

ELIDAH SALES TRAINING

Company Background

Incontinence

ELITONE Product

Clinical Experience

Continuum of Care

Billing



Training Objective

This module provides background information that will enable successful conversations with clinicians and patients. Topics include:

- Company
- Incontinence
- ELITONE & ELITONE URGE Product
- Clinical Experience
- Continuum of Care
- Billing

-  Why this matters
-  Link to additional info
-  Fun facts

Company

- Mission – Make incontinence treatment more convenient, accessible, and effective
- Founders – Gloria Kolb (CEO) and Eric Kolb (CTO), biomedical engineers
- Timeline
 - 2014 – Initial concept
 - 2016 – Clinical Studies
 - 2019 – [FDA clearance \(stress\)](#)
 - 2022 – DME Partnership with VGM
 - 2023 – [FDA clearance \(urge\)](#)

The founders each have 25+ years in medical devices and degrees from MIT, Stanford University, and Rensselaer Polytechnic Institute. They have designed ELITONE to be highly effective, easy to operate, and comfortable to wear.

Gloria dealt with incontinence for years and was frustrated with available treatments, which led to the development of ELITONE. This personal experience, and conversations with hundreds of women like her, drove the patient-centric design.

- The company name Elidah is a contraction of Gloria and Eric's kids' names.
- Elidah is women owned, and the majority of the staff are women.

Company

- IP – US and International patents on the perineal-applied GelPad
- Funding – Largely funded by the National Science Foundation (NSF), National Institutes of Health (NIH), Department of Defense (DOD)
- Awards and Recognition – Many, many honors!

The Department of Defense grant supported development of a male version of ELITONE (more on that later).

Government grants are incredibly hard to obtain. Receiving multiple grants to develop a new incontinence therapy validates the clinical need, the market size, the cost to the US Healthcare system, and ELITONE's innovative technology.



Company

- Sales History

- Heavy focus on DTC sales channel, primarily through [elitone.com](https://www.elitone.com)
- Recent partnership with VGM enables rapid expansion to Healthcare Provider channel.
- Urge Indication – 2023 (opens market to nearly all incontinence, original device now stress & mixed)

- Product Pipeline

- Male Device – 2024 (incontinence leading complication of prostatectomy. Clinical study with NIH in 2023)
- Vulvodynia – 2026 (1 in 10 women suffer this painful condition. No easy treatment options)

- The company is poised to grow quickly and aims to become the leader in non-invasive treatments for pelvic floor disorders.
- New product introductions means you will have frequent opportunities to call on clinicians.



Incontinence

- Prevalence
 - 1 in 3 women (and 1 in 2 over 50y)
 - Often starts mild with occasional leaks
 - Untreated, almost always progresses
- Demographics
 - Affects all ages
 - SUI often starts after childbirth (trauma to muscles)
 - UUI often starts later in life
- Impact
 - 80% express emotional distress
 - 70% fear traveling more than 30 minutes from home
 - Pad users have 4x increased risk of UTI

- Incontinence affects MANY women, but most don't talk about it, and many clinicians don't ask about it.
- Incontinence affects women younger than most people think.
- Treating incontinence has an enormous impact on mental health.

Incontinence

- Stress Urinary Incontinence (SUI) → ELITONE
 - Leaks due to coughing, sneezing, exercise which put pressure on the bladder
 - Weak pelvic floor muscles not being able to hold the valve (urethra) closed under that extra pressure.
- Urge Urinary Incontinence (UUI) → ELITONE URGE
 - Sudden urge to urinate caused by unintended bladder contraction
 - Neurologic causes
 - Often called Overactive Bladder (OAB), but really is OAB or “urgency” if able to make it to bathroom in time.
 - Nocturia is waking up $\geq 2x$ per night to pee, often asso. with UUI
- Mixed - Combination of SUI and UUI → ELITONE
- Overflow – No signal to empty bladder
- Fecal – Uncontrolled emptying of the bowel

Your customers may not know that:

- Treatment options vary by incontinence type.
- Devices are FDA cleared based on the type of incontinence they treat.
- Patient demographics vary by incontinence type, but a lot of overlap

