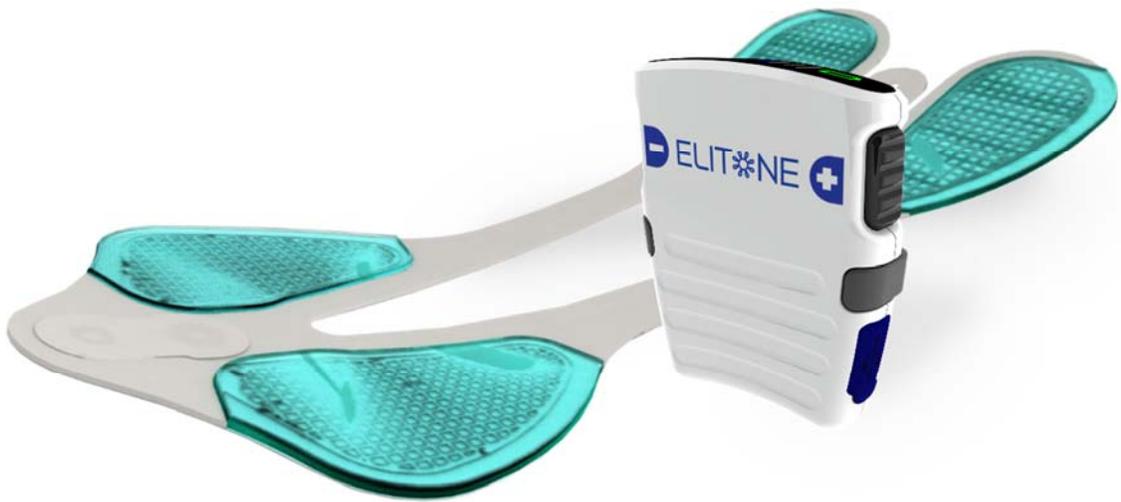


ELIT*NE



Practice Implementation Guide



MM-1019 REV 2 – 1/2020



January 2020

Dear Healthcare Provider,

Thank you for selecting ELITONE for your patients. It provides an innovative solution that addresses numerous challenges in treating female stress urinary incontinence. The purpose of this guide is to help you effectively implement ELITONE into your practice. In doing this, we hope that our goals are well aligned with yours. Namely, (1) providing patients with a non-invasive therapy to treat mild to moderate SUI, (2) achieving positive patient outcomes and (3) minimizing the burden of product training and follow-up on you, your staff and your patients.

We look forward to working with you and hearing about your experience with ELITONE. Please contact Elidah at customercare@elitone.com or 978-435-4324 with any questions or concerns.

Sincerely,

A handwritten signature in black ink that reads "Gloria Kolb".

Gloria Kolb
CEO
Elidah, Inc

About ELIDAH: Elidah is a women owned business located in Connecticut. It is committed to developing products that enhance the lives of women. ELITONE® was largely developed through funding from the National Science Foundation and maintains ISO 13485 certification as a medical device manufacturer.



Contents

Who Should Use ELITONE	4
Why We Developed ELITONE®	4
Intended Use	4
Contraindications	4
Warnings / Precautions / Adverse Reactions / Notes	5
Product Overview	7
How it Works	7
Device Operation	8
Recommended Treatment Regimen	10
Tips / FAQ's	10
How to Order / Purchase	11
Pricing	11
Stocking and Materials	12
Billing and Reimbursement	12
Physician Resources	12
Warranty / Guarantee / Product Returns	13
Appendices	13

Who Should Use ELITONE

Why We Developed ELITONE®

Through hundreds of interviews with clinicians and women with incontinence, Elidah identified a significant need for a treatment alternative for stress urinary incontinence (SUI). Women expressed the need for a conservative, non-invasive treatment that they could easily incorporate into their busy lives. ELITONE was developed to meet this need, and Elidah is excited to offer it to your patients.

