**EFFECTIVE RESULTS**

In clinical trials evaluating the Secca procedure, up to 84% of patients experienced a clinical response to treatment. Additionally, there were fewer side effects with Secca than with surgery. Failure to improve after this treatment does not prevent patients from having surgery or an implant at a later date.

**FAQs**

**Is the Secca Treatment for You?**
Some patients are able to control their symptoms by altering their diet and/or taking fiber supplements, or through the use of anti-diarrheal medications. Many patients benefit from biofeedback (muscle retraining). However, if patients are unsatisfied or don’t respond to these conservative options, Secca therapy may be a good option.

**What can patients expect in terms of improvements in bowel incontinence?**
As every patient’s underlying cause for bowel incontinence may be different, their response to Secca therapy may also be somewhat different. Some patients see improvement more quickly than others and studies show the symptoms may continually improve for 6 months or longer. Some patients’ symptoms may worsen immediately after Secca therapy and this worsening may last for 2 to 3 weeks.

**Do patients experience pain after Secca Therapy?**
Patients may experience pain immediately after Secca Therapy, which in most cases can be managed with OTC analgesia (acetaminophen), or in severe cases narcotics, such as Vicodin or Darvacet. Patient should refrain from using NSAIDS for 14 days after the Secca procedure.

 **SAFETY INFORMATION**

**INDICATIONS FOR USE:** The Secca System is intended for the treatment of fecal incontinence in those patients with incontinence to solid or liquid stool at least once per week and who have failed more conservative therapy.

**CONTRAINDICATIONS:** There are no known absolute contraindications to the use of radiofrequency in humans. The use of electrosurgery is contraindicated when, in the judgment of the physician, electrosurgical procedures would be contrary to the best interest of the patient. The following may be considered contraindications specific to this procedure: Crohn’s disease or ulcerative colitis (inflammatory bowel disease); Collagen vascular disease (Raynaud’s, Systemic Sclerosis); History of anal abscess, fistula or prolapse; Constipation or chronic diarrhea as sole cause or the major contributor in bowel incontinence; Abnormal blood coagulation or use of anticoagulant or platelet anti-aggregation therapy (other than aspirin); Subject has undergone pelvic irradiation; Subject is pregnant; Subject has current or history of laxative abuse; Poor surgical candidate, or reduced life expectancy that limits follow-up; Subject suffers from unstable psychiatric disorder(s); Subject is less than 18 years of age; Subject has any type of anorectal foreign body implant, such as a bulking agent.

**WARNINGS:** Use of electrosurgery for the treatment of fecal incontinence may result in the following complications: Bleeding from the anal canal with the possible need for surgery (to correct bleeding), and/or transfusion; Burn related to position of return electrode; Diarrhea related to antibiotic prophylaxis; Difficulty having a bowel movement, constipation; Fever; Hypoxia and other injury related to conscious sedation; Infection with possibility for surgery and/or antibiotics to correct infection; Injury to the anorectal lining with possible stricture formation; Nausea; Over-tightening or stricture formation (making the anal sphincter too tight; Pain during the procedure or transiently after the procedure; Pain or difficulty with bowel movements; Pain or difficulty with urination; Perforation with possibility for surgery and/or antibiotics to correct perforation; Pudendal nerve injury; Rectovaginal fistula with possibility for surgery and/or antibiotics to correct fistula; Submucosal hematoma, minor; Surgery, colostomy, and/or antibiotics to correct injury or infection related to procedure; Transient worsening of fecal incontinence symptoms.

(SAFETY INFORMATION ABOVE IS DIRECTLY FROM THE IFU)