<https://elitone.com/incontinence-definition/>

Incontinence

- Treatment Options – SUI
 - Kegel Exercises
 - Physical Therapy
 - Kegel Trainers
 - Intravaginal Electrical Stimulation
 - External Electrical Stimulation
 - Magnetic Stimulation
 - Surgery

<https://elitone.com/kegel-exercise-devices-comparison/>

- There are many treatment options, but most are highly intrusive, risky, and/or expensive. ELITONE (external electrical stimulation) provides a non-intrusive, low-risk, inexpensive alternative.
- External electrical stimulation has only been available for a few years, so many clinicians will be unaware of it.
- Intervaginal devices, implants, and medications all come with risks, ranging from UTIs to removal surgery.

- Treatment Options – UUI/OAB
 - Medication
 - Implanted Neuromodulation
 - Percutaneous Tibial Nerve Stimulation

[Urge Infographic](#)

Incontinence



- OAB Market
 - 33MM in the US
 - Geriatric (70+y)
 - Rely on Medicare
- Urge incontinence is #1 reason for entry to nursing homes
 - Lost dignity – as others clean/change
- “Chained” to toilet, and mostly bothered by OAB, even with both
- Specialists (Urologists and Urogynes) often see more OAB patients than SUI
- Medication has so many side effects, most are off in 5 mos
 - Anticholinergics – dangerous
 - Beta3 Agonists (expensive \$450/mo)
- Implants lose effectiveness too
- Nocturia (waking to pee) = Loss of sleep = diminished health

- The mix of urge and stress is: 50% stress, 16% urge, and 34% mixed (i.e., both stress and urge).
- Since ELITONE sends out both signals (50Hz and 10Hz), if patients have both they should get original ELITONE. ELITONE URGE has only 10Hz, and so no muscle strengthening component.

Product

“**ELITONE** is a first-of-its-kind, automatic pelvic floor exerciser. It’s worn under your clothes and rebuilds your muscle tone for you. It exercises your pelvic floor longer and stronger than you can on your own.”

“**ELITONE URGE** is the first and only non-intrusive treatment for urge incontinence (overactive bladder) and has fewer side-effects than medication.”



Product

- Value Propositions – WHY ELITONE
 - Easy – Use at home (convenient). Easy to operate. Move around during treatment. Doesn't take up your time.
 - External - No vaginal probe. No risk of infection. Worn under clothing (discreet).
 - Effective – Strong clinical evidence. Only 4% return rate
 - Economical – Many women spend more on pads each year. Much less than surgery.
 - Low risk – No side effects, 60-day return

