

# A HealthTech Report

## **Mechanical devices for the treatment of urinary incontinence following obstetric fistula repair**

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# I. Introduction

The most severe and distressing long-term condition following obstructed labor is obstetric fistula. Yet the condition is entirely preventable. Prolonged labor is estimated to account for 76% to 97% of obstetric fistulas and is also a major cause of maternal mortality. Obstetric fistulas occur when the descending fetus is unable to pass through the mother's pelvis. The fetal head enters the vagina, but the shoulders cannot pass through the pelvis. Without access to medical care to relieve the obstruction, the woman may remain in labor for days. The fetal head compresses the vaginal tissue and widespread ischemic damage of the soft tissue occurs. Once this process has occurred, the necrotic tissue in the surrounding area leaves an opening between the vagina and the bladder (vesico-vaginal fistula [VVF]) or vagina and rectum (recto-vaginal fistula [RVF]).<sup>1</sup>

Once a woman develops an obstetric fistula, surgical treatment is required to repair the fistula. However, after successful surgical closure of an obstetric fistula, 15% to 30% of cases may continue to suffer from urinary incontinence (UI).<sup>2</sup> The development of UI following the successful closure of the fistula leads to significant emotional problems for the patient.

Despite the magnitude of the problem of UI after obstetric fistula repair, only around 6% to 8% of women return for further treatment.<sup>3</sup> The treatment to correct the UI depends on the severity of the case. Some women can have another corrective surgery while others do not qualify for surgery or surgery fails. For those women whom surgery fails, alternative treatments using nonsurgical devices such as urethral plugs are required. These patients will require the use of devices to stop leakage of urine for the rest of their life, which poses a financial burden to the patients and the health system in general.

Urethral plugs used for the treatment of UI after fistula repair are typically adaptations of treatments used for UI in developed nations, and oftentimes these devices do not fully accommodate the needs of women with UI after obstetric fistula repair.

This report assesses urethral plugs for the treatment of UI following fistula repair, identifies barriers for wide use of the technology, and provides recommendations for adapting the device to a low-resource setting. Literature research, interviews with experts in the field of obstetric fistula, and discussions with commercial manufacturers of current technologies were conducted to complete the report.

## II. Project goal and objectives

### ***Goal***

The goal of the project is to assess current availability and market opportunities of mechanical devices used for the treatment of UI following obstetric fistula repair in low-resource settings.

## **Objectives**

1. Assess the need for low-cost urethral plug devices for the treatment of UI following obstetric fistula repair.
2. Develop an inventory of available mechanical devices used to treat UI following surgical repair of obstetric fistula through web searches, literary searches, and interviews with experts.
3. Characterize design modifications of urethral plugs to meet the needs of women with UI following obstetric fistula repair.
4. Characterize the market opportunities for a reduced cost, generic product.

## **III. Methods**

We conducted a landscape analysis of the mechanical devices that are currently used to treat the symptoms of UI following obstetric fistula repair. Subsequently, we reviewed the literature to document the use of these technologies for this purpose in low-resource settings. In addition, we informally interviewed key experts who could provide relevant information related to the clinical use, effectiveness, and barriers that limit the distribution of the devices used to treat UI after obstetric fistula repair (see Annex 1 for interview questions). We also contacted manufacturers of urethral plugs, the only device currently used to treat UI post-fistula repair in low-resource settings, to obtain information about cost and market availability of the device in low-resource settings.

## **IV. Health need**

Based on clinical studies, the incidence of obstetric fistula in Africa is 0.08% of births.<sup>4</sup> This incidence is for all fistulas, including VVFs and RVFs, as no studies evaluate the incidence of each of them separately. Only VVFs lead to UI, even after surgical repair.

In general, the treatment for obstetric fistula is surgical repair of the defect. About 80% to 90% of women with VVF can potentially be cured by a simple vaginal surgery.<sup>4</sup> However, due to external factors such as transportation, financial resources, stigma associated with the conditions, and other factors related to access to medical care, surgical treatment does not always occur. Additionally, even when women undergo surgery, there is still a chance that women will develop post-fistula incontinence. A woman with a simple fistula involving the urethra has been reported to have a 50% risk of post-fistula incontinence compared to a 100% risk in those with complex fistula.<sup>3</sup>

Further confusion is caused by the fact that the term “success rate” is defined in various ways. For women, success is restoration of urinary continence. For some surgeons, success is confirmation that a fistula is closed and for others it is restoration of complete continence. It is important to harmonize the criteria for success to facilitate meaningful comparisons of treatment outcomes.<sup>5</sup>

The two major defects that may contribute to incontinence following fistula repair are:

- Soft tissue destruction of the intrinsic sphincter mechanism at the vesico-urethral junction.
- Changes in bladder function consisting of one of the following: loss of capacity, loss of contractibility, loss of sensation of filling, and reduction in size and compliance because of chronic exposure to an unprotected environment.<sup>6</sup>

Other factors associated with UI post-fistula repair are: involvement of the urethra, increasing diameter of the fistula, and vaginal scarring with the need for vaginal reconstruction.<sup>7</sup>

In a study that followed women six months after fistula repair, the researchers proposed that urethral plugs are used in women with post-surgery incontinence grade 4 and 5.<sup>8</sup> Table 1 summarizes the grades of incontinence that a woman can suffer following post-fistula repair.

**Table 1:** Incontinence grading system.<sup>8</sup>

Incontinence grade	Description of incontinence
1	Cured, no incontinence.
2	Incontinent with cough, strain, or exertion.
3	Incontinent on walking.
4	Incontinent on walking, sitting, and/or lying but voiding some urine.
5	Incontinent on walking, sitting, and/or lying but not voiding any urine.

Residual incontinence after fistula repair is more frequent in fistulas involving the urethra and/or the bladder neck. This range is wide because follow-up with patients after they have had their fistula repaired is minimal in low-resource settings. Some women might experience mild symptoms but never come back for treatment. Despite the high prevalence of residual incontinence reported, no exact cause or appropriate treatment for this condition has been established.<sup>9</sup> Thus, there is no therapeutic approach for these cases. In developed countries, surgical treatment is the first option (bladder neck suspension), but in low-resource settings this might be technically difficult due to the lack of access to care, the high cost of surgery, not enough surgeons trained in the procedure, and limited resources. In addition, long-term postoperative evaluations are usually extremely difficult as these patients usually live in isolated rural areas that are far from a hospital.

