

a self-inserted, intraurethral product for immediate control of stress urinary incontinence



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introduction

Urinary incontinence (the involuntary leakage of urine) is a medical problem that impacts the lives of approximately 13 million Americans and currently costs approximately \$15 to \$24 billion annually.^{1,2} Women are affected by urinary incontinence (UI) twice as frequently as men,³ and it is not a problem only among older women, as is often assumed. In women between the ages of 15 and 64 years, the incidence of UI can be as high as 30%.¹ Active women in this age range can find their activities restricted and their overall quality-of-life substantially limited by UI.

Underreported, underdiagnosed - Although UI is common, it remains underreported and underdiagnosed, because of factors such as patient embarrassment and lack of physician inquiry. Another reason UI often goes undiagnosed is that it is frequently considered a normal and unavoidable part of the aging process. Although this perception remains prevalent, health care professionals now know that UI can often be cured or alleviated.²

Management guidelines - The Agency for Health Care Policy and Research (AHCPR) has published guidelines on managing incontinence that include a detailed evaluation checklist and initial care recommendations. The evaluation checklist includes taking a history, performing functional and environmental assessments, assessing voiding diaries, and performing a physical examination.¹

Treatment Options - Women no longer have to suffer silently as UI deteriorates their quality-of-life. Today there is a wide range of treatment options that can help women avoid the economic, social, psychological, and physical consequences of UI. With your help, a woman can make the choices that best suit her lifestyle and condition.

Types of urinary incontinence - There are three main types of UI, designated according to such symptoms as stress, urge, and overflow. Often, women will present with more than one type of UI.

- *Stress incontinence* occurs during coughing, sneezing, laughing, or other physical activities that increase intra-abdominal pressure.¹
- *Urge incontinence* is associated with the involuntary loss of urine, accompanied by an abrupt and strong desire to urinate.¹
- *Overflow incontinence* is the involuntary loss of urine associated with overdistention of the bladder.¹

Stress urinary incontinence (SUI) - SUI presents as the involuntary loss of urine during coughing, sneezing, laughing, or other physical activities that increase intra-abdominal pressure. Urine loss occurs when intra-abdominal pressure increases in the absence of a detrusor contraction. The most common cause of SUI in women is urethral hypermobility, the significant movement of the urethra and bladder neck during exertion when intra-abdominal pressure is raised.¹

Stress urinary incontinence may also be caused by an intrinsic urethral sphincter deficiency (ISD), a condition in which the urethral sphincter cannot retain urine in the bladder. Such a deficiency can cause urine leakage during stress activities and during activities of minimal exertion. ISD may be congenital in women with myelomeningocele, epispadias, or pelvic denervation or it may be acquired following trauma, radiation therapy, or a sacral cord lesion. Multiple surgical procedures, estrogen depletion, and advanced age are also associated with ISD.¹

Stress urinary incontinence can have a strong negative impact on a woman's life. Because of discomfort, shame, or fear of embarrassment, a woman with SUI may not exercise as much or socialize with friends and family as much as she would like. These restrictions can affect her physical and emotional health and result in depression, anxiety, a reduced sense of self-worth, and withdrawal from society.⁴ She may become preoccupied with urinary odor and wetness to the point of obsession. She may experience skin breakdown, urinary tract infections, and urosepsis; in short, her entire quality of life may be disrupted by SUI.

treatment options for SUI

Fortunately, there are a number of treatment options available to women with SUI. These options are divided into four main categories: behavioral, device, pharmacologic, and surgical. Patients often prefer nonsurgical options to help them control their incontinence. A recent study demonstrated that 67% of patients who were asked to choose between behavioral techniques, pharmacologic agents, and surgery chose nonsurgical treatments.⁵

Treatment options vary in risk, efficacy, and outcome. After discussing the benefits and risks of each option with your patient, prudent care dictates the least invasive option with the fewest potential side effects that is appropriate for her.¹ Often, simple behavioral measures can substantially reduce the level of incontinence.

The discussion that follows is not meant to be exhaustive but rather to serve as an overview of current therapeutic information. For a more thorough discussion, please consult the guidelines published by the AHCPR .

