



ELITONE®

LIVE LIFE LEAK FREE®

 Elidah

Burden of Incontinence

- 25% of premenopausal women and 40% of postmenopausal women report leakage¹
- <50% of women who consider it a problem seek help^{2,3}
- 100% of women with SUI report negative effect on quality of life⁴
- 80% express emotional distress⁵
- 70% don't want to travel more than 30 minutes from home⁶

1. Rogers, R.: Urinary Stress Incontinence in Women; N Engl J Med 2008; 358:1029-36
2. Herzog AR, Fultz NH. Prevalence and incidence of urinary incontinence in community-dwelling populations. J Am Geriatr Soc 1990;38:273-81
3. Hannestad YS, Rortveit G, Sandvik H, Hunskaar S. A community based epidemiological survey of female urinary incontinence: the Norwegian EPICONT study. J Clin Epidemiol 2000;53:1150-7
4. Gümüşsoy S., Kavlak O., Donmez S. Investigation of body image, self-esteem, and quality of life in women with urinary incontinence. Int. J. Nurs. Pr. 2019;25:e12762
5. Li F.L.W., Le Low L.P., Lee D.T. Chinese women's experiences in coping with urinary incontinence. J. Clin. Nurs. 2007;16:610-612
6. Yoo R., Spencer M. Continence Promotion and Successful Aging: The Role of the Multidisciplinary Continence Clinic. Geriatrics. 2018;3:91



Significant Clinical Need

30M post-menopausal
women in US

100M pre-menopausal women



30M women with
incontinence

Pelvic floor surgery

- Implant complications

Intravaginal devices

- Intrusive (physically, time)
- Infection risk

Physical Therapy

- Standard of Care
- Patient compliance - challenging

Kegels

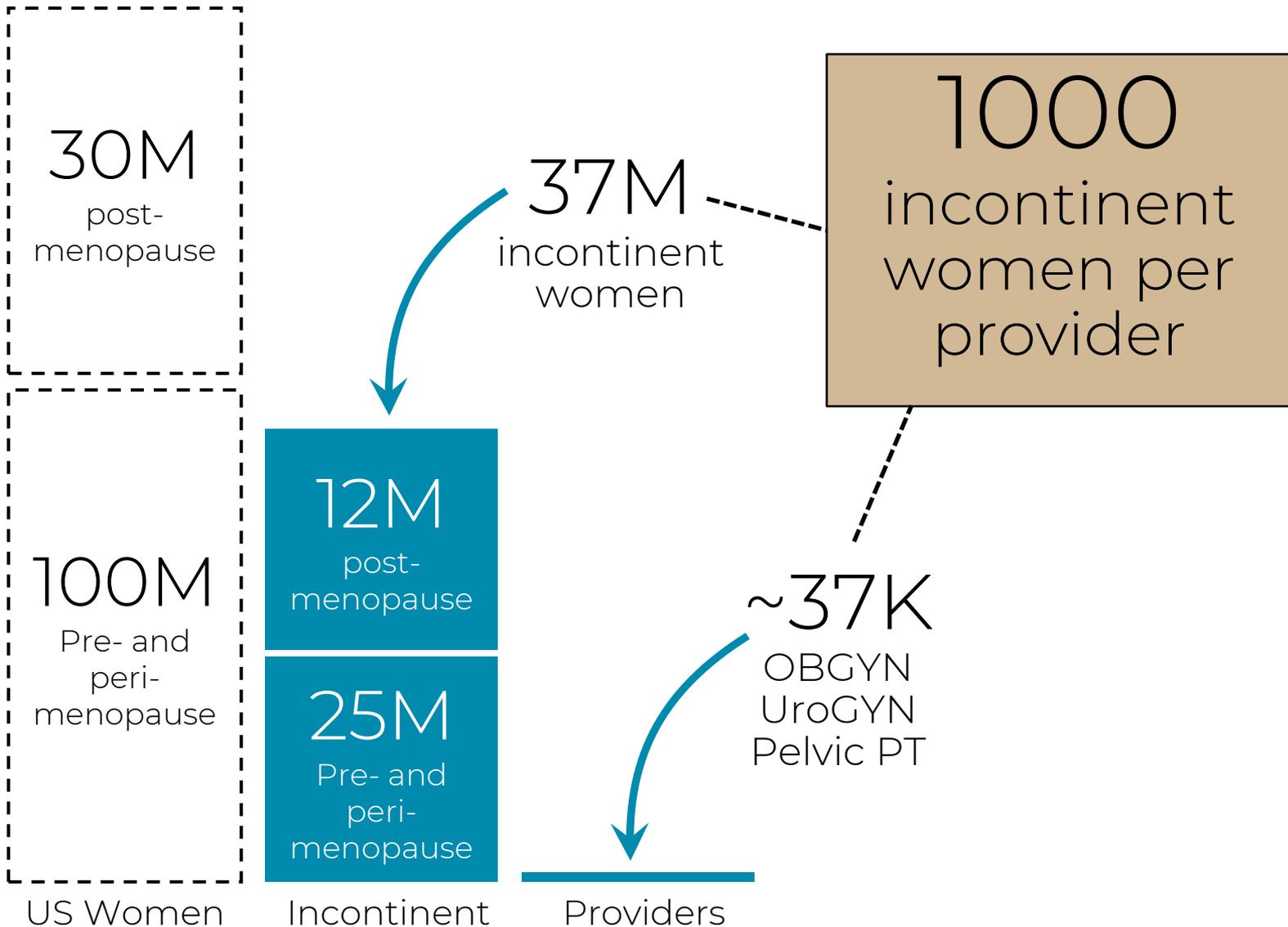
- Low compliance
- 30% perform incorrectly⁷