## V. Inventory of available technologies

The treatments of choice for women with post-obstetric fistula incontinence are based almost entirely on adaptations or direct applications of solutions developed in the industrialized world for UI of a completely different nature. Ideally, the specific or unique features of the problems should guide treatment decisions in the developing world, but unfortunately decisions are often guided by what is locally available, which is not always the most adequate.<sup>6</sup>

In general, medical interventions for urinary incontinence following obstetric fistula repair can be divided into (1) surgical interventions and (2) nonsurgical interventions. For the most

part, the treatment will depend on the extent, severity, and associated factors related to each case. If surgery is indicated, it is usually considered the primary treatment, especially in women who maintain bladder tissue and capacity. It is important to note that although surgery might seem the primary treatment, surgical interventions in low-resource settings are often not possible for several reasons:

- Low access to skilled personnel that can perform surgical interventions to correct UI.
- No access to urodynamic diagnostic equipment that is needed to diagnose the problem accurately.
- Poor access to medical services.

### ***Nonsurgical interventions for the treatment of UI following fistula repair***

Nonsurgical interventions include:

- Pelvic floor exercises.
- Pelvic floor stimulation.
- Pharmacologic treatment.
- Minimally invasive treatments.
- Mechanical devices.

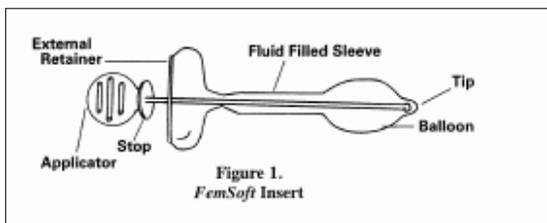
The focus of this report is on mechanical devices that are described below. See Annex 2 for a description of the aforementioned nonsurgical interventions other than mechanical devices.

### ***Mechanical devices***

#### **Urethral plugs**

Urethral plugs are intraurethral devices used to treat the symptoms of UI. It is the only device that is currently used for the treatment of UI following obstetric fistula repair in low-resource settings. Currently, there is only one device commercially available in the market: *FemSoft*<sup>®</sup> Insert: Rochester Medical Corporation, Stewartville, MN, United States.

The *FemSoft*<sup>®</sup> Insert is a silicon-based catheter encased in an oil-filled sleeve that has a balloon on its tip. On the opposite end, the tube and silicone sleeve join to form a soft tunnel called the “external retainer” (Figure 1). A disposable plastic applicator is used to provide a means for insertion.<sup>10</sup> When the plug is inserted into the urethra, it blocks urinary leakage.



**Figure 1.**  
Parts of the *FemSoft*<sup>®</sup> Insert.<sup>i</sup>

<sup>i</sup> Source: Rochester Medical Corporation. Available at: [http://www.rocm.com/pdfs/FemSoftFAQs/FemSoft\\_Insert\\_Clinician\\_FAQs.pdf](http://www.rocm.com/pdfs/FemSoftFAQs/FemSoft_Insert_Clinician_FAQs.pdf). Accessed September 25, 2009.

The *FemSoft*<sup>®</sup> Insert is removed and discarded when the woman wants to urinate. Afterwards, a new device is inserted. The device is supplied sterile and is available in three diameter sizes (16, 18 and 20 French size-Fr) with two lengths for each diameter (3.5 cm and 4.5 cm). Complications from the use of urethral plugs are: urinary tract infection, device migration, urethral irritation, device expulsion or urine leakage with a device in place, and device breakage. For a complete list of contraindications and more information on complications see Annex 3.

Only anecdotal information and case studies of the use of urethral plugs in developing countries are available in the literature. Up to now, no controlled clinical trials have been performed to evaluate the effectiveness of the device in these settings.

A case study describing the use of urethral plugs at the Addis Adaba Fistula Hospital in Ethiopia, in two women with fistula with ongoing UI following fistula repair was published in 2005. In both cases, women used the *FemSoft*<sup>®</sup> Insert urethral plug device (Rochester Medical Corporation, Stewartville, MN, USA).<sup>11</sup>

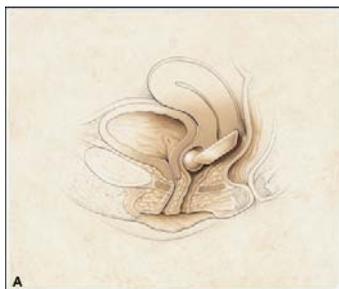
The use of urethral plugs in these two cases helped women achieve continence and also improved bladder function with a significant reduction in the number of voids and nocturia. In general, the urethral plug showed to be effective for these cases with little complication. However, long-term follow-up is required.

## Pessaries

The pessary, a passive device used to maintain the correct position of pelvic organs, is an effective tool in the management of several gynecological problems. The pessary is most commonly used in the management of pelvic support defects. However, pessaries have also been used for the treatment of UI, especially in women where corrective surgery is not recommended or in women in which surgery has failed.<sup>12, 13</sup>

Pessaries for UI compress the urethra against the upper posterior portion of the symphysis pubis and elevates the bladder neck. This causes an increase in outflow resistance and corrects the angle between the bladder and the urethra so that maneuvers that increase intra-abdominal pressure like coughing are not strong enough to cause leakage of urine. Any pessary that can accomplish this will help relieve stress UI.<sup>12</sup>

The pessaries most commonly used for the treatment of UI in developed countries are the incontinence ring and incontinence dish pessaries (Figures 2 and 3).



**Figure 2 (left).**<sup>ii</sup>  
Incontinence dish pessary used for UI in place.

**Figure 3 (right).**<sup>iii</sup>  
Incontinence ring (above) and incontinence dish (below), used for UI.



<sup>ii</sup> Culligan P, Heit M. Urinary incontinence in women: Evaluation and management. *American Family Physician*. December 1, 2000;62(11):2433–2444, 2447, 2452.

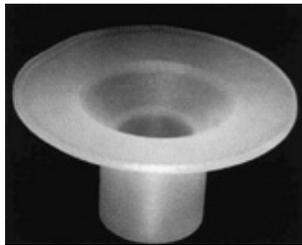
<sup>iii</sup> Nager C, Richter HE, Nygaard I, et al. Incontinence pessaries: size, POPQ measures, and successful fitting. *International Urogynecology Journal and Pelvic Floor Dysfunction*. September 2009;20(9):1023–1028.

There are no reports or data of using pessaries in women with UI following obstetric fistula repair.<sup>7</sup> However, a long-term assessment of the incontinence ring pessary in developed countries demonstrated only a 16% success rate for the treatment of mixed and UI. Complications from pessary use include: vaginal abrasions, ulcerations, urinary tract infections, and vaginal infections.<sup>14</sup>

The use of pessaries for this indication in developing countries is not common because most patients with incontinence post-repair have distorted, rigid, scarred vaginas, some of which are completely obliterated or the scar is so rigid that the vagina itself feels like a canal of bone (as per an email communication with Dr. Andrew Browning on September 2, 2009). In addition, pessaries are not usually available in developing countries, which limit the applicability of such technology.