Behavioral techniques - First-line therapy for women with SUI includes simple, noninvasive behavioral methods. Behavioral SUI management options include bladder training and pelvic muscle exercises (Kegel exercises), which can be enhanced by biofeedback, vaginal cones, and electrical or magnetic stimulation. These management techniques are thought to work by increasing pelvic muscle strength and endurance.²

Devices - Currently available devices are either intravaginal supports, occlusive devices, or intraurethral prostheses.

- *Intravaginal supports*: Common types of intravaginal devices include the continence ring and the bladder neck support prosthesis. Patients require individual fittings for these devices and training on how to insert and remove them properly.
- *Occlusive devices*: Single-use occlusive devices include self-adhesive patches and silicone-domed caps that fit over the external urethral meatus.

- *Intraurethral prostheses:* The *FemSoft* Insert is a small, single-use, liquid and silicone device that a woman can easily insert into her urethra. The latex-free insert consists of a narrow silicone tube, completely encapsulated by a soft, comfortable, fluid-filled sleeve. As a woman inserts the device, the sleeve slides into and conforms to the urethra, creating an effective seal at the neck of the bladder to prevent unintended urine leakage. Women require individual fittings for the *FemSoft* Insert and training on how to insert and remove it properly.

Pharmacologic agents - Pharmacologic interventions work best when they are used in conjunction with other behavioral treatments.³ Drug therapy for SUI works by increasing striated and/or smooth muscle tone, thereby augmenting urethral muscle strength and resistance. For patients with SUI, two pharmacologic agents are recommended by the AHCPR: alpha-adrenergic agents (phenylpropanolamine, pseudoephedrine, ephedrine, epinephrine, and norepinephrine) and estrogen replacement agents.¹

Surgical approaches - When nonsurgical approaches have failed, surgery may be indicated. Matching patients to the appropriate surgical technique is of the utmost importance. Prior to surgery, patients should receive a thorough clinical evaluation that includes estimating surgical risk, confirming diagnosis and symptom severity, and appraising the probable impact of surgery on the patient's quality of life.⁵

For women with urethra and bladder neck hypermobility who have SUI, the AHCPR recommends retropubic or needle suspension rather than anterior vaginal repair. For women with SUI who have ISD, the AHCPR recommends a sling procedure if there is coexisting hypermobility; if there is no hypermobility, the AHCPR recommends periurethral bulking injections. Artificial sphincters are sometimes used for women with ISD, although this procedure is associated with a high complication rate and is not usually recommended.¹

The logo for FemSoft insert is located in the bottom right corner of the page. It features the brand name "FemSoft" in a stylized, blue, serif font with a registered trademark symbol (®) to the upper right. Below "FemSoft", the word "insert" is written in a smaller, blue, sans-serif font. The entire logo is enclosed within a light green, rounded rectangular border.

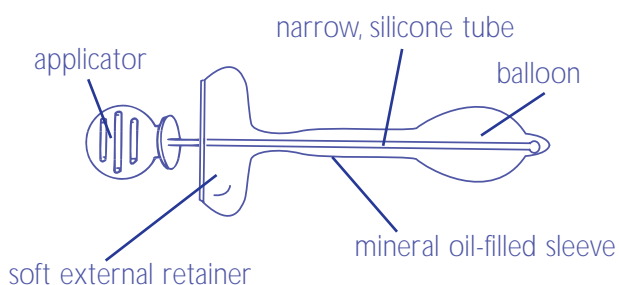
FemSoft[®]
insert

the FemSoft Insert

The *FemSoft* Insert is a self-inserted, intraurethral product that provides an immediate return of control to women suffering from SUI. A sterile, single-use product, the *FemSoft* Insert is safe, easy to use, and worn comfortably until the user is ready to urinate. It is then easily removed for voiding. A new one is then inserted if continued protection from leakage is desired.

Description - The *FemSoft* Insert consists of a narrow silicone tube entirely encased in a soft, thin, mineral oil-filled sleeve. The sleeve, also silicone, forms a balloon on its tip. On the opposite end, the tube and sleeve join to form the soft, oval-shaped external retainer of the insert. A disposable applicator is used to provide a means for insertion.

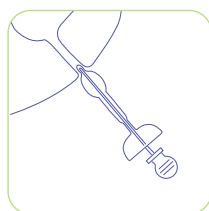
To protect delicate tissue, the *FemSoft* Insert is smooth and seamless, with no hard surfaces. Its unique design allows a woman to insert and remove the product without operating any valves or other mechanisms.



