

ANALYTICA

CEO Presentation to
Analytica Annual
General Meeting

22 November 2018



Forward-Looking Statements

This presentation contains forward-looking statements that involve risks and uncertainties.

Although we believe that the expectations reflected in the forward looking statements are reasonable at this time, Analytica can give no assurance that these expectations will prove to be correct.

Actual results could differ materially from those anticipated.

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2018

- New GMP-compliant manufacturer for US market
- Quality System implementation.
- Ongoing collection and analysis of real-world evidence.
- ARTG inclusion for prolapse
- Industry recap

New Manufacturing

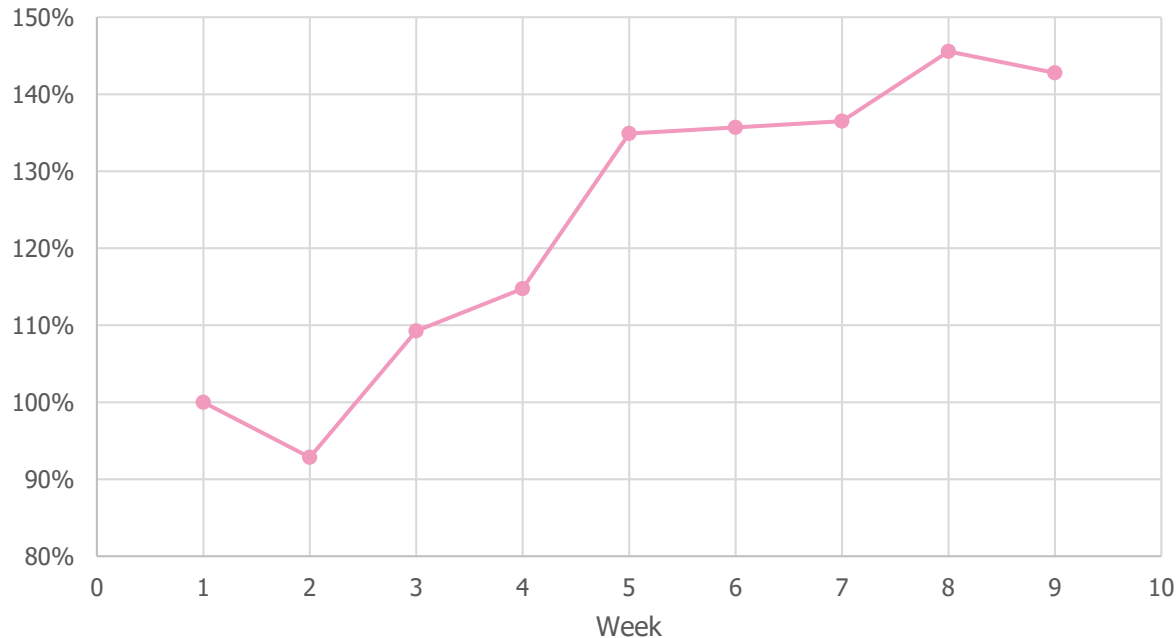
- Previous Contract Manufacturer was also our Registered Manufacturer of PeriCoach with FDA.
 - CM no longer wanted that regulatory exposure. Analytica was the only customer to whom they provided this service.
- Now Analytica will be the Registered Manufacturer with the FDA.
- New Contract Manufacturer is GMP compliant (US FDA)
- Decision to continue manufacturing in Australia:
 - Capability.
 - Accessibility.
 - Culture and legal environment.
 - Overall costs are lower even though per unit COGS may be higher.
 - Can always move later as volumes and other costs dictate.

Quality System Implementation

- A full quality system is a requirement for the registered manufacturer.
- Having the quality system allows Analytica more flexibility with how and what we manufacture in future.
- Established in Analytica over the last 6 months.
- Initially designed to be QSR compliant, to allow re-entry into US ASAP
- Also designed to be ISO 13485-compliant.
 - Analytica *may* pursue certification to ISO 13485 in 2019 (though this is not required for CE mark or ARTG)

Real-World Data - Strength

% of Baseline Strength, n=176



By week 5 almost one third of users have more than 50% improvement in strength ($p=0.004$).

Pelvic floor strength doubled in ~16 weeks.

