

# TRAINING MANUAL

*for professionals*



*FemSoft*<sup>®</sup>  
insert

  
**Rochester**<sup>®</sup>  
MEDICAL

**Device**

**Related:**

The FemSoft Insert should be properly sized to the woman. Use of an improper size could result in device migration or patient discomfort.

The FemSoft Insert is provided sterile to prevent infection. Women should not use a FemSoft Insert if the package is open or damaged, or if the device has been contaminated before use.

**Patient**

**Related:**

Appropriate patient education, training, and monitoring by a qualified health care professional is required for safe patient use. The booklet Instructions for Women is intended as a supplement to patient education supplied by a health care professional.

The safety and effectiveness of the FemSoft Insert have not been evaluated in pregnant women and the effects are unknown.

Women should be instructed not to use FemSoft during sexual intercourse. The safety and effectiveness of this practice has not been demonstrated.

Women who present with a history of frequent urinary tract infections (UTI) should be advised that they may be at risk of infection with the use of FemSoft. Additionally, these women should be monitored closely for symptoms of UTI during device use.

FemSoft is a disposable, single use device. Women should be instructed not to re-use a FemSoft Insert due to the increased risk of infection.

Women should be instructed to wash hands and avoid touching the device prior to its insertion, as described in the Instructions for Women.

Women should discontinue use of the FemSoft Insert and seek medical advice if symptoms of possible urinary tract, vaginal, or venereal infection develop. If an infection is diagnosed, FemSoft should not be used until the infection has been successfully treated.

Women should be instructed to remove FemSoft at night, before going to sleep. Continuous 24-hour use of the FemSoft Insert increases the risk of complications.

Women should be instructed to remove and replace the FemSoft Insert at least once every 6 hours to help reduce the chance of UTI. The FemSoft Insert should always be removed when a woman feels the need to void.

Women should be instructed not to force the insertion of the device due to the risk of injury to the peri-meatal area or urethra.

If a woman reports visible haematuria or bleeding but no other symptoms of UTI, she should be instructed to temporarily discontinue use of FemSoft. After her symptoms have been resolved, she may continue using FemSoft. If her symptoms persist, she should be instructed to contact her clinician. If the symptoms recur after resuming device use, she should be instructed to discontinue use of the device and contact her clinician.

Use of FemSoft should be discontinued in those women who develop abrasion of the bladder wall, urethra and/or urethral meatus. Device use may be resumed once these conditions are fully resolved.

Women 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.

Pocket Folder Here

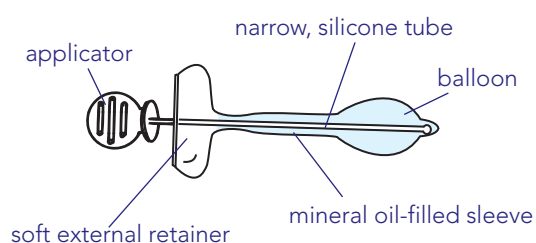
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**Description:** FemSoft is a sterile, disposable, single-use device made from silicone and containing biocompatible mineral oil.

FemSoft comprises an inner silicone tube encased in a soft, compressible, fluid-filled sleeve that is expanded at the proximal end to form a balloon that sits comfortably in the bladder neck to retain the device.

A soft, silicone retainer at the distal end prevents proximal migration and allows the device to be removed easily when required. The whole device is pre-installed on a disposable applicator.



FemSoft is supplied in a peel-open pouch with lubricant in boxes of 28 inserts.

There are two lengths and each length comes in 3 sizes:

STANDARD LENGTH	LONG LENGTH
Size 1	Size 1
Size 2	Size 2
Size 3	Size 3

The standard length measures 35mm from the base of the balloon to the start of the external retainer. The long length measures 45mm.

The sizes measured below the balloon are nominally:

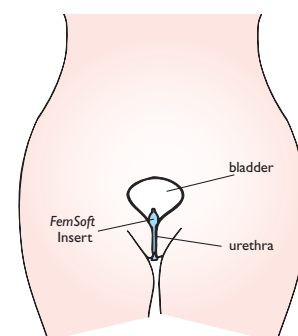
- Size 1: 16Ch
- Size 2: 18Ch
- Size 3: 20Ch

**Function:**

The unique characteristics of the FemSoft Insert's mineral oil-filled sleeve provide the mechanism for its insertion, retention and removal. Once in place, the soft compressible sleeve conforms to the anatomy of the urethra and bladder neck to prevent leakage of urine.