<https://elitone.com/clinicians/#easy>

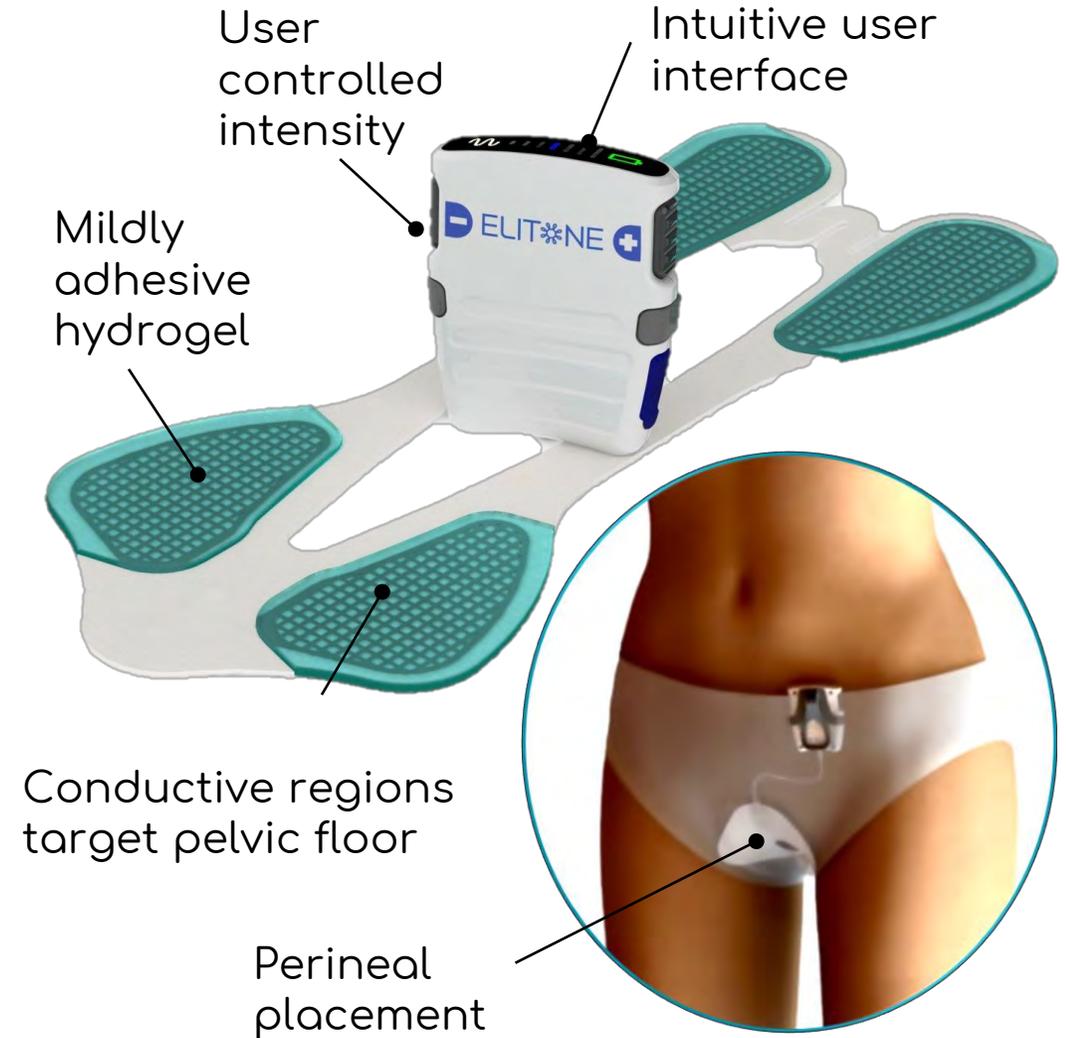
Vaginal treatments require a dedicated time and place, which isn't easy for working women and busy moms. ELITONE allows treatment anytime and anywhere.

For some cultures, intra-vaginal products and treatments are a not even an option.

Each of these E's drive compliance. The more the women uses the device, the more benefit she'll see, and the more likely she is to keep going.

Product

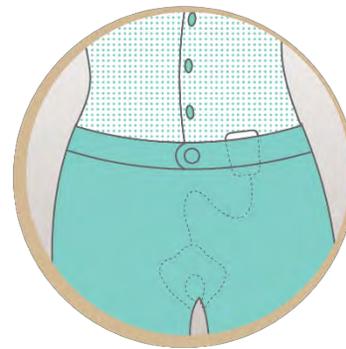
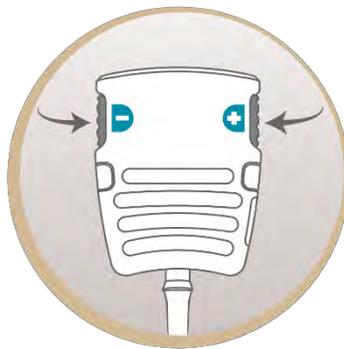
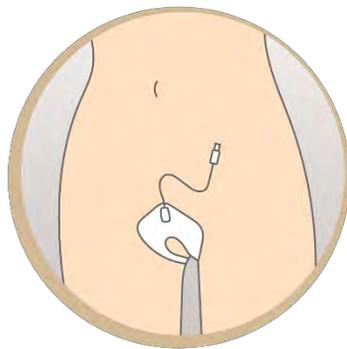
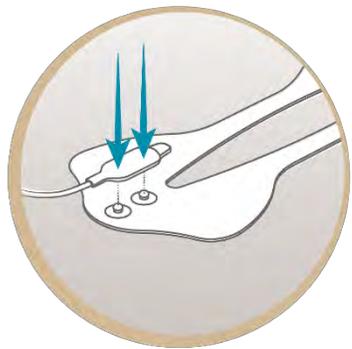
- The GelPad is applied to the perineal region and transmits a small electrical current to pelvic floor.
 - A small controller allows the user to adjust the stimulation intensity to achieve maximum benefit.
 - The GelPad is one-size-fits-all. Each one can be used 3-5 times and then replaced.
 - Does require hair trimmed (but not shaved necessarily)
-
- **ELITONE:** Regular use tones the pelvic floor, resulting in fewer leaks
 - **ELITONE URGE:** Calms the bladder muscle spasms reducing urgency leaks



The engineering team evaluated dozens of hydrogel formulations to select one that doesn't pull hair. The formulation is similar to that used in electrodes for neonates and geriatric patients with fragile skin.

