

secca®

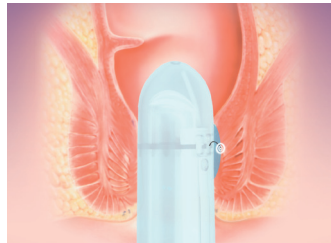
A MINIMALLY INVASIVE AND EFFECTIVE BRIDGE
BETWEEN CONSERVATIVE THERAPY AND SURGERY
FOR BOWEL INCONTINENCE



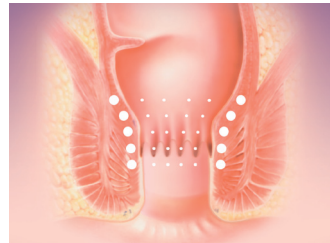
Candidates for the Secca procedure experience incontinence at least once a week, have failed traditional therapies (fiber, medications, biofeedback, overlapping sphincter repair), desire a less invasive treatment than surgery, or are not optimal candidates for surgery due to lack of a sphincter injury. In this patient group, studies have demonstrated that up to 80% of patients experience a significant improvement in incontinence symptoms.

HOW SECCA WORKS

- Minimally invasive
- Safe and well tolerated
- Effective bridge between conservative therapy and surgery



CONCENTRATED
RF ENERGY
DELIVERED
TO TISSUE



MULTI-LEVEL
DENATURED
COLLAGEN
LESIONS CREATED



ANAL SPHINCTER
FUNCTION IS
SIGNIFICANTLY
IMPROVED



Secca therapy involves delivery of radiofrequency energy to the muscles of the anal canal, which results in a change in tissue compliance and corresponding improvement in incontinence symptoms. This outpatient procedure takes approximately 45 minutes and is performed in an endoscopy suite or ambulatory surgery unit with the patient under general anesthesia or conscious sedation. Patients go home approximately 1-2 hours after the procedure and typically resume normal activities within several days.



MEDERI THERAPEUTICS INC

secca-therapy.com

8 Sound Shore Drive, Suite 160
Greenwich, CT 06830
203 930 9900
mederitherapeutics.com

SECCA® Procedure for the Treatment of Fecal Incontinence: Results of a Five-Year Follow-Up.

Takahashi T, Morales M, Garcia-Osogobio S, Valdovinos MA, Belmonte C, Barreto C, Zarate X, Bada O, Velasco L. SECCA® Procedure for the Treatment of Fecal Incontinence: Results of a Five-Year Follow-Up. *Dis Colon Rectum* 2008;51:355-359.

CONCLUSION: Significant and sustained improvements in fecal incontinence and quality of life are seen at five years after treatment with the Secca system. This treatment should be considered for patients suffering from fecal incontinence not amenable to surgery and who have failed conservative management.

Radiofrequency energy delivery, using the Secca device, into the anal canal muscle is a new modality that, in this study has safely provided five-year improvement in Wexner, FIQL scores and patient quality of life on an outpatient basis. Although not all patients improve, the majority can expect significant clinical response with minimal risk. Furthermore, there are no “bridges burned” by providing the Secca early in the treatment spectrum for patients suffering from fecal incontinence.

The SECCA® Procedure: A New Therapy for Treatment of Fecal Incontinence.

Efron JE, M.D., F.A.C.S., F.A.S.C.R.S. The SECCA® Procedure: A New Therapy for Treatment of Fecal Incontinence. *Surg Tech Intl* XIII December 2004;107-110.

CONCLUSION: The Secca device has been approved by the Federal Drug Administration (FDA) for use in the United States (US). Many centers in the U.S. have started performing the procedure off protocol. Currently, a randomized, multi-center, single-blinded study is being completed in the U.S. to rule out the placebo effect as a cause for the improvement seen in prior trials. The available data, however, suggests the Secca procedure is effective in improving continence in many patients with minimal risk.

The Secca procedure may offer a bridging technique for patients who do not respond to medical therapy or biofeedback, are not candidates for sphincter repair, and who do not want to undergo the more invasive surgical procedures such as implantation of an artificial bowel sphincter. Performing the procedure does not preclude the patient from undergoing other more invasive procedures to help improve their continence if they do not respond well to the Secca procedure.

Safety and Effectiveness of Temperature-Controlled Radiofrequency Energy Delivery to the Anal Canal (Secca Procedure) for the Treatment of Fecal Incontinence.

Efron JE, Corman ML, Fleshman J, Barnett J, Nagle D, Birnbaum E, Weiss EG, Noguerras JJ, Sligh S, Rabine J, Wexner SD. Safety and Effectiveness of Temperature-Controlled Radiofrequency Energy Delivery to the Anal Canal (Secca Procedure) for the Treatment of Fecal Incontinence. *Dis Colon Rectum* 2003;46:1606-1618.

CONCLUSION: The Secca procedure offers a useful therapeutic option for patients with fecal incontinence. The procedure is safe, performed on an outpatient basis, and does not preclude patients from undergoing more invasive interventions. The results demonstrate some improvement with respect to the symptoms of fecal incontinence and quality of life.

Extended Two-Year Results of Radio-Frequency Energy Delivery for the Treatment of Fecal Incontinence (the Secca Procedure)

Takahashi T, Garcia-Osogobio S, Valdovinos M, Belmonte C, Barreto C, Velasco A. Extended Two-Year Results of Radio-Frequency Energy Delivery for the Treatment of Fecal Incontinence (the Secca Procedure). *Dis Colon Rectum* 2003;46:711-715.

CONCLUSION: A significant improvement in symptoms of fecal incontinence and quality of life persists two years after radio-frequency delivery to the anal canal, which demonstrates durability of this intervention.

Radiofrequency Energy Delivery: A New Option for the Treatment of Fecal Incontinence.

Melega E, Dodi G, Masin A, Cavallari F, Migliorini G, Lise M. Radio-frequency Energy Delivery: A New Option for the Treatment of Fecal Incontinence. (Abstract presented at the International Meeting of Coloproctology, Saint Vincent, Italy. September 10 – October 3, 2003).

CONCLUSION: This preliminary report regards an ongoing study testing a new option for fecal incontinence. The functional results are promising, in view of the simplicity and safety of the SECCA procedure.

Radiofrequency Energy Delivery to the Anal Canal for the Treatment of Fecal Incontinence.

Takahashi T, Garcia-Osogobio S, Valdovinos MA, Mass W, Jimenez R, Jauregui AL, Bobadilla J, Belmonte C, Edelstein PS, Utley DS. Radiofrequency Energy Delivery to the Anal Canal for the Treatment of Fecal Incontinence. *Dis Colon Rectum* 2002;45:915-922.

CONCLUSION: Radio-frequency energy delivery deep to the mucosa of the anal canal for treatment of FI is a new modality that, in this study group, safely improved the Wexner and FIQL scores, eliminated protective pad use in most patients, and improved patient quality of life. These symptom improvements were accompanied by a reduction in the threshold and maximal rectal distention volumes on ARM, alluding to a possible, yet undefined mechanism. A U.S. multicenter trial is underway to define further the precise role and mechanism of action of RF delivery for the long-term management of this disorder.