The insert readily adjusts to anatomical variations among women and further adjusts to changes in urethral shape that occur with body movement and/or changes in intra-abdominal pressure.

The insert is removed and discarded when the woman wants to void. Afterwards, a new device can be inserted if continued protection from leakage is desired.

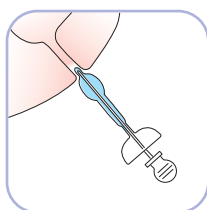


**Indication:** The FemSoft Insert is indicated for the management of stress urinary incontinence in adult females.

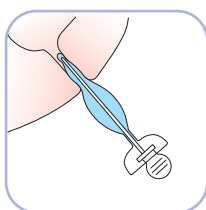
**Insertion:** With the applicator in place, lubricate the balloon by dipping it in the gel provided in the pack and advance the tip into the urethra. Fluid from the balloon will displace into the sleeve to allow FemSoft to pass into the bladder.

When the tip enters the bladder the fluid transfers automatically back into the balloon to retain the device.

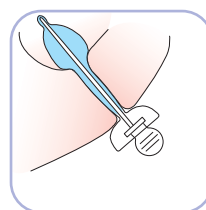
Remove and discard the applicator.



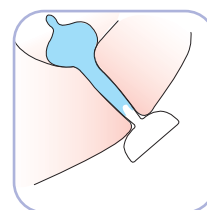
Tip inserted



Insertion  
proceeds

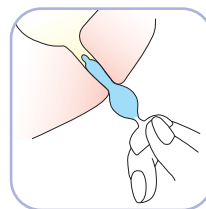


Advanced into  
bladder



Applicator removed

**Withdrawal:** Hold the external retainer, relax and slowly withdraw the device. Do not reuse.



withdrawal

**Contra-  
indications:**

FemSoft should not be used in patients with an active bladder infection or other urinary tract infection. FemSoft is contraindicated in patients with the following conditions:

- Conditions where passage of a catheter through the urethra is not clinically advisable e.g a history of urethral stricture; bladder augmentation; pelvic radiation or other anatomic or pathogenic conditions.
- Conditions which put the patient at considerable risk of urinary tract infections e.g. patients who are immunocompromised.
- Patients fitted with a prosthetic heart valve or other implanted device.
- Interstitial cystitis, pyelonephritis or a history of severely compromised urinary tract mucosal tissue.
- Intolerance of any form of antibiotic treatment.
- Patients currently receiving anticoagulation therapy.
- Overflow incontinence or neurogenic bladder.

**Patient**

**Evaluation:** Before considering FemSoft for the management of stress urinary incontinence, conduct a patient evaluation in accordance with local guidelines and procedures, including history, physical examination, post-void residual urine (PVR) and urinalysis.

**Patient**

**Selection:** Review the patient's profile in respect of the indications and contraindications for FemSoft Insert use and refer to the precautions and warnings given in this Training Manual.

**Presentation  
of Options:**

After discussing available treatment options, introduce FemSoft as a non-surgical option that provides immediate control over wetness and odour, with a level of effectiveness that approaches surgical results.

Demonstrate the FemSoft Insert's soft, conformable design by removing the applicator and gently manipulating the device in the palm of your hand. Allow the women to handle the FemSoft Insert (without the applicator) to personally experience the softness.

Describe the product as being 'placed inside the body' as this helps women understand its application without the alarm sometimes associated with 'self-inserted device'. It may also be helpful to explain that the product is placed in the urethra like a tampon is placed in the vagina.

If the woman is interested in evaluating FemSoft to manage her stress urinary incontinence continue with the sizing procedure and initial training. This usually requires about 20 minutes.

## HOW YOUR PATIENT CAN OBTAIN FURTHER SUPPLIES OF FEMSOFT



**STEP 1 – PATIENT REGISTRATION**  
Patient registration by phone, fax or post



**STEP 2 – SCRIPT EASY SERVICE**  
The Script-easy service liaises with patient and GP to obtain prescription



**STEP 3 – HOME DELIVERY**  
Home delivery by confidential carrier every month

For fast reliable delivery of FemSoft urethral inserts please call the Script-easy confidential prescription service

**Script-easy**  
CONFIDENTIAL PRESCRIPTION DISPENSING SERVICE

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

Your patient will also receive a complimentary cosmetic bag, wipes and hand sanitiser with their first order.

Contact Script-easy by Freephone on **0800 0121699**

For healthcare professionals, there is a sizing and training kit.

