FEMSOFT® INSERT
INSTRUCTIONS FOR PHYSICIANS

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

FEMSOFT INSERT DESCRIPTION

The FemSoft® Insert is a sterile, disposable, single use intra-urethral device intended for use in managing female stress urinary incontinence. Fig. 1. It consists of a narrow silicone tube entirely enclosed in a soft, thin, mineral oil filled silicone sleeve. The silicone sleeve forms a balloon on the tip of the Insert. On the opposite end the tube and silicone sleeve join to form a soft funnel called the "external retainer". A disposable plastic applicator is used to provide a means for insertion.

Figure 1.
(Unchanged from 1570188 Draft Rev. F. 05/24/99)

The unique characteristics of the mineral oil filled sleeve provide the mechanism for insertion and retention of the insert. As the FemSoft is advanced into the urethra, fluid in the balloon is transferred toward the external retainer to facilitate passage through the urethra. Fig.2.

Figure 2.
(Unchanged from 1570188 Draft Rev. F. 05/24/99)

Once the tip of the insert is advanced to the bladder, fluid returns to fill the balloon to maintain the appropriate position of the device in the bladder neck and urethra. Movement of fluid occurs automatically in response to pressure applied to the device during insertion or removal. Manipulation of the device by the user is not required.

Once in place, the soft compressible sleeve conforms to the anatomy of the urethra and bladder neck to reduce leakage of urine.

The FemSoft Insert is removed and discarded when the woman wants to void. Afterwards, a new device can be inserted.

The FemSoft Insert is supplied sterile and pre-lubricated. It is available in three diameter sizes (16, 18, 20 Fr.) with two lengths (3.5 and 4.5 cm) for each diameter.

INDICATIONS FOR USE

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

CONTRAINDICATIONS

The 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 pathologic conditions where passage of a catheter through the urethra is not clinically advisable.
- Are immunocompromised, have a prosthetic heart valve or other implanted device, or have any other conditions in which the patient is 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.

WARNINGS/PRECAUTIONS

Patient Related:

- Appropriate patient education, training and monitoring by a qualified health care professional is required for safe patient use. The patient instruction booklet is intended as a supplement to the patient education provided by a health care professional.
- The safety and effectiveness of the FemSoft Insert has not been evaluated in pregnant women and the effects are unknown.
- Patients should be instructed not to use the FemSoft Insert during sexual intercourse. Although a limited number patients reported sexual intercourse while using the device during the clinical study, the safety and effectiveness of this practice has not been demonstrated.
- Patients who present with a history of frequent urinary tract infections (UTIs) should be advised that they may be at increased risk of infection with the use of the FemSoft Insert. Additionally, these patients should be monitored closely for symptoms of UTI during device use.
- The FemSoft Insert is a disposable single use device. Patients should be instructed not to reuse a FemSoft Insert due to the increased risk of infection.
- Patients should be counseled to wash hands and avoid touching the device prior to its insertion , as described in the patient labeling.
- Patients should discontinue use of the FemSoft device and seek medical evaluation if symptoms of possible urinary tract, vaginal, or venereal infection develop. If an infection is diagnosed, the Insert should not be used until the infection has been successfully treated.
- Patients should be instructed to remove the FemSoft Insert at night before going to sleep. Continuous 24-hour use of the FemSoft Insert increases the risk of complications.
- Patients should be instructed to remove the FemSoft Insert and replace at least once every 6 hours to help reduce the chance of UTI. The FemSoft Insert should always be removed when the patient feels the need to void.
- Patients should be instructed not to force insertion of the device due to the risk of injury to the perimeatal area or urethra.
- If the patient reports visible hematuria or bleeding but no other symptoms of UTI, she should be instructed to temporarily discontinue use of the FemSoft Insert. After her symptoms resolve, she can continue using the FemSoft Insert. If her symptoms persist, she should be instructed to contact her physician. If the symptoms recur after resuming device use, she should be instructed to discontinue use of the device and contact her physician.
- Sixteen women (10.6%) had episodes of urethral or periurethral irritation or discomfort, especially during the first few weeks of use. In most of these women the device was temporarily discontinued, the rest continued using the device although they experienced slight discomfort. In another 4 women (2.7%), signs of irritation of the bladder wall were found on routine cystoscopic examinations. No treatment was required for these 4 and they continued to use the device.
- Use of the FemSoft Insert should be discontinued in those patients who develop abrasion of the bladder wall and/or urethral meatus. Device use may be resumed once these conditions are fully resolved.
- Patients with mental impairment (i.e., due to illness, excess alcohol use, excess use of certain medications, or other causes) may have reduced ability to use the device safely.
- The long-term safety and effectiveness of the FemSoft Insert has not been evaluated, therefore continued close patient follow-up is recommended.

