservative centred outcomes.

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<sup>6</sup> Price N, et al. Pelvic floor exercise for urinary incontinence: A systematic literature review. *Maturitas* (2010), doi:10.1016/j.maturitas.2010.08.004

<sup>7</sup> Hagen S, et al. A randomized controlled trial of pelvic floor muscle training for stages I and II pelvic organ prolapse. *Int Urogyn J* (2009) 20:45-51.





**Terms of Reference 4** considers financial incentives. With recent scrutiny on implant surgeries there should be a considerable incentive to provide independent evidence that conservative treatments have been attempted and that patients have complied. \$299 is a small price to pay for an evidence point for legal risk mitigation for surgeons, hospitals, and implant manufacturers.

Most importantly, the PeriCoach system also can deliver clinicians detailed records of pelvic floor muscle exercise treatment as well as progress, following the treatment algorithm for stress urinary incontinence and prolapse management prior to surgical intervention, mitigating the potential for mesh legal actions.

Analytica believes that universal use of the PeriCoach system in pre-pregnancy and post-partum women would save taxpayers and the community billions of dollars in environmentally unfriendly incontinence pads, risky surgical treatments, and nursing home costs. Incontinence and dementia are the leading causes of admission to nursing homes, and incontinence is their predominant cost.

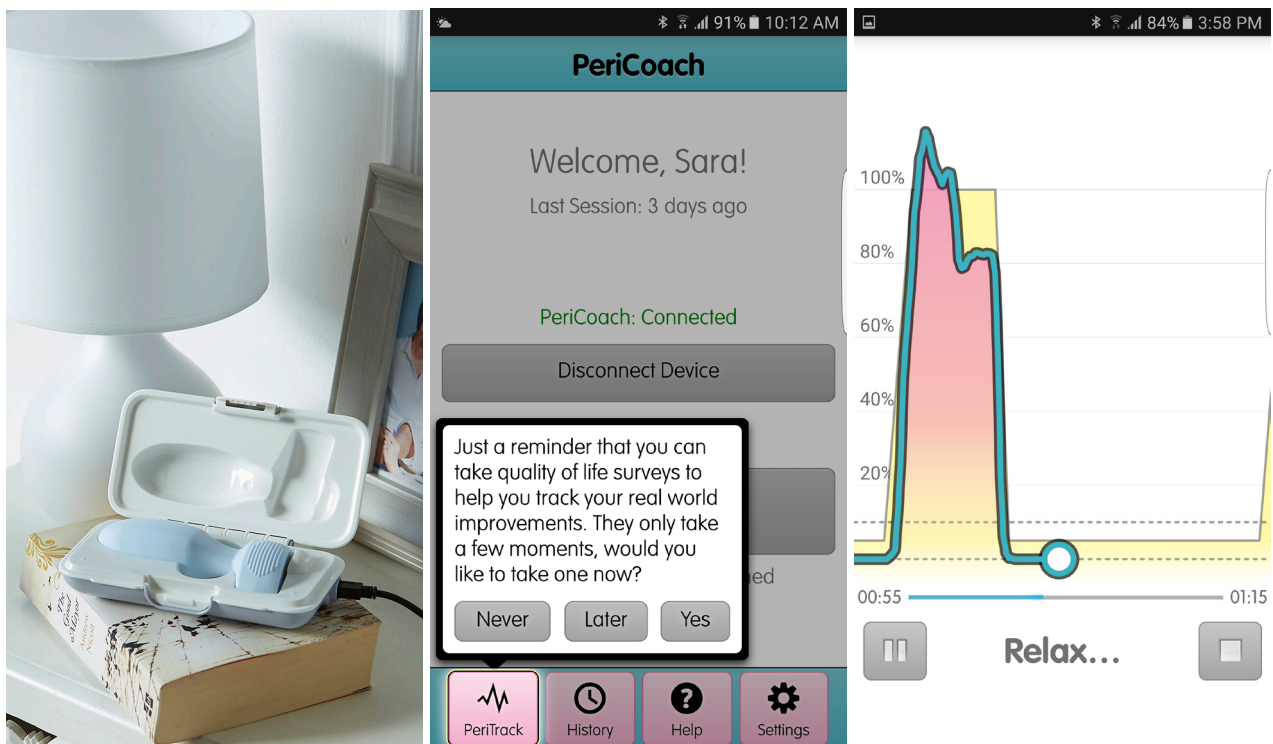


Figure 1: L-R: PeriCoach device and charging case, Smartphone app user interface, Real-time guidance during an exercise session.



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