### Occlusive devices

Occlusive devices block urinary leakages at the external urethral meatus. They use adhesive or suction to prevent urinary leakage.<sup>14</sup> External urethral devices have demonstrated efficacy in mild UI, but without proper adherence to the area close to the urethral meatus they can become ineffective and cause local irritation. They are not considered the first choice for the treatment of UI.<sup>15</sup> In addition, the use of occlusive devices for the treatment of UI following obstetric fistula repair in low-resource settings has not been reported.



**Figure 4.**<sup>iv</sup>  
Picture of the FemAssist urethral cap.

## VI. Key informant interviews

Between July and September of 2009, nine experts who have performed surgical repair of obstetric fistulas and have treated patients with UI in low-resource settings were interviewed, as follows:

- Dr. Stephen Arrowsmith, Vice President for International Programs, Worldwide Fistula Foundation-USA, United States.
- Dr. Andrew Browning, Medical Director, Barhirdar Hamlin Fistula Centre, Ethiopia.
- Dr. Joseph Ruminjo, Clinical Director, EngenderHealth/Fistula Care Project, United States.
- Dr. David Lyth, Urologist, Aberdeen West African Fistula Centre, Sierra Leone.
- Dr. Laura Hart, Urogynecologist, One by One, United States.
- Dr. Judith Goh, Professor Griffith University, Australia.

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<sup>iv</sup> Tincello DG, Adams EJ, Bolderson J, et al. A urinary control device for management of female stress incontinence. *Obstetrics and Gynecology*. March 2000;95(3): 417–420.

- Dr. John Kelley, Urogynecologist, Kitovu Hospital, Uganda.
- Dr. Darius Maggi, Founder of West Africa Fistula Foundation, United States.
- Dr. Richard Wong, Obstetrician and Gynecologist, Medical Teams International, United States.

### ***Treatments used for urinary incontinence following fistula repair***

Experts agreed that the treatment of UI following fistula repair needs to be individualized depending on the severity of the case. It is important to determine bladder capacity to then decide what treatment should be indicated.

Based on the interviews, the most commonly used methods to treat UI in low-resource settings are:

- Pelvic floor exercises.
- Surgical repair of second fistula—when a second fistula is present.
- Pubic sling surgery—only performed when the tissues of the vagina and urethra are still kept.
- Urethral plugs—in women in which no other surgery can be performed or in those in which surgery fails.

Other treatments that were reported by experts, but that are not as common are:

- Injection of bulking agents into the urethra—this procedure needs to be repeated several times, and it can be costly.
- Pharmacologic interventions—anticholinergic agents (oxybutynin).

Experts did not report use of any other noninvasive devices, such as pessaries or occlusive devices. In the case of pessaries, they are not used because most patients with incontinence post-repair have distorted, rigid, scarred vaginas, some of which are completely obliterated or the scar is so rigid that the vagina itself feels like a canal of bone, as per an email communication with Dr. Andrew Browning. In regards to occlusive devices such as urethral caps, experts mentioned they have not used them due to lack of access in low-resource settings. Since occlusive devices have not been tried in women with UI post fistula repair, there is no way to access whether they work or not for this purpose.

### ***Use of urethral plugs for UI following obstetric fistula repair***

The majority of experts interviewed have used or heard of urethral plugs for the treatment of UI following obstetric fistula repair. Experts that had used the device for treatment of UI provided both positive and negative feedback on the technology as reported from their patients.

#### **Positive aspects:**

- Patients were dry—some experts reported that at least 65% of women who used the plugs were dry.
- Patients reported the urethral plugs were easy to use once they were trained on how to use them.

- Bladder capacity increased over time, which allowed the patient to be eligible for a corrective operation.
- Good patient satisfaction.

#### **Negative aspects:**

- Repetitive use of the device leads to irritation of the urethra.
- Using a disposable device on a regular basis is costly. Women with this complication do not usually have the means to pay for a regular supply of plugs. Therefore, the responsibility to supply patients with plugs is on a health system, that in most cases does not work well.
- The device migrated into the bladder in some patients. When this occurred, women had to have surgical intervention to remove the device from the bladder.
- Fit of the device varies over time. Experts reported that the urethra of patients using the device can increase in size overtime and that the plug does not fit properly when this occurs. This problem limits the effectiveness of the device.
- One expert reported that the plug can lead to reopening of the fistula in 10% of cases and that he stopped using them for outpatient care for this reason.
- The bladder can become overactive after prolonged use.

#### ***Availability of urethral plugs in developing countries***

Experts reported that urethral plugs are not sold in developing countries; therefore, the availability of these devices is very limited. Physicians who have used the urethral plugs have obtained them as donations from the manufacturer (Rochester Medical). Some physicians who have not used the device have not done so because they could not access the plugs in the country where they work.

#### ***Reuse of urethral plugs***

In low-resource settings, women reuse the urethral plugs because supply is not regular. Interview data suggest that women use one plug for one month for 12 hours per day. Women wash the plug between uses and reinsert it. Experts mentioned that reusing the plug did not increase the risk of the urinary tract infections. However, they mentioned that there is no official data about reuse and urinary tract infection.

#### ***Payment for treatment***

Current payment for fistula repair and incontinence treatment varies from place to place. However, in most settings the cost of treatment is subsidized by nongovernmental organizations, governments, or private individuals. Patients pay for their cost of transportation.

#### ***Barriers that limit the use of urethral plugs in low-resource settings***

##### **Device-related barriers:**

- Cost.
- No commercial availability in countries where obstetric fistulas are prevalent.
- Repetitive use; the device requires continual use to minimize the symptoms of UI.

- Current size of the device does not accommodate all women with UI after obstetric fistula repair.

**Patient-related barriers:**

- No regular supply. Even in the centers that specialize in obstetric fistula repair there is a reliance on donations of urethral plugs, thus a regular supply is not guaranteed.
- Women have to come back to restock.
- A significant number of patients have bladder instability in addition to their obstetric fistula problem. In such patients, using the plug is contraindicated because it can cause vesicoureteral reflex.
- Lack of follow-up. Most patients in whom obstetric fistulas are repaired do not come back for follow-up.

***Improving urethral plugs to treat UI following obstetric fistula repair***

Experts suggested the following possible design modifications of the urethral plug to adapt its use for UI following obstetric fistula repair:

- *Size:* Providing a wider array of sizes of urethral plugs would be useful to accommodate the needs of this population. In most cases, after obstetric fistula repair, the urethras are quite short and urethral plugs can be quite large. With continued use, the plug can increase the size of the urethra and the woman will need a much larger diameter of a plug.
- *Reusability:* Designing a product that can be reusable is mandatory in a low-resource setting.
- *Cost:* Any device used to treat UI following obstetric fistula repair will need to be lower cost. Women with this complication must use the device for the rest of their lives, and, in general, this population does not have the resources to pay for costly treatments.
- *Supply:* The distribution and regular supply of the product will need to be maintained. The cost of supporting a system for product distribution and possibly transportation of women to the health center to obtain regular supplies must also be addressed.
- *Minimize complications:* An ideal device would be one that does not increase the risk of UTI and that can stay in place without any possibility of migration.

