



INSTRUCTIONS FOR WOMEN

DESCRIPTION AND INTENDED USE

Approximately 10-25% of adult women experience urinary incontinence. One common type of urinary incontinence is stress incontinence. In stress incontinence urine leakage can occur without warning when there is a sudden rise in pressure on the bladder such as when coughing, sneezing, walking, exercising, or lifting. Many factors can cause stress incontinence, most commonly hormonal changes that occur during menopause and weak pelvic floor muscles, usually a result of pregnancy and childbirth.

The *FemSoft*® Insert is a disposable, single use device intended for use by adult women with stress urinary incontinence to regain control of accidental leakage of urine. Simply placing the *FemSoft* Insert in a woman's urethra as shown in Figure 1 helps prevent accidental leakage.

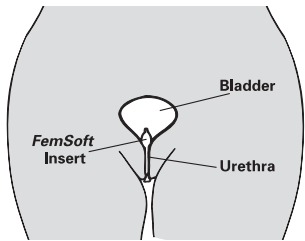


Figure 1.
FemSoft Insert Positioned In Urethra

To urinate, the *FemSoft* Insert is removed and a new one is inserted after urination.

For some women the *FemSoft* Insert may only be needed for vigorous activities (for example, aerobics or tennis). Others may use it every day during typical daily activities such as housework, shopping, social activities or on the job. The *FemSoft* Insert should only be used when needed.

The *FemSoft* Insert, shown in Figure 2, is covered with a thin silicone sleeve filled with mineral oil. The sleeve makes it soft and comfortable. The softness of the *FemSoft* Insert allows it to conform to the anatomy of the urethra and the junction of the urethra and bladder to prevent urine leakage.

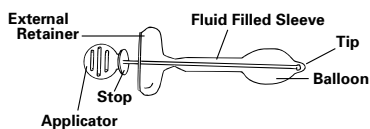


Figure 2. *FemSoft* Insert

The *FemSoft* Insert is supplied installed on an "applicator" for ready use. When the *FemSoft* Insert is in place in the urethra a "balloon" holds it in position. To remove the *FemSoft* Insert, a woman simply grasps the "external retainer" and pulls it out slowly and gently.

DO NOT use the *FemSoft* Insert if:

- You currently have a bladder or urinary tract infection.
- You currently have or previously have had scarring or narrowing of the urethra (urethral stricture), surgery to enlarge the bladder (bladder augmentation), x-ray treatments to the pelvic area for cancer (pelvic radiation), or other conditions where passage of a catheter through the urethra is not clinically advisable.
- You have ongoing conditions related to the urinary tract, for example chronic, painful bladder inflammation (interstitial cystitis), compromised urinary tract tissue, poorly functioning (neurogenic) bladder, overflow incontinence, kidney stones, bleeding, etc.
- You are not able to fight an infection (immuno-compromised), have an artificial heart valve or other implanted device (e.g., breast implant or artificial joint) or have any other condition that puts you at an increased risk from an infection.
- You are allergic to or cannot take any form of antibiotic medication.
- You are currently taking a blood-thinning medication.

Temporarily STOP USING the *FemSoft* Insert and CONTACT your clinician if:

- A bladder or other urinary tract infection is present (see 'When to Contact Your Clinician' below).
- Any type of vaginal or venereal infection is present.
- You notice any unusual bleeding from the vaginal area (that is not menstrual) or blood in your urine.
- You know or think you are pregnant.

If any of these conditions occur, your clinician will let you know when it is safe to start using the *FemSoft* Insert again.

CAUTION

If you are pregnant or think you are, call your clinician as soon as possible to talk about whether you can use the *FemSoft* Insert. Use of the insert has not been studied during pregnancy, and its effects are unknown.

If you have any other questions about whether you should use the *FemSoft* Insert, ask your clinician.

WARNINGS and PRECAUTIONS

Rx Only: U.S.A. (Federal) law restricts this device to sale by or on the order of a clinician trained in the management of urinary incontinence.

Using the *FemSoft* Insert incorrectly can cause infection, irritation, or injury. Also, if you frequently had urinary tract infections in the past, you might have an increased risk of infection with use of the *FemSoft* Insert. Here are some important points to remember to help you use the *FemSoft* Insert correctly.