Medication

- Severe side effects

7. Bo K, Kvarstein B, Nygaard I. Lower urinary tract symptoms and pelvic floor muscle exercise adherence after 15 years. *Obstet Gynecol.* 2005;105(5):999-1005. DOI: 10.1097/01.AOG.0000157207.95680.6d.

Significant Clinical Need



Mission Driven Founders

“ We have a world-wide vision. We want women to get back to an active life and to start living again



” **Gloria Kolb & Eric Kolb**

- MIT, Stanford, RPI engineering
- 25 years medical device experience
- 40+ Patents
- Monroe, CT
- Founded Elidah, Inc. in 2014.

Regulatory Approval



13485:2016



Medicare



Indication for Use:

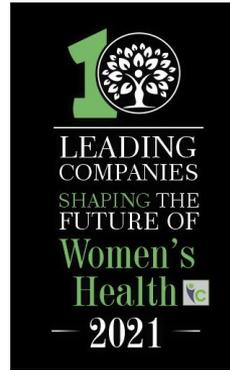
ELITONE is a non-implanted muscle stimulator designed to treat **stress urinary incontinence** in women. It applies stimulation to the pelvic floor muscles and surrounding tissues.

ELITONE URGE is a non-implanted muscle stimulator designed to treat **urge urinary incontinence** in women. It applies stimulation to the pelvic floor muscles and surrounding tissues.

3.6%



Marketplace Approval



Patient Approval

- “ At 51 years old, I was not ready to stop living. Hooray, I found Elitone!!! Now every time I sneeze, cough and laugh I am not afraid of what will happen.” – *Nancy, Age 51, Mom of 3*
- “ Definitely worth the price. I was very skeptical at first, but it really works! I felt a difference pretty quickly. It's just such a nice feeling not to pee when I cough, sneeze, laugh, whatever!! So very happy with this purchase. – *Amy P*
- “ This device is awesome. I now have very few, if any, “accidents” and I can now go much longer between bathroom visits, which is great when traveling. – *Janice*



Easy. External. Effective.



