Liberty® Pelvic Floor Stimulation

A logical first choice for treatment of urinary incontinence

Non-surgical pelvic floor treatments and therapies avoid the significant complications that are associated with many current surgical treatments for urinary incontinence (UI). In cases of mild to moderate cases of UI, doesn't it make sense to provide a therapy that has high patient success without the risk of complication?

Pelvic floor stimulation (PFS) is a non-surgical treatment which activates natural neuromuscular mechanisms. In the case of stress incontinence, PFS automates Kegel exercises via a pudendal nerve reflex. In the case of urge incontinence, PFS inhibits inappropriate bladder contractions.

Unlike other treatments, PFS has no side effects, always exercises the correct muscles, and does not require active patient participation.

The Liberty® System is the easiest to use and most cost-effective PFS system available. It consists of a stimulation device and a choice of three comfortable exercisers.

- Liberty's simplified design exercises the correct muscles and is easy to use, therefore helping increase patient compliance to the therapy program you prescribe.
- Maintain UI patients in your practice, rather than referring them out to a specialist.
- Covered by Medicare and most insurers

Order Information

PFS-200
Liberty Pelvic Floor Stimulator System
(Includes carrying case and batteries)

Choose from three exerciser probes:

PFS-041
Vaginal Exerciser

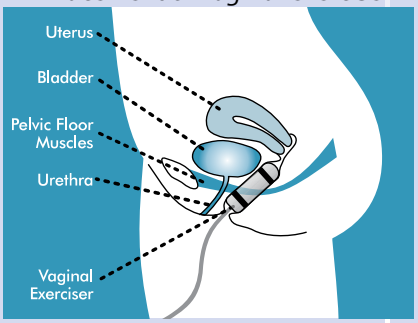
PFS-042
Extended Vaginal Exerciser

PFS-043
Rectal Exerciser

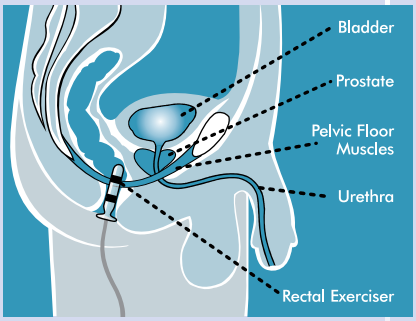
UTAH MEDICAL PRODUCTS INC.

Liberty® Pelvic Floor Stimulation

Placement of vaginal exerciser



Placement of rectal exerciser



For Clinical and Ordering Information

Call 800-533-4984

UTAH MEDICAL PRODUCTS INC.

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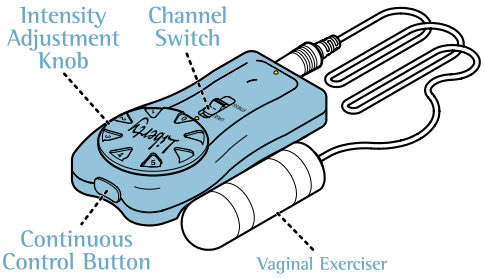
pn 5976 rev 122718

Product Overview



Liberty is a user-friendly system indicated for Stress, Urge, or Mixed urinary incontinence that has only three controls:

1: The Channel Switch permits selection for either Stress or Urge incontinence. The Stress mode is associated with strengthening and toning the pelvic floor muscles and the Urge mode stimulates the detrusor inhibitory reflex. Mixed incontinence can be treated by alternating channels with each treatment.

2: The Intensity Adjustment Knob controls the intensity of stimulation. This is adjusted for each individual patient.

3: When pressed, the Continuous Control Button delivers uninterrupted stimulation to determine the appropriate intensity level and exerciser placement.

Treatment Protocol

The treatment protocol should be established to meet the patient's individual needs based on the type and severity of incontinence, pelvic strength and ability to meet a treatment schedule. Common protocols are 15 minutes, twice a day, every day or every other day. Following cure or improvement, a maintenance program of 2-3 treatments per week should be implemented.