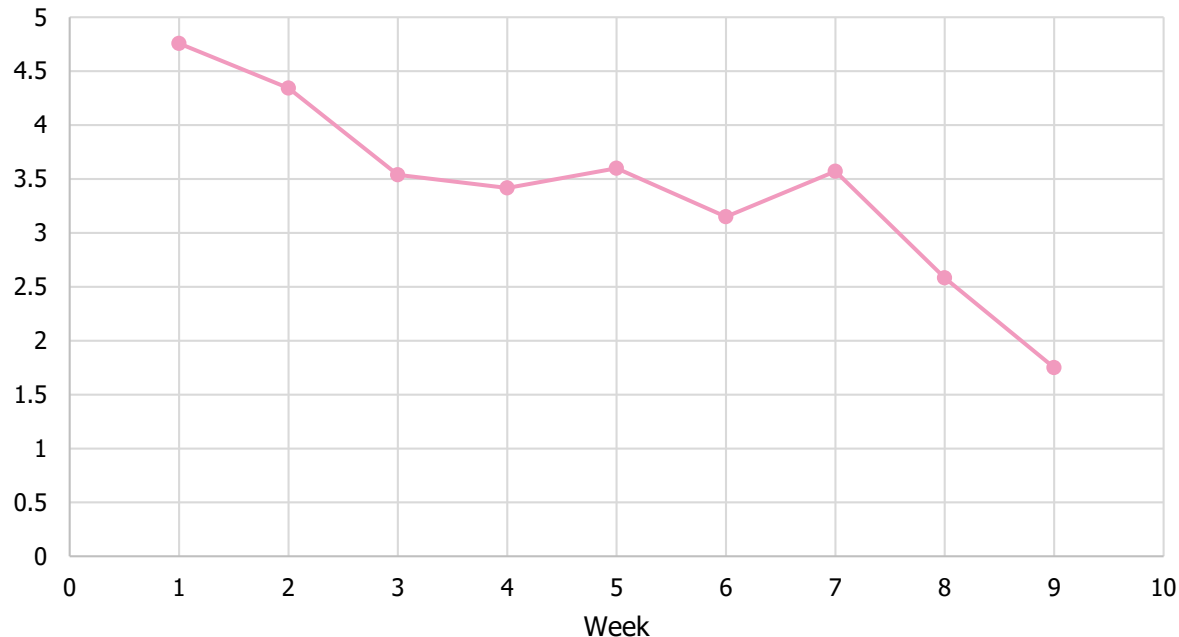


Pelvic Floor
Strength
doubled in
~16 weeks

Rehabilitating
pelvic floor
strength is the
basis of Kegel
exercise

Real-World Data – Leakage Events

Leakage Episodes per day n=37



By week 3 more than 60% of users report more than 30% reduction in leakage episodes (p=0.0059). In 8 weeks >¾ of users have >80% improvement in leak episodes.

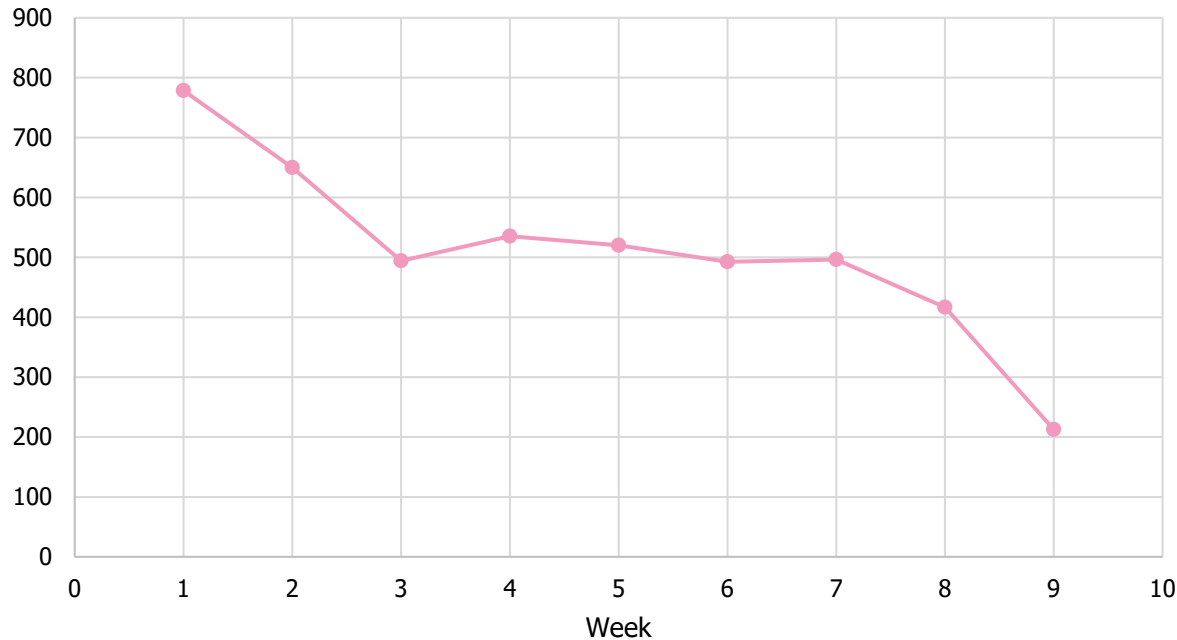


More than ¾ of users have more than 80% improvement in episodes in 8 weeks

Fewer leaks = less impact on a woman's day.
Fewer pads.
Less cost.