Device Related:

- The FemSoft Insert should be properly sized to the patient. Use of improper size could result in device migration or patient discomfort. During the study, one device migrated into the bladder and was removed cystoscopically.
- The FemSoft Insert is provided sterile to prevent infection. Patients should not use a FemSoft Insert if the package is open or damaged or if the device has been contaminated prior to insertion.

ADVERSE EVENTS, COMPLICATIONS AND RISKS

The FemSoft Insert clinical trial enrolled 150 patients, 70 of whom were followed for at least 12 months. Table 1 below reports all of the adverse events observed during the clinical study.

Table 1.
Summary of Adverse Events

EVENT TYPE	NUMBER OF EVENTS/SUBJECT				TOTAL NUMBER OF EVENTS	TOTAL NUMBER (%) OF SUBJECTS WITH EVENT
	1	2	3	4		
Bacteriuria > 10,000 CFU	23	17	3	1	70	44 (29.3%)
Symptomatic UTI	26	8	3	0	51	37 (24.6%)
Urinary Symptoms*	27	6	1	0	42	34 (22.6%)
Asymptomatic UTI	8	2	0	0	12	10 (6.6%)
Insertion Trauma	8	1	0	0	10	9 (6.0%)
Device Performance**	5	2	0	0	9	7 (4.6%)
Bladder/Urethral Irritation (Cystoscopic Evaluation)	5	0	0	0	5	5 (3.3%)

*Including urgency, frequency, nocturia.
**Sleeve breakage.

Other reported symptoms which occurred at rates of <3% in the 150 patients include: hematuria and spotting (2%; n=3 each); vaginal yeast infection (1.3%; n=2); and back pain; migration; and pyelonephritis (possibly related to pre-xisting renal stones) (<1%; n=1).

SUMMARY OF CLINICAL STUDIES

A prospective, multi-center, observational, non-randomized study of the use of the FemSoft Insert in controlling stress urinary incontinence in adult women was carried out at eight clinical sites. Each patient served as her own control.
Study Protocol: The study consisted of a six week screening period during which evaluations included incontinence history, physical examination, urinalysis, urine culture (x 2), pad weight test (x 2), voiding diary (x 2), Quality of Life (QOL) questionnaire (x 2), cystometry, abdominal leak point pressure, and cystoscopy. At the completion of the screening period women who met all of the inclusion and exclusion criteria were enrolled in the 12-month evaluation of the FemSoft device. Follow up evaluations included urinalysis and culture, voiding diary, satisfaction and QOL questionnaire, pad test, abdominal leak point pressure, and cystoscopy.
Study Population: One hundred fifty women were enrolled into the 12-month study using the FemSoft Insert.
Subject Demographics: Mean age of subjects was 53.5 years ranging from 27 to 78 years.
Subject Histories: Duration of urinary incontinence was 10.9 years (SD 8.3) ranging from 1 to 40 years. Ninety-nine women (66%) were postmenopausal and 51 (34%) were premenopausal. The severity of stress incontinence was rated by physicians as mild in 47 (31.3%) subjects, moderate in 84 (56.0%) and severe in 19 (12.7%) women. Seventy-two (48%) of the women reported having urgency symptoms in addition to stress urinary incontinence symptoms; however, all women with mixed incontinence had stress as the primary component.
Follow-up Visits: Follow up visits completed included 109 women at 3 months, 96 at 6 months and 70 at 12 months. Of the 150 women enrolled, 57 withdrew from the study within 12 months. Of these 57 patients, 50 withdrew from the study within the first 3 months. The reasons for patient withdraw from the clinical study include: difficulty with insertion including general dissatisfaction and/or discomfort (n=15); lost to follow-up (n=11); protocol too demanding (n=8); non-device related health reasons (n=8); UTI (n=6); personal reasons unrelated to device (n=3); patient could not be properly fitted (n=3); protocol noncompliance (n=2); and bladder spasm (n=1).
Pad Weighing Tests: Mean baseline urine loss (measured by pad weight) was 40.1 gm (range 2.8 to 258.8 gm). Results of pad weighing tests carried out at the 3, 6 and 12 month follow up visits are shown in Tables 2 and 3. Table 2 shows the overall pad weight reduction for all patients at each follow-up. Table 3 statifies pad weight reduction by

baseline pad weight urine loss since this patient characteristic was determined to have a significant effect on outcome. Statistically significant reductions were seen at all follow up periods. At 3 months, 90% of the patients were dry (< 2 gm urine loss) during pad weighing tests with the device in place.