Specifications

• Stimulation Frequency	Stress: 50 Hz Urge: 12.5 Hz
• Stimulation Program	5 sec stimulation followed by 10 sec rest Cycle continues for 30 minutes
• Output:	0 mA to 65 mA, symmetric biphasic
• Pulse Width:	300 µsec at 50% peak
• Batteries	Two type 123 Lithium cells
• Typical battery life	60 hours at 45 mA

Efficacy of Pelvic Floor Stimulation

	Detrusor Instability	Genuine Stress Incontinence
Reduced Symptoms	2-3 weeks	6-8 weeks
Significant Improvement or Cure	3 months	3-6 months
Objective Cure	43%-49%[1,2]	39%-45%[8,9]
Objective (>50%) Improvement	69%-80%[3-7]	62%-88%[8-11]

1 Brubaker L (1997)
2 Primus G (1998)
3 Siegel SW (1997)
4 Smith JJ (1996)
5 Caputo RM (1993)
6 Zollner-Nielsen (1992)
7 Yalcin (2002)
8 Yamanishi T (1997)
9 Richardson DA (1996)
10 Sand PK (1995)
11 Barroso (2004)

Contraindications

- Neurological deficiency preventing proper sensory perception or stimulation
- Currently pregnant or attempting to get pregnant
- Use of a cardiac pacemaker or a history of rate or conductive disturbances
- Irregular menstrual bleeding cycles
- Urinary or vaginal infections, localized lesions or other undiagnosed symptoms
- History or current symptoms of urinary retention

Liberty®

Pelvic Floor Stimulation for Incontinence

INCONTINENCE: A QUIET EPIDEMIC

More than 15 million American men and women suffer from incontinence. Incontinence is the involuntary loss of urine severe enough to have adverse social or hygienic consequences. The associated embarrassment related to incontinent episodes leads many men and women to avoid social contacts, which can lead to isolation and increased suffering. Still, more than half of these people will not seek medical assistance. The U.S. Department of Health and Human Services' Agency for Health Care Policy and Research issued a report in 1996 supporting current research that has found most patients can experience improvement, if not total continence restoration, with treatment. They recommend the least invasive treatments as the first choice for sufferers of incontinence.

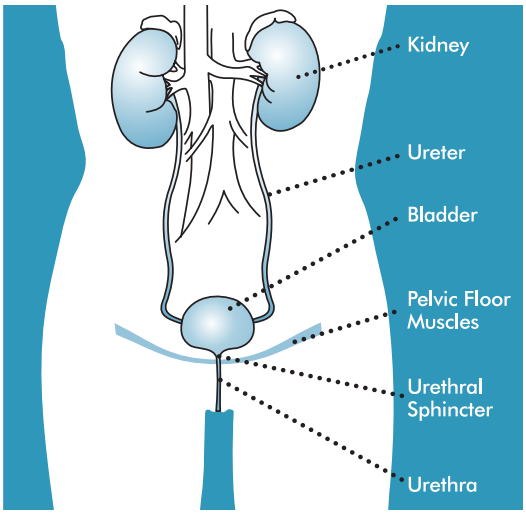
Pelvic Floor Stimulation (PFS) is a non-surgical treatment aimed at strengthening and toning the pelvic floor muscles to treat stress and mixed incontinence or to assist in calming involuntary muscle contractions, thus reducing urge incontinence. Unlike so many treatments for incontinence, PFS has no significant side effects. PFS has been used as an effective treatment for decades. PFS is especially helpful to the patient who is unable to perform a pelvic floor exercise either due to extreme weakness or to not knowing how to voluntarily contract the correct pelvic floor muscles. In the past, these men and women were unable to benefit from behavioral therapy and often had to resort to surgery with all of its cost, risks, side effects and long recovery. Now patients suffering from incontinence may be able to obtain continence using PFS therapy.

Utah Medical Products, Inc.'s Liberty® System is designed to treat urge, stress, and mixed urinary incontinence. The treatment consists of electrostimulation of the pelvic floor nerve and muscle tissues, using a tampon shaped device that is place in either the vagina or rectum. Patients will find the Liberty attractive because:

- the treatment is non-invasive,
- it has no significant side effects,
- it is easy to use,
- it is affordable, compared to other alternatives, and
- it is covered by most insurances.