To prevent infection:

- WASH** hands thoroughly with soap and water prior to handling a *FemSoft* Insert.
- DO NOT** use a *FemSoft* Insert if the package is open or damaged prior to use.
- DO NOT** use a *FemSoft* Insert if it has been contaminated (touched or dropped) prior to use.
- DO NOT** re-use a *FemSoft* Insert.
- CHANGE** the *FemSoft* Insert and empty your bladder when you feel the need to void and at least once every 6 hours. The *FemSoft* Insert is not intended to prevent normal urination.
- DO NOT** use the *FemSoft* Insert for 24 hours every day, as this will increase the risk of complications such as infection. Remove at night for sleep.
- DRINK** an adequate amount of fluids when using the *FemSoft* Insert. Normally a person should drink 6-8 glasses of water a day.

To prevent irritation or injury:

- DO NOT** force the *FemSoft* Insert on insertion.
- DO NOT** use the *FemSoft* Insert during sex.

Before using the *FemSoft* Insert you should read this entire booklet to ensure a full understanding of the correct use and the potential complications that can occur. You should also receive personal instructions from your clinician to help you learn how to insert and remove the device and about the complications that can occur.

POTENTIAL COMPLICATIONS AND RISKS

Potential complications from use of the *FemSoft* Insert are listed below. Some of these could require treatment by a clinician. Other unknown complications could also occur.

- Bacteria in the urine may occur.
- Bladder infection may occur. If left untreated, bladder infection could lead to more serious complications.
- The *FemSoft* Insert could move (migrate) into the tube that drains urine from the body (urethra) or bladder.
- Injury or irritation to the urethra or bladder may result from use. Injury or irritation may cause bleeding or bloody urine.
- Some women may experience pain or uncontrolled bladder contraction (bladder spasm) during use.
- Some women may not be able to retain the *FemSoft* Insert.
- The silicone sleeve of the *FemSoft* Insert may break resulting in release of mineral oil into the bladder, urethra or external genitalia.

WHEN TO CONTACT YOUR CLINICIAN

The following guidelines will help you decide what to do for the common problems that can occur with use of the *FemSoft* Insert. If you experience any other problem that you believe is associated with the use of the *FemSoft* Insert, you should discontinue its use and consult your clinician.

Urinary Tract Infection

Discontinue use of the *FemSoft* Insert and promptly contact your clinician if you experience signs of a urinary tract infection including burning on urination, foul smelling urine, bloody urine, back pain, pelvic pain, frequent need to urinate during the day or at night, or unexplained fever.

Mild Irritation, Light Spotting of Blood or Discomfort with Insertion or Removal

If these symptoms occur, the *FemSoft* Insert should be discontinued for 1-2 days until the symptoms completely resolve. Use of the *FemSoft* Insert may then be resumed. If the symptoms reoccur frequently or persist 1-2 days after discontinuing *FemSoft* Insert use, contact your clinician.

Persistent Heavy Spotting of Blood or Bloody Urine

Discontinue use and promptly contact your clinician.

FemSoft Insert Migration

If you suspect that a *FemSoft* Insert has moved into your urethra or bladder, first void with a moderately full bladder and check to see if the *FemSoft* Insert was expelled in your urine. If not, contact your clinician.

FemSoft Insert Expulsion or Urine Leakage with a FemSoft Insert in Place

Contact your clinician for an evaluation to determine if you are using the proper technique to insert the *FemSoft* Insert or if the *FemSoft* Insert size should be adjusted.

FemSoft Insert Breakage

The sleeve of the *FemSoft* Insert can break releasing mineral oil into the bladder, urethra or external genitalia. If this occurs, remove the *FemSoft* Insert. Oil released into the bladder or urethra will be expelled with subsequent voiding. Use a tissue to wipe oil from external tissues and insert a new *FemSoft* Insert.

ALTERNATIVE TREATMENTS

Other non-surgical options for managing female stress urinary incontinence include medications, absorbent pads, external devices worn to block the urethra, or pelvic floor muscle rehabilitation using Kegel exercises, biofeedback or electrical stimulation. Surgical options include bladder sling/suspension procedures, injectable bulking agents, and implantation of an artificial urinary sphincter. Studies using these various treatment alternatives have shown a wide range of success rates. For more information about these alternative treatments, contact your clinician.