Table 2.
PAD WEIGHING TESTS

Visit	With Insert	Without Insert	P-value
3 Mo. F/U Avg. Loss gm (SD) N	3.2 (13.1) 100	35.9 (34.2) 100	< 0.001
6 Mo. F/U Avg. Loss gm (SD) N	1.3 (7.1) 98	33.1 (45.3) 98	< 0.001
12 Mo. F/U Avg. Loss gm (SD) N	0.5 (3.3) 68	26.3 (45.8) 68	< 0.001

Table 3.
OBSERVED IMPROVEMENT IN URINE LOSS BY BASELINE SEVERITY

URINE LOSS SUB-GROUPS	3 MONTHS			6 MONTHS			12 MONTHS		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Low (≤ 15 gm)	31	13.04	14.89	32	13.08	14.94	23	5.78	6.49
Moderate (15-36.4 gm)	33	24.40	20.79	34	24.31	20.01	20	27.12	39.22
High (>36.4 gm)	36	57.13	37.55	32	58.18	67.92	25	43.01	61.29

Voiding Diaries:
Using the data from voiding diaries the number of urinary incontinence episodes per day during periods with and without the device were compared. Rates are calculated on the basis of 24-hour days where the number of hours devices were used and urinary incontinence (UI) episodes occurring during device use and non-use were recorded by subjects. Nighttime hours were included as periods of non-use, which tends to artificially lower the frequency of UI during periods of non-use. The average difference in the rate of UI between periods of FemSoft use and non-use across all follow-up periods was statistically significant ($p<0.001$). During the entire follow-up period the average reduction in daily incontinence episodes was 0.81 (SD 1.99). The overall incidence of UI during follow-up was 60% less than that seen during the baseline screening period.

User Satisfaction
User satisfaction with the FemSoft Insert was measured with a self-administered questionnaire. Responses to questions concerning use and satisfaction with the FemSoft Insert are shown in Table 4. There were no discernable trends in average scores by length of follow up.

Table 4.
USER SATISFACTION DATA

Characteristic	Mean Score (SD)
Ease of insertion (1=very easy, 5=difficult)	2.46 (0.97)
Ease of removing (1=very easy, 5=difficult)	1.33 (0.44)
Comfort while inserting (1=very comfortable, 5=uncomfortable)	2.39 (0.84)
Comfort while wearing (1=very comfortable, 5=uncomfortable)	1.87 (0.63)
Comfort while removing (1=very satisfied, 5= unsatisfied)	1.56 (0.53)
Satisfaction with dryness (1=very satisfied, 5= unsatisfied)	1.53 (0.56)

Overall, 95% of patients reported that they would continue using the device.

Quality of Life(QOL)
QOL, as measured using a validated, self-administered, incontinence specific questionnaire[7], improved between the response at baseline and the responses during follow up. There was a statistically significant improvement in QOL score between baseline and each follow up interval $p<0.001$.

PATIENT EVALUATION, EDUCATION AND FOLLOW UP
Pre Treatment Evaluation of Incontinence

In accordance with the recommendations of the Department of Health and Human Services Clinical Practice Guideline for Urinary Incontinence [1] a basic evaluation including history, physical examination, PVR (post void residual urine) and urinalysis should be completed prior to initiation of treatment for urinary incontinence. If indicated by the results of the basic evaluation a more extensive work up may be appropriate.

Prior to initiating treatment women should be counseled on all of the available treatment options and the associated risks and benefits of each.

Patient Education

The cornerstone to a successful result with the FemSoft Insert is thorough patient education and sensitive, readily available support while women are learning to use the device. Women in a clinical study of the device identified the two single most important factors to their success in learning to use the device as the initial instruction provided by the clinic nurse and being able to contact the nurse with questions thereafter.

