

FemSoft[®]
insert



A simple and gentle solution
to stress urinary incontinence

The logo for Rochester Medical, featuring a stylized white wave graphic above the word "Rochester" in a serif font, with "MEDICAL" in a smaller, all-caps sans-serif font below it.

Getting started

How do I obtain supplies of Femsoft?

Your healthcare professional will provide you with your first supply and will tell you to obtain a prescription from your GP for further supplies. Ask your healthcare professional to write down the description and codes of the Femsoft Insert selected for you. The order numbers shown here will help to identify the correct size.

DESCRIPTION	FP10 CODE	PIP CODE
FemSoft Insert Style 1 Standard	71201	351-4874
FemSoft Insert Style 2 Standard	71202	351-4882
FemSoft Insert Style 3 Standard	71203	351-4866
FemSoft Insert Style 1 Long	72201	351-4908
FemSoft Insert Style 2 Long	72202	351-4924
FemSoft Insert Style 3 Long	72203	351-4957

Supplies can be obtained from Script-*easy*, the confidential dispensing service operated by Rochester Medical Ltd., or from your chemist. Script-*easy* offers you a discreet and convenient way to obtain supplies quickly and easily. There is no additional cost for this service to either you or your GP. Just call and your Script-*easy* customer service adviser will obtain your prescription from your GP and send out your FemSoft Inserts without delay.



Contact Script-*easy* by freephone on 0800 0121699.

Fast, reliable delivery of Femsoft

Script-*easy* is a convenient and confidential way to obtain all your prescription products (not medicines). Our friendly and well trained staff will ensure you receive the correct product and you can be assured of a fast, reliable response to your monthly prescriptions.

Script-*easy* is convenient for you. Just call the Freephone helpline to arrange for next day delivery with no bulky packages to carry home.

Best of all, this service is complimentary, there is no charge to you, and it is approved by the NHS.

Call now to enroll with Script-*easy* and obtain your complimentary cosmetic bag, wipes and hand sanitiser spray with your first prescription.



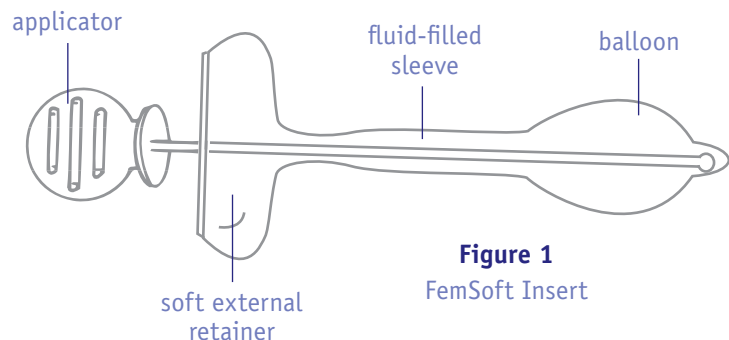
FREEPHONE HELPLINE 0800 0121699

FemSoft Insert

What is FemSoft?

FemSoft is a small, single-use, liquid and silicone product that you insert yourself to instantly stop unintentional urine leakage. Using FemSoft will immediately return your control and peace of mind. It's safe, easy to use, and worn comfortably until you are ready to urinate. At that time, you simply remove the insert and empty your bladder. After you urinate, you insert a new one if you want continued protection from leakage.

FemSoft is made with materials that are safe for you and the environment. Each device is covered with a thin silicone sleeve filled with mineral oil, as shown in Figure 1. The sleeve forms a balloon at the tip. On the opposite end is a soft, oval-shaped exterior retainer. A disposable applicator provides the means for insertion.