Product

- Treatment – 20 minute sessions, 5x/week, 6-12 weeks
- Placement – GelPad applied to the perineal region
- Device Operation – Patient increases stimulation intensity to tolerable level. Treatment turns off automatically after 20 minutes.
- Maintenance – After 6-12 weeks of treatment most women reduce how often they treat (varies widely).



- 20 minutes a day for 6 weeks is a small time commitment for women who have often been dealing with incontinence for decades.
- During treatment women can move around or be in whatever position is comfortable for them.
- The device is so discreet, no one knows your wearing it.

<https://elitone.com/start/>

The engineering team evaluated dozens of hydrogel formulations to select one that doesn't pull hair. The gel is similar to those used in electrodes for neonates and geriatric patients with fragile skin.

Product

- ELITONE is for women:
 - Who want an at-home treatment
 - Who want a cost-effective solution
 - Who are averse to intra-vaginal alternatives
 - Who want a conservative (low risk) treatment
- ELITONE is not for women with:
 - Implanted electrical devices (e.g., pacemaker)
 - Metal implants in pelvic region (e.g., hip replacement, copper IUDs(Paraguard))
 - And other contraindications (see link below)

<https://elitone.com/faqs/#indications>

- ELITONE has been successfully used by women from their 20's to their 90's, and over a wide range of BMIs.
- Most women prefer external treatment over internal, home-use over in clinic, and a conservative option over riskier alternatives (e.g., surgery).
- FDA requires all electrical muscle stimulators to carry standard contraindications regarding implanted devices. ELITONE does not present risks unique to its design.
- Although copper IUDs are contraindicated, hormonal devices are okay to use (e.g. Minera, Skyla, Liletta)

Product

- Device
 - Controller, Patient Cable, Charging Cable, Beltclip, User Manual
- GelPads in 5/pack
 - Reusable at least 3x (more like 5-8x)
 - Resealable bag
 - 2-year shelf life
- Starter Kit
 - Device + 2 GelPad Packs (Retail Price: \$399)
- Bundle (website)
 - Device + 6 GelPad Packs (Retail Price: \$503)

- About 20% of online customers purchase the Bundle.
- The device is assembled in Monroe, CT