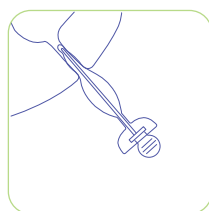
Function - The unique characteristics of the mineral oil-filled sleeve provide the mechanism for insertion and retention of the *FemSoft* Insert. As the insert is advanced into the urethra, the encased fluid is transferred toward the external retainer to facilitate the insert's passage through the urethra. Once the tip of the *FemSoft* Insert

has entered the bladder, the fluid returns to fill the balloon, creating a seal at the bladder neck and urethra. This transfer of fluid occurs automatically, eliminating the need for any manipulation by the user.

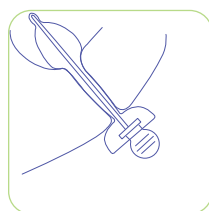
The fluid-filled sleeve readily adjusts to anatomical variations among women. It further adjusts to changes in urethral shape that occur with body movement and/or changes in intra-abdominal pressure. This feature allows the insert to maintain constant contact with the urethral tissues, thereby preventing urine leakage while protecting delicate tissue from trauma, abrasion, or excess pressure.



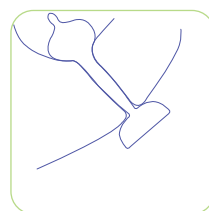
Tip inserted



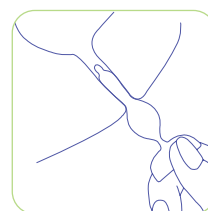
Insertion proceeds



Advanced into bladder



Applicator removed



Withdrawal

Sizes - To meet individual anatomical needs, the *FemSoft* Insert is available in six configurations, including three diameter sizes and two lengths in each size.

Packaging - Each *FemSoft* Insert comes in a sterile, single-use package that fits discreetly in a purse or pocket. The *FemSoft* Insert is supplied ready to use, on a disposable applicator and with lubricating gel.

Contraindications - Use of the *FemSoft* Insert is contraindicated in women who:

- Have an active bladder or other urinary tract infection
- Have a history of urethral stricture, bladder augmentation, pelvic radiation, or other anatomic or pathological conditions where passage of a catheter through the urethra is not clinically advisable
- Are immunocompromised, or have a prosthetic heart valve or other implanted devices, or have any other conditions which make the patient at significant risk from urinary tract infection
- Have interstitial cystitis, pyelonephritis, or a history of severely compromised urinary tract mucosal tissue
- Cannot tolerate any form of antibiotic treatment
- Are currently receiving anticoagulation therapy
- Have overflow incontinence or neurogenic bladder

Adverse events, complications, and risk factors - Adverse events known to occur with use of the *FemSoft* Insert include:

- Urinary tract infection
- Bacteriuria, pyuria
- Migration of the insert into the urethra or bladder
- Irritation or injury of the urethra or bladder
- Bleeding, hematuria, microscopic hematuria
- Pain or bladder spasm
- Periodic expulsion or inability to retain the *FemSoft* Insert
- Silicone sleeve breakage, resulting in the release of mineral oil into the bladder, urethra, or external genitalia

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*clinical
data*

The safety and efficacy of the *FemSoft* Insert for management of female SUI were evaluated in a multisite, nonrandomized, observational clinical trial using each participant as her own control. Eight clinical centers participated in the trial.

Trial design - Each participant was evaluated during a six-week screening period to determine whether she met the trial inclusion criteria. Evaluations during the screening period consisted of physical examination, cystoscopy, cystometry, abdominal leak point pressure (aLPP), urinalysis, and urine culture. Exercise pad-weighting tests, voiding diaries, and quality-of-life questionnaires were also incorporated in the screening process. Women meeting the trial inclusion criteria after the completion of the screening period were enrolled in the study.

During the follow-up period women used devices as desired to manage their incontinence. During the first year, follow-up visits were conducted every three months. In year two, follow-up visits were conducted every four months. Follow-up efficacy evaluations included repeat voiding diaries, exercise pad-weighting tests, and satisfaction and quality-of-life questionnaires. Urinalyses, urine cultures, cystoscopies, cystometries, and aLPPs were used to assess safety. All adverse events occurring throughout the trial were documented.

