Solesta®

Inject Control, Confidence and Quality of Life

A quick, nonsurgical treatment for patients with fecal incontinence

INJECT SOLESTA

Inject: Solesta

FECAL INCONTINENCE - A COMMON CONDITION

Recent research shows that up to 18% of the general population worldwide suffer from fecal incontinence (FI).[1] However, due to the shame and emotional toll of this condition - many people avoid seeking treatment, and the number of cases is likely higher.[2]

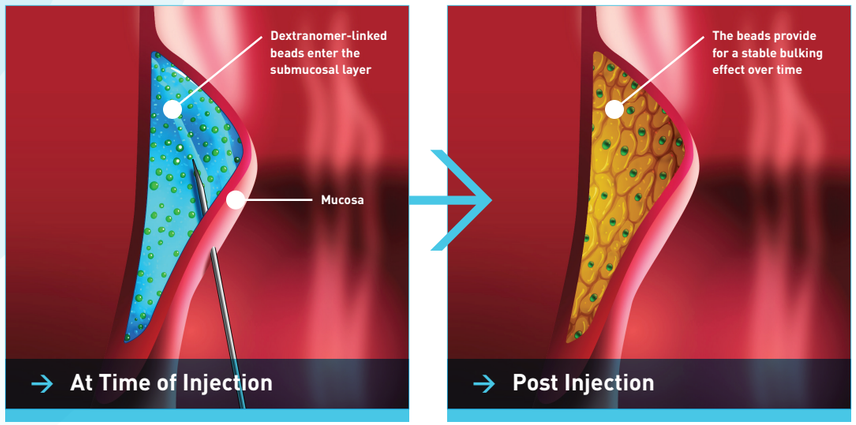
Solesta is an injectable outpatient procedure for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy.[3]

THE NATURAL SOLUTION

- Biocompatible tissue bulking agent injected into the submucosal layer of the anal canal
- Easily injectable, viscous gel made from two polysaccharides
  - Non-Animal Stabilized Hyaluronic Acid (NASHA®) undergoes a process to form a gel with increased viscosity and stability
  - Dextranomer (Dx) microspheres measure between 80 µm and 250 µm

NASHA has been in medical use for over two decades in more than 40 million procedures worldwide[4]

The beads provide a framework for fibrin and collagen deposition eventually forming durable, tissue-like formations in the anal canal[5]



The NASHA/Dx implant is stable, remains in position, and does not disappear over time[6]

Administering Solesta

SUPPLIED IN ONE KIT[3]

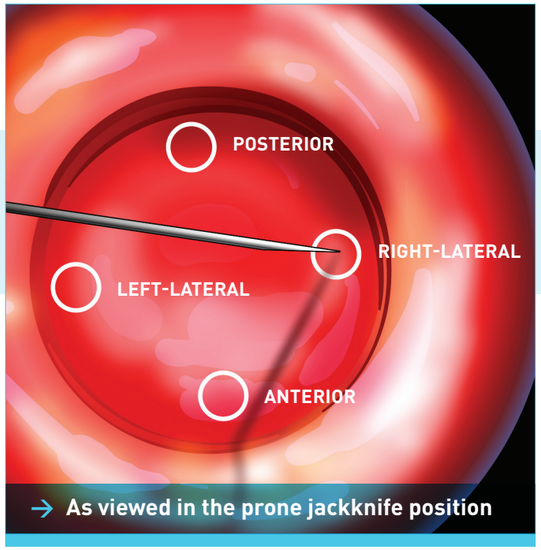
- 4 pouches with 1 mL prefilled glass syringes with a Luer-lock fitting
- Syringe is equipped with a plunger stopper; a plunger rod and a finger grip
- 4 sterile needles (SteriJect® 21G x 4¾ inches, 0.80 x 120 mm)
- Patient record labels
- Package insert

A QUICK, SIMPLE NONSURGICAL OUTPATIENT PROCEDURE[3]

- Administration takes approximately 10 minutes
- No anesthesia is required
- Injected via simple anoscopy

Four 1 mL syringes of Solesta are injected into the submucosal tissue 5 mm above the dentate line in a posterior, left-lateral, anterior, right-lateral sequence

Important:
Do not inject Solesta intravascularly. Injection of Solesta into blood vessels may cause vascular occlusion. Injection in the midline of the anterior wall of the rectum should be avoided in men with an enlarged prostate.