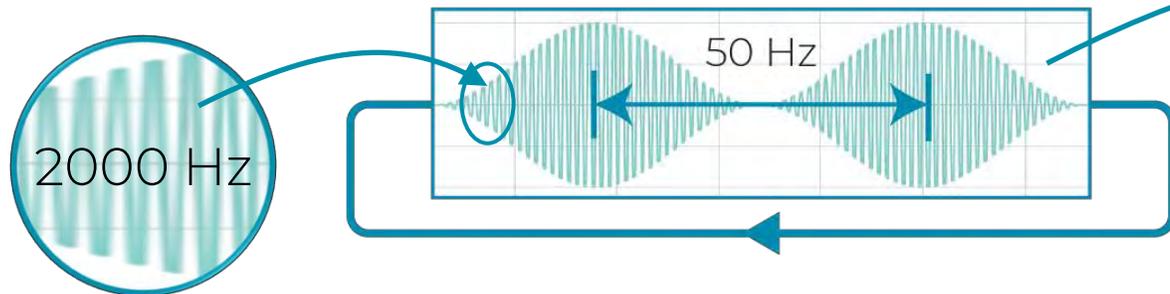
Product

- Targeted Waveform

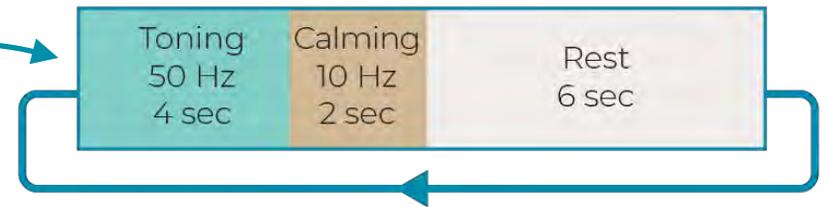
- Modulated at 2000Hz for comfortable transmission through skin and fat to underlying muscles
- 50Hz stimulation frequency for muscle contraction and toning
- 10 Hz frequency for bladder calming
- Short rest to allow muscle recovery
- Repeated for 100 contractions each treatment

- The design of the waveform is very important for electrical muscle stimulation
- ELITONE's unique waveform is specifically designed to treat stress incontinence.

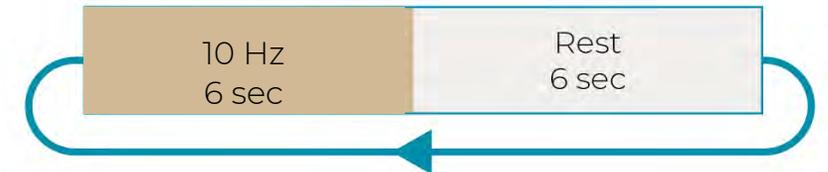
- Electrical muscle stimulation has been used clinically for over 100 years.
- Transcutaneous Electrical Nerve Stimulation (TENS) is similar to electrical muscle stimulation but uses a higher frequency (Hz) to manage pain.



ELITONE: Toning + Calming Waves



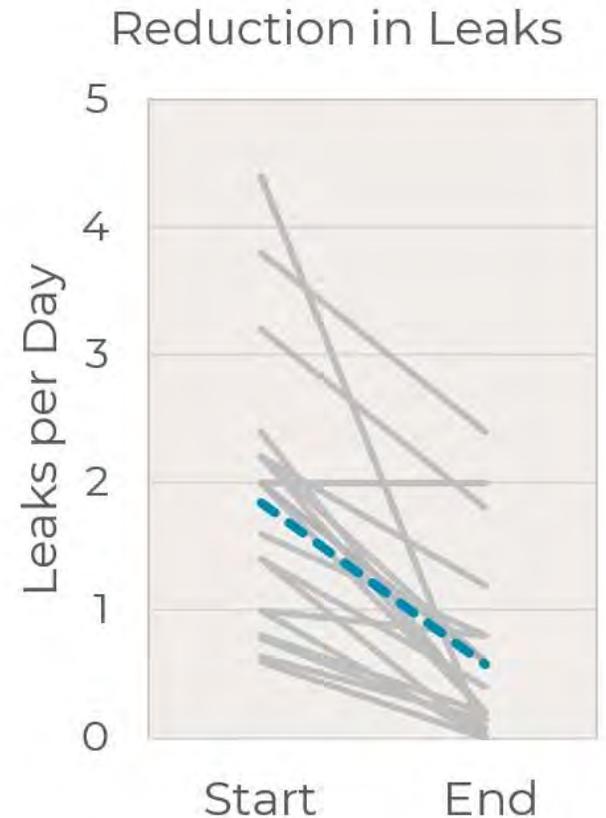
ELITONE URGE: Calming Wave



<https://elitone.com/clinicians/#targeted-waveform>

Clinical Experience

- **ELITONE** 20 Patient Case Series
Mild/moderate SUI subjects averaged 10+ years with incontinence
 - ELITONE treatment for 6 weeks
 - 95% had reduction in daily leaks
 - 75% had clinically significant reduction (defined as $\geq 50\%$ change)
 - 85% had a reduction in pad use
 - Incontinence Quality of Life score reduced by 14.6 points (>2.5 is clinically significant)