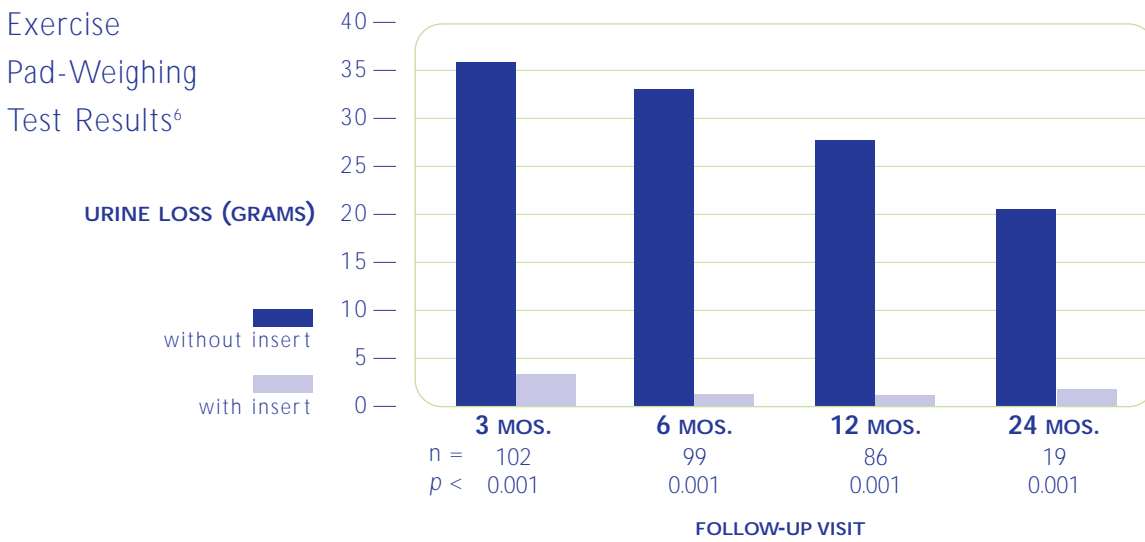
Study population - One hundred fifty women were enrolled in the trial. The average age of participants was 53.5 years (range 27 to 78 years). The average duration of SUI in participants was 10.9 years (SD 8.3, range 1 to 40 years). Forty-eight percent of the participants had urgency symptoms in addition to SUI. Severity of SUI for the group ranged from severe to mild.

Sixty-six percent of participants were postmenopausal, and 34% were premenopausal. Use of the *Femsoft* Insert was not evaluated in pregnant women. Sixty-seven women withdrew from the trial for the following reasons: difficulty with device insertion, lost to follow-up, protocol too demanding, personal reasons, unwilling to continue after urinary tract infection or recurrent urinary tract infection, unable to retain device or bladder spasm.

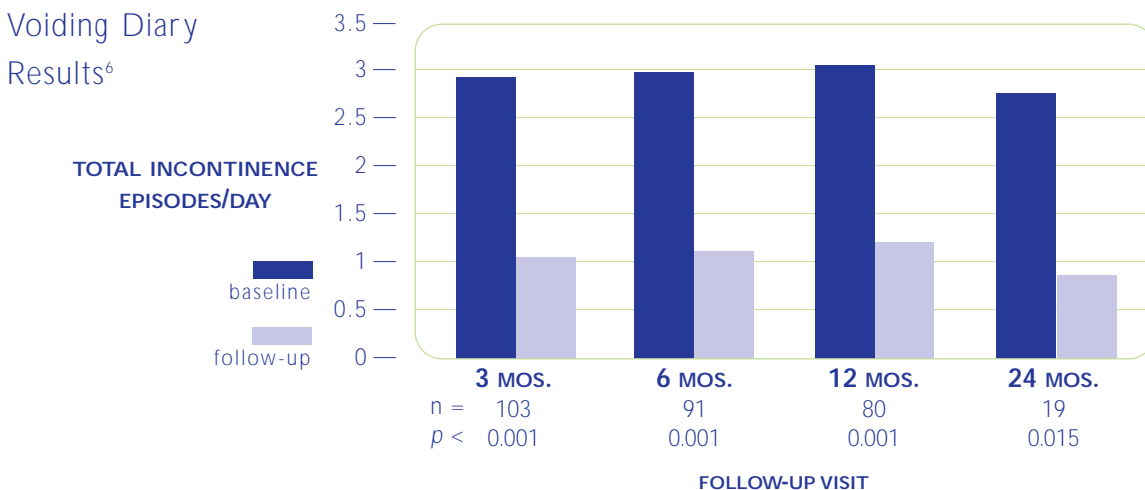
Results - Follow-up results include evaluations from 114 women at three months, 102 women at six months, 87 at 12 months, and 22 at 24 months. Average follow-up for participants was 14.6 months (SD 8.3).

