

## QUESTIONS & ANSWERS

Q: What can I expect in terms of improvement in my fecal incontinence?

It is common for symptoms to temporarily worsen due to antibiotics and stool softeners prescribed after the procedure. Patients typically begin to experience improvement in fecal incontinence symptoms between one to three months after treatment. This improvement may continue for the next 6 months. Clinical studies showed that 60% to 80% of patients reported improvement in fecal incontinence symptoms.

Q: Will I experience any pain during or after the Secca procedure?

Most patients experience no discomfort or only mild discomfort during the procedure. After the procedure, you may experience some minor discomfort for 1-5 days, which can be alleviated with pain medications prescribed by your doctor.

### INDICATIONS, CONTRAINDICATIONS AND WARNINGS

**INDICATIONS FOR USE:** The Secca<sup>®</sup> 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. **PROCEDURE-SPECIFIC CONTRAINDICATIONS:** Crohn's disease or ulcerative colitis (inflammatory bowel disease), collagen vascular disease (Raynaud's, Systemic Sclerosis), anal abscess or fistula, constipation or chronic diarrhea as sole cause or the major contributor in fecal 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, ASA IV, subject suffers from unstable psychiatric disorder(s), subject is less than 18 years of age. **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 dispersive 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; worsening of fecal incontinence symptoms, transient.

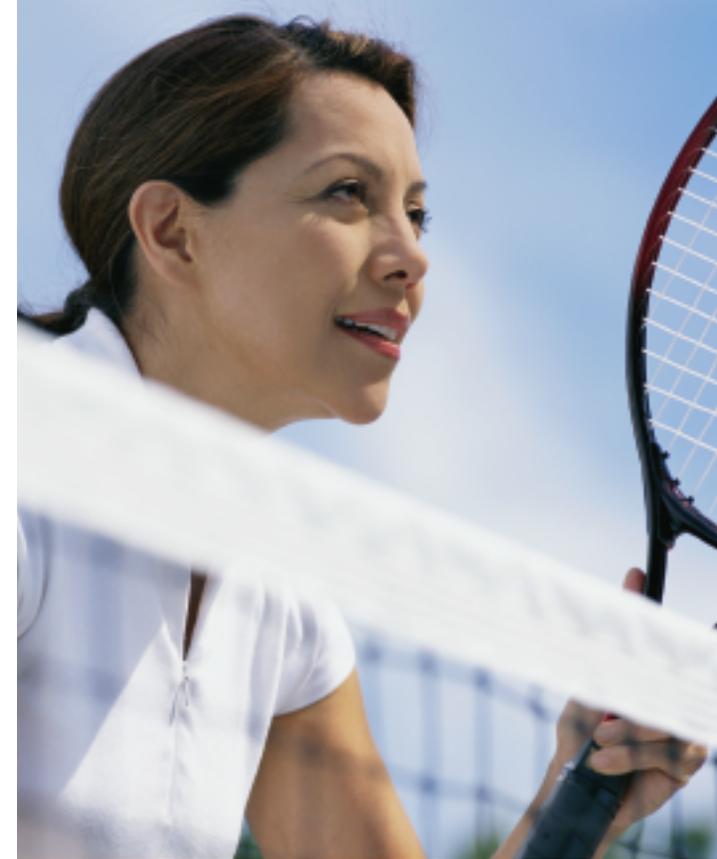


The minimally invasive treatment for fecal incontinence



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## BOWEL CONTROL...

More people than you think have problems with control.

Ask your physician about a new treatment that can help.



Sets Patients Free



# AS MANY AS 1 IN 13 ADULTS HAS PROBLEMS WITH BOWEL CONTROL...

*...but it's rarely discussed. Many people incorrectly assume it is a normal consequence of aging or is a normal problem for women after childbirth. If this condition is affecting your daily life, ask your doctor about treatments that can help.*

## WHAT IS FECAL INCONTINENCE?

Fecal incontinence is the inability to control the bowels, which results in the leakage of stool or gas. There are many causes of fecal incontinence, including injury from childbirth, injury from a previous surgery, nerve-related diseases, and age-related changes in muscle tone.

Fecal incontinence has a dramatic impact on quality of life. Many patients stay home, alter their schedules because of their bowel condition, or avoid social interactions due to the fear and embarrassment of incontinence events. It doesn't have to be that way.

## IS THE SECCA PROCEDURE FOR YOU?

Some patients are able to control fecal incontinence by altering their diet, taking fiber supplements, or taking anti-diarrheal medications. Others may benefit from biofeedback (muscle retraining). However, for many patients, these treatments are not effective in controlling symptoms.

**If you are one of these patients, the Secca procedure may be an attractive choice for you.** The Secca procedure is a simple, outpatient procedure that takes approximately 30 to 45 minutes. Patients typically return home within 1 to 2 hours of treatment, and may resume normal activities within a few days.

Surgery may also be an option, depending on the cause and severity of your symptoms. Ask your physician what treatment option would be most appropriate for you.



Mild Incontinence —————> Severe Incontinence



## THE SECCA PROCEDURE

The Secca procedure involves the delivery of low levels of heat to the muscle of the anal canal. Through the body's natural healing process, the tissue contracts and muscle tone is improved.

A special instrument is placed into the anal canal.



The physician delivers controlled levels of radiofrequency energy to heat small areas of the tissue, causing the collagen to contract.



As these heated areas heal, additional collagen is deposited and the muscle is strengthened.