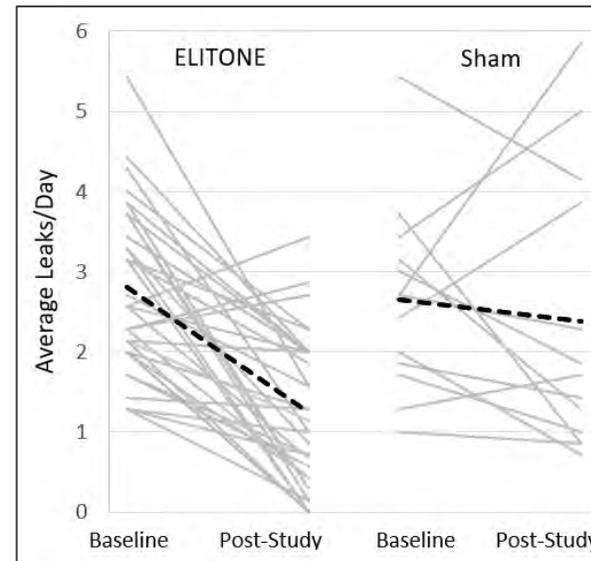
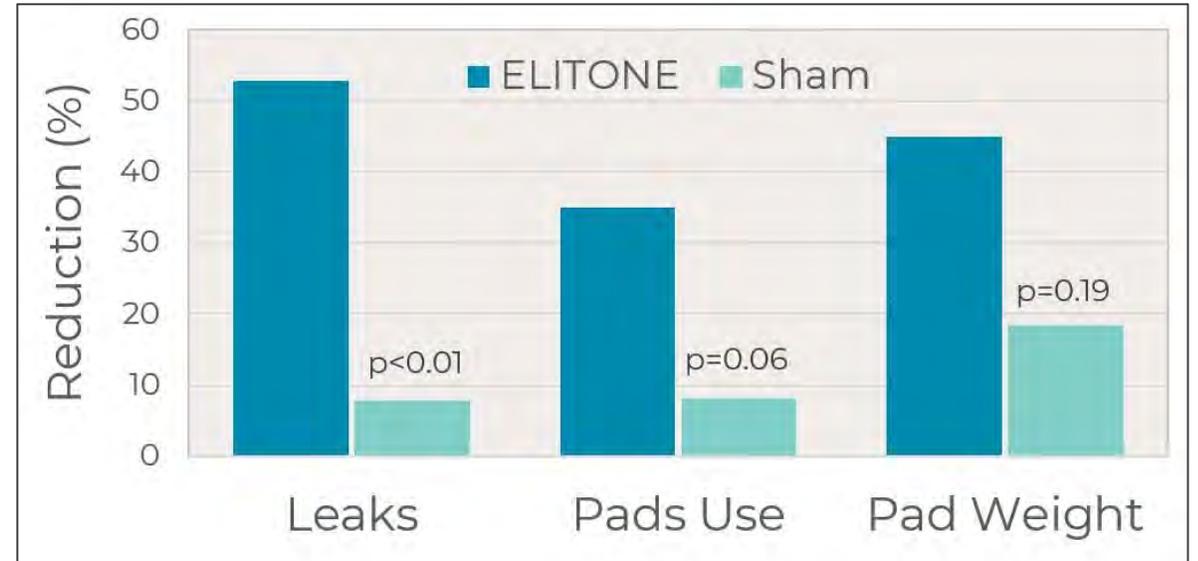


<https://elitone.com/clinicians/#clinical-data>

- This is the clinical data used to receive FDA clearance.
- The design of this study closely mimicked the real-world use of ELITONE.
- Conservative treatments historically work for ~50% of women, so these results are strong.
- Study published in peer reviewed Journal of Women's Health Physical Therapy.

Clinical Experience

- **ELITONE** Randomized Controlled Trial
 - 48 Subjects treated for 12 weeks.
 - Leaks reduced by 52.8%, which was significantly different from the sham.
 - Pad use and pad weight were also reduced.
- **ELITONE** Ultrasound Visualization
 - Bladder and pelvic floor visualized during muscle contraction.
 - The direction and magnitude with ELITONE was similar to Kegel exercises alone.



<https://elitone.com/clinicians/#clinical-data>

Clinical Experience

Presented/Poster at:



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

- **ELITONE URGE** 34 Patient Case Series

- 6 weeks of home-use treatment
- Baseline (2.1 urge leaks/day) vs 6th week
- Leaks, pad use, I-QoL, bathroom visits
- Avg age: 58 years



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

- 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 say they have a 90+% success rate, but 1) only after they remove non-responders 2) because of nerve fatigue, it often doesn't last

Clinical Experience

- 60-Day Money Back Guarantee on website orders (addresses the “Will it work for me?” objection)
- <4% Return Rate for being ineffective (consistent over 2 years)
- Customer Service team diligently tracks customer calls and feedback, which informs product and process improvements, including info of our FAQ page.
- Our many, many wonderful reviews show how ELITONE is changing women’s lives.

