elitone® for MEN

Transperineal Neuromuscular Stimulation for Accelerated Continence Recovery Following Prostate Surgery

FDA CLEARED

Medicare Covered and other payers

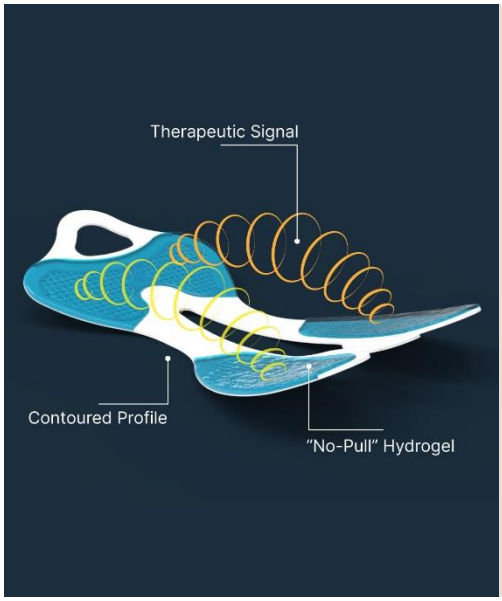
100% money-back guarantee

★★★★½ 4.5 stars average review

1. Clinical Opportunity

Patient Expectations ≠ Clinical Reality

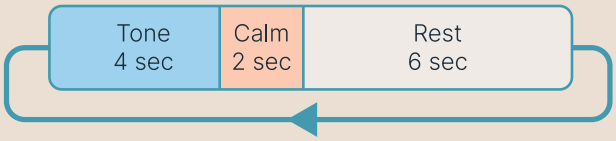
- Continence recovery after prostatectomy is gradual and variable: ~40–70% of men report leakage at 6 weeks, ~20–40% at 3 months, and ~5–20% at 12 months.
- First-line management includes self-directed Kegel exercises (often done incorrectly or inconsistently) and a "wait and see" observational approach.
- When recovery is slower than expected, ongoing leakage may influence patient satisfaction with their overall outcome, despite a technically successful procedure.



2. Mechanism of Action

Transperineal Neuromuscular Stimulation

Elitone for Men delivers electrical impulses through the perineum to activate the muscles responsible for urinary continence. This produces pelvic floor contractions that are often stronger and sustained longer than patients can achieve on their own, bypassing inconsistent volitional exercises common early after surgery. This accelerates recovery versus natural healing.



3. Treatment Protocol

At-home, High Adherence

Treatment is delivered at home in structured 20-minute sessions, five times per week, typically for 6–12 weeks. Patients can perform other routine activities during use. It integrates easily with pelvic floor physical therapy when prescribed, and offers a guided at-home option for patients who do not pursue PT. This supports consistent use throughout recovery.

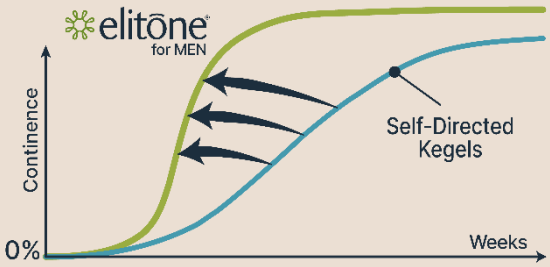
elitone.com/men/clinicians

Elitone for Men: Filling a critical gap in post-prostate continence recovery

4. Clinical Evidence

FDA-Cleared for Accelerated Recovery

Elitone for Men is FDA-cleared to speed continence recovery. Clinical data demonstrate significant improvements in urinary continence outcomes compared to baseline, supporting its role as a conservative, non-invasive therapy during early recovery. A detailed review of study design, outcomes, and supporting literature is available.