MINIMAL POST PROCEDURE IMPACT ON PATIENTS[3]

- Patients may resume limited physical activity immediately
- Solesta is unlikely to impede future procedures
- Patients are able to resume a normal lifestyle and engage in all physical activities after one week (e.g. jogging, bicycling, horseback riding, sexual intercourse, etc.)

Solesta's Proven Efficacy

ROBUST CLINICAL STUDIES [3]

Clinical data supporting the safety and effectiveness of Solesta are available from three clinical studies. The open-label and proof-of-concept studies were followed for 24 months and demonstrated similar safety results as the pivotal study. The pivotal study was followed for 36 months and included a cross-over option for patients initially randomized to Sham.

- **Pivotal Study:** a multicenter, randomized, sham-controlled double-blind, pivotal study of 206 patients (aged 18-75 years old) who did not respond to conservative therapy, had a CCFIS of 10 or more, and had 4 or more solid or liquid fecal incontinence episodes in the 2 weeks prior to undergoing the procedure. Study conducted under an Investigational Device Exemption (IDE).
- **Open-Label Study:** a prospective, multicenter, open-label study of 115 patients (aged 18-80 years) who failed conservative treatment, had 4 or more solid or liquid fecal incontinence episodes in the previous 28 days, and had a CCFIS score of ≥5. Study conducted outside the United States.
- **Open-Label, Proof-of-Concept Study:** a single center study of 34 patients (aged 18-80 years) with a Miller score of ≥6 and at least 1 fecal incontinence episode weekly. Study conducted in Sweden.

The majority of patients (over 84%) in all three studies were female.

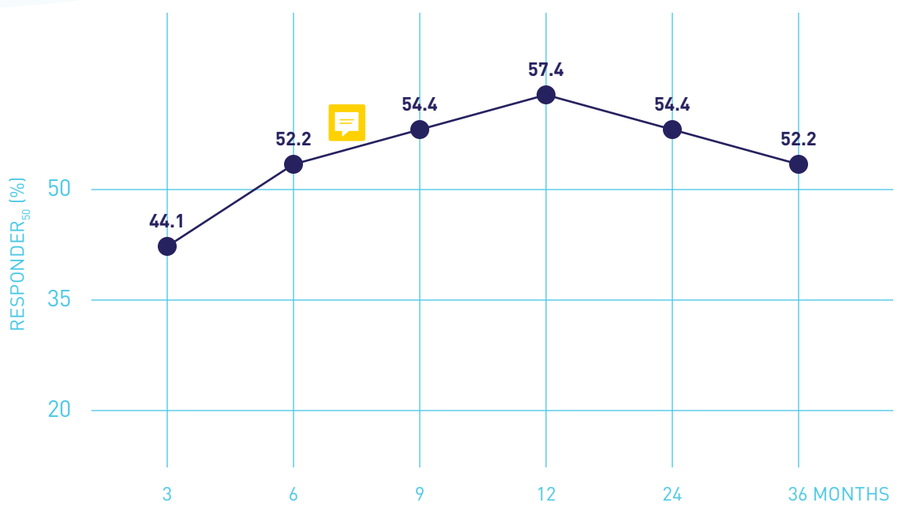
SOLESTA EFFICACY HIGHLIGHTS

42.7%	Reduction in the median number of FI episodes in as little as 3 months[9]
53.3%	Reduction in the median number of FI episodes through 36 months[3]
~2X	Increase of incontinence free days through 36 months[3,10]
>50.0%	Improved Embarrassment and Coping/Behavior FIQOL scores at 12 months[3]
3X	Greater improvement in FIQOL Lifestyle score for patients receiving Solesta vs. Sham[3]