- Our return policy is the most generous of all devices.
- The low return rate is a strong indicator that ELITONE is highly effective.
- We are often praised by customers for the quality and speed of our responsiveness.

<https://elitone.com/return-policy/>

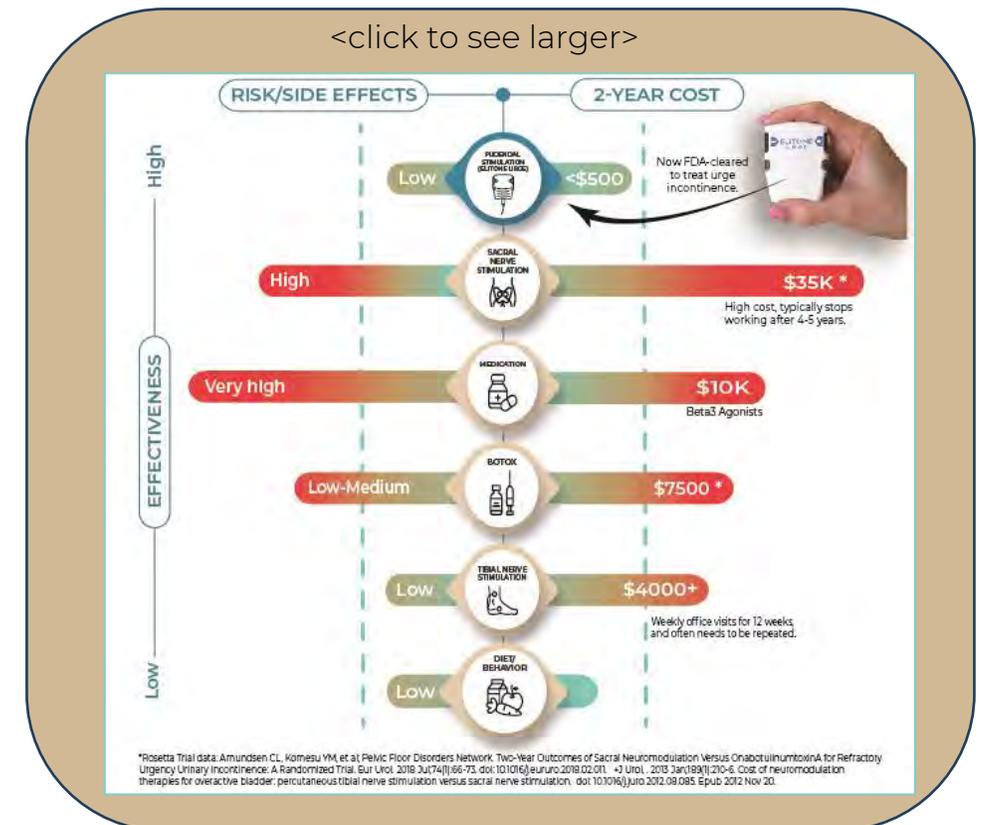
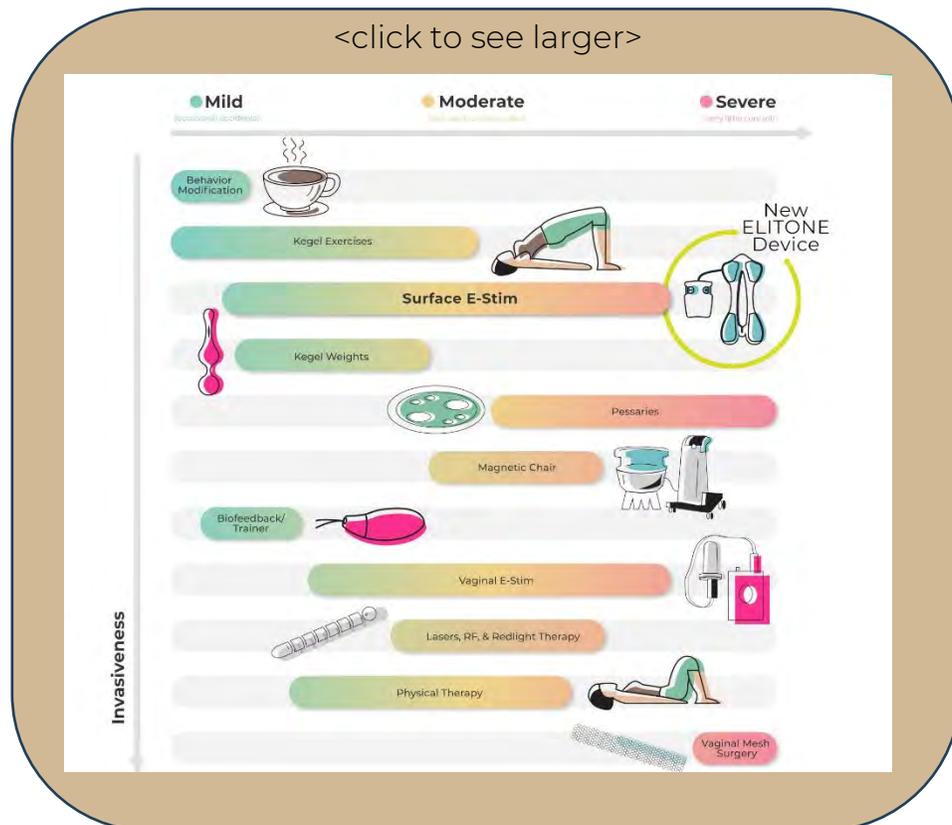
<https://elitone.com/faqs/>