HOW TO USE THE FEMSOFT INSERT

You should expect that it will take 1-2 weeks to learn to use the *FemSoft* Insert, depending on your frequency of use. **Be patient with yourself while learning to use the *FemSoft* Insert.** For the first week or so, use the *FemSoft* Insert during unstressful periods when you have plenty of time. If you do not understand the instructions, or are having difficulty using the *FemSoft* Insert, consult your clinician for additional training.

Know Your Anatomy:

To properly use the *FemSoft* Insert you will need to understand the anatomy in your genital area to identify the urethra where the *FemSoft* Insert will be inserted. Figure 3 shows the female anatomy.

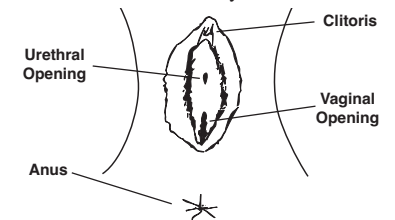


Figure 3.

Anatomy Of The Female Genitalia

Note the location of the opening to the urethra in relationship to the vaginal opening and the clitoris. Use a mirror to locate and become familiar with the location of your own urethral and vaginal openings and clitoris. You may want to use a mirror while you are learning to use the *FemSoft* Insert. With experience, many women will be able to insert the *FemSoft* Insert without a mirror.

Using the FemSoft Insert:

- Use the *FemSoft* Insert during the day when protection is needed from leaking accidents. Remove the *FemSoft* Insert, empty your bladder and replace with a new insert at least once every 6 hours, even if you do not need to urinate. Remove at night for sleep.
- The *FemSoft* Insert is not intended to prevent normal urination. Remove the *FemSoft* Insert when you need to urinate. Insert a new *FemSoft* Insert after urination.
- The *FemSoft* Insert can be used during menstruation if desired. If sanitary pads are used, the *FemSoft* Insert may not be needed during menstruation.

Inserting the FemSoft Insert:

- Wash your hands well with soap and water.
- Empty your bladder.
- Similar to a tampon, the *FemSoft* Insert can be inserted while lying, standing, sitting on the toilet or standing with one foot on the toilet or a stool. Figure 4 (see back) shows some of the different positions that can be used for insertion. Choose the position that is most comfortable for you.

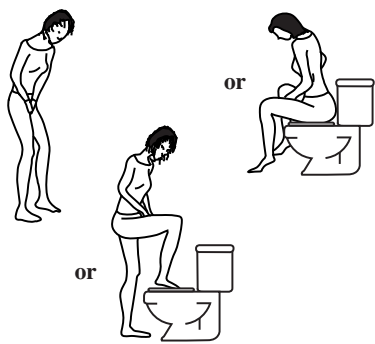
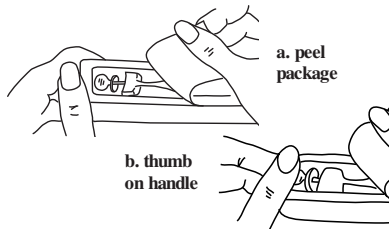


Figure 4. Body Position Choices For Insertion

- The *FemSoft* Insert is supplied in a sterile package and installed on its applicator. Open the *FemSoft* Insert package as shown in Figure 5. Peel the package apart. When package is partially open, put your thumb over the applicator handle to hold the *FemSoft* Insert. Continue to peel cover to completely open package, including the small compartment of lubricating gel.



Figures 5a & b. Peel To Open Package

- Remove the *FemSoft* Insert from the package as shown in Figure 6. Handle the applicator only. Be careful not to touch the outside of the *FemSoft* Insert. **Important: To prevent an infection do not use a *FemSoft* Insert if the insert has been touched or dropped prior to use.**

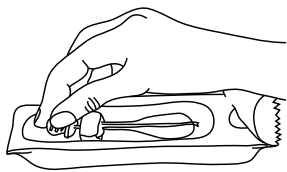


Figure 6.

Handle Applicator To Remove From Package

- Dip the balloon end of the *FemSoft* Insert into the lubricating gel as shown in Figure 7. Cover the entire end of balloon with gel for easier insertion.