Using the FemSoft Insert Instructions for Women as a guide, education and training of women should consist of the following:
Device insertion and removal.
1. Review the anatomy using an anatomical model.
2. Demonstrate device insertion and removal using an anatomical model.
3. Use a mirror to assist the women to locate and identify her own urethra.
4. Insert and remove a device in the woman's urethra while she uses a mirror to observe.
5. Have the woman insert and remove the device herself (using a mirror if necessary) while observing and coaching her.

Informing Women of Potential Adverse Events and Complications

Using the FemSoft Insert Instructions for Women as a guide, a thorough explanation of all the potential adverse effects, their signs and symptoms as well as instructions on the actions to take if they occur should be given to the women including:
Urinary Tract Infection
Women should be instructed to discontinue use of the device and promptly contact their physician if they experience signs of a urinary tract infection including burning on urination, foul smelling urine, hematuria, back pain, pelvic pain, atypical frequency or nocturia, or unexplained fever.

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

These are likely related to irritation or trauma resulting from device insertion, particularly during the first few weeks when some women have not yet become adept at insertion of the device. If the above symptoms occur the device should be discontinued until the symptoms completely resolve. Use of the device may then be resumed. If the ymptoms reoccur frequently or persist after 24-48 hours after discontinuing device use women should be instructed to contact their physician.

Persistent Heavy Spotting of Blood or Hematuria

Women should be instructed to discontinue device use and promptly contact their physician.

Device Migration

If a women suspects that a device has migrated into the bladder she should first void with a moderately full bladder and check to see if the device was expelled in the urine. If not she should contact her physician.

Device Expulsion or Urine Leakage with a Device in Place.

Women should contact their physician for an evaluation to determine if the proper technique is being followed to insert the device or if the device size should be adjusted.

Device Breakage

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

Important Safety and Prevention Measures that Should be Reviewed

Using the FemSoft Insert Instructions for Women as a guide, women should be advised of the measures that can be taken to reduce the risk of urinary tract infection including:

- Drinking an adequate amount of fluids.
- Washing hands thoroughly prior to device insertion.
- Not using a device that has been accidentally contaminated prior to use such as by touching or dropping the device.
- Never attempting to reuse a device and never using a device if the package appears opened or damaged.
- Never using the device 24 hours a day.
- Changing the device and emptying the bladder at least once each 6 hours. The FemSoft Insert should always be removed when the patient feels the need to void.
- If a vaginal infection occurs women should be instructed to discontinue device use until the symptoms have completely resolved.

Suggested Patient Follow Up

Schedule the patient for a return visit in 7 to 14 days after the initial training session. Interview the woman to determine if there have been any difficulties with device insertion and removal, any signs and symptoms of adverse events, and if any leakage has occurred with the device in place. Adjust the device size as appropriate for reports of leakage and discomfort. Provide additional training on device insertion and removal if necessary. Reiterate and review potential adverse events, safety and prevention measures.

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

HOW SUPPLIED

FemSoft Inserts are supplied as sterile single use devices available in 6 configurations including 3 diameter sizes with 2 lengths in each size:

Size 1 (16 Fr) in standard (3.5 cm) and long (4.5 cm) lengths
Size 2 (18 Fr) in standard (3.5 cm) and long (4.5 cm) lengths
Size 3 (20 Fr) in standard (3.5 cm) and long (4.5 cm) lengths

The device size is the diameter of the urethral section of the device and the length is the urethral length measured from the external retainer to the balloon.

Physician Sizing Kit

1 Physician Instruction booklet.
Selection of sterile FemSoft Inserts including each of the 3 sizes in both lengths.

FemSoft Insert Starter Kit for Women
1 FemSoft Insert Instructions for Women
10 sterile FemSoft Inserts (one size)
purse case
1 compact mirror

Refills
Box of 28 sterile Inserts of any one size.

INSTRUCTIONS FOR USE
Placing the FemSoft Insert
1. The FemSoft Insert is supplied sterile pre-lubricated and installed on its "applicator". Using aseptic technique, remove the FemSoft Insert from the package by grasping the applicator with the thumb and index finger as shown in Fig. 3.

Figure 3.
(Unchanged from 1570188 Draft Rev. F. 05/24/99)

2. Spread the labia to expose the urethral meatus. Insert the tip of the FemSoft Insert into the urethra. Use slow, gentle pressure to advance the FemSoft Insert into the urethra until the "stop" on the applicator rests against the woman's body. Fig. 4.

Figure 4.
(Unchanged from 1570188 Draft Rev. F. 05/24/99)

3. Use the thumb and index finger to hold the FemSoft Insert against the woman's body. Slowly withdraw the applicator from the device. Fig. 5.