Latest Insurance Information

5. Safety and Risk Profile

Non-invasive, 1st-Line

External GelPad, no systemic side-effects, no surgical risks. Select contraindications include (see User Manual for full list):

- Electronic implants
- Active cancer
- Pelvic floor surgery within the last 3 weeks
- Persistent incontinence more than 12 months post-prostatectomy

6. Position in Treatment Pathway

Structured Recovery Program

- Early intervention post-prostate surgery to accelerate continence recovery
- Enhances pelvic floor exercises and physical therapy outcomes
- Supports recovery before considering surgical options

Supports Reimbursable Clinical Interaction (up to $300 extra billable coding per patient)

- CPT 97750 Physical Performance Test
- CPT 97302 Application of Electrical Stimulation
- CPT 98960 Education and Training for Patient Self Management
- CPT 97112 Neuromuscular Re-education
- CPT 99214/99215 Evaluation & Management of an Established Patient Visit

7. Impact on Practice

Operational Simplicity

Prescribed for at-home use. No setup, programming, or ongoing device management.

Minimal Staff Burden

Requires minimal staff time beyond standard patient education. No recurring visits or hands-on therapy required.

Clinical Value

Adds conservative, non-invasive option that aligns with guideline-based care pathways.

Elitone Family of Products

Elitone for Men is part of the Elitone family of FDA-cleared, non-invasive neuromuscular stimulation therapies, which also includes Elitone for women with stress urinary incontinence and Elitone URGE for women with overactive bladder and urge urinary incontinence.

Learn more at **elitone.com**

Accelerating Continence Recovery After Prostate Surgery:
Clinical Evidence Supporting Elitone® for Men

Overview: Elitone for Men is the only FDA-cleared, non-invasive neuromuscular electrical stimulation (NMES) therapy designed to aid early continence recovery in men immediately following prostate surgery. In an IRB-approved prospective case series, patients using Elitone for Men experienced a 61% reduction in 24-hour pad weight by Week 6 and a 92% reduction by Week 12. Compared to a literature-derived natural recovery profile, these outcomes represent substantially greater leakage reduction and an estimated acceleration of continence recovery of over four weeks by Week 12. The therapy was used independently at home with high patient satisfaction and no reported adverse events, supporting its practicality in routine post-operative care.

Introduction

Urinary incontinence is an expected and nearly universal consequence of prostate surgery. Although most men are told that continence will gradually return over six to twelve months, the early recovery period is often marked by daily leakage, pad dependence, lifestyle restriction, and frustration. During this time, patients are commonly advised to "do Kegels and wait."

Clinical guidelines recommend pelvic floor muscle therapy to accelerate recovery, yet participation is low. Many men are not trained preoperatively, perform exercises incorrectly, lack access to pelvic floor physical therapists, or avoid therapy due to the invasive digital rectal exam. As a result, most men progress through early recovery without effective therapeutic support.

Elitone for Men was developed to address this gap by providing a non-invasive, at-home method of delivering therapeutic neuromuscular stimulation to the pelvic floor muscles during the critical early recovery window following catheter removal.

Elitone for Men comprises a GelPad (electrode) and rechargeable Controller

Methods

An IRB-approved prospective case series evaluated Elitone for Men in post-prostatectomy patients using objective and validated measures of continence recovery.

Participants: Men recovering from recent prostate surgery and experiencing stress urinary incontinence (SUI) were recruited. Treatment began approximately one month after surgery, corresponding to roughly two weeks after catheter removal. Participants were required to be using at least one pad per day. Sixteen participants completed study requirements and were included in the final analysis.

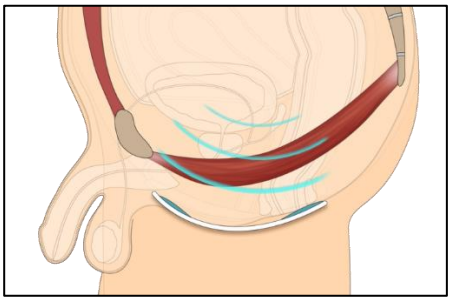
Intervention: Participants self-administered 20-minute treatment sessions, five times per week for twelve weeks using a pre-programmed device. All treatment occurred in the home without clinician supervision. Participants recorded daily leakage events, treatment sessions, and pad usage throughout the study.

Outcome Measures: The primary outcome measure was the 24-hour pad weight test, performed over three consecutive days at baseline, Week 6, and Week 12.