**VII. Product specifications and design modifications**

Improving the design of the urethral plug to adapt it for use in women who suffer from UI post-fistula repair is essential to address the needs of this population and to create market opportunities in low-resource settings. Based on the interviews with experts, urethral plugs used to treat UI post-fistula repair should have the following performance specifications:

- *Reusable.* A durable design that allows for multiple uses.
- *Affordable.*

- *Available in multiple sizes.* Accommodates size and length of urethras of women with UI post-fistula repair.
- *Easy to use.* A device that does not require extensive training and supervision by health professionals and that can be easily used by women.
- *Minimal side effects.* A device with design features that prevent migration into the bladder, urinary tract infections (UTIs), and urethral irritation.

### **Design modifications**

Table 2 summarizes the potential design changes that could achieve the product specifications noted above to address the needs of women with UI post-fistula repair.

**Table 2:** Design modifications of urethral plug.

<b>Product requirement</b>	<b>Current design</b>	<b>Potential design modifications</b>
<b>Reusable</b>	Nonreusable silicone-made insert.	<ul style="list-style-type: none"> <li>▪ Change the hardness of the silicone to make it thicker and more robust, which can make it more resistant to disinfection treatments such as chemical disinfection and/or boiling.</li> <li>▪ Use alternative materials, perhaps indigenous materials that are more durable.</li> <li>▪ Manufacture an additional piece to accompany the device—a container for a clean environment to store the device between uses.</li> <li>▪ Explore costs and requirements of an alternative regulatory pathway to re-label the current device as reusable.</li> </ul>

<b>Product requirement</b>	<b>Current design</b>	<b>Potential design modifications</b>
<b>Affordable</b>	Current market price. US: \$1.87/device UK: \$1.05/device	<ul style="list-style-type: none"> <li>▪ Redesign a device that permits reuse; this will also decrease cost.</li> <li>▪ Outsource the manufacturing of the product.</li> <li>▪ Source alternative materials to silicone.</li> </ul>
<b>Multiple sizes</b>	<p>Sizes available:</p> <p>Size 1 (16 Fr) in either 3.5-cm or 4.5-cm length</p> <p>Size 2 (18 Fr) in either 3.5-cm or 4.5-cm length</p> <p>Size 3 (20 Fr) in either 3.5-cm or 4.5-cm length</p> <p>Note: 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.</p>	<ul style="list-style-type: none"> <li>▪ Design devices with size &lt; 16 Fr to accommodate small urethras and &gt; 20 Fr to accommodate for urethras that have stretched after repetitive use.</li> <li>▪ Design devices &lt; 3.5 cm in length to compensate for the short length of some urethras in women with great damage to their urethral tissue.</li> </ul>
<b>Easy to use</b>	Experts mentioned in the interviews that the device is currently easy to use.	<ul style="list-style-type: none"> <li>▪ Assess ease of use with user groups in various settings.</li> </ul>
<b>Minimal complications</b>	Currently, the design of the device allows for the possibility of migration. In addition, having a device inserted into the urethra can predispose women to UTIs.	<p><i>Ideas to address migration:</i></p> <ul style="list-style-type: none"> <li>▪ Mold external retainer of the insert to make it more rigid.</li> </ul> <p><i>Ideas to address UTI:</i></p> <ul style="list-style-type: none"> <li>▪ Chlorhexidine wipes to disinfect the genital area prior to insertion of the plug.</li> <li>▪ Coat the device with an antimicrobial agent that maintains activity after repetitive use.</li> <li>▪ Manufacture an additional piece to accompany the device—a container for a clean environment to store the device between uses.</li> </ul>

## VIII. Cost considerations and market opportunities

Although UI impacts the lives of approximately 13 million people in the United States and costs the system approximately US\$15 billion to US\$24 billion annually, limited nonsurgical options exist.<sup>15</sup> Among nonsurgical options are pharmaceuticals, consumables (over-the-counter absorbent products), and incontinence devices. Due to their accessibility as a consumer product and relatively high awareness in the affected population, the category leaders are over-the-counter absorbent products such as Depend<sup>®</sup> (Kimberly Clark, USA), Attends<sup>®</sup> (Attends Healthcare Products, USA), or TENA<sup>®</sup> (Svenska Cellulosa Aktiebolaget SCA, Sweden).

The strong awareness and general availability of protective noninvasive consumables and limited Medicare and private insurance coverage for incontinence devices has resulted in limited market options and share for incontinence devices such as the urethral plugs and occlusive devices. The *FemSoft*<sup>®</sup> Insert (Rochester Medical Corp., USA) is the only such product remaining on the market despite attempts to enter the market with similar devices by startups such as UroMed/Alliant (USA) with the Reliance Insert and large multinationals such as Braun Melsungen with the urethral plug VIVA.

As the only noninvasive commercially available device, *FemSoft*<sup>®</sup> Insert represents perhaps the best baseline technology for introduction of a developed-world product into a low-resource setting to meet the needs of women with UI post-obstetric fistula repair.

### **Market assessment**

Approximately 2 million women live with an untreated obstetric fistula worldwide, with a reported incidence rate of 50,000 to 100,000 per year. Global capacity for obstetric fistula repair is estimated to be between 6,500 to 7,000 women per year with between 15% to 30% experiencing postoperative incontinence.<sup>2</sup> Based on our estimates, the addressable population that can benefit from these devices is between 975 and 2,100 women annually. However, if it is assumed that obstetric fistula repair capacity grows to cover all new cases at the high end of 100,000 per year, the estimated addressable population that could benefit from the device would be between 15,000 to 30,000 women per year.

PATH initiated discussions with Rochester Medical Corporation, the manufacturer and distributor of the sole urethral plug currently available on the worldwide market and was provided with the device's retail price. The *FemSoft*<sup>®</sup> Insert retails for between US\$1.87 in the United States to US\$1.05 in the United Kingdom—their two target markets for distribution. Cost models built around the company's recommended guidelines. These guidelines are urinating three times per day followed by insertion of a new sterile device. The result is an estimated first year annual health system cost of US\$1 million and US\$2.5 million to meet the needs of the currently addressable low-resource setting population (975 to 2,100 women).