Perineal placement

Intuitive user interface

User controlled intensity



Low-tack hydrogel

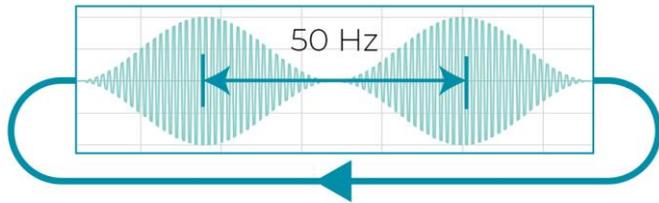
Conductive regions target pelvic floor



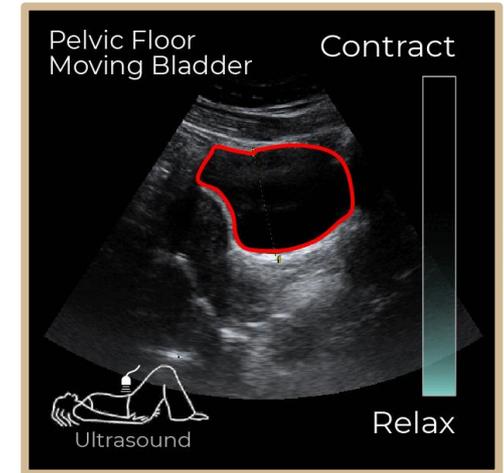
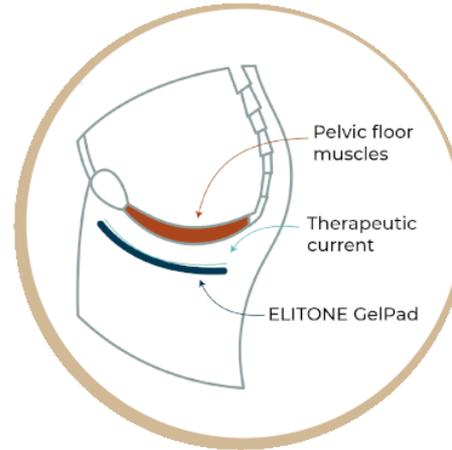
Starter Kit

Device and 6-weeks of Disposable GelPads

Advanced Clinically-Proven Stimulation



Pre-modulated waveform (PMW)
for comfort and efficacy



ELITONE: Toning + Calming Waves



ELITONE URGE: Calming Wave

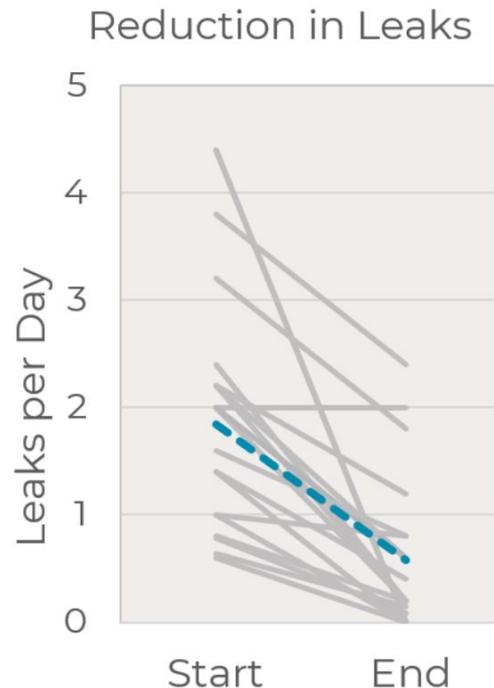
100 Kegel contractions in 20 minute treatment

ELITONE: Impactful Clinical Outcomes

Journal of
Women's Health
Physical Therapy

Surface-applied electrical muscle stimulation for self-administered treatment of female stress urinary incontinence.

- 20-patient series
- 10+ years managing incontinence
- 6 weeks of home-use treatment
- 1st week vs 6th week
- Leaks, pad use, I-QoL, usability