NORMAL FUNCTION OF THE URINARY SYSTEM

The urinary system consists of the kidneys, ureters, bladder, urethra, and the pelvic floor muscles. The kidneys function as a filter to remove waste products from the circulatory system. The waste products are moved through the ureters for storage in the bladder. The spherical-shaped bladder is composed of smooth muscles. These muscles relax during bladder filling and expand like a balloon to accommodate the storage of urine. Upon urination, these muscles contract, forcing the urine out. The urethra extends from the base of the bladder. It is a hollow muscular tube that empties the bladder. The urethra has a sphincter muscle at the connection of the urethra to the bladder, which acts like a spigot to turn the flow of urine on and off. The sphincter muscles contract (the spigot is turned off) during bladder filling and storage and relax (the spigot is opened) during emptying. The brain and spinal cord regulate this complex system, and malfunction in any part of this system can lead to incontinence.



Stress Incontinence

Stress Incontinence is a bladder storage defect. The bladder is unable to store urine until voluntary urination occurs. This is either due to pelvic support problems such as weak surrounding muscle, a urethral sphincter defect, or both. Urine is lost when the patient laughs, coughs, sneezes, or does any other physical activity that increases the abdominal pressure to a level which overcomes the bladder's retention capability.

Urge Incontinence

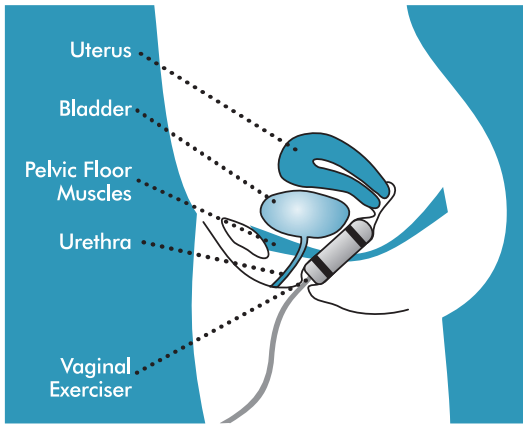
Urge Incontinence is a bladder-filling defect. Involuntary muscle contractions cause a loss of urine associated with a strong desire to urinate. Normally, bladder muscles accommodate slow filling by expanding. As the bladder fills, nerve receptors are stimulated which send messages to the brain. Around the age of 2, a child learns how to suppress the bladder's signals until an appropriate time to urinate. For those with urge incontinence, the bladder may contract inappropriately at any time during filling.

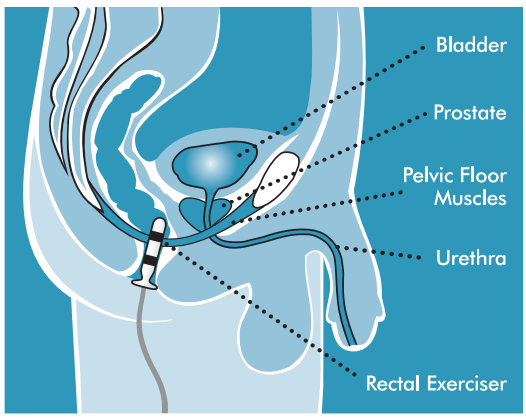
Mixed Incontinence

Mixed Incontinence is a combination of stress and urge incontinence.

PELVIC FLOOR STIMULATION (PFS) FOR INCONTINENCE

PFS for the treatment of Incontinence is not new, having been applied in useful therapy since the 1960s. It is clear from years of clinical study and experience that electrostimulation of the pelvic floor nerve and muscle tissue has therapeutic effects for stress, urge, and mixed incontinence. Numerous studies have reported that more than 70% of patients are improved or cured.





Pelvic floor exercises (Kegel exercises) are often prescribed for patients to enhance control of urination. PFS magnifies the beneficial effect of pelvic floor exercise. One major benefit of electrostimulation is that, unlike exercise therapy, the correct muscles are always exercised. This therapy also permits treatment of patients who do not have enough muscle strength to correctly perform exercises at all.