This preliminary cost model is sensitive to changes in device cost and reusability, with the greatest impact resulting from increasing device reuse. For example, if the device was reusable rather than disposable, (following usage patterns in line with the reported rates observed by Dr. Browning of one new device per month), the annual cost to the health system would be reduced to the range of US\$11,700 to US\$27,720 for the first year. Table 3

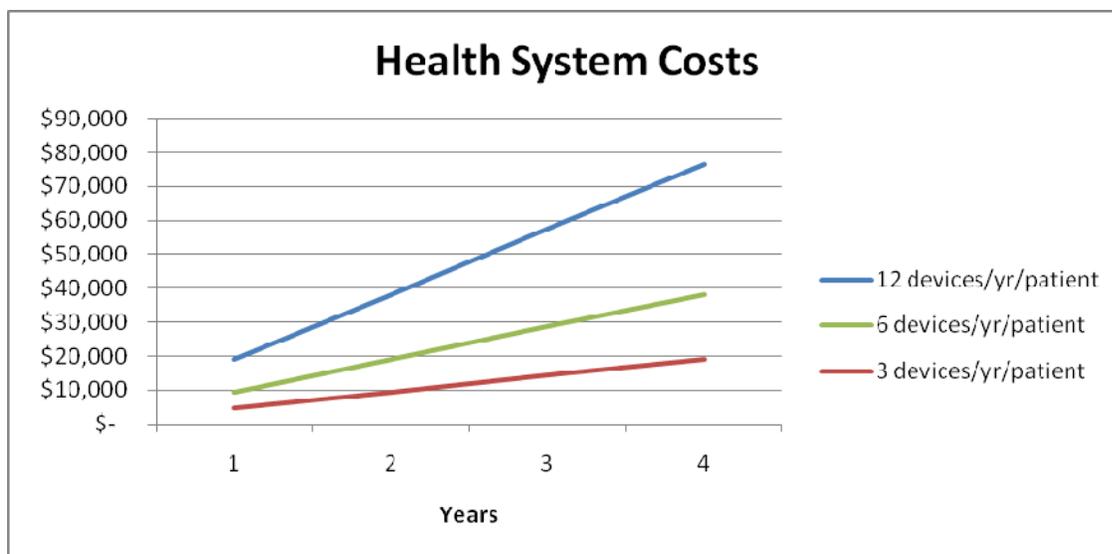
below summarizes the cost changes based on device reuse and additional savings by increasing reusability beyond the one device per month threshold.

**Table 3:** Cost sensitivity analysis with device reuse.

Sensitivity with device reuse (# of devices/year)	Coverage of addressable population		
	Low Range (in US dollars)	Middle Range (in US dollars)	High Range (in US dollars)
3	\$2,925	\$4,843	\$6,930
6	\$5,850	\$9,686	\$13,860
12	\$11,700	\$19,373	\$27,720
365	\$355,875	\$589,247	\$843,150

Due to continued long-term use and the assumption that usage drop-off will be offset by increased capacity for obstetric fistula repair (resulting in an increased need for urethral plug products), market growth is linear and cumulative—consistently adding annual incremental cost to the system (see Figure 5 below). However, it is important to note that significant increases to global capacity for obstetric fistula repair or improved compliance would have an exponential impact on the rate of demand and system cost growth.

**Figure 5.** Comparing growth in health system costs and sensitivity to device reuse over time.



### **Strategic partnership opportunities**

In 2008, Rochester Medical Corporation, the developer and owner of the intellectual property and distribution rights for the *FemSoft*<sup>®</sup> Insert, had total worldwide sales of US\$35 million across their entire line of extended and acute care products with a net income of US\$759,000.<sup>16</sup> The primary markets for the *FemSoft*<sup>®</sup> Insert are the United States and the United Kingdom, and Rochester Medical is currently not actively exploring other markets.

Discussions with the senior marketing manager for the *FemSoft*<sup>®</sup> Insert have resulted in positive preliminary results, with the company expressing interest in working with PATH to develop a product that would meet the needs of women in low-resource settings.

The requirement for supply-side sustainability is a business model that demonstrates revenue opportunities that offset development and manufacturing costs. The recommended commercialization strategy is a two-phase funding plan:

1. Identify product requirements and development needs for adaptation of the device for use in low-resource settings, thereby reducing upfront development costs for Rochester Medical Corporation and addressing product affordability.
2. Secure demand-side funding through specific grants or via the ministries of health and identify a stable distribution system to provide accessibility of this device into key health care settings.

## **IX. Recommendations**

### ***1. Conduct a user assessment in one country in East Africa and one country in West Africa***

Prior to undertaking any design modifications, it is important to obtain information directly from women who are using this device to fully understand how the device can be improved to serve the needs of this population. A user assessment could be conducted in partnership with organizations that are currently providing health service delivery to women with UI post-fistula repair.

Importantly, the user assessment would also serve as an opportunity to explore alternative solutions to treat this problem such as:

- Absorbent underwear (such as Depend<sup>®</sup> products) in both reusable and disposable forms.
- Sanitary pads in both reusable and disposable forms.

### ***2. Design modification of existing device***

Improving the design of the urethral plug to adapt it for use in women who suffer from UI post-fistula repair is important to create market opportunities and to address the needs of this population in low-resource settings. As noted earlier, design modifications should be:

#### **Reusable:**

- Change the hardness of the silicone.
- Use alternative materials.
- Manufacture an additional piece to accompany the device—a container for a clean environment to store the device between uses.
- Explore reusable off-label use of the device with Rochester Medical Corporation.

#### **Affordable:**

- Redesign a device to permit reuse; this will decrease cost.
- Outsource manufacturing of the product.
- Source alternative materials to silicone.

#### **Multiple sizes:**

- Design modification that creates devices with more sizes than those currently available to accommodate for the length and width of urethras of women with UI post-fistula repair.

**Minimal complications :**

- Mold the external retainer of the insert to make it more rigid.
- Use chlorhexidine wipes to disinfect the genital area prior to insertion of the plug.
- Coat the device with an antimicrobial agent that maintains activity after repetitive use.
- Manufacture an additional piece to accompany the device—a container for a clean environment to store the device between uses.

**3. *Strengthen dialogue with private company***

It is essential to strengthen the dialogue with Rochester Medical Corporation about a joint venture to perform design modifications of the urethral plug device to adapt its use to low-resource settings.

**4. *Validate product requirement specifications of a refined product***

Gather field experts to validate the product requirement specifications of a refined product and possibly share experiences and information on the challenges and available treatments of UI in low-resource settings. This activity could be performed in collaboration with the Fistula Foundation and other agencies engaged in fistula work.

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- <sup>3</sup> Browning A. Prevention of residual urinary incontinence following successful repair of obstetric vesico-vaginal fistula. *BJOG: An International Journal of Obstetrics and Gynaecology*. 2004;111:357–361.
- <sup>4</sup> Dolea C, AbouZahr C. Global burden of obstructed labor in the year 2000. Available at: [http://www.who.int/healthinfo/statistics/bod\\_obstructedlabour.pdf](http://www.who.int/healthinfo/statistics/bod_obstructedlabour.pdf). Accessed September 25, 2009.
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- <sup>6</sup> Gutman RE, Dodson JL, Mostwin JL. Complications of treatment of obstetric fistula in the developing world: Gynatresia, urinary incontinence, and urinary diversion. *BJOG: An International Journal of Obstetrics and Gynaecology*. 2007;99:S57-S64.
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- <sup>10</sup> Rochester Medical Corporation. *FemSoft*® Insert-Instructions for physicians. July 2008.
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- <sup>12</sup> Viera A, Larkins-Pettigrew M. Practical use of the pessary. *American Family Physician*. 2002;66(1):30.
- <sup>13</sup> Júnemann K-P. The management of female urinary stress incontinence: II. The use of devices. *BJU International*. 2001;87:449–455.
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<sup>15</sup> Rochester Medical Corporation. *FemSoft*® Insert Compendium.