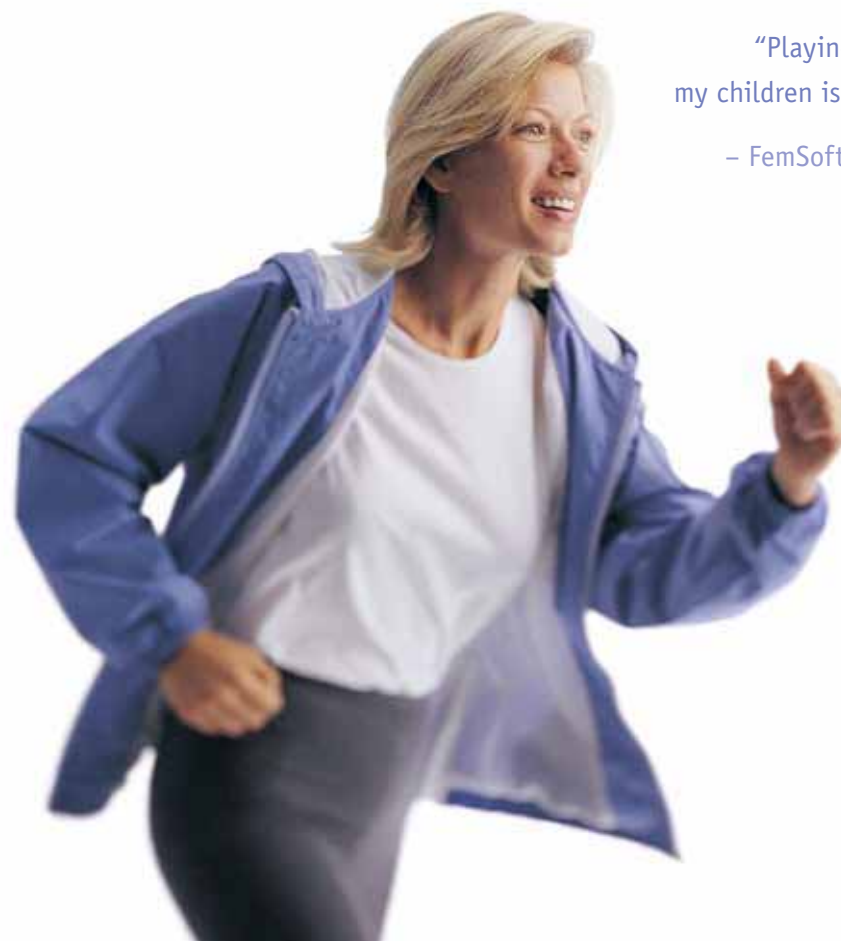
How does FemSoft work?

As you advance FemSoft into your urethra, the fluid is automatically transferred towards the external retainer to facilitate the insert's passage. Once the FemSoft tip has entered your bladder, the fluid effortlessly returns to fill the balloon. This creates a seal at the junction of the bladder and urethra that prevents the unintentional flow of urine.

FemSoft's unique fluid-filled design allows it to adjust to changes in the shape of your urethra that occur when your body moves and when there are changes in your intra-abdominal pressure. That means as you sneeze, cough, laugh, or move, FemSoft maintains constant contact with your urethral tissues and prevents leakage.

Why is FemSoft unique?

The patented, fluid-construction of FemSoft is a breakthrough in technology. FemSoft is smooth and seamless. It is so soft and pliable that many women who use it are unaware they have it in place. Its unique design allows you to insert and remove the product without operating any valves or other mechanisms. Best of all, FemSoft puts you in control; you can use it as you need it.



"Playing soccer with my children is a joy again."

– FemSoft user, age 34





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Your personal guide to using FemSoft

If you've stopped exercising, altered your social life, or adjusted the way you dress because of incontinence, you are not alone. Women who suffer from stress urinary incontinence (SUI) often become preoccupied with urinary odour and wetness. Too often they significantly change their lifestyles because of discomfort and embarrassment.

This complete guide to FemSoft will show you how that can change. In addition, please refer to the FemSoft *Instructions for Women* available in each box of FemSoft.


FemSoft®
insert

What is incontinence?

Urinary incontinence (the involuntary loss of urine) is a medical problem that impacts the lives of millions of women of all ages, most of whom have stress urinary incontinence (SUI).¹ In women between the ages of 15 and 64 years, the incidence of incontinence can be as high as 30%.² Stress urinary incontinence is marked by the involuntary leakage of urine during coughing, sneezing, laughing, or other physical activities that increase pressure on the bladder.