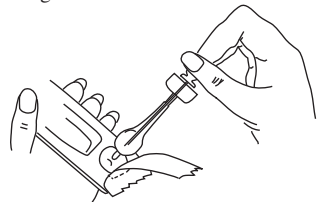


Figure 7. Lubrication Of *FemSoft* Insert

- Pull your clothing away and spread your legs apart. Use one hand to spread your labia and expose the opening to the urethra. Use the other hand to insert the "tip" of the *FemSoft* Insert into the urethra as shown in Figure 8.

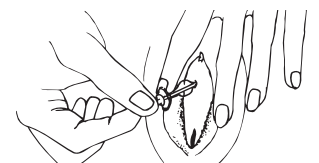
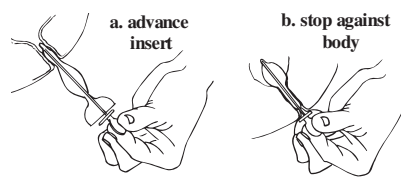


Figure 8. Spread Labia And Insert *FemSoft* Tip Into Urethra

- Use slow, gentle pressure to advance the *FemSoft* Insert into the urethra until the applicator "stop" rests against your body as shown in Figure 9.



Figures 9a & b.
Advance *FemSoft* Insert Into Urethra

Important: To prevent injury never force the *FemSoft* Insert into your urethra. As you slowly advance the *FemSoft* Insert into the urethra, the fluid in the balloon is transferred back towards the stop thus allowing easy passage of the *FemSoft* Insert through the urethra. When the tip of the *FemSoft* Insert enters the bladder, the fluid transfers back to the balloon to hold the *FemSoft* Insert in place.

- Hold the *FemSoft* Insert external retainer against your body while slowly withdrawing the applicator from the *FemSoft* Insert as shown in Figure 10. Discard the applicator.

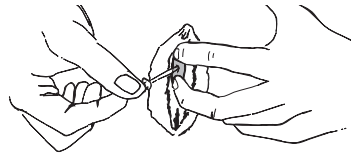


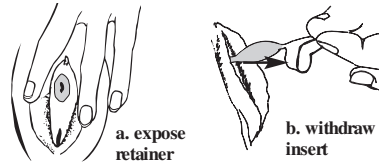
Figure 10. Withdraw Applicator From *FemSoft* Insert

Important: Do not leave the applicator in the *FemSoft* Insert after the insert is placed in your body as this will cause discomfort and may cause injury.

- Use tissue to wipe excess lubricant from the external retainer if you wish.

Removing the *FemSoft* Insert:

- Wash your hands well with soap and water.
- Using one hand spread the labia to expose the *FemSoft* Insert as shown in Figure 11.



Figures 11a & b. Spread Labia To Expose *FemSoft* External Retainer

- If the external retainer is difficult to grasp due to moisture, dry with tissue. Grasp the external retainer of the *FemSoft* Insert. Relax but do not urinate. Pull the *FemSoft* Insert out slowly and gently. Do not hold or squeeze the fluid filled sleeve when removing the *FemSoft* Insert.

Important: To prevent infections do not re-use the *FemSoft* Insert.

SUMMARY OF CLINICAL TRIALS

The *FemSoft* Insert was studied in a clinical trial of 150 women at 8 clinical centers. After being evaluated to determine if they were appropriate candidates to use the *FemSoft* Insert, women used *FemSoft* Inserts as they desired for 1 year. During the year women had repeated evaluations to determine how the *FemSoft* Insert was working and whether any adverse events or complications were occurring.

Fifty-seven women withdrew from the trial during the follow-up period. Of these 57 women, 50 withdrew during the first 3 months. The following reasons were given for withdrawal from the trial; 15 due to difficulty with insertion or general dissatisfaction with the method of incontinence control, 11 were lost to follow-up after failing to keep appointments and respond to contacts, 8 found the study protocol too demanding, 8 for non-device related health problems, 6 due to urinary tract infections, 3 for personal reasons unrelated to the study, 3 because they could not be properly fit with the *FemSoft* Insert, 2 were withdrawn by the investigator for non-compliance, and 1 for bladder spasm.