FemSoft efficacy

exercise pad-weighing tests. Results of the exercise pad-weighing tests with and without a FemSoft Insert in place show that the device is highly effective in controlling urine leakage. Women at all follow-up visits achieved statistically significant reductions in leakage with the insert in place compared to times when the insert was not in place. Results for each study period are shown in the graph below.

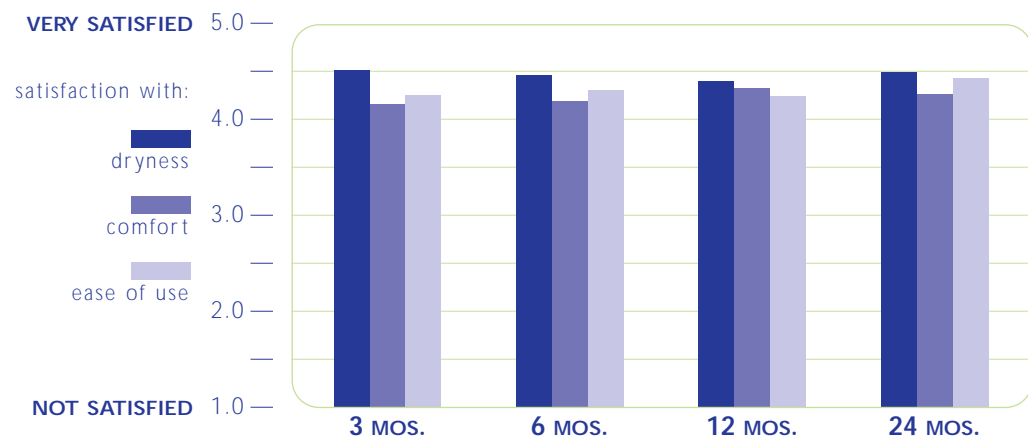


voiding diaries. Voiding diaries kept throughout the trial supported a comparison of the numbers of SUI episodes between screening and follow-up periods and between periods of use and nonuse of the insert during follow-up periods. The results show that use of the FemSoft Insert produced statistically significant reductions in the number of SUI episodes at all intervals. Results for each study period are shown in the graph below.



satisfaction. User satisfaction was measured with a device-specific questionnaire. Women rated their satisfaction with ease of use, comfort, and dryness. Throughout the follow-up period, women indicated a high degree of satisfaction with all measures of ease of use, comfort, and satisfaction with dryness. Results for questionnaire categories are shown in the graph below.

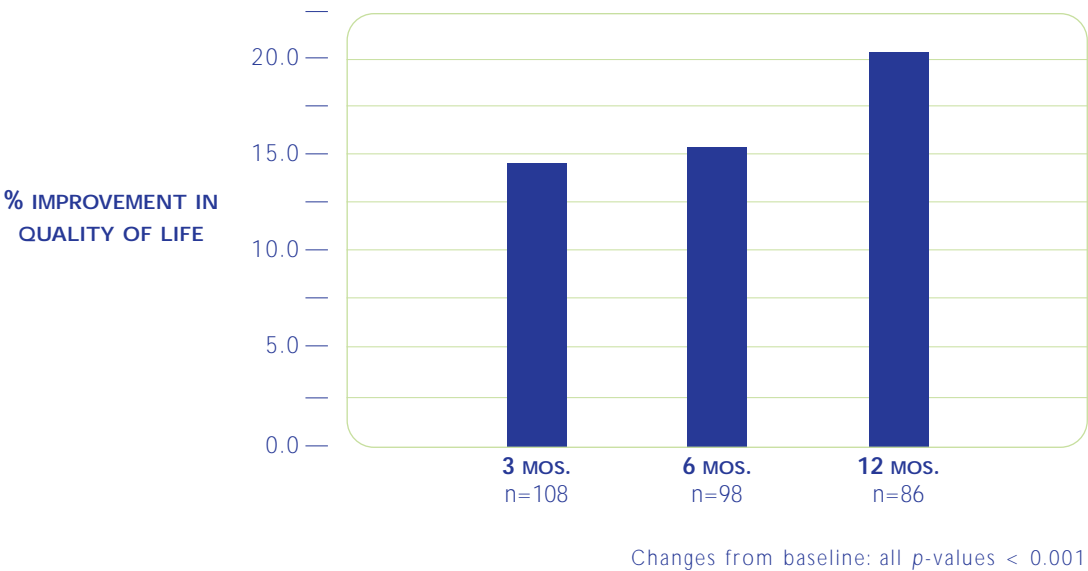
Women's Satisfaction Questionnaire Results⁶