ELITONE is recommended for women with mild-moderate SUI. These women may leak occasionally to many times a day. Although they may not consider themselves to be “incontinent”, they typically manage their symptoms with continuous use of adsorbent pads. For many of these women the symptoms affect their physical and emotional wellbeing.

Women who may particularly benefit from ELITONE include:

- Busy Moms
- Working women
- Postpartum care
- Aversion to vaginal devices
- Limited access to physical therapist
- Perform Kegels incorrectly

Intended Use

In the United States ELITONE has the following intended 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.

Women may present with stress urinary incontinence and/or urge urinary incontinence. Distinguishing between these incontinence types is straightforward and can be achieved by asking the patient about the situations that lead to hear leaks. The product labeling includes the following language to help in this determination:

Do you experience urine leakage when you laugh, sneeze, cough or exercise? Do you wear pads because you leak? That urine leakage is known as stress incontinence..... ELITONE is not recommended if you ONLY have symptoms of urinary frequency or urgency (using the restroom very frequently or having to rush to the restroom), with NO symptoms of leakage when coughing, laughing, sneezing or exercising.

Contraindications

The following contraindications pertain to ELITONE. These are additionally identified on the product packaging and within the user manual.

Do NOT use if you have/are:

- Pregnant or attempting to become pregnant. The safety of electronic muscle stimulators during pregnancy has not been established.
- An electronic implant (e.g. cardiac pacemaker, implanted defibrillator) or suffer from heart problems.
- Cancer, epilepsy, or cognitive dysfunction.
- Pelvic floor surgery within the last six weeks.
- Complete denervation of the pelvic floor.
- History or symptoms of urinary retention, extra-urethral incontinence, or overflow incontinence.
- Conductive intra-uterine devices (IUD/Coil) or metal implants in the abdominal or pelvic area, including the hip and lumbar spine.

Warnings / Precautions / Adverse Reactions / Notes

The following warnings, precautions, adverse reactions and other notes are additionally identified within the ELITONE user manual.

- Read all instructions prior to use. Failure to follow these directions may result in personal discomfort or injury, or damage to the device.
- The long-term effects of chronic muscle stimulation are unknown.
- The device is intended for indoor use only.
- Exposure of the Controller to liquids may result in personal injury or damage to the device. Do not use while bathing, swimming, or otherwise submerged.
- Consult your healthcare provider prior to use if you are fewer than six weeks postpartum or fewer than three months post-caesarean section.
- If a tissue irritation, allergic reaction, or burn occurs beneath the GelPad, discontinue use immediately and contact your healthcare provider. Some reddening of the skin, lasting for several hours, may occur under normal use.
- Discontinue treatment and consult a healthcare provider if you feel light-headed or faint while using the device.
- Use of equipment should be discontinued upon signs of treatment-related stress or discomfort.
- The device should not be used while driving, operating machinery, or any other activity in which involuntary muscle contraction may put the user at risk.
- Use only with ELITONE GelPads.
- Use only with ELITONE GelPad cable. Use with other cables could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.
- The GelPad is for single person use. Reuse of the GelPad by another user could cause cross-infection of skin disease.
- Only apply the GelPad as instructed. Applying the GelPad to or in proximity of the chest, neck, head, face, or eyes could result in serious injury.
- Do not power on the device prior to applying the GelPad and connecting it to the Controller.
- Only apply the GelPad to normal, intact, clean, healthy skin.