<sup>16</sup> Rochester Medical Corporation 2008 Annual Report. Available at: [http://library.corporate-ir.net/library/84/848/84808/items/319015/70729331-6876-4B40-959D-BDEACEA74D6A\\_ROCM\\_AR\\_2008.pdf](http://library.corporate-ir.net/library/84/848/84808/items/319015/70729331-6876-4B40-959D-BDEACEA74D6A_ROCM_AR_2008.pdf). Accessed October 2, 2009.

# **Annex 1. Questions to interview experts in the field of obstetric fistula repair**

## **Urethral Plugs for the Treatment of Urinary Incontinence Due to Obstetric Fistula**

### **Questions to experts:**

**1. What are the most common treatment options you see or implement for urinary incontinence following obstetric fistula repair?**

**2. Have you prescribed urethral plugs for urinary incontinence following obstetric fistula repair in the past?**

Yes No

If no,

*2.1 Why didn't you prescribe them?*

*2.2 What other things are you prescribing to treat women with urinary incontinence due to obstetric fistula?*

If yes,

*2.3 What is the device name that you use?*

*2.4 Do you have a rough estimate of how the device's cost compares to alternative treatments?*

*2.5 Are you able to buy the device directly from the manufacturer?*

**3. Did the device give satisfactory results in the patients treated?**

Yes No

If no,

*3.1 What problems did you encounter with the use of urethral plugs in your patients?*

If yes,

*3.2 What were the satisfactory results observed in your patients?*

**4. What would make urethral plugs good or better for women?**

**5. Are you familiar with a brand named FemSoft?**

**6. Do you know of any other devices (even home made) that have been used to treat women with urinary incontinence after fistula repair?**

**7. Have you gotten any feedback from patients using the plugs?**

**8. Do patients re-use the FemSoft?**

Yes No

If yes,

*8.1 How many times do they re-use the urethral plugs?*

**9. Did the patients that use urethral plugs experience repetitive urinary tract infections?**

Yes No

If yes,

*9.1 Did they continue using the plugs?*

**10. What would be a reasonable cost for a technology like this?**

**11. How is the treatment usually paid for? Patient, hospital, pro bono?**

**12. Does your organization have any plans to support this problem (urinary incontinence following obstetric fistula repair)?**

**13. What else should we take into consideration when thinking about this problem?**

## **Annex 2: Supplemental information on other nonsurgical interventions for the treatment of urinary incontinence**

### ***Noninvasive treatments***

#### **a. Pelvic floor exercises**

Pelvic floor exercises are the most commonly used method to treat urinary incontinence (UI) worldwide. According to interviews, this method is currently being used in developing countries because it may be the easiest therapy to implement in under-resourced settings since it does not require special equipment, additional health care infrastructure, or other costly resources.<sup>1</sup>

Pelvic floor muscle exercises, also called pelvic muscle exercises or Kegel exercises, are an essential part of the behavioral treatment techniques that help increase bladder control and decrease bladder leakage. These techniques require conscious effort, consistent discipline, and are a lifetime commitment.<sup>2</sup>

Pelvic floor exercises appear to be more effective than no therapy for UI, and they have been shown to improve mild to moderate urge and UI. When performed correctly, these exercises help strengthen the muscles that support the bladder. Through regular exercise, women can build control and endurance to help improve, regain, and maintain bladder and bowel control.<sup>1</sup> However, studies in developed countries have shown that less than 50% of women continue to exercise regularly, leading to a two-year cure rate of only 8%.<sup>3</sup>

#### **b. Pelvic floor stimulation**

Pelvic floor stimulation (PFS) can help women with UI contract and therefore strengthen their pelvic floor. Pelvic floor stimulation is based on the principles of treating nerves which supply the pelvic floor muscles. When a muscle is weak, regular treatment with an external stimulus may make the muscle contract.<sup>3</sup>

PFS is the controlled delivery of small amounts of stimulation to the nerves and muscles of the pelvic floor and bladder. The stimulation is generated through a tampon-like sensor that is placed in the vagina or by surface electrodes that are placed around the anus. The sensor or electrode is attached by a cable to a small battery-operated device used

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<sup>1</sup> Hay-Smith J, Mørkved S, Fairbrother KA, Herbison GP. Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women. *Cochrane Database of Systematic Reviews*. 2008;4. Article Number CD007471. DOI:10.1002/14651858.CD007471.

<sup>2</sup> National Association for Continence website. Non-Surgical Treatments for Female Stress Urinary Incontinence. Available at: <http://www.nafc.org/index.php?page=non-surgical-treatment-for-female-stress-urinary-incontinence>. Accessed September 25, 2009.

<sup>3</sup> Robert M, Ross S. Conservative management of urinary incontinence. *Society of Obstetricians and Gynaecologists Clinical Practice Guideline*. Number 186, December 2006.

privately in the home or a larger clinical device in a doctor's or therapist's office. Sometimes PFS is called electrical stimulation or "E-Stim".<sup>2</sup> The advantage of this therapy is that it does not require voluntary patient effort, but its disadvantages are that the passive muscle contractions are weaker and this method requires the patient to be close to a facility that has access to the equipment, which can be difficult to implement in a developing-country setting.<sup>3</sup>

### **c. Pharmacologic treatment**

Alpha-adrenergic agonists and estrogens are sometimes used to treat UI. Alpha-adrenergic agonists stimulate urethral closure and estrogens have been used widely to treat UI due to their ability to increase urethral vascularity and thickness. In addition, estrogens help sensitize alpha-adrenergic receptors in the bladder neck, which can theoretically improve urethral closure. The lack of evidence that estrogen therapy improves UI, combined with other concerns about long-term use of hormone therapy, has made estrogen a poor choice for treatment of UI.<sup>4</sup>

Other medications that have been used to treat UI are: Pseudoephedrine and Duloxetine, neither is approved by the United States Food and Drug Administration for this indication.<sup>4</sup> It is important to note that pharmacologic treatment for UI is not currently used in developing countries due to the cost and availability of medications for this purpose. In addition, the physio-pathology of UI following fistula repair is different than that of UI in women that have not had obstetric fistula. Therefore, the role that medications play in this case is not well known.