Studies have suggested that low frequency and low intensity PFS

tends to be effective in calming the involuntary muscle contractions, offering therapeutic effects for urge incontinence. Higher frequencies with higher intensity are associated with strengthening pelvic floor muscles. Patients also experience more muscle awareness, thus helping them learn correct pelvic floor exercises.

THE LIBERTY SYSTEM FOR YOU

The Liberty System is a pelvic floor electrostimulation device for the treatment of urge, stress, and mixed urinary incontinence in women and men. The treatment consists of intermittent stimulation of the pelvic floor nerve and muscle tissues using a tampon shaped exerciser inserted into the vagina or a smaller exerciser inserted into the rectum. The treatment program will be tailored by a medical professional to address your needs. The results you receive are dependent on your compliance with this program.

Using Liberty

The initial placement and treatment are completed under medical supervision. You should read and follow the Instructions for Use included with the system before continuing your self administered sessions.

To determine if PFS therapy using Liberty is appropriate for you, contact your medical professional for more information.

GUIDELINES FOR SELECTION

Liberty PFS therapy may be appropriate for you if:

- You have good general health, both mentally and physically.
- You experience stress incontinence not associated with intrinsic sphincter deficiency.
- You experience urge incontinence due to detrusor instability or of idiopathic (unknown) origin.
- You experience mixed incontinence.
- You have normal menstrual cycles and are not pregnant or attempting to get pregnant.
- Your vagina is anatomically normal and free of any infections or lesions.
- You do not have a cardiac pacemaker or a history of abnormal heart rhythm or conductive disturbances.
- You do not have a history of urinary retention or current symptoms.
- Your nervous system permits you to accurately feel the level of electrostimulation.
- You are able to understand and demonstrate understanding of the use of the Liberty System.

In order to receive the maximum benefit, you must be comfortable with the treatment and be willing to comply with the therapy plan prescribed for you.

For Product & Ordering Information, contact
1 (800) 533-4984
or
www.LibertyFromIncontinence.com

Utah Medical Products, Inc.
7043 South 300 West
Midvale, Utah 84047
800-533-4984 ◆ 801-566-1200
Fax: 801-566-2062

pn 58222 rev 122718

ORDER FORM

Utah Medical Products, Inc.
Phone: 1-800-533-4984 — Fax: (801) 566-2062

Patient Information

Name | Date of Birth (mm/dd/yyyy)

Address | Phone #

City | State | Zip

e-mail

Prescription Information

I am prescribing: The Liberty® PFS System (PFS-200) with:

- ☐ **Vaginal Exerciser (PFS-041)**
- ☐ **Extended Handle Vaginal Exerciser (PFS-042)**
- ☐ **Rectal Exerciser (PFS-043)**

HCPCS Code: E0740

Diagnosis: ☐ Urge Incontinence ☐ Stress Incontinence ☐ Mixed Incontinence ☐ Pelvic Floor Dysfunction ☐ Other_____

Physician Signature | Prescribing Physician's Name | Date

X _____

Physician Address | Phone #

Ship to Address | City | State | Zip

Ship to the Attention of | Date Needed: | Phone #

Prescriber's primary contact | Phone # | Email

Patient Purchase Agreement

With my signature and initials below, I agree:

1. That my order for the Liberty System is subject to shipping/handling charges and state tax (if applicable).
2. Patient Initials _____ Payment must be made in full before the Liberty System can be shipped.
3. If I have insurance or Medicare, that **a) I am authorizing payment in full for purchase of the Liberty system, b) I am completely responsible for making the insurance claim with my insurance company/Medicare, and c) UTMD is not responsible for any difference between the cost of the system and insurance reimbursement I may receive or for any insurance coverage denial.**
4. Patient Initials _____ The Liberty PFS-200 system ONLY may be returned within 30 days of shipment to be eligible for refund, and only if pre-arranged with UTMD, with the exception that the Liberty Exerciser Probes (PFS-04x) are not eligible for return or refund.
5. Insurance/Medicare benefit eligibility and quotes provided to me by UTMD are **NOT** a guarantee of coverage and/or reimbursement and/or payment.