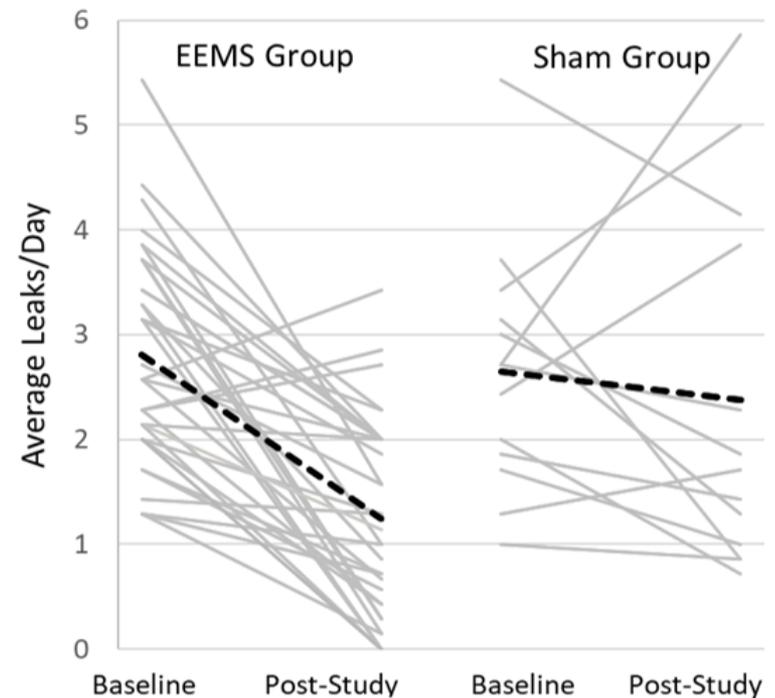
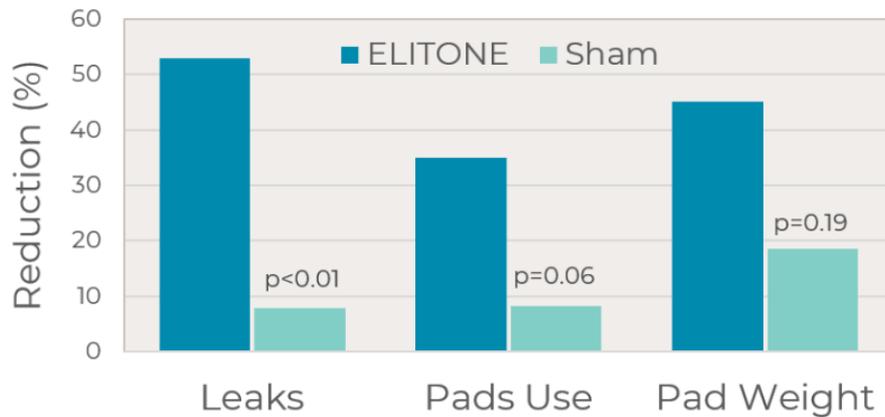
- 95% improved
- 72% average reduction
- 75% clinically significant reduction
- 85% pad reduction
- I-QoL 95% stat. sig. improvement
- 100% comfortable

- 50% Reduction considered clinically significant [FDA published guidance]
- 32% improvement rate with intravaginal devices [AHRQ meta analysis]

ELITONE: Impactful Clinical Outcomes

Self-directed external electrical stimulation for the treatment of stress urinary [*manuscript under review*]

- 48-Subject RCT with sham device
- 12 weeks of home-use treatment
- Baseline vs. 12th week
- Leaks, pad use, I-QoL, pad weight



- 50% Reduction considered clinically significant [FDA published guidance]
- 32% improvement rate with intravaginal devices [AHRQ meta analysis]

ELITONE URGE: First At-Home Treatment

Calms Overactive Bladders

- 34-patient series
- 6 weeks of home-use treatment
- Avg age: 58 years



- 85% pad reduction
- I-QoL improved 21.8 pts (about 10x clin sig level)
- All 22 metrics of QoL improved

Data presented at: ICS & SUFU

- ELITONE URGE and sacral implants work directly on primary nerves. Tibial (ankle devices) work on peripheral (secondary) and so will usually be less effective.
- Sacral neurostimulators high success rate, is based on data after they removed nonresponders in a trial

Patient Access

- Medicare
- Cash
- HSA/FSA
- Payment Plan
- Private Insurer Coverage*

* Dependent on patient's plan





Which patient type is most suited to benefit from ELITONE(s)?