Another important aspect to consider is that the problem in developing countries affects a population that is much younger than that of developed countries. Thus, the use of medications for the rest of a woman's life can have significant financial and physical impact on the patient and the health system in general.

## ***Minimally invasive treatments***

### **Injection of bulking agents into the urethral wall**

Periurethral injection of collagen results in high short-term cure rates, but effectiveness diminishes over time. From numerous studies (in developed countries) on the efficacy of periurethral injections for the treatment of UI, the improvement rate varies from 40% to 90%, with a success rate of ~ 50%.<sup>5</sup>

The advantages of injectable procedures are: lower number of complications, reduced morbidity, and the fact that they can be performed on an outpatient or day hospital basis.<sup>6</sup>

Many agents have been used, but none of them has proven to be entirely effective. Among the agents used are: autologous fat, teflon, collagen, silicone, urovive (microrballoons), and duraspere. Studies have shown no difference among these agents

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<sup>4</sup> Weiss B. Selecting medications for the treatment of urinary incontinence. *American Family Physician*. 2005;71:315–322,329.

<sup>5</sup> Meschia M, Pifarotti P, Gattei U, Crosignani PG. Injection therapy for the treatment of stress urinary incontinence in women. *Gynecological and Obstetric Investigation*. 2002;54:67–72.

<sup>6</sup> McGuire E. Urethral bulking agents. *Nature Clinical Practice Urology*. 2006;3( 5):234-235.

for the treatment of UI. The differences are the means of injecting the agent, and the stability of the agents. Some (such as the autologous fat) are very easy to administer, but reabsorb fairly quickly requiring multiple injections.<sup>6</sup>

The cost of injection with bulking agents and the transitory improvement limits its application in developing countries.

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



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## introduction

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

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

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

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

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

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

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

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

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

## treatment options for SUI

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

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

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

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

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

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

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

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

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

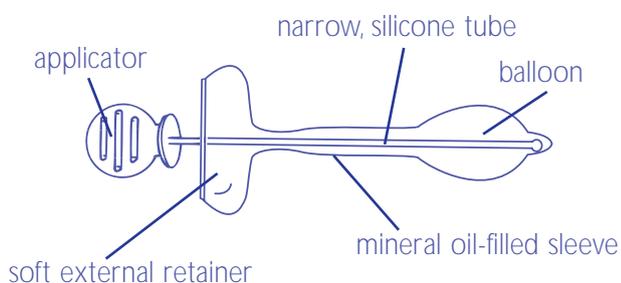
For women with urethra and bladder neck hypermobility who have SUI, the AHCPR recommends retropubic or needle suspension rather than anterior vaginal repair. For women with SUI who have ISD, the AHCPR recommends a sling procedure if there is coexisting hypermobility; if there is no hypermobility, the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

## the FemSoft Insert

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

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

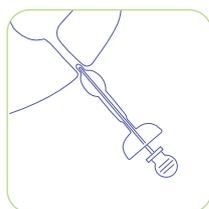
To protect delicate tissue, the *FemSoft* Insert is smooth and seamless, with no hard surfaces. Its unique design allows a woman to insert and remove the product without operating any valves or other mechanisms.



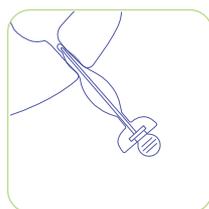
**Function** - The unique characteristics of the mineral oil-filled sleeve provide the mechanism for insertion and retention of the *FemSoft* Insert. As the insert is advanced into the urethra, the encased fluid is transferred toward the external retainer to facilitate the insert's passage through the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

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

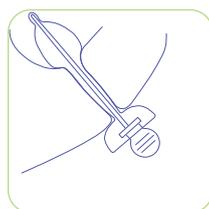
The fluid-filled sleeve readily adjusts to anatomical variations among women. It further adjusts to changes in urethral shape that occur with body movement and/or changes in intra-abdominal pressure. This feature allows the insert to maintain constant contact with the urethral tissues, thereby preventing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



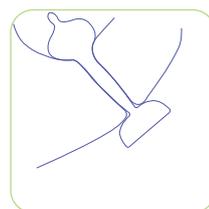
Tip inserted



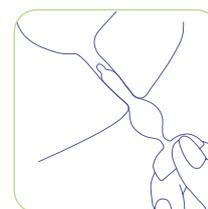
Insertion proceeds



Advanced into bladder



Applicator removed



Withdrawal

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

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

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

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

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

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

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

*FemSoft*<sup>®</sup>  
insert



*clinical  
data*

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

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

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

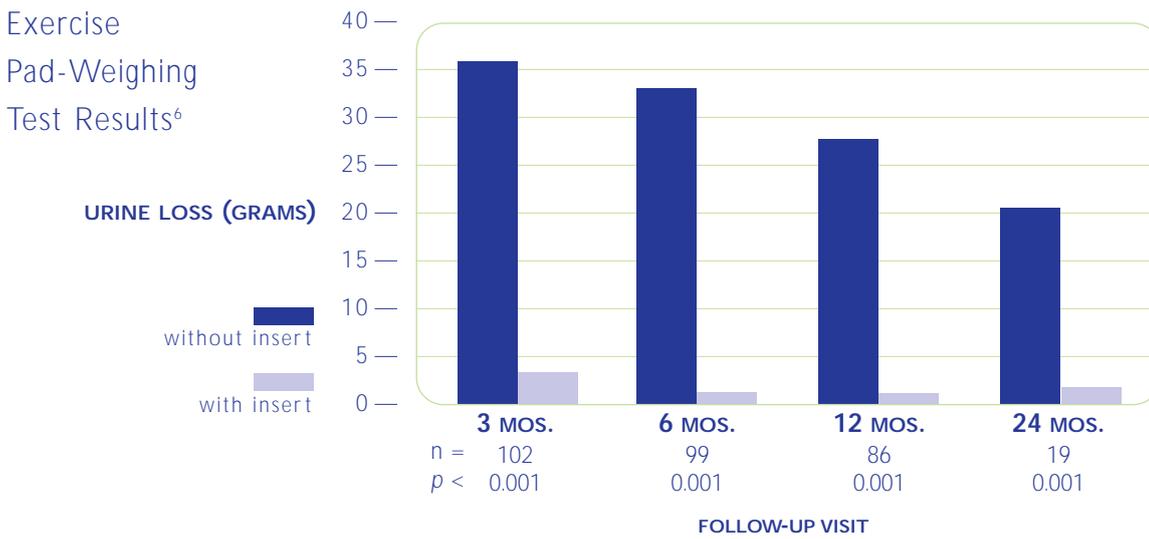
**Study population** - One hundred fifty women were enrolled in the trial. The average age of participants was 53.5 years (range 27 to 78 years). The average duration of SUI in participants was 10.9 years (SD 8.3, range 1 to 40 years). Forty-eight percent of the participants had urgency symptoms in addition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