- Do not place the GelPad over or in proximity to cancerous lesions, open wounds, rashes, recent scars, swollen, red infected or inflamed tissue, or skin that is susceptible to acne, thrombosis or other vascular problems.
- Use caution if GelPad application area lacks normal sensation.
- Replace the GelPad if it no longer sticks firmly to the skin.
- Do not use GelPads or the GelPad Cable if they have visible damage.
- Do not connect the GelPads or GelPad Cable to other objects.
- Do not modify or attempt to repair this device.
- Do not touch the gel, metal studs, or snaps with your fingers while the Controller is on.
- Do not use more than once per day or at an intensity that exceeds your comfort level. Treatment should not cause undue discomfort or muscle fatigue.
- Turn the Controller off before removing GelPad.
- Keep device out of reach of children and pets. ELITONE is for use by adults only.
- Do not attempt to use the device while it is charging or connected to the charging cable.
- Do not use the product while sleeping.
- Use the toilet before starting a treatment session.
- Best results may be achieved by removing/trimming hair from the application site.
- Do not use the device with any other product which delivers electrical current to the body (e.g. muscle stimulators, high frequency surgical equipment) as this could result in burns or other injury.
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g. cardiac monitors, ECG alarms), which may not operate properly when the device is in use.
- Do not use in close proximity (e.g. 1 meter) to shortwave or microwave therapy equipment, as this may produce instability in the Controller's output.
- Wireless communication equipment such as wireless home network devices, mobile phones, cordless telephones, base stations, and walkie-talkies can affect this device. See the EMC Information section of this User Manual for additional information.
- Consult your healthcare provider before using the device if:
 - You have any serious illness or injury not mentioned in this guide.
 - You have an underlying neurological condition (e.g. Multiple Sclerosis or Parkinson's disease).
 - You have a tendency to hemorrhage, following acute trauma or fracture.
 - You take insulin for diabetes.
 - You suffer from muscle or joint problems, including pelvic pain or a paravaginal defect.
 - You suffer with suspected or diagnosed heart disease.
 - You underwent a recent surgical procedure and where muscle contraction may disrupt the healing process.
 - You have any doubt about using the device.

Product Overview

This section provides an overview of the ELITONE device specifications, its operation, and the recommended treatment regimen. Consult the ELITONE user manual for full details. If you do not have a copy of the user manual contact Elidah at customercare@elitone.com.

How it Works

ELITONE delivers electrical muscle stimulation to the pelvic floor muscles and surrounding tissues. This stimulation causes the muscles to contract and relax throughout 20 minute therapeutic treatment sessions. With regular use over 6-12 weeks, stress incontinence symptoms are reduced.

Electrical muscle stimulation is often referred to as “EMS”, or “E-Stim” or “NMES” (neuromuscular electrical stimulation). Some patients may refer to it as “TENS” (i.e. transcutaneous electrical nerve stimulation), which is a similar technology but designed to output to sooth pain. EMS has been used for decades to treat a wide variety of musculoskeletal and neuromuscular conditions, including stress incontinence. The electrical currents used in EMS are relatively small (measured in milliamps) and do not pose a significant safety risk. In treating stress incontinence, stimulation is traditionally delivered administered through a vaginally inserted probe. Women often perceive these solutions to be highly invasive and are resistant to adopt them into a regular treatment regimen.

ELITONE delivers EMS via a GelPad (electrode) applied to the perineal tissue. This results in a device that is substantially less invasive, more comfortable, and more convenient than traditional solutions. Key features include the following:





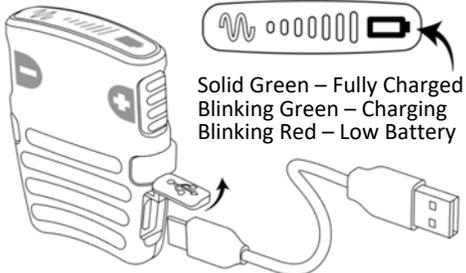
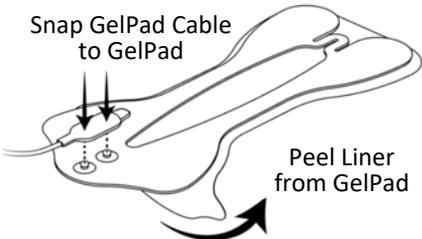
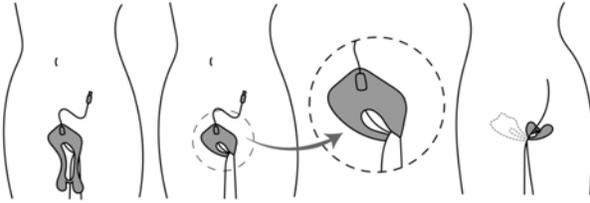
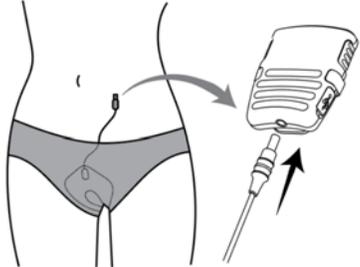
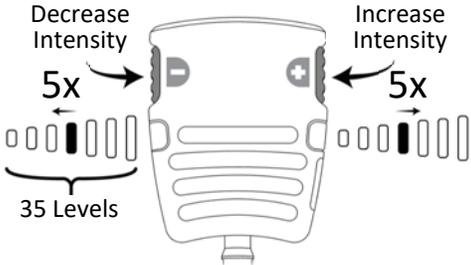
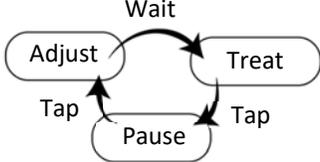
The GelPad is applied to the perineal tissues and is worn under a patient's clothing. Electrical current passes through the pelvic floor muscles as depicted by the yellow arrow.

Patients do not need to understand exactly how EMS works, but it may be helpful to briefly explain that electrical current is the natural messaging system in the body in order to alleviate concerns patients may have regarding “shocking” their body.

Device Operation

ELITONE had been cleared for Over-the-Counter use. To achieve this, testing demonstrated that patients are capable of operating ELITONE without training or regular intervention from a healthcare provider. The provided product labeling and user manual are sufficient to ensure safe and effective use.

That said, your patients may benefit from receiving brief training on the proper operation of ELITONE. Reviewing the operation provides the opportunity to confirm that the GelPad is being placed properly, that the device is set to a suitable intensity, and that the patient understands the recommended treatment regimen. The following table summarizes the operational steps presented in the user manual. Additional video instruction can be found at <http://www.elitone.com/start>.

<p>Overview of Device Operation</p> <p>Consult the ELITONE user manual for detailed instruction</p>	<p>1</p>	 <p>Solid Green – Fully Charged Blinking Green – Charging Blinking Red – Low Battery</p> <p>Ensure battery is fully charged. Use a standard USB power supply to charge the battery. A cable is provided with the device.</p>
<p>2</p>  <p>Snap GelPad Cable to GelPad</p> <p>Peel Liner from GelPad</p> <p>Connect GelPad Cable to GelPad. Remove liner and save for later use.</p>	<p>3</p>	 <p>Position the GelPad with the cable end low on the pelvic area. Wrap the GelPad rearward and press the sticky areas against the skin.</p>
<p>4</p>  <p>Put on clothing and connect the cable to the controller.</p>	<p>5</p>	 <p>Decrease Intensity 5x</p> <p>Increase Intensity 5x</p> <p>35 Levels</p> <p>Press a button to begin treatment and adjust the stimulation intensity to achieve a strong but comfortable muscle contraction.</p>
<p>6</p>  <p>During treatment the stimulation can be paused and adjusted without restarting.</p>	<p>7</p>	 <p>Solid Orange – Contract Off – Relax Blinking Orange - Paused</p> <p>Treatment alternates between contracting and relaxing the pelvic floor muscles, and automatically turns off after 20 minutes.</p>

Recommended Treatment Regimen

The ELITONE user manual describes a recommended treatment regimen comprising:

- 20 Minute treatment sessions (The device turns off automatically after 20 minutes)
- 4-5 sessions per week
- 6-12 weeks of treatment

Women may see improvement in their symptoms after only a few weeks, but it is recommended that they continue treatment regimen for at least 6 weeks. After completing 6-12 weeks of treatment patients may continue to use ELITONE to maintain the treatment benefits. This “maintenance” use typically occurs less frequently (e.g. once per week, or 3 days in a row every month).