Although SUI is common, it remains under-reported and under-diagnosed. Women are often embarrassed to discuss SUI with their healthcare professional, and many GPs don't routinely inquire about incontinence. Until recently, SUI was mistakenly considered an unavoidable part of the aging process.¹ Healthcare professionals now know that SUI can be controlled and that women can manage its symptoms and live healthy, productive lives whether they develop SUI when they're 18 or 80.

What causes stress urinary incontinence?

Many factors can cause SUI, most commonly weak pelvic floor muscles, usually a result of pregnancy and childbirth, and hormonal changes that occur during menopause.

What treatments are available?

Today a wide range of treatment options are available to help you avoid the psychological, physical, social, and economic consequences of incontinence. Treatment choices include exercises to help strengthen the pelvic floor muscles, devices, oral medications, and surgery. With the help of your healthcare professional, you can make the choice that best suits your lifestyle and condition.

"I stand a lot at work, and when I sneeze I don't have to worry about accidents when I'm wearing FemSoft."

– FemSoft user, age 46



Will FemSoft work for me?

Your healthcare professional will let you know if FemSoft is right for you. Because some medical conditions may increase the risks of using an inserted device, a thorough examination by a qualified clinician is necessary. Women with chronic cystitis, kidney stones, and those on certain medications may be advised not to use FemSoft. Certain previous surgical procedures may also make its use inadvisable. If your healthcare professional finds that FemSoft is appropriate for you, you will be trained so you are comfortable using it on your own.

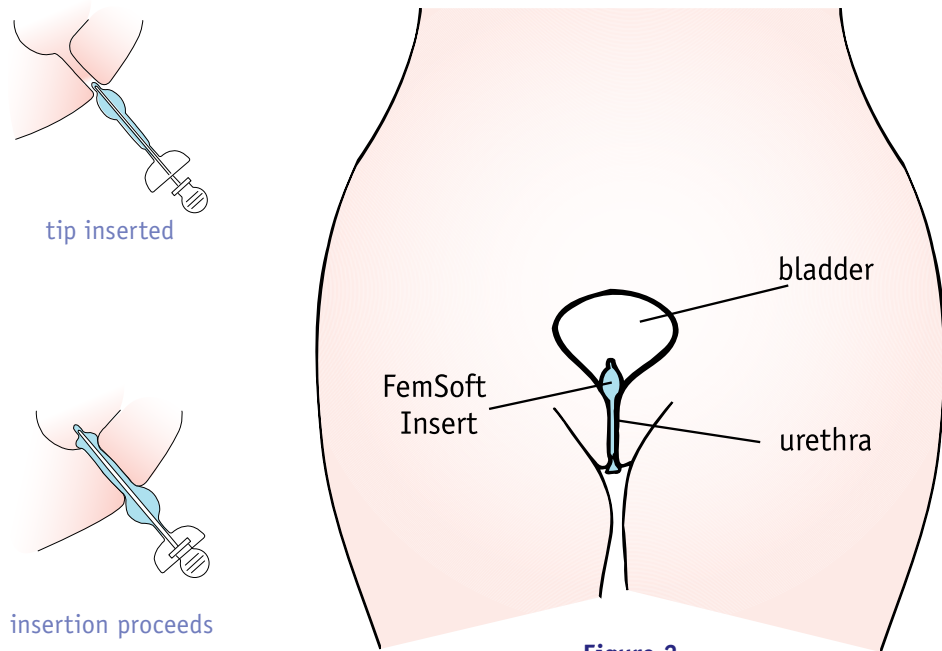


Figure 2
FemSoft positioned in urethra

How do I get it?

Because every woman's body is different, everyone who uses FemSoft must first be evaluated by a clinician and fitted with the correct size of insert. Your healthcare professional will give you specific instructions on how to use FemSoft and how to obtain supplies on prescription.