DURABLE EFFICACY

- 30% increase of $Responder_{50}$ rate from month 3 to month 12[9]
- All three studies show durability of the treatment effect to 24 months as evidenced by proportion $Responder_{50}$[3]
- The pivotal study, the only study followed to 36 months, showed durability of treatment effect to 36 months[3,9]
- $Responder_{50}$ defined as proportion of patients with 50% reduction in the number of incontinence episodes compared to baseline, has been used to objectively evaluate response to treatments for FI in other studies[3]

MEAN # OF FI-FREE DAYS INCREASES THROUGH 12 MONTHS
(n=136:Pivotal Study) [3,9]



Significant Improvements for Patients with FI Through 36 Months

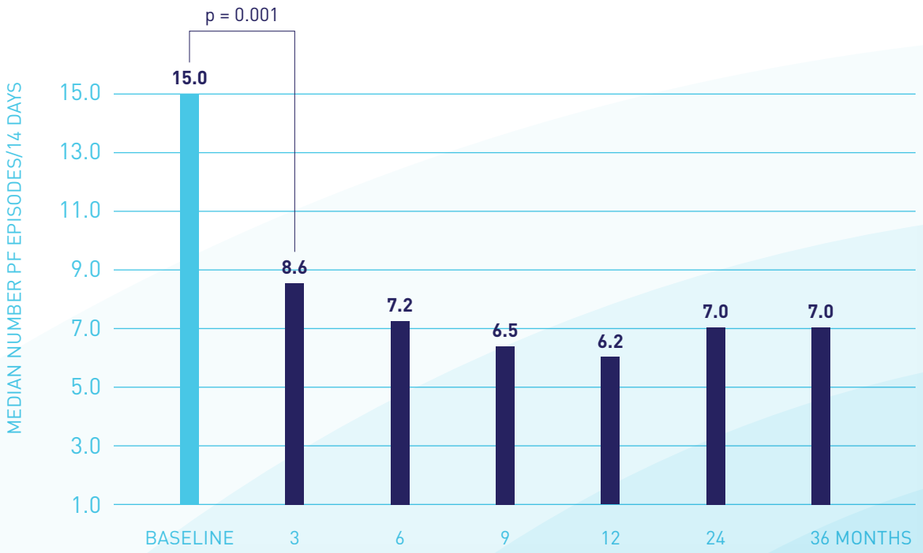
REDUCE FI EPISODES

Dramatic reductions in FI episodes at each time point up to 36 months from baseline [3,9]

42.7% Reduction in the median number of FI episodes in as little as 3 months[9]

53.3% Reduction in the median number of FI episodes through 36 months[3]

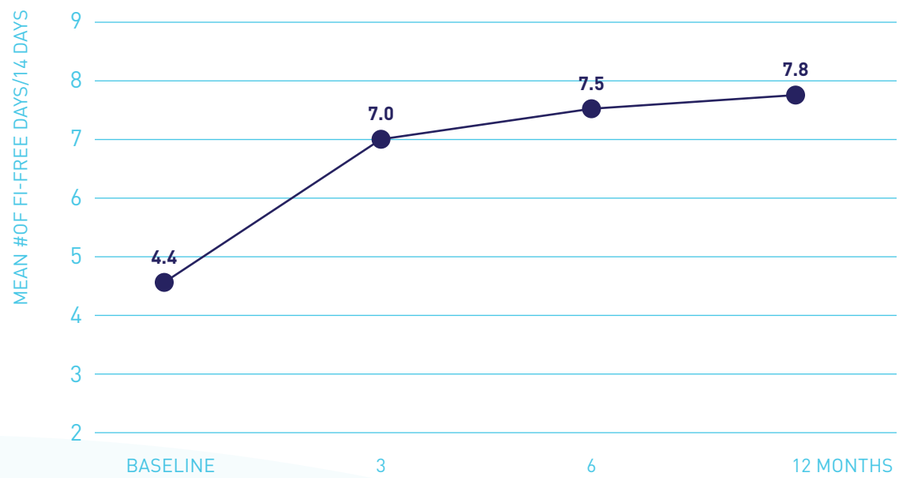
SOLESTA REDUCED FECAL INCONTINENCE EPISODES AT EACH FOLLOW-UP TIME POINT THROUGH 36 MONTHS (n=136:Pivotal Study) [3,9]