Clinicians may recommend an alternate treatment regimen at their discretion. A Daily Log is provided (Appendix B) aid your patients in keeping track of their device use.

Tips / FAQ's

An extensive list of Frequently Asked Questions (FAQ's) is provided in the ELITONE user manual and on the website. The following “Tips” include key points to communicate to patients to help them achieve maximum benefits.

- Encourage women to read the user manual completely and to contact you and/or customercare@elitone.com, 978-435-4324, if they have questions or concerns.
- Encourage patients to treat at as high an intensity level as comfortably tolerable. Electrical stimulation can be an unusual sensation. They may first feel stimulation on the surface (i.e. skin), but it's important to firmly press the GelPad onto the body, get good contact, and increase the intensity to a level that achieves a strong contraction of the pelvic floor muscles.
- Encourage women to try different GelPad positions, as moving the GelPad forward or backward one inch may have a perceptible effect on muscle contraction. For most women, positioning the GelPad very low on the pubis is preferred.
- Encourage regular, consistent use. A Daily Log is provided as an Appendix to aid women in planning and tracking their treatment sessions.
- Speed of improvement and resulting variation in treatment length is partially dependent on the severity of incontinence when they started, on consistent use of ELITONE, and on the intensity they treat at.
- Set reasonable expectations. It may take weeks of consistent use to realize an improvement, and for some women leaks may not totally go away after 6-12 weeks of use. It's important to discuss what the patient's objectives are and to remind them of the improvement they've achieved. Use of the Daily Log can help demonstrate a reduction in leaks and pad usage.
- For patients who are concerned with “shocking” themselves, remind them that EMS has been used safely for decades to treat a wide range of medical conditions. You can also reassure them that they have control over the stimulation intensity and that the treatment is not designed to inflict any pain.
- A numbing effect on the surface may allow the user to increase intensity after a few minutes.

How to Order / Purchase

This section details the processes for getting ELITONE to your patients. ELITONE has both over-the-counter (OTC) and prescription clearance. This means that no prescription is necessary to purchase ELITONE. Women can purchase ELITONE based solely off of your “recommendation” or without any involvement of a healthcare professional. However, you may find that your patients are more likely to pursue and continue treatment with ELITONE with a prescription in hand. Additionally, women may be more likely to receive reimbursement if they have a prescription for ELITONE (see Billing and Reimbursement).

1. Clinician makes a recommendation or writes a prescription for ELITONE. The ELITONE Patient Brochures (Appendix C) includes a section for documenting a prescription. If additional detail is required, the Detailed Written Order (Appendix A) or the clinics own templates may be used to document the prescription.
2. Patient visits www.elitone.com/order and places an order for ELITONE. Payment is required with order.
3. Elidah ships ELITONE to the patient’s home address in discreet packaging.
4. Patient reads User Manual and begins treatment.
5. OPTIONAL: Clinician follows up with patient as needed before or during 6-12 week treatment regimen.

Pricing

ELITONE is competitively priced at \$495. This includes:

- Rechargeable Controller
- 10 GelPads (Two packs of five, packaged separately)
- Cable to Connect to GelPad (i.e. GelPad Cable)
- User Manual
- Accessories including USB Cable for recharging, Belt Clip and Carrying Case



Additional 5-packs of GelPads cost \$28. These prices reflect pricing at the printing date for this guide. Visit www.elitone.com for current pricing.

This pricing is meant to be competitive with treatment alternatives and to allow many women to pay for ELITONE out of pocket. If you have a patient who is surprised by the cost, have them consider the following:

- The average cost to manage symptoms, including the cost of pads and extra laundry services, averaged \$750 per year.¹
- How much is it worth to not have to worry (or be embarrassed) about leaks.