The kit includes:

- A range of sizes of FemSoft
- Mirrors
- Patient user guides
- Discreet lilac sample bags



FemSoft prescriptions through Script-easy come with thoughtful accessories including carrying case, hand sanitiser, and individual feminine wipes.



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selecting appropriate length & size

**Sizing**

**Procedure:** Choosing the correct size will help ensure that the device sits comfortably in the urethra, is retained in place and prevents urine loss. The device itself is used to determine the optimum size and the sizing procedure should be carried out in a room with an examination table and an area that can be used to have the woman perform exercises. Sanitary pads should be available. To begin, sizing should be performed with the woman in the dorsal recumbent position, as if for catheterisation, and with her bladder somewhat full so that leakage with a device in place can be evaluated. Use the following procedure to select the appropriate device length and size, referring to the diagram in Figure 1.

**Selecting**

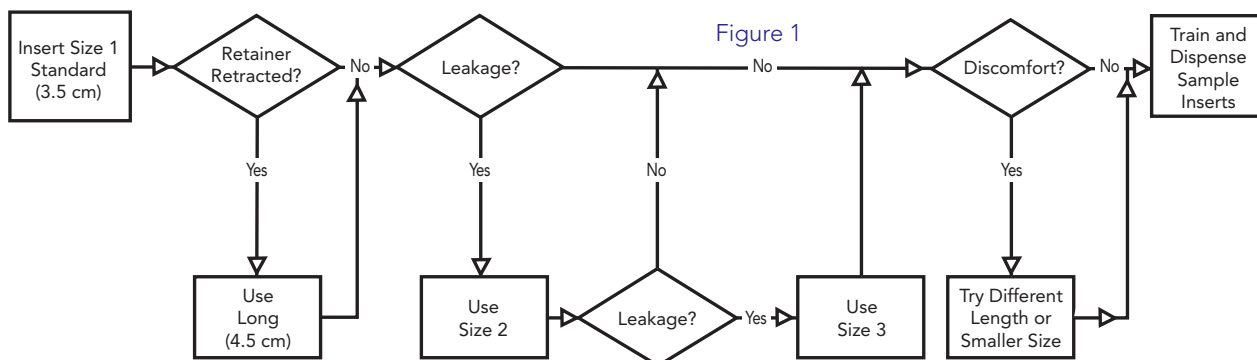
**Device Length:** When fitted correctly, the retaining sleeve should not be distorted or pulled into the meatus. Start with a size 1, Standard length FemSoft and, after the device has been inserted, hold the external retainer and slowly withdraw until a slight resistance is felt, indication that the device 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 or is retracted against the meatus, remove the device and fit a size 1, long FemSoft.

**Selecting**

**Device Size:** With the woman still in the recumbent position and with the appropriate length of Size 1 device in place, ask the woman to cough or Valsalva. Observe the area around the device for leakage.

If leakage occurs, remove the Size 1 device and try a Size 2, increasing to a Size 3 if necessary, until no leakage is observed. Then have the woman stand with a pad in place and perform stressful exercise such as running on the spot or coughing hard with her legs spread apart. If urine leakage occurs, increase the device size to 2 or 3 until no leakage occurs during exercise. Subsequent, additional adjustment of the device size may be required if the woman finds that leakage occurs during daily use.

It is normal for women to experience an awareness or slight discomfort or irritation when first wearing the insert. This should subside after a woman becomes accustomed to the device (a few to several days depending on number of devices used). In the event discomfort is significant or doesn't subside after reasonable time, an adjustment in the device size should be considered. This should include a re-evaluation of both the device length and size. Most commonly, persistent discomfort is related to the device length being either too long or too short, and less commonly to the device diameter size.



**Training:** Have the woman insert and remove a device of the selected size while observing and coaching her.

**Note:** Most women will find using a mirror beneficial while learning to place the insert. A mirror is provided in the Sizing and Training Kit.

Have the woman independently insert and remove an insert of the selected size.

Instruct the woman to call you if she has any difficulty inserting the FemSoft Insert, experiences leakages with the insert in place or observes adverse signs or symptoms. If the woman experiences symptoms of a UTI, she should contact her GP immediately.