Complications Reported with the *FemSoft* Insert:

Approximately two-thirds of all women who participated in the trial experienced at least one adverse event while using the *FemSoft* Insert. These were as follows:

Infection: Women gave urine samples at each visit to check for bacteria in the urine. Twenty-nine percent of the women had bacteria in their urine. Twenty-five percent of the women had a urinary tract infection that was treated with antibiotic medications.

Urinary Symptoms: Twenty-three percent of the women reported urinary symptoms such as sensation of needing to urinate (urgency), frequent urination and bladder spasm.

Bleeding: Six percent of the women experienced bleeding when they injured the skin around the opening to the urethra when trying to insert a *FemSoft* Insert. No treatment was necessary and the women were able to resume using the *FemSoft* Insert after 1-2 days. This type of problem usually occurred early when women were still learning how to use the *FemSoft* Insert. In addition, three women had blood in their urine and three noted spotting of blood.

***FemSoft* Insert Problems:** There were nine complaints about the *FemSoft* Insert. These included reports of expelling *FemSoft* Inserts and breaking of the *FemSoft* Insert sleeve with release of the mineral oil. This number reflects 0.01% of all *FemSoft* Inserts used in the study.

Other: The following adverse events occurred infrequently (less than 3%): one woman experienced *FemSoft* Insert migration into the bladder (the insert was removed by cystoscopy); one woman sustained a small scratch in her urethra near the bladder (the scratch was not severe and did not require treatment); and one woman who was known to have stones in her kidney prior to using the *FemSoft* Insert had a kidney infection. (It was uncertain whether the kidney infection resulted from using the *FemSoft* Insert or not.)

Improvements Reported with the *FemSoft* Insert:

To measure how well the *FemSoft* Insert was working, women had a pad test. This consisted of exercising with a full bladder with and without a *FemSoft* Insert in place. During the tests women wore pads that were weighed afterward to determine how much urine the woman had lost during the test. These tests were done at 3, 6 and 12 months after starting to use the *FemSoft* Insert. At each time period the results showed that the *FemSoft* Insert was effective in preventing urine loss with a full bladder. By this test, approximately 9 out of 10 women were dry while using the *FemSoft* Insert.

To further test how the *FemSoft* Insert was working the women kept diaries for a week before each visit, recording the number of leaking accidents they had when they were using a *FemSoft* Insert and when they were not. The results showed a significant reduction in leaking accidents occurring when the *FemSoft* Insert was used compared to when it was not used. The women reported, on average, 1 fewer leakage accident per day when using the *FemSoft* Insert in comparison to when not using the *FemSoft* Insert.

A special questionnaire that measures quality of life was used to see if reducing leaking accidents by using the *FemSoft* Insert improved a woman's overall quality of life. The questionnaires were given before starting to use the *FemSoft* Insert and after. The results showed a significant improvement in the women's quality of life when using the *FemSoft* Insert compared to before using the insert.

Women also filled out a questionnaire about their experience and satisfaction using the *FemSoft* Insert. Questionnaires were filled out at 1 week, 1, 3, 6, 9, and 12 months after starting the *FemSoft* Insert. Results of all questionnaires filled out by women are shown on Tables 1 and 2.

Table 1. Satisfaction And Comfort With *FemSoft* Insert Use

CHARACTERISTIC	AVERAGE SCORE
<i>Ease of insertion</i> (1=very easy, 5=difficult)	2.46
<i>Ease of removing</i> (1=very easy, 5=difficult)	1.33
<i>Comfort while inserting</i> (1=very comfortable, 5=uncomfortable)	2.39
<i>Comfort while wearing</i> (1=very comfortable, 5=uncomfortable)	1.87
<i>Comfort while removing</i> (1=very comfortable, 5=uncomfortable)	1.56
<i>Satisfaction with dryness</i> (1=very satisfied, 5=unsatisfied)	1.53

Table 2. Women's Experience Using *FemSoft* Insert

QUESTION	% YES	% NO
Are there activities where you have decided not to use the <i>FemSoft</i> Insert?	33%	64%
Are you participating in activities you had stopped due to leaking accidents?	36%	63%
Have you worn a <i>FemSoft</i> Insert during sex?	3%	96%
Has a <i>FemSoft</i> Insert accidentally come out?	36%	64%
Do you want to continue to use the <i>FemSoft</i> Insert?	95%	5%
Would you recommend the <i>FemSoft</i> Insert to a friend?	97%	1%



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