Solesta®

Inject Control,

Confidence and an Improved Quality of Life

A minimally invasive, outpatient treatment for patients with fecal incontinence

PROVEN EFFICACY FOR UP TO 36 MONTHS[12]

What is fecal incontinence?

Fecal incontinence (FI) is commonly defined as the involuntary loss of gas, solid or liquid feces, or mucus. The severity of fecal incontinence ranges and can have a devastating impact on your patients' quality of life[1,2], including embarrassment, social isolation, and even loss of employment[3].

COMMON SYMPTOMS

- Having an accident before getting to the bathroom
- Passing stool during normal, everyday activities
- Passing fecal matter while passing gas
- Not being able to hold in gas
- Difficulty staying clean

How to diagnose patients with FI

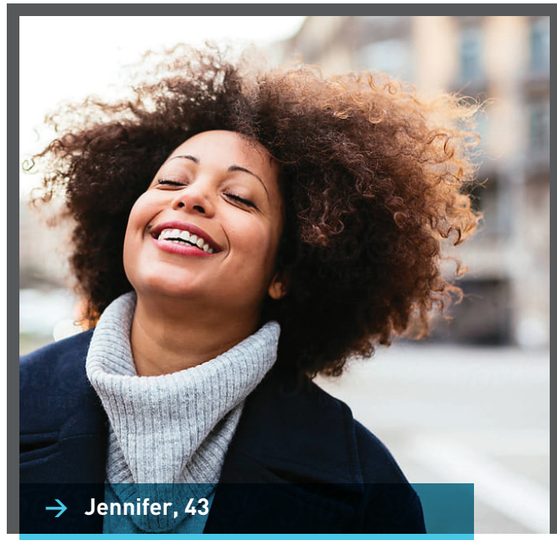
Diagnosing FI is the first step in getting your patients the help they need. Once properly diagnosed, patients can have a better understanding of the treatment options available to them.

TESTS TO DIAGNOSE FECAL INCONTINENCE MAY INCLUDE

- **Anal manometry test**[1]
- **Anorectal ultrasound**[1]
- **Stool tests**
- **Colonoscopy, Sigmoidoscopy, Proctosigmoidoscopy, Anoscopy**
- **Digital rectal exam** (DRE)

Who suffers from FI?

An estimated 7-12%[9] of people suffer from some form of FI. This condition affects people of all ages, genders, and races. Patients suffering from FI have higher rates of unemployment, increased absenteeism, loss of productivity and reduced quality of life. As the population of adults aged 65 and over increases, the prevalence of FI is expected to increase as well.



Jennifer, 43

- Married with children, ages 4 and 7
- Height 5' 7"
- Weight 145 lbs
- IT Specialist
- Enjoys swimming and hiking

Henry, 66

- 3 grandkids
- Height 6'
- Weight 180 lbs
- Retired
- Avid golfer

QUESTIONS TO ASK YOUR PATIENTS ABOUT FI

- How long have you been having accidents?
- How often do you have accidents? *(e.g. 2 years; every 3 days)*
- Describe your emotions after having an accident *(e.g. frustration, sadness, embarrassment)*
- How have bowel control problems affected your social, family or work life?

The Cleveland Clinic Fecal Incontinence Score (CCFIS) and the Fecal Incontinence Quality of Life (FIQL) are the most commonly used scoring systems to assess severity of FI.[13]

Treatment options for FI

HELP PATIENTS REGAIN CONTROL

While there is no quick fix for FI, there are several options available to treat the condition. Patient care guidelines uniformly recommend considering the use of bulking agents when treating FI. Solesta fits into the FI Patient Care Guidlines* stepwise approach as a "minimally invasive" treatment option. If you have patients who fail conservative therapy, then utilizing Solesta should be the next step for treatment.

PATIENT CARE GUIDELINES

CONSERVATIVE TREATMENT OPTIONS[1-4]

- Dietary management
- Pharmacological agents
- Bowel management programs
- Pelvic floor therapy/biofeedback
- Percutaneous tibial nerve stimulation

MINIMALLY INVASIVE OPTIONS[1-4]

- Injection of bulking agents
  Solesta® - only bulking agent approved by FDA for FI
- Radio frequency anal sphincter remodeling
- Barrier devices

FIRST-LINE SURGICAL OPTIONS[1-4]

- Correction of anatomical pathologies
- Sacral neuromodulation (SNS)
- Sphincter replacement (sphincteroplasty)
- Artificial bowel sphincteroplasty
- Magnetic sphincter

SECOND-LINE SURGICAL OPTIONS[1-4]

- Colostomy
- Graciloplasty

*Reviewed guidelines include those developed by the American College of Gastroenterology, American Gastroenterological Association, American Society of Colon and Rectal Surgeons and the Agency for Healthcare Research and Quality

Solesta minimally invasive treatment

SAFETY PROFILE

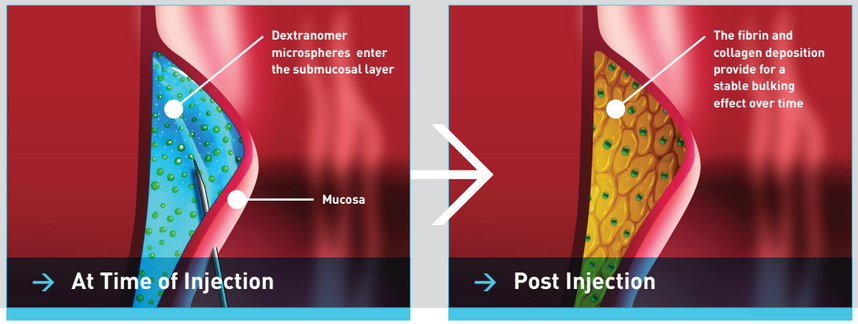
The efficacy, safety, and durability of Solesta have been reported in several long-term, prospective, multi-center, observational trials, including a large post-approval study. These trials confirm that Solesta provides statistical and clinically significant, positive long-term outcomes.

WHAT IS SOLESTA?

- 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®) that undergoes a process to form a gel with increased viscosity and stability
  - Dextranomer (Dx) microspheres that measure between 80 µm and 250 µm

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

THE SOLESTA TREATMENT



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

NASHA has been in medical use for over two decades in more than 50 million procedures worldwide.[4] The NASHA molecule is in all of Palette Life Sciences' products and has been used to cure children suffering from