Figure 5.
(Unchanged from 1570188 Draft Rev. F. 05/24/99)

4. Use a tissue to wipe excess lubricant from external retainer if needed.

Removing the FemSoft Insert
1. Spread the labia to expose the FemSoft Insert.
2. Grasp the external retainer and slowly and gently withdraw the device. Do not hold or squeeze the fluid-filled sleeve while removing the FemSoft Insert as this will prevent the flow of fluid from the balloon. Figure 6.

Figure 6.
(Unchanged from 1570188 Draft Rev. F. 05/24/99)

3. Do not reuse a FemSoft Insert.

Selecting the Appropriate Length and Size FemSoft Insert
To optimize patient comfort select the smallest size that is effective (prevents urine loss) for a particular woman. Sizing should be carried out in a room with an examination table and a space that can be used to have the woman perform exercises. Sanitary pads should be available. Sizing should be performed with the woman in the dorsal recumbent position as if for catheterization and with her bladder somewhat full so that leakage with a device in place can be evaluated. Use the procedure outlined below to select the device length and size.
Selecting the Appropriate Length Device.
Insert a size 1 (16 Fr.) standard length (3.5 cm) device. After the device has been inserted grasp the external retainer and withdraw the device slowly until a slight resistance is felt indicating that the balloon is seated in the bladder neck. If the external retainer rests gently against the meatus, or if the sleeve is visible, the standard length should be used. If the external retainer is positioned quite snugly against the meatus the woman should use a long

device.

Selecting the Appropriate Size Device.

With the appropriate length (determined as above) size 1 (16 Fr.) device inserted ask the woman to cough and Valsalva. Observe for leakage around the device. Increase the device size until no leakage is observed. Have the woman place a pad, stand and perform some stressful exercise such as jumping jacks, running in place or coughing hard with legs spread apart. Increase the device size to 2 (18 Fr.) or 3 (20 Fr.) until no leakage around the device occurs during exercise. Subsequent, additional adjustment of the device size may be required if the woman finds that leakage occurs during daily use.

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FEMSOFT® INSERT
INSTRUCTIONS FOR WOMEN

.UTION: U.S.A (Federal) law restricts this device to sale by or on the order physician trained in the ..anagement of urinary incontinence.

DESCRIPTION AND INTENDED USE

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

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.

Figure 1.
FEMSOFT INSERT POSITIONED IN URETHRA
(Figure unchanged from Rev. F, 5/21/99)

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 allows it to conform to the anatomy of the urethra and the junction of the urethra and bladder to prevent urine leakage.

igure 2.
FEMSOFT INSERT DIAGRAM
(Figure unchanged from Rev. F, 5/21/99)

The FemSoft Insert is supplied pre-lubricated and installed on an "applicator" for ready use. When the FemSoft Insert is in place in the urethra a "balloon" holds it in place. 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 (immunocompromised), 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 for developing an infection.
- You are allergic to or cannot take any form of antibiotic
- You are currently taking a blood-thinning drug.

emporarily STOP USING the FemSoft Insert and CONTACT your physician if:

- A bladder or other urinary tract infection is present (see 'When to Contact Your Physician' below).
- Any type of vaginal or venereal infection is present.

- You notice any unusual bleeding from the vaginal area (that is not menstual) or blood in your urine.
- You know or think you are pregnant

If any of these conditions occur, your physician 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 physician 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 physician.

WARNINGS and PRECAUTIONS

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 device 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 or at least once every 6 hours. The FemSoft Insert is not intended to prevent normal urination.
- **DO NOT** use the device 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 device on insertion.
- **DO NOT** use the device 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 doctor 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 doctor. Other unknown complications could also occur.

- Bacteria in the urine.
- 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 PHYSICIAN

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 continue its use and consult your physician. You may also call the FemSoft help-line at 1-800-FemSoft (1-800-336-7638).

Urinary Tract Infection

Discontinue use of the FemSoft Insert and promptly contact your physician 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 the above 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 physician.

Persistent Heavy Spotting of Blood or Bloody Urine

Discontinue use and promptly contact your physician.

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 physician.

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

Contact your physician 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.

Device 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 artifical 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 physician.