☐ Visa
☐ Master Card
☐ Discover
☐ American Express

Card # | Expiration Date

Name on Card: | CVV:

I understand and agree to the Patient Purchase Agreement above and authorize my credit card to be charged accordingly.

Patient Signature | Date

X _____

Liberty®
UTAH MEDICAL PRODUCTS INC.

LIBERTY® LETTER OF MEDICAL NECESSITY

The following information documents the medical necessity for the treatment and purchase of Liberty® products. IT IS ONLY REQUIRED FOR MEDICARE ORDERS AND SUBMISSION TO PRIVATE INSURANCES WHEN MAKING A CLAIM. This form must be completed and signed by the patient's attending physician to be valid.

Utah Medical Products, Inc. ◆ 7043 South 300 West ◆ Midvale, Utah 84047 ◆ 1-800-533-4984

PATIENT INFORMATION

Name _____ Date of Birth _____

Address _____ Phone # _____

MEDICAL NECESSITY INFORMATION

ICD-10-CM Diagnosis Codes

LIST IN ORDER OF RELEVANCE (enter primary Dx first):

1 _____ 4 _____

2 _____ 5 _____

3 _____ 6 _____

Typical codes for reference

N39.3	Stress Incontinence (Female or Male)
N39.41	Urge incontinence
N39.42	Incontinence without sensory awareness
N39.45	Continuous leakage
N39.46	Mixed incontinence
N39.490	Overflow incontinence
N39.498	Other specified urinary incontinence
R15.9	Fecal incontinence
R32	Unspecified urinary incontinence
R39.81	Functional urinary incontinence
R39.89	Other symptoms and signs involving the genitourinary system
N31.9	Neuromuscular dysfunction of bladder, unspecified
N32.8	Other specified disorders of bladder
N36.4	Urethral functional and muscular disorders
N40.1	Enlarged prostate with lower urinary tract symptoms
N94.89	Other specified conditions associated with female genital organs and menstrual cycle
R10.2	Pelvic and perineal pain
M62.40	Contracture of muscle, unspecified site
M62.50	Muscle wasting and atrophy, not elsewhere classified, unspecified site
M62.81	Muscle weakness (generalized)
M62.838	Other muscle spasm
M99.05	Segmental and somatic dysfunction of pelvic region

Liberty® is prescribed to: (check all that apply)
- ☐ Improve urethral closure function
- ☐ Improve urethral sphincter function
- ☐ Inhibit unwanted bladder contractions
- ☐ Inhibit irritable bladder muscle
- ☐ Other: _____
- ☐ Other:

Are the pelvic nerves intact? ☐ Yes ☐ No

Prognosis: ☐ Excellent ☐ Good ☐ Fair ☐ Poor

Anticipated benefit from use: (check all that apply)
- ☐ Increased pelvic muscle strength
- ☐ Increased pelvic muscle coordination
- ☐ Hypertrophy of pelvic floor muscles
- ☐ Decreased urinary leakage
- ☐ Decreased involuntary detrusor contractions
- ☐ Increased voiding interval
- ☐ Neuromuscular re-education
- ☐ Other: _____
- ☐ Other: _____

Is the expected need for the Liberty System at least 13 months? ☐ Yes ☐ No (if NO, how long? _____ months)

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

Documentation demonstrating inadequate progress of PME training must be included with this letter.

Was the trial concluded, and has the patient had an in-office visit with the Ordering Physician, within six months prior to the Date of Signature*? ☐ Yes ☐ No

Comments:

Prescribing Physician's Name _____ NPI # _____

PECOS Certified? ☐ Yes ☐ No

Email Address _____

Facility ID number: _____ Phone _____

I certify that the medical necessity information provided on this form is accurate and complete to the best of my knowledge.

Physician Signature ***(Medicare no longer accepts signature stamps)*** *Date of Signature

X _____