¹ Source: (1) Leslee L. Subak, MD, Linda Brubaker, MD, Toby C. Chai, MD, et al., High Costs of Urinary Incontinence Among Women Electing Surgery to Treat Stress Incontinence, *Obstet Gynecol.* 2008 April; 111(4): 899-907.

- How much is the convenience of at-home treatment worth (e.g. fewer visits to a physical therapists office)
- Symptoms will likely get worse with time, so treating incontinence now can be much more affordable than the more extreme interventions that might be required in the future.
- There may be a “point of no return” when the ligaments are so stretched, conservative treatment will no longer work.

Stocking and Materials

Contact customercare@elitone.com or 978-435-4324 for information on stocking ELITONE and/or materials in your clinic.

Some clinics may prefer to stock ELITONE in their practice, allowing their patients more immediate access to the product (and possibly better compliance in getting a treatment.) Stocking the product may also allow the clinician to provide a greater level of product training and oversight.

Available materials (automatically sent with bulk purchase) for your practice are:

Start-Up Kit

- 25 Patient brochures
- 1 Brochure stand
- 1 Patient talk-through guide

Billing and Reimbursement.

ELITONE is a cost effective solution for treating stress urinary incontinence, and the device is priced to make self-pay a reasonable option for many patients. Elidah does not warrant that private insurers will reimburse for the ELITONE device. If a patient wishes to pursue reimbursement we recommend that they self-submit to their insurer. As noted above, ELITONE does not require a prescription, but a prescription is recommended for patients who intend to seek reimbursement.

Medicare covers ELITONE using HCPC Code E0740, which is a capped rental at \$62/month. You must be a Medicare Accredited DME provider to bill Medicare for the ELITONE device.

Visit elitone.com or contact customercare@elitone.com for the current status of reimbursement through Medicare or private payers.

The pricing page <https://elitone.com/pricing/> details options including FSA/HSA payments, and 6 month no-interest monthly payment plan.

Physician Resources

Visit www.elitone.com/clinicians for additional resources for you and your patients.

For qualified practices, ELITONE is happy to provide printed Patient Brochures that can be used to encourage them to treat their incontinence and to inform them about the advantages of ELITONE. A representative brochure is provided in Appendix C. Contact customercare@elitone.com to request brochures.

Clinics who routinely recommend or prescribe ELITONE may be eligible to receive a demonstration unit.

Warranty / Guarantee / Product Returns

Currently, there is a 60 day refund policy. If the patient purchases ELITONE from your office, please have them save the receipt with date as proof of purchase. Please visit the website for updates www.elitone.com/return-policy and for any additional coverage or guarantee. Elidah offers a 30-day warranty for defects in workmanship.

Appendices

- A. Detailed Written Order
- B. Daily Log
- C. Patient Brochure

Detailed Written Order

PATIENT INFORMATION

Patient Name: _____	Date of Birth: _____
Address: _____	Phone #: _____
Insurance Company: _____	Group #/ID#: _____
Insured Name: _____	Insurance Phone #: _____
Secondary Insurance: _____	Group #/ID#: _____
Insured Name: _____	Insurance Phone #: _____

MEDICAL INFORMATION

Diagnosis & ICD-10 CM Code: N39.3 Stress Urinary Incontinence, female
 Other: _____

Has patient undergone and failed a 4 week documented trial of Pelvic Muscle Exercise (PME) training?
 Yes No

Is patient cognitively intact? YES NO

Are the pelvic nerves intact? YES NO

ELITONE device prescribed to: Decrease urinary leakage associated with stress urinary incontinence
 Other: _____

Prognosis: Excellent Good Fair Poor

PRESCRIPTION

I am prescribing the ELITONE device (HCPCS Code E0740) with GelPads (HCPCS Code A4595)

