

Long-Term Results of the *FemSoft*[®] Urethral Insert for the Management of Female Stress Urinary Incontinence

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ABSTRACT

A 5-year ongoing, controlled multicenter study enrolled 150 women. Outcome measures included pad weight tests (PWT), voiding diaries (VD), quality of life (QOF) and satisfaction questionnaires. Outcome measures during the baseline period were compared to evaluations during the follow-up. Concurrent evaluations with and without device use were also performed. Safety evaluations included urinalysis and culture, leak-pressure (LPP) and cystoscopy. Adverse events (AE) were recorded throughout the study.

One to 2 years of follow-up were collected on all study participants (mean 15 months). Statistically significant reductions in overall daily incontinence episodes ($p < 0.000$) and PWT urine loss ($p < 0.001$) were observed with the device at all follow-up intervals, and 93% of women had a negative PWT at 12 months. Women were satisfied with ease of use of the device, comfort and dryness, and significant improvements in QOL were observed ($p < 0.001$).

Subgroup analysis revealed that the insert was effective, despite the presence of urgency, low LPP, failed surgery and advanced age. AE included symptomatic urinary tract infection in 31.3%, mild trauma with insertion in 6.7%, hematuria in 3.3%, and migration in 1.3% of women. The results of PWT and VD demonstrated device efficacy. Women were satisfied and significant improvements in QOL were observed. AE were transient and required minimal or no treatment.

The urethral insert should be considered as an option for the management of SUI.

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