Cohort of women with 12-month follow-up: n = 87
Differences between visits: all *p*-values > 0.524

quality of life. A validated, 22-item, incontinence-specific quality-of-life instrument was used in the trial.⁷ Women scored each item of the instrument using a 5-point rating scale, with a score of 1 being extremely concerned about the incontinence problem and 5 being not concerned at all. Results from the quality-of-life assessment indicated that a statistically significant improvement at all follow-up intervals was achieved ($p < 0.001$).

Quality-of-Life Instrument Results⁶



Complications and adverse events - Adverse events occurred in 99 of the 150 women who participated in the trial. No serious or unanticipated device-related complications occurred during the trial. Rates for individual types of adverse events are shown on the table below.

The most commonly reported complications were UTIs. The risk of UTI was highest in the first 7-day period of product use (29.1%), and dropped to an average rate of 2.9% in subsequent 30-day intervals.

Complications and Adverse Events⁶

* including urgency, frequency, nocturia

EVENT TYPE	TOTAL NUMBER (%) OF SUBJECTS WITH EVENT
• bacteriuria	53 (35.3%)
• symptomatic UTI	45 (30.0%)
• urinary symptoms*	35 (23.3%)
• asymptomatic UTI	10 (6.7%)
• insertion trauma	10 (6.7%)

The following adverse events occurred infrequently ($\leq 6\%$): device performance (sleeve breakage), hematuria, spotting, bladder/urethral trauma or irritation (cystoscopic evaluation), migration.

Study conclusions - The results of the clinical study demonstrate that the *FemSoft* Insert is safe and effective for use by adult women with SUI and mixed stress and urge incontinence.

- The clinical data indicate that the insert is effective in returning control of involuntary urine loss in women with SUI, as demonstrated by the results of pad-weight testing and voiding diaries.
- Women reported a high degree of satisfaction with ease of use, comfort, and dryness when using the insert.
- A statistically significant improvement in women's quality-of-life while using the insert was demonstrated using a validated, incontinence-specific quality-of-life instrument.
- No serious or unanticipated insert-related complications occurred during the trial. Adverse events were within the rates and severity anticipated for the device type.
- The risk of urinary tract infection was low, despite a high number of device insertions (>77,000). The urinary tract infections that occurred were readily treated with a short course of antibiotics.
- Reports of trauma to the tissues of the external genitalia, urethra, and bladder were infrequent, mild in nature, and resolved without the need of treatment.
- Results of numerous microscopic urinalyses for the presence of red blood cells and numerous cystoscopies rarely revealed abnormal findings related to the use of the insert, further demonstrating the absence of trauma to tissues caused by the device.
- There was no evidence suggesting a worsening of SUI.

patient evaluation,
education, and
follow-up

Pre-treatment evaluation of incontinence - In accordance with the AHCPR recommendations, a basic evaluation including history, physical examination, post-void residual urine, and urinalysis should be completed before initiation of treatment for SUI. If indicated by the results of the basic evaluation, a more extensive work-up may be appropriate.

Before initiating treatment, women should be counseled on all the available management options and the associated risks and benefits of each. The *FemSoft* Insert *Instructions for Women* guides the explanation of potential adverse effects and their signs and symptoms. Women should also receive instructions on proper actions to take if any adverse events occur.

Educational support - Successful use of the *FemSoft* Insert depends largely on proper patient education, training, and monitoring by a sensitive and qualified health care professional. Women who participated in a *FemSoft* Insert clinical study identified the two most important factors in their success in using the insert as the initial instruction provided by the clinical staff and being able to subsequently contact the clinical staff with questions.

