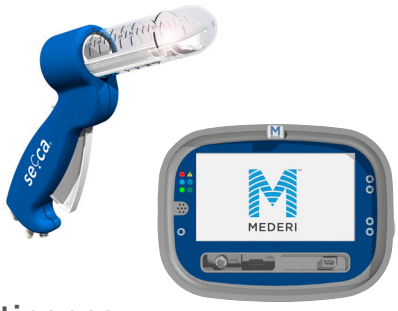
SAFE | EFFECTIVE | DURABLE

secca®



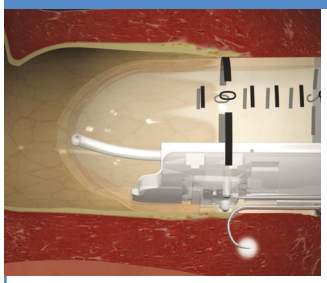
Secca therapy is a safe, effective and minimally invasive procedure that bridges the treatment gap between conservative therapies and invasive surgery or implants for bowel incontinence, or BCD (bowel control disorder).

SECCA - THE PATIENT

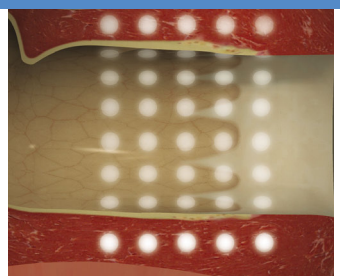
Candidates for the Secca procedure experience incontinence at least once a week, have failed conservative therapies (fiber, medications, biofeedback), desire a less invasive treatment than foreign implants or surgery, or are not optimal candidates for surgery. In this patient group, studies have demonstrated that up to 84% of patients experience a significant improvement in incontinence symptoms.

Because Secca doesn't involve surgery, or introduce foreign substances, it can be utilized in a variety of patient groups, and doesn't preclude other treatment options.

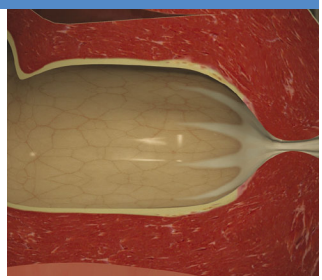
HOW SECCA WORKS



CONCENTRATED RF ENERGY DELIVERED TO TISSUE



MULTI-LEVEL TREATMENT REMODELS THE INTERNAL ANAL SPHINCTER



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. Patients go home approximately 1-2 hours after the procedure and typically resume normal activities within several days.

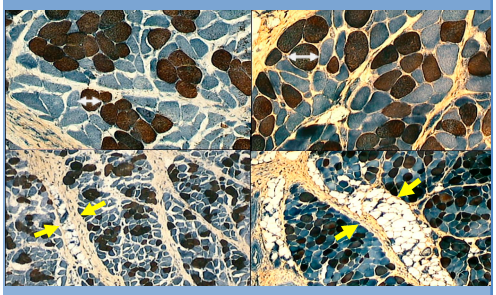
SECCA - THE NUMBERS

84%
EXPERIENCE SIGNIFICANT SYMPTOM IMPROVEMENT

5
YEARS DURABLE SYMPTOM RELIEF

<1%
COMPLICATION RATE

3,000+
PROCEDURES



RECENTLY PRESENTED ANIMAL STUDIES EXAMINE THE MECHANISM OF NON-ABLATIVE RF TREATMENT OF SMOOTH MUSCLE

- Structural changes to and growth of the smooth muscle (size and amount) and redistribution of the interstitial cells of cajal
- A change to stimulate myofibroblasts which influences muscle production
- A change in the muscle fiber to connective tissue ratio, this ratio becomes higher because the amount of connective tissue decreases while muscle fiber tissue increases
- Increase in Collagen 1 (connective tissue)
- Decrease in Collagen 3 (fibrosis scleroprotein)