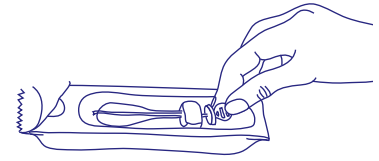
#### **Patient**

**Follow-up:** Make a follow up appointment within 7-14 days for evaluation and to provide additional training if there have been difficulties with product insertion and/or removal. Interview the patient and observe for signs and symptoms of adverse events as well as for reports of leakage, expulsion or discomfort. Ensure that the woman is fully aware of the adverse events that can occur and the safety and prevention measures to take. Make a further appointment if necessary. Additional information about FemSoft can be found in the Instructions for Women (found in each box of FemSoft) and in the Sizing and Training Kit.

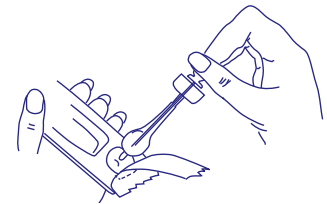
**Placing the**

**FemSoft Insert**

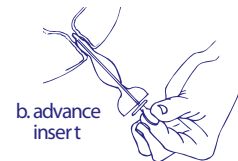
1. The FemSoft Insert is supplied sterile and installed on its "applicator". Only touching the applicator, remove the FemSoft Insert from the package by grasping the applicator with the thumb and index finger.



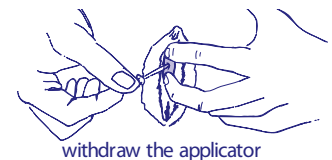
2. Dip the balloon end of the FemSoft Insert into the lubricating gel. Cover the entire end of the balloon with the gel for easier insertion.



3. 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.



4. Use the thumb and index finger to hold the FemSoft Insert's external retainer against the woman's body. Slowly withdraw the applicator from the device. Use a tissue to wipe excess lubricant from external retainer, if needed.

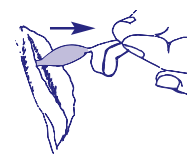


**Removing the**

**FemSoft insert**

1. Spread the labia to expose the FemSoft Insert.

2. Hold 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.



3. Do not re-use a FemSoft Insert.

A prospective, multi-centre, observational, non-randomised trial of the use of the FemSoft Insert in controlling stress urinary incontinence in adult women was carried out at eight clinical sites. Each woman served as her own control.

**Patient**

- Population:**
- 150 women with an average age of 53.5 years (range 27-78).
  - Average duration of incontinence 10.9 years (range 1-40).
  - Women with failed SUI surgery were included as well as those with no prior SUI treatments.
  - The severity of SUI was rated by clinicians as mild in 47 (31.3%) women, moderate in 84 (56%) women and severe in 19 (12.7%) women.
  - 72 women reported having urgency symptoms in addition to SUI symptoms; however, all women with mixed incontinence had SUI as the primary component.

**Outcome**

- Measures:**
- Voiding diary/incontinence episodes (UI)
  - Standardised pad weighing test (PWT)
  - Satisfaction questionnaire
  - Validated quality of life (QOL) tool

- Results:**
- Average follow-up: 19 months
  - Average insert use: 5.7 hours per day
- Statistically significant results were obtained for all outcome measures.

Diary:

2.19 UI per day without the insert compared to 0.56 UI per day with FemSoft Insert.  
At 24 months, 74% were completely dry when using the device.

Patient Satisfaction:

Participants rated measures of their satisfaction with the FemSoft Insert including dryness, ease of insertion/removal and comfort with insertion/wearing/removal.  
The average score of all measures combined, rated on a scale of 1 to 5 (1 being very satisfied), ranged from 1.5 to 1.8 at follow-up visits.

PWT:

Statistically significant differences in PWT urine loss with and without the insert were seen at all follow-up visits. (p<0.001)  
At 24 months 86% of women were completely dry when using the device.

QOL:

Statistically significant improvements in QOL were seen at all follow-up visits compared to the pre-use period (p<0.001).

SAFETY:

Leak point pressure and cystoscopy were done throughout the follow up period. No change in leak point pressures were seen within one year of insert use and cystoscopy indicated only infrequent, transient irritation; six observations in total, with none requiring treatment.

ADVERSE EVENTS:

Bacteriuria was observed on routine culture in 39.3% of subjects (not treated). Symptomatic UTI occurred in 31.3% of subjects (2-3% subjects per month) mostly within the first few weeks, when training was taking place. Transient urinary symptoms (urgency, frequency, etc.) occurred in 24.7% of subjects. Insertion trauma (discomfort, minor bleeding, spotting) occurred in 6.7% of subjects. Haematuria (gross or microscopic) occurred in 3.3% of subjects. Migration occurred in 0.6% of subjects (2 women with over 90,000 devices used).