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

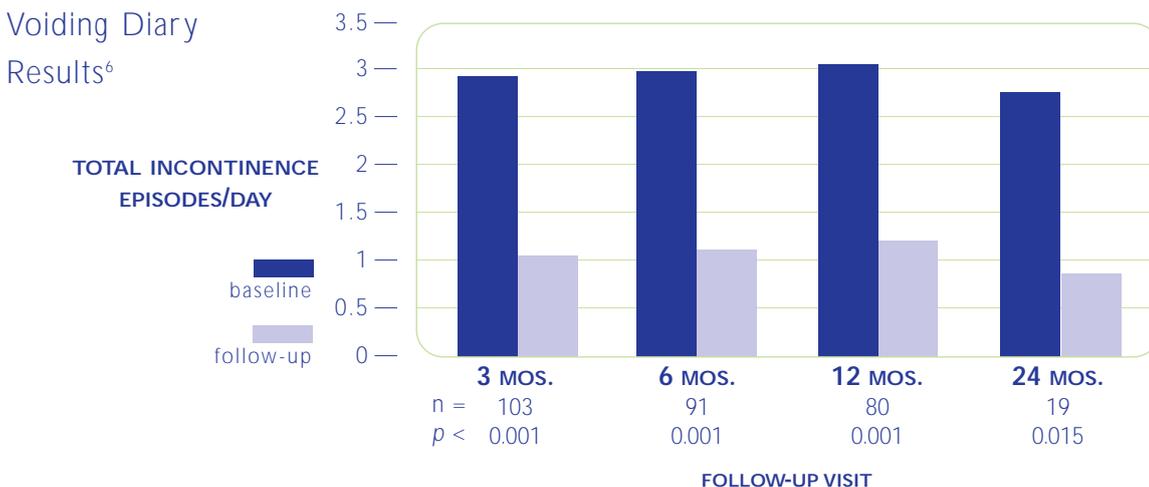
**Results** - Follow-up results include evaluations from 114 women at three months, 102 women at six months, 87 at 12 months, and 22 at 24 months. Average follow-up for participants was 14.6 months (SD 8.3).

**FemSoft efficacy**

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

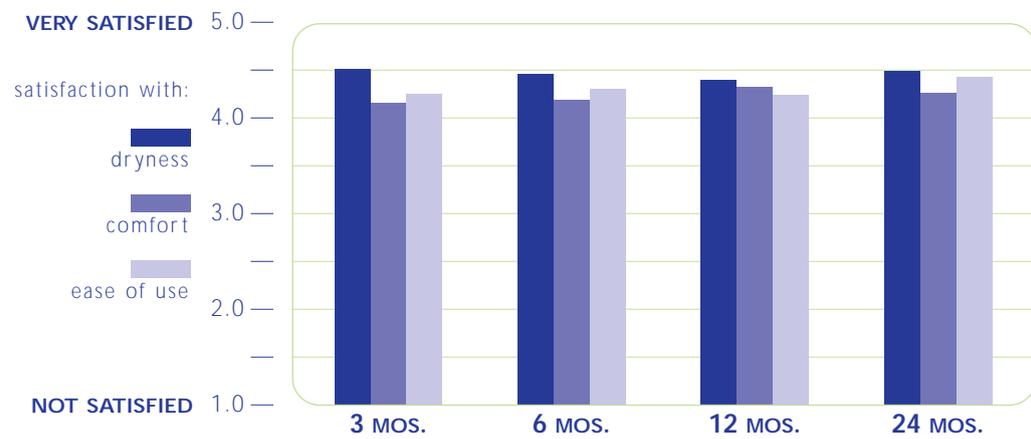


*voiding diaries.* Voiding diaries kept throughout the trial supported a comparison of the numbers of SUI episodes between screening and follow-up periods and between periods of use and nonuse of the insert during follow-up periods. The results show that use of the FemSoft Insert produced statistically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



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

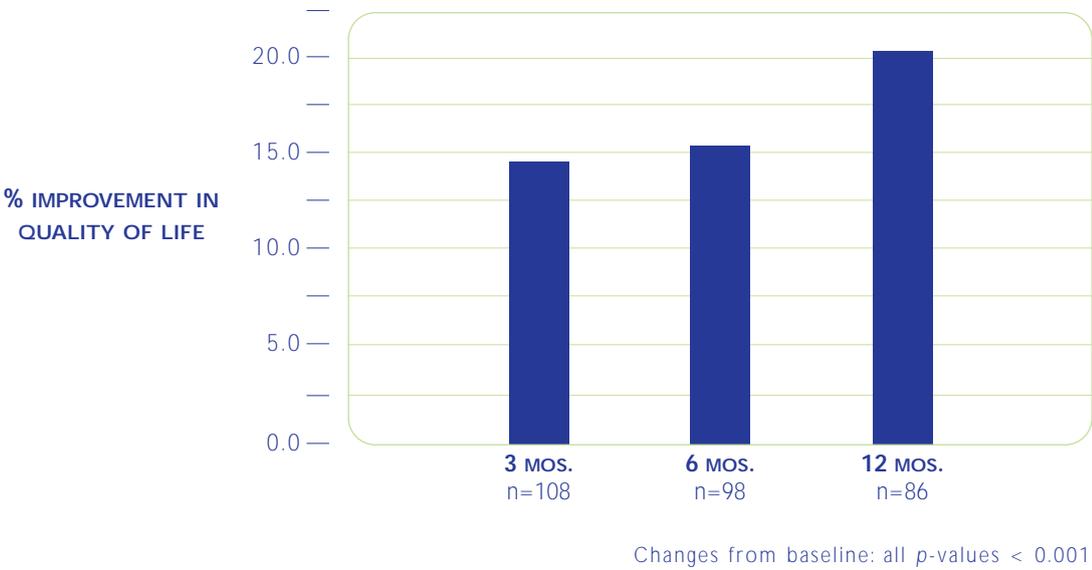
### Women's Satisfaction Questionnaire Results<sup>6</sup>



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

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

### Quality-of-Life Instrument Results<sup>6</sup>



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

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

#### Complications and Adverse Events<sup>6</sup>

\* including urgency, frequency, nocturia

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

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

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

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

patient evaluation,  
education, and  
follow-up

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

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

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

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

**Education and training should consist of the following:**

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

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

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

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

## conclusion

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

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

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

## references

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

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

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

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

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

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

**ADVERSE EVENTS, COMPLICATIONS AND RISKS:** The following adverse events have been reported with use of the device. Bacteriuria 29%, symptomatic UTI 25%, urinary symptoms 23%, asymptomatic UTI 7%, insertion trauma 6%, bladder/urethral trauma/irritation 3%, hematuria, spotting, vaginal yeast infection, back pain, migration, pyelonephritis (possibly related to pre-existing renal stones) less than 3%.<sup>8</sup>



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