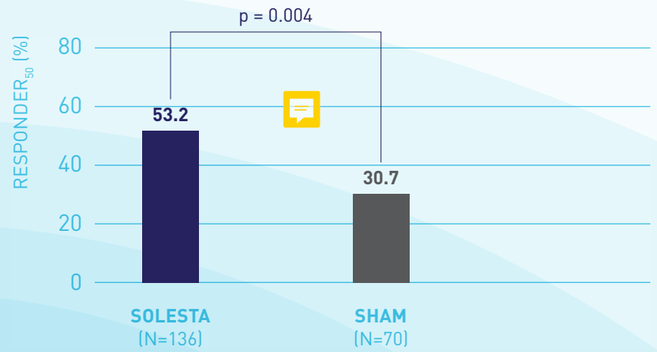
INCREASE FI FREE DAYS

- ~2x increase of incontinence free days [3,10]
- All three studies show an increase in in number of FI free days [3]
- The mean increased number of FI free days at 6 and 12 months was greater in Solesta Treatment vs. SHAM [3,10]

RESPONDER$_{50}$ WITH SOLESTA REMAINED ROBUST UP TO 36 MONTHS (n=136:Pivotal Study) [3,9]



RESPONDER$_{50}$ RATE WAS SIGNIFICANTLY HIGHER WITH SOLESTA VS. SHAM AT 6 MONTHS (n=206:Pivotal Study) [3]



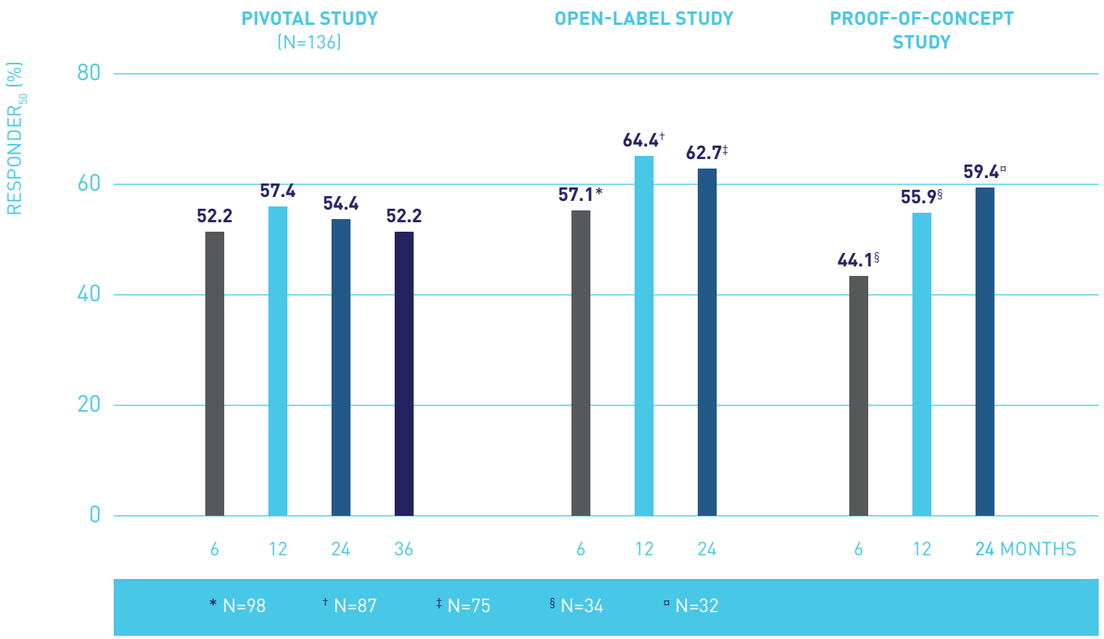
GREATER CONTROL

- Superiority was shown for Solesta vs. Sham at 6 months [3]
- The sham group received 4 needle sticks identical to the Solesta treatment group, but without therapy [3]
- Responder$_{50}$ defined as proportion of patients with 50% reduction in the number of incontinence episodes compared to baseline, has been used to objectively evaluate response to treatments for FI in other studies