HOW TO USE THE FEMSOFT INSERT

You should expect that it will take 1-2 weeks or more 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 un-stressful periods when you have plenty of time. If you do not understand the instructions, or are having difficulty using the FemSoft Insert, consult your physician 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
(Figure unchanged from Rev. F, 5/21/99)

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 opening and clitoris. You may want to use a mirror while you are learning to use the FemSoft Insert. With experience, most women will be able to use the FemSoft Insert

without a mirror.

Using the FemSoft Insert

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

Inserting the FemSoft Insert

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

Figure 4.
BODY POSITION CHOICES FOR INSERTION
(Figure unchanged from Rev. F, 5/21/99)

4. The FemSoft Insert is supplied in a sterile pouch. It is pre-lubricated and installed on its "applicator". Open the FemSoft Insert pouch as shown in Figure 5.

Figure 5.
PEEL TO OPEN POUCH
(Figure unchanged from Rev. F, 5/21/99)

5. 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 device has been touched or dropped prior to use.**

Figure 6.
HANDLE APPLICATOR TO REMOVE FROM POUCH
(Figure unchanged from Rev. F, 5/21/99)

6. Spread your legs apart and pull your clothing away. 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 7.

Figure 7.
SPREAD LABIA AND INSERT FEMSOFT TIP INTO URETHRA
(Figure unchanged from Rev. F, 5/21/99)

7. Use slow, gentle pressure to advance the FemSoft Insert into the urethra until the applicator "stop" rests against your body as shown in Figure 8.

Figure 8.
ADVANCE FEMSOFT INTO URETHRA
(Figure unchanged from Rev. F, 5/21/99)

Important: To prevent injury never force the FemSoft into your urethra.

As you slowly advance the FemSoft Insert into the urethra, the fluid in the "tip" 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 "tip" to hold the FemSoft Insert in place.

8. Hold the FemSoft Insert "external retainer" against your body while slowly withdrawing the "applicator" from the device as shown in Figure 9. Discard the applicator.

Figure 9.
WITHDRAW APPLICATOR FROM DEVICE
(Figure unchanged from Rev. F, 5/21/99)

Important: Do not leave the "applicator" in the device after it is placed in your body as this will cause discomfort and may cause injury.

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

Removing the FemSoft Insert
1. Wash your hands well with soap and water.
2. Using one hand spread the labia to expose the FemSoft Insert as shown in Figure 10.

Figure 10.
SPREAD LABIA TO EXPOSE FEMSOFT EXTERNAL RETAINER
(Figure unchanged from Rev. F, 5/21/99)

3. 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 reuse the FemSoft Insert.

SUMMARY OF CLINICAL STUDIES

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 device women used devices as they desired for 1 year. During the year women had repeated evaluations to determine how the device 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, 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, and 2 were withdrawn by the investigator for non-compliance.

Complications with the FemSoft Insert

Approximately 2/3 of all women who participated in the study experienced at least one adverse events while using the device. These complications 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 device. No treatment was necessary and the women were able to resume using the device after 1-2 days. This type of problem usually occurred early when women were still learning how to use the device. In addition, three women had blood in their urine and three noted spotting of blood.

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

Other: The following adverse events occurred infrequently (<3%): one woman experienced device migration into the bladder; one woman sustained a small scratch in her urethra near the bladder (the scratch was not severe and did not require treatment); and one women 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 device 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. During the tests women wore pads that were weighed afterward to determine how much urine they 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 device was effective in preventing urine loss with a full bladder. By this test, approximately 9 out of 10 women were dry while using the insert.

To further test how the FemSoft Insert was working the women kept diaries 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 patients reported on average 1 fewer leakage accident per day when using the device in comparison to when not using the device.

A special questionnaire that measures quality of life was used to see if reducing leaking accidents by using the FemSoft Insert improved a person'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 it.

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 USE

Characteristic	Average Score
Ease of insertion (1=very easy, 5=difficult)	2.46
Ease of removing (1=very easy, 5=difficult)	1.33
Comfort while inserting (1=very comfortable, 5=uncomfortable)	2.39
Comfort while wearing (1=very comfortable, 5=uncomfortable)	1.87
Comfort while removing (1=very satisfied, 5= unsatisfied)	1.56
Satisfaction with dryness (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 FemSoft?	33 %	64 %
Are you participating in activities you had stopped due to leaking accidents?	36 %	63 %
Have you worn a FemSoft during sex?	3 %	96 %
Has a FemSoft accidentally come out?	36 %	64 %
Do you want to continue to use?	95 %	5 %
Would you recommend to a friend?	97 %	1 %

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Patents Pending
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