- Herman et al, SAGES & DDW Posters 2013

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MEDERI

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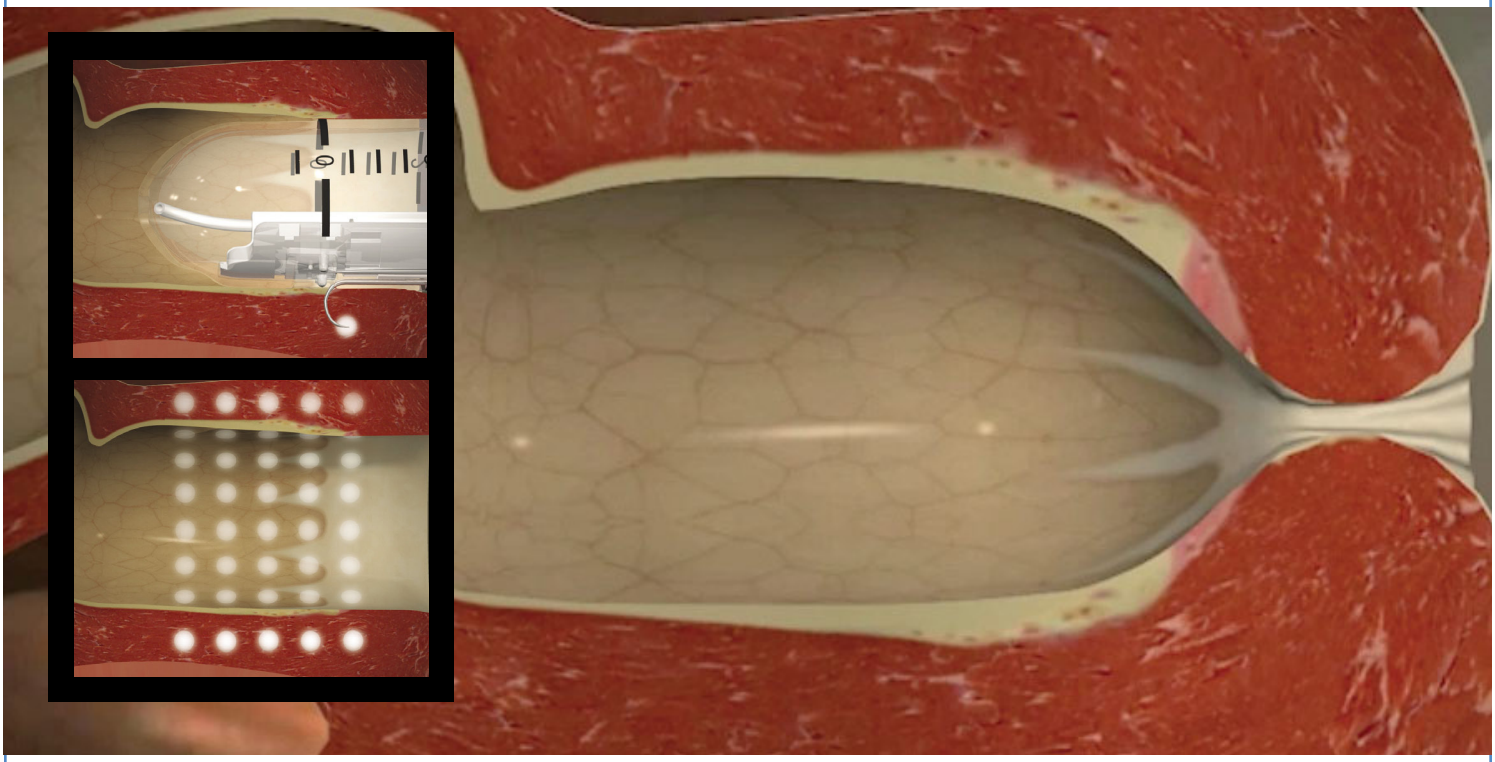
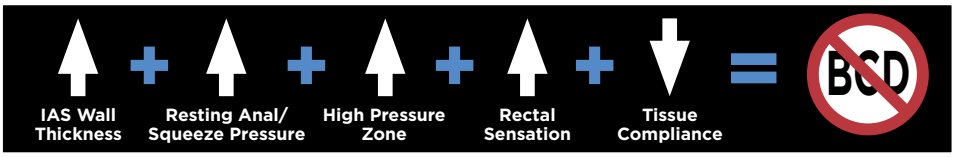
Clinical studies on file.

173-5020K

SECCA | RF MECHANISMS OF ACTION





INCREASED IAS WALL THICKNESS

"Endo Anal Ultrasound (EAUS) revealed significant thickening of IAS (at 6 months) in group I patients."

Radiofrequency Anal Sphincter Remodeling: The Influence of Patient Selection on Long-Term Outcome. Herman, Roman M.; Nowakowski, Michal; Herman, Roma B. Jagiellonian University, Krakow, Poland. *Presented at 23rd Annual International Colorectal Disease Symposium February 2012.*

INCREASED RESTING ANAL PRESSURE AND LENGTHENING OF HIGH PRESSURE ZONE

"A significant increase of BAP and SAP was noticed after 6 months. Length of high pressure zone increased significantly throughout the entire follow-up. Prior to surgery, none of the patients presented normal rectoanal reflexes. After surgery, a gradual return and normalization of RAIR was observed 6 months after Secca procedure."

Radiofrequency waves in the treatment of faecal incontinence. Preliminary report. Piotr Walega, Katarzyna jasko, jakub Kenig, Roman Maria Herman, Wojciech Nowak *Proktologia 2009*, 10 (2), p. 134-143

INCREASED RECTAL SENSATION

"The most striking remarks were that four patients said that they felt urge and now had 5 min to reach the toilet instead of 1 min...there was a tendency to increased rectal sensitivity concerning urge and maximal tolerated volume,"

Temperature controlled radiofrequency energy (Secca) to the anal canal for the treatment of fecal incontinence: pilot seems promising. R. F. Felt-bersma; C. J. Mulder; Gastroenterology, VU University Medical centre, Amsterdam, Netherlands. *European Journal of Gastroenterology & Hepatology.* 2007, 19:575–580.

"...the significant improvements reported in patient's rectal sensation may be an important key in the management of FI because patients may be better able to sense, and thus manage, their bowel contents on a timely basis."

SECCA procedure for the treatment of fecal incontinence: results of five-year follow-up. Takahashi-Monroy T, Morales M, Garcia-Osogobio S, Valdovinos MA, Belmonte C, Barreto C, Zarate X, Bada O, Velasco L. Service of Colon and Rectal Surgery, Department of Surgery, Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran, Mexico, DF, Mexico. *Dis Colon Rectum*. 2008 Mar;51(3):355-9. Epub 2008 Jan 19.

DECREASED TISSUE COMPLIANCE

"Rectal compliance decreased from 5,6 - 4,0 - 4,2 in the RF group."

Radiofrequency Anal Sphincter Remodeling (Secca) vs Biofeedback for the treatment of FI: Anorectal Motility & Clinical Results. Herman, Roman M.; Nowakowski, Michal; Herman, Roma B. Jagiellonian University, Krakow, Poland. *Presented at DDW May 2011.*

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