A comprehensive education program is available to ensure that using the *FemSoft* Insert becomes an easy, comfortable way to control SUI for both women and their physicians. The *Instructions for Women* provides a review of precautions and guides women in the correct insertion technique. A brief instructional video, an anatomical model, and sizing guidelines are also available. In addition, women can use a toll-free line to contact the *FemSoft* Resource Center with questions.

Education and training should consist of the following:

1. A review of the anatomy using an anatomical model.
2. A demonstration of insertion and removal techniques using an anatomical model.
3. Insertion and removal in the woman's urethra while she uses a mirror to observe.
4. Having the woman insert and remove the device herself (using a mirror if necessary) while observing and coaching her.

Recommended follow-up - Recommended follow-up procedures for women using the *FemSoft* Insert include scheduling each woman for a return visit seven to 14 days after her initial training session.

- Interview the woman to determine whether there have been any difficulties with product insertion and removal.
- Look for any signs and symptoms of adverse events and ask whether any leakage has occurred with the insert in place.
- Adjust the size of the insert appropriately if there are reports of leakage and/or discomfort.
- Provide additional training on device insertion and removal, if necessary.
- Reiterate and review potential adverse events and safety and prevention measures.

Thereafter, women should be periodically evaluated to determine the status of their incontinence and their satisfaction and success with the use of the *FemSoft* Insert.

conclusion

Stress urinary incontinence is a problem that affects women of all ages, many of whom restrict their activities and limit their lifestyles. New solutions are available that can successfully control SUI without surgery or medications. One of the most exciting is the new *FemSoft* Insert, which offers women the opportunity for self control. This soft, comfortable urethral insert instantly prevents urine leakage. Constructed of soft, biocompatible silicone and surrounded by a mineral oil-filled sleeve, the *FemSoft* Insert gently conforms to urethral tissue, minimizing tissue trauma.

Clinical data demonstrate that the *FemSoft* Insert is safe and highly effective. The product also earned a high degree of satisfaction and acceptance among the women using it to manage their stress or mixed (stress and urge) incontinence. In fact, over 95% of women who used the *FemSoft* Insert reported they would recommend it to a friend.

No serious or unanticipated device-related complications occurred during the *FemSoft* Insert clinical trial. Adverse events were within the rates and severity anticipated for the device type. The most common events were bacteriuria and urinary tract infections.

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8. *FemSoft* Insert *Instructions for Physicians* (p/n 8000015), Rochester Medical Corporation, 1999.

See *Instructions for Physicians* for a complete list of references.

CAUTION: USA (Federal) law restricts this device to sale by or on the order of a physician trained in the management of urinary incontinence.

INDICATIONS: The *FemSoft* Insert is indicated for the management of stress urinary incontinence in adult females.

CONTRAINDICATIONS: Not for use in women with bladder or other urinary tract infection (UTI), urethral stricture, bladder augmentation, pelvic radiation, or conditions where urethral catheterization is not clinically advisable, immunocompromised, at significant risk from UTI, interstitial cystitis, pyelonephritis, severely compromised urinary mucosa, unable to tolerate antibiotic treatment, on anticoagulants, overflow incontinence or neurogenic bladder.

WARNINGS/PRECAUTIONS: Patient education and monitoring by a qualified professional is required for safe use. History of frequent UTI may increase risk of UTI. Continuous 24-hour use increases the risk of complications. Replace every 6 hours to reduce UTI risk. Discontinue for urinary, vaginal, venereal infection; hematuria; bleeding; abrasion, irritation of the bladder, urethra, urethral meatus. Mental impairment may reduce ability to use safely. Safety and efficacy have not been evaluated in pregnant women or with long term use. Use of improper size could result in migration or discomfort. Do not use during sexual intercourse.

ADVERSE EVENTS, COMPLICATIONS AND RISKS: The following adverse events have been reported with use of the device. Bacteriuria 29%, symptomatic UTI 25%, urinary symptoms 23%, asymptomatic UTI 7%, insertion trauma 6%, bladder/urethral trauma/irritation 3%, hematuria, spotting, vaginal yeast infection, back pain, migration, pyelonephritis (possibly related to pre-existing renal stones) less than 3%.⁹



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5,906,575; Patents Pending.

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