Real-World Data – Leakage Volume

Leakage Volume per day (mL) n=37



By week 3 more than 60% of users report more than 30% reduction in leakage volume ($p=0.0017$). In 8 weeks, $>3/4$ of users have $>80\%$ improvement in leak volume.



More than $3/4$ of users have more than 80% improvement in leak amount in 8 weeks

Less leakage means less discomfort, less laundry, and smaller pads

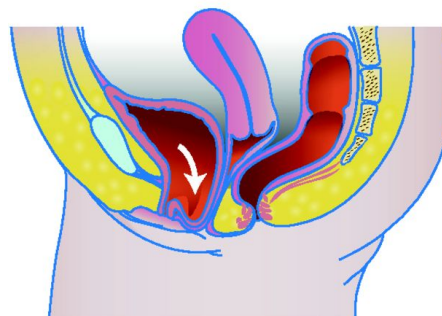
**At the conclusion of the 8-week challenge
>75% of users have >80% reduction in
leakage volume and episodes.**

This is a highly meaningful and significant improvement
in continence symptoms.

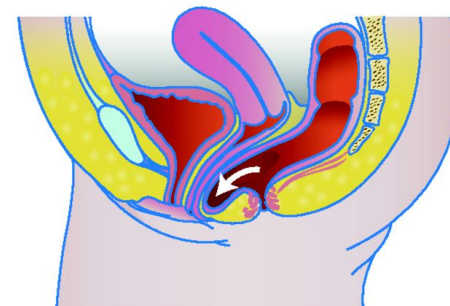
Expanded Pelvic Organ Prolapse Indication

- 1 in 5 women will experience pelvic organ prolapse (POP)¹
- 60% of women presenting for POP have UI,²
- and close to 40% of women presenting with UI have POP²
- Analytica has ARTG inclusion for POP (ARTG 302462)
- Work underway for CE Mark and a new US FDA 510(k) submission.

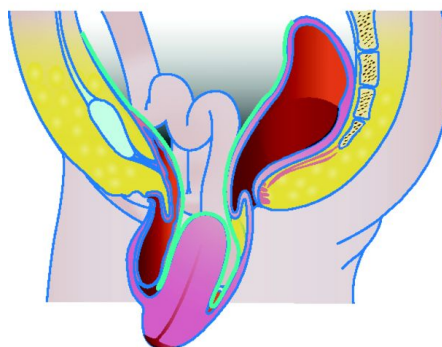
A Anterior vaginal prolapse (cystocele)



B Posterior vaginal prolapse (rectocele)



C Uterine prolapse



D Post-hysterectomy vaginal vault prolapse

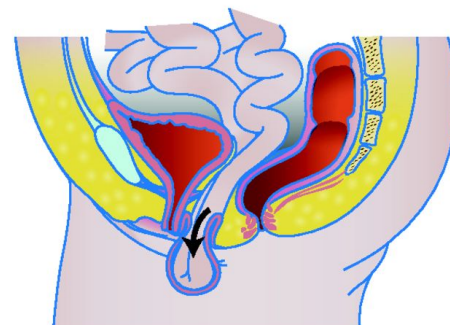


Image from Bmj.com

1. Nygaard, I., et al. (2008). Prevalence of Symptomatic Pelvic Floor Disorders in U.S. Women. *JAMA*; 300(11): 1311–1316.

2. Buchsbaum, GM., (2006). Urinary Incontinence and Pelvic Organ Prolapse. *Minerva Urol Nefrol*. Dec:58(4):311-9

Industry key events

- Australian Senate Mesh Inquiry
 - ALT submission
 - Recommendation 6 ~ Ensure informed consent
 - Recommendation 7 ~ Use conservative treatments first
- New entrants
 - Stim, EMG, and traditional pressure perineometers
 - PeriCoach still the leading technology
 - Measures the muscles that matter, technique feedback, Data.
- Vaginal Laser Rejuvenation
 - USFDA announcement warning doctors about the lack of evidence