Secondary outcomes included:

- SUI leakage frequency
- Incontinence Quality of Life questionnaire (I-QoL)
- Pad usage
- Patient satisfaction and usability feedback

A reduction of 50 percent or more in leakage volume was considered a clinically meaningful responder.



GelPad applied to the posterior region immediately posterior to the scrotum, transmits neuromuscular stimulation through the pelvic floor musculature.

Worn discreetly under clothing

Clinical Study Results

The study demonstrated substantial and progressive reductions in leakage.

Average 24-hour pad weight declined from 608 grams at baseline to 238 grams at Week 6, representing a 61% reduction. By Week 12, average leakage had declined to 47 grams, a 92% reduction from baseline. 80% of participants achieved a clinically meaningful response by Week 6, increasing to 92% by Week 12.

SUI leaks per day declined by 61% at Week 6 and by 82% at Week 12.

Quality of life improved substantially. I-QoL scores improved by an average of 20.9 points, with 94% of participants exceeding FDA's 2.5-point threshold for clinically meaningful improvement.

All participants reported satisfaction and would recommend the treatment No adverse events occurred during the study.

Participants demonstrated independent and correct use, supporting suitability for unsupervised home and OTC use.

Literature-Based Method for Establishing Natural Recovery Control

To contextualize these findings, a structured literature review was performed to establish a representative baseline recovery profile for post-prostatectomy continence in men receiving no active therapy beyond self-directed pelvic floor exercises.

A systematic search of PubMed and referenced literature identified studies reporting multiple early post-operative continence assessments using the 24-hour pad weight test. Studies involving supervised pelvic floor therapy were excluded to reflect standard self-care conditions. Five studies met all criteria, representing 215 subjects.

Because study designs and absolute pad weights varied, pad weights were normalized to baseline values and mapped to common post-operative time points. A sample-size-weighted recovery curve was constructed to represent expected natural recovery at Week 6 and Week 12.

Treatment with Elitone for Men accelerated recovery by more than 4 weeks at Week-12 assessment compared to literature controls

Results: Outcomes vs Natural Recovery

When compared to the literature-derived recovery profile, Elitone for Men demonstrated substantially greater reductions in leakage at both time points.

At Week 6, the reference recovery profile showed a 45% reduction in pad weight, compared to 61% with Elitone for Men. At Week 12, the reference profile showed a 68% reduction, compared to 92% with Elitone for Men.

These differences correspond to an absolute improvement of approximately 34-35% at both time points.

Applying the slope of the historical recovery curve, these improvements correspond to an estimated acceleration of continence recovery of approximately one and a half weeks at Week 6 and more than 4 and a half weeks at Week 12.

Notably, the 92% reduction at Week 12 with Elitone for Men exceeded six-month outcomes reported in most of the reference studies.

Clinical Meaning of Accelerated Recovery

Although measured in weeks, this degree of acceleration has meaningful clinical implications. The duration of pad dependence influences the risk of skin irritation, incontinence-associated dermatitis, and secondary infection. Prolonged leakage contributes to maladaptive behaviors such as guarding and fluid restriction, which carry additional health risks.

Earlier restoration of continence supports a more natural return to baseline pelvic function and may influence long-term outcomes, as early recovery has been associated with improved continence at one year.

Psychosocial, Economic, and Health System Implications

Shortening the period of incontinence reduces embarrassment, social withdrawal, and limitations on activity, travel, work, and intimacy. It reduces the economic burden of pads and skin care and may allow earlier return to work, normal routines, and sexual function.

For providers and health systems, improved early recovery may reduce follow-up visits, communications related to leakage management, and progression to advanced interventions such as slings or artificial urinary sphincters.

Conclusion

The clinical evaluation of Elitone for Men demonstrates significant reductions in leakage within six weeks and continued improvement through twelve weeks, with high patient satisfaction and no adverse events.

When viewed in the context of published historical recovery data, these results show a meaningful acceleration of continence recovery relative to natural healing.

Elitone for Men provides men with a practical, non-invasive, evidence-based way to take an active role in their recovery during the most challenging phase following prostate surgery.

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MM-1074 REV 1 4/026