<https://elitone.com/reviews/>

Continuum of Care – 2nd line of treatment

- ELITONE should be recommended for SUI after Kegel Exercises
- SUI Treatment Infographic: Invasiveness vs severity

- ELITONE URGE should be recommended for UUI after diet modification
- OAB Treatment Infographic: Side Effects vs Cost



Miscellaneous - Competition

- Innovo (Atlantic Therapeutics)
 - External electrical stimulation
 - Bike shorts design in 11 sizes that must be fitted. Often either the waist or thighs do not fit. Also breaks often.
 - Must have legs bent and not move.
- Emsella (BTL)
 - Magnetic muscle stimulation
 - 6-9 office visits at \$300 each
- Vaginal Trainers (Elvie, KegelSmart, Kgoal, Pericoach, Intimina)
 - Intravaginal biofeedback, Kegels Training App
 - NO FDA approvals
 - Use in privacy, infection, time-consuming



Billing

- ELITONE and ELITONE URGE both fall under the same billing codes.
- Medicare Primary covers Elitone as a capped rental for 13 months, roughly \$650 in total
 - Requirement: Rx and proof of failed at least 4-week structured Kegel program
- Medicare Advantage (MA) plans- mostly are following the Primary Medicare coverage
 - We do have exceptions depending on the plans purchased by the senior
- 22 state Medicaid plans are covering ELITONE mostly as a purchase item and profitable for the VGM member.
- Private insurance depends mostly plan-specific
 - BCBS which lists the device as investigational.
 - Others cover it on a case-by-case basis
 - HSA/FSA _universal coverage.

<https://elitone.com/reimbursement/>

For those clinicians not treating incontinence, additional \$150-200 revenue. Example:

- Session with ELITONE (2x since longer than 15 min) -97302
- Neuromuscular Reeducation – 97112
- Physical performance measurement (2x since longer than 15 min) - 97750

Miscellaneous – Videos and Other Resources

- The videos page provide content to help you learn more about ELITONE, and to share with your customers. Topics include:
 - ELITONE unboxing
 - What you wish your friends told you about incontinence
 - A clinician’s perspective on treating incontinence
 - An interview with the CEO
 - ABC News health segment featuring ELITONE
 - Video reviews
- Checkout Elidah’s YouTube channel for additional video content
- The Resources page includes dozens of blogs on relevant topics

<https://elitone.com/videos/>

<https://elitone.com/resources/>

<https://youtube.com>