"FemSoft has changed my life. I can play tennis, go shopping, even tap dance, and never worry about leaking or ruining my clothes."

– FemSoft user, age 61



Instructions

What advice and precautions apply?

Before using FemSoft you should read this entire booklet, and the *Instructions for Women* found in each box of FemSoft, to ensure you have a full understanding of the correct use. You should also receive personal instruction from your healthcare professional to help you learn how to insert and remove FemSoft and about the complications that can occur.

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

To prevent infection:

- WASH hands thoroughly with soap and water before handling FemSoft.
- DO NOT use a FemSoft Insert if the package has been opened or damaged before 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. FemSoft is not intended to prevent normal urination.
- DO NOT use a FemSoft Insert 24 hours a 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 FemSoft. Normally, a person should drink 3 to 4 pints of water a day.

To prevent irritation or injury:

- DO NOT force FemSoft on insertion.
- DO NOT use FemSoft during sexual activity.

How do I insert and remove FemSoft?

Your healthcare professional will teach you how to insert and remove FemSoft. You should expect that it will take 1 to 2 weeks to become completely familiar with FemSoft depending on your frequency of use. Be patient with yourself while learning to use FemSoft.

You may want to use a mirror while you are learning to use FemSoft. With experience, many women will be able to insert FemSoft without a mirror.

For the first week or so, use FemSoft during less stressful periods when you have plenty of time. If you don't understand the instructions, or are having difficulty using FemSoft, consult your healthcare professional for additional training.

Know your anatomy:

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

Note the location of the opening to the urethra in relation 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.

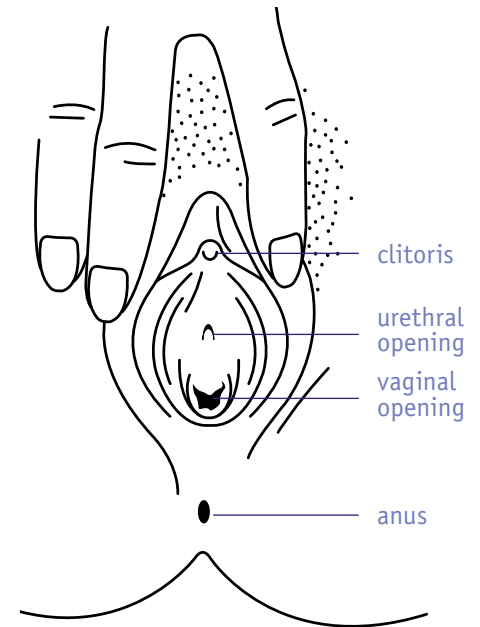


Figure 3
Anatomy of the female
genitalia

Inserting FemSoft:

1. Wash your hands thoroughly with soap and water.
2. Empty your bladder.
3. Similar to a tampon, FemSoft can be inserted while lying down, standing, sitting on the toilet, or standing with one foot on the toilet or a stool. Figure 4 shows some of the different positions that can be used for insertion. Choose the position that is most comfortable for you.
4. FemSoft is supplied in a sterile package and installed on its applicator. Open the FemSoft package, as shown in Figure 5. Completely peel open the package, including the small compartment of lubricating gel.
5. Remove FemSoft from the package, as shown in Figure 6. Handle the applicator only. Be careful not to touch the outside of FemSoft.

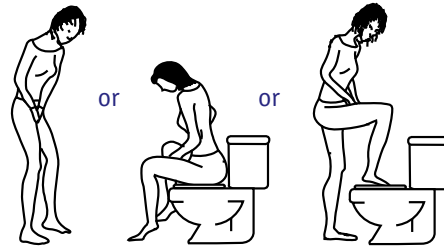


Figure 4
Body position choices
for insertion

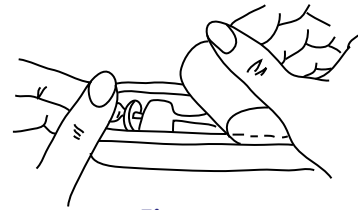


Figure 5
Peel to open package

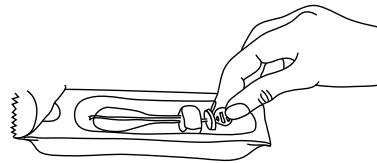


Figure 6
Handle applicator only to
remove from package

IMPORTANT: To prevent an infection, do not use a FemSoft Insert if it has been touched or dropped before use.