Quantity: One ELITONE Device + 2 GelPads Other _____

Length of Need: Lifetime (≥ 13 months) Other _____

Prescribing Physician Name: _____	UPIN #: _____
Facility Address: _____	NPI #: _____
Physician Signature: _____	Phone #: _____
Date: _____	FAX #: _____

Deliver To: Clinician's Facility Patient's Home*

I certify that I am the physician identified in this form. I have reviewed all sections of the physician's written order. Any statement on my letterhead attached here to has been reviewed and signed by me. The patient's record contains supporting documentation which substantiates the utilization and medical necessity of the ELITONE device and physician notes will be provided to an authorized distributor upon request. I understand any falsification, omission or concealment of material fact may subject me to civil or criminal liability. *My above signature indicates my approval to ship the instrument to my patient's home and releases shipper from any liability from its use prior to proper instrument education and training.

ELITONE® Patient Bi-Fold Brochure (outside)

Contact customercare@elitone.com for printed copies of the most current brochures.

Buy ELITONE.
Then bye, pads!



elitone.com

LIVE LIFE LEAK FREE

NEXT STEPS

1. Visit elitone.com/product/elitone/ to order your ELITONE
2. Your ELITONE will be shipped directly to you
3. Begin treatment
4. Follow-up with your physician as necessary

ELITONE

810 Main St. Suite C
Monroe, CT 06468

customercare@elitone.com
978.435.4324

You do not need a prescription to buy ELITONE, but getting one may help you obtain reimbursement through your insurance provider. Visit elitone.com for more information.

R for ELITONE®

Date: _____

Patient Name: _____

Has patient undergone and failed a 4-week documented trial of pelvic muscle exercise training?

Yes (End Date: _____) No

Use ELITONE device _____ times per week for _____ weeks.

Clinician Name: _____

Phone Number: _____

Practice Location: _____

Clinician Signature: _____

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

ELITONE is covered by Medicare under HCPCS code E0740.

MM-1026 REV 1 9/19

Give up leaking.
Not laughing.



ELITONE

Supported
by doctors.
Preferred
by women.



ELITONE® Patient Bi-Fold Brochure (inside)

Contact customercare@elitone.com for printed copies of the most current brochures.

Give up leaking. Not dancing.



"The device is very effective. It crazy helped with my incontinence."
Liberty – 37



Do you leak when you laugh, sneeze, cough or exercise? Do you wear pads because you leak? If so, you likely have stress urinary incontinence. Incontinence can rob you of so many joys of life. It's hard to be confident and active when you are worrying about leaks. But there is a simple solution to get you back to living leak free.

The solution

ELITONE is a first of its kind device that allows non-invasive treatment of stress urinary incontinence. ELITONE uses gentle, low-frequency pulses to stimulate weakened pelvic floor muscles by doing perfectly-timed Kegels – for you. With regular use, those embarrassing leaks will go away.



"Prior I had constant problems with incontinence. ELITONE changed my life. I now have complete control over urination again! No surprises, no worries."
Diana – 66



A woman's solution to a woman's issue.

Gloria Kolb is CEO of Elidah, inventor of ELITONE and mother of three. She has engineering degrees from MIT and Stanford. "I started Elidah because I wanted to help women regain control and confidence."

Why ELITONE?

✓ Easy

ELITONE was designed to fit conveniently into your life. Wear it for 20-minute sessions while working, lounging, cooking, pretty much anytime. ELITONE is used 4-5 times per week for 6-12 weeks.



Apply



Adjust



Wear



Live

✓ Non-invasive

Wear the comfortable GelPads under your clothes, where a pad would go, adjust the stimulation level on the handheld controller, and forget about it!

✓ Effective

In a recent survey at the American College of Obstetricians and Gynecologists, 9 out of 10 gynecologists would prescribe ELITONE to their patients. FDA-reviewed data shows that 95% of women who used ELITONE achieved an average 71% reduction in leaks.



"I really feel that the device made an impact. I ran 3 miles and didn't leak!"
Lesley – 56