DEPENDABLE RESULTS WITHOUT SURGERY

- Treatment with Solesta was associated with high response rates in all 3 clinical studies at 6, 12 and 24 months [3]
- Solesta was proven effective for up to 36 months in the pivotal clinical study [3]
- Responder$_{50}$ defined as proportion of patients with 50% reduction in the number of incontinence episodes compared to baseline, has been used to objectively evaluate response to treatments for FI in other studies

EFFICACY WITH SOLESTA WAS PROVEN OVER TIME IN THREE CLINICAL STUDIES [3]



IMPROVED QUALITY OF LIFE

- 3x greater improvement in Fecal Incontinence Quality of Life (FIQOL) Lifestyle score for patients receiving Solesta vs Sham [3]
- >50% improved Embarrassment and Coping/Behavior scores at 12 months [10]
- Solesta has no device-related restrictions that interfere with a patient's quality of life [3]

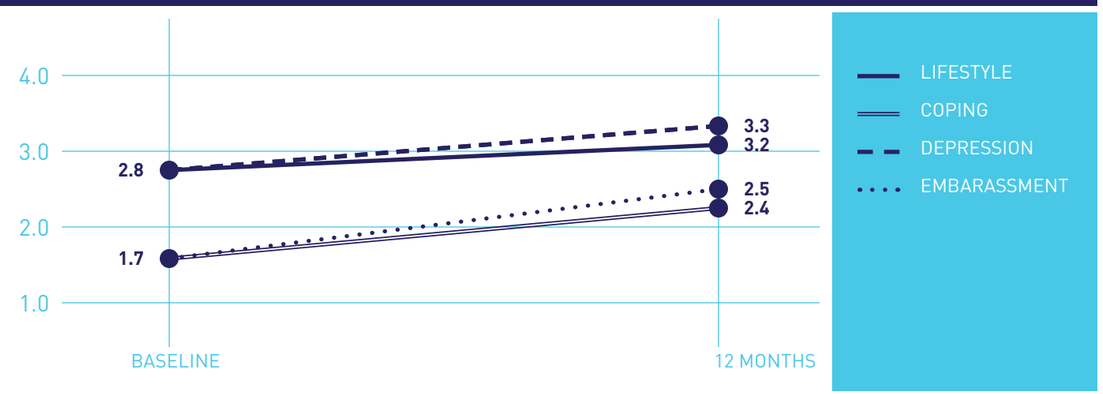
Fecal Incontinence Quality of Life Score: The FIQOL score measures the effectiveness of therapy to correct Fecal Incontinence. The scale consists of 29 questions in four categories: Lifestyle, Coping & Behavior, Embarrassment and Depression & Self-Perception

Category Ranges: 1 to 4 for Lifestyle, Coping/Behavior, and Embarrassment; 1 to 6 for Depression/Self-Perception [11]

LIFESTYLE	COPING/BEHAVIOR	DEPRESSION/ SELF-PERCEPTION	EMBARRASSMENT
→ Getting out of the house → Socializing → Traveling	→ Staying close to restrooms when away from home → Trying to prevent bowel accidents by staying very near a bathroom → Keeping the possibility of bowel accidents always top of mind	→ Feeling of sadness hopelessness discouragement → Feeling unhealthy → Enjoying life less	→ Feeling ashamed → Worrying over getting to the toilet in time → Worrying about smelling like stool

FIQOL SCORE – SIGNIFICANT IMPROVEMENT COMPARED WITH BASELINE WAS OBSERVED WITH SOLESTA AT 12 MONTHS IN ALL 4 CATEGORIES (P<0.0001) [1]