6. Dip the balloon end of FemSoft into the lubricating gel, as shown in Figure 7. Cover the entire end of the balloon with the gel for easier insertion.
7. Spread apart the labia with your non-dominant hand and expose the opening of your urethra. Use the other hand to insert the tip of FemSoft into your urethra, as shown in Figure 8.
8. Use slow, gentle pressure to advance FemSoft into your urethra until the applicator stop rests against your body, as shown in Figures 9a and 9b.

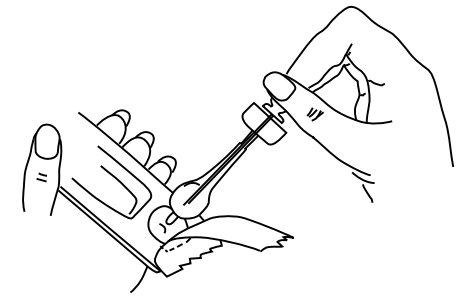


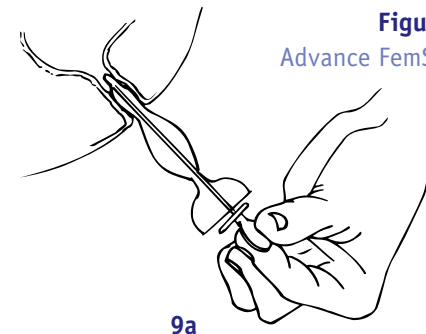
Figure 7
Lubrication of FemSoft Insert



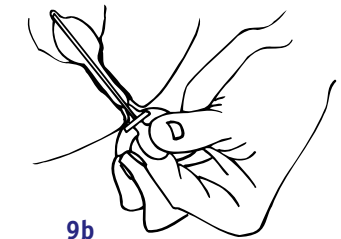
Figure 8
Spread labia and insert
FemSoft tip into urethra

IMPORTANT: To prevent injury, never force the FemSoft Insert into your urethra. As you slowly advance FemSoft into your urethra, the fluid in the balloon is transferred back toward the external retainer, thus allowing easy passage of FemSoft through your urethra.

Instructions continued on next page.



9a



9b

Figures 9a and 9b
Advance FemSoft Insert into urethra

9. Hold the FemSoft external retainer against your body while slowly withdrawing the applicator from the insert, as shown in Figure 10. Discard the applicator.

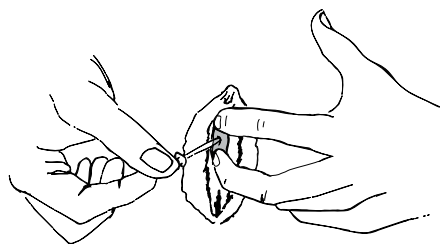


Figure 10
Withdraw applicator from
FemSoft Insert

IMPORTANT: Do not leave the applicator in FemSoft after the insert is placed in your body, as this will cause discomfort and may result in injury.

10. Use a tissue to wipe excess lubricant from the external retainer if you wish.
11. Now wash your hands again.

Removing FemSoft:

1. Wash your hands well with soap and water.
2. Using your non-dominant hand, spread the labia to expose the FemSoft external retainer, as shown in Figure 11.
3. If the external retainer is difficult to grasp because of moisture, dry it with tissue. Grasp the FemSoft external retainer. Relax, but do not urinate. Pull the FemSoft Insert out slowly and gently, as shown in Figure 12. Do not hold onto or squeeze the fluid-filled sleeve when removing the insert.
4. Finish by disposing of the insert and wash your hands with soap and water.

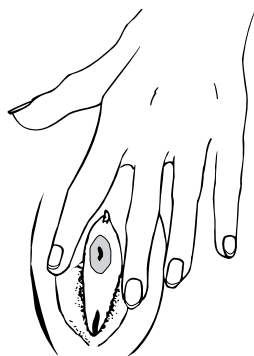


Figure 11
Spread labia to expose FemSoft
external retainer

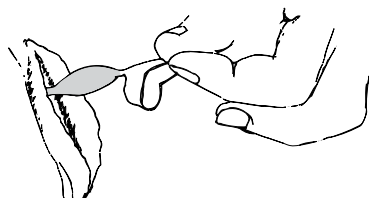


Figure 12
Slowly pull out the FemSoft Insert

IMPORTANT: To prevent infections, do not re-use a FemSoft Insert.

When and for how long can I use FemSoft?

For some women FemSoft 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 when working. FemSoft should only be used when needed.

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

Are there any risks associated with FemSoft?

Complications from use of FemSoft are rare and are listed below. Some of these could require treatment by a GP. (See “When should I contact my GP or healthcare professional?”)

- Urinary tract infection may occur. If left untreated, bladder infection could lead to more serious complications, so contact your GP immediately.
- The FemSoft Insert could move (migrate) into the urethra or bladder (0.0023% incidence), and you should contact your GP if you suspect this has happened.
- Injury or irritation to the urethra or bladder may result from use. Injury or irritation may cause bleeding or bloody urine. If you notice blood in your urine or experience bleeding, you should contact your GP immediately for advice.
- Some women may experience pain or uncontrolled bladder contraction (bladder spasm) during use and should discontinue use.
- Some women may not be able to retain the insert. Femsoft is available in 3 different balloon sizes and a larger balloon may help.
- The silicone sleeve of the insert may break, resulting in the release of mineral oil into the bladder or urethra. This is perfectly harmless and mineral oil will be expelled when you next urinate.

When should I contact my GP or healthcare professional?

A follow-up visit will usually be scheduled within 7 to 14 days. At that time your healthcare professional will discuss your experience with FemSoft, perhaps adjust the size, provide any additional training, and answer any questions you may have.

Temporarily STOP USING FemSoft and CONTACT YOUR GP or HEALTHCARE PROFESSIONAL if:

- A bladder or other urinary tract infection is present.
- 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 GP or healthcare professional will let you know when it is safe to start using FemSoft again.

CAUTION: If you are pregnant or think you are, call your healthcare professional as soon as possible to discuss whether you can use FemSoft. Use of the insert has not been studied during pregnancy, so its effects are unknown.

The guidelines that follow will help you decide what to do about the common problems that can occur with the use of FemSoft. If you experience any other problem you believe is associated with the use of FemSoft, you should discontinue its use and consult your GP or healthcare professional.

- **Urinary tract infection** – Discontinue use of FemSoft and promptly contact your GP if you experience signs of a urinary tract infection, including burning on urination, foul-smelling urine, bloody urine, back pain, pelvic pain, a 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, FemSoft should be discontinued for 1 to 2 days until the symptoms completely resolve. Use of FemSoft may then be resumed. If the symptoms recur frequently or persist 1 to 2 days after discontinuing FemSoft use, contact your healthcare professional.

- **Persistent, heavy spotting of blood or bloody urine** – Discontinue use and promptly contact your GP or healthcare professional.
- **FemSoft migration** – If you suspect that the insert has moved into your urethra or bladder, first void with a moderately full bladder and check to see whether the insert is expelled in your urine; if not, contact your GP.
- **FemSoft expulsion or urine leakage with FemSoft in place** – Contact your healthcare professional for an evaluation to determine whether you are using the proper technique to insert FemSoft or if the FemSoft size should be adjusted.
- **FemSoft breakage** – The sleeve of the insert can break, releasing mineral oil into the bladder, urethra, or external genitalia. If this occurs, remove FemSoft. 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.

“I feel a freedom now...
I can plan activities
I once avoided.”

– FemSoft user, age 48