(206 Patients, Low Score = Low QOL) [4]



WELL-STUDIED SAFETY AND TOLERABILITY [3]

- 96% of adverse events were mild or moderate over 36 months
  - 96% of the events required no intervention or required medical or simple noninvasive interventions
- The most common types of adverse events were post-treatment proctalgia, minor anal or rectal bleeding (hemorrhage), post-treatment fever, abdominal complaints (diarrhea and constipation), and injection-site pain
  - All instances of bleeding were listed as hemorrhages, regardless of intensity, in accordance with international standards
  - Most treatment-related adverse events were experienced soon after injection with Solesta; the highest incidence occurred during the 48-hour interval following first injection
- Only 3 adverse events or 1.3% of the treatment-related adverse events, were deemed serious (2- rectal abscess, 1- E. coli bacteremia) and resolved within 35 days.

COMMON TREATMENT-RELATED ADVERSE EVENTS FROM A 36-MONTH STUDY (n=197:Pivotal Study) [3]

All adverse events were those reported in at least 2 patients

Adverse Event	Events	% Patients
Proctalgia	42	21.3
Injection site bleeding	17	8.6
Rectal bleeding	15	7.6
Pyrexia	14	7.1
Injection site pain	10	5.1
Diarrhea	10	5.1
Anal hemorrhage	9	4.6
Anorectal discomfort	9	4.6

Available Now: Solesta Reimbursement

INTRODUCING THE SOLESTA REIMBURSEMENT ASSISTANCE PROGRAM

The one step program for you and your staff- where your practice assumes no financial risk for product acquisition.

- Simply fill out the Service Request form available at MySolesta.com – and we will do the rest

The Solesta Reimbursement Assistance Program minimizes barriers that delay or prevent access to Solesta and provides personalized reimbursement support to you and your patients.

PROGRAM BENEFITS

- Designed to create a seamless reimbursement experience for your practice
- Researches each patient's benefits individually to find the option with the lowest cost-sharing for them
- Manages all communications with your patient's healthcare insurance
- Helps your office save time and energy while keeping you informed every step of the way
- Your practice assumes no financial risk for product acquisition

For more information on the Solesta Reimbursement Assistance Program

Tel 1.877.546.7150
Email info@palettelifesciences.com
Web MySolesta.com/solesta-reimbursement

SOLESTA CODING AT A GLANCE

Providers should contact the Solesta Reimbursement Assistance Program **(1-877-546-7150)** for information on each patient's individual benefit options, as well as assistance with prior authorization requirements, appeals, and general information on coding, coverage and payment policies.

PATIENT DIAGNOSIS

ICD-10-CM Diagnosis

- **R15:** Fecal incontinence
- **R15.0:** Incomplete defecation
- **R15.1:** Fecal smearing
- **R15.2:** Fecal urgency
- **R15.9:** Full incontinence of feces

DRUGS AND BIOLOGICS

NDC/NHRIC

- **89114-850-03:** Solesta Injectable Gel- 1 kit of four 1 mL prefilled syringes

HCPCS

- **L8605:** Injectable bulking agent, dextranomer/ hyaluronic acid copolymer implant, anal canal, 1 ml

PROFESSIONAL SERVICES

CPT

- **46999:** Unlisted procedure, anus

Solesta®

Solesta Certification and Training

GET CERTIFIED TODAY

Physicians must be experienced in performing anorectal procedures and trained and certified in order to administer Solesta.

Like administering Solesta, training and certification is simple and straightforward.

Completing training and certification will allow you to participate in our online Physician Finder, so patients can easily find you.

Just follow three easy steps at **MySolesta.com**

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For product information, adverse event reports and product complaint reports, contact:

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Solesta is an injectable product indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (e.g. diet, fiber therapy, antimotility medications, pelvic floor exercises (Kegels), biofeedback). Please see complete Prescribing Information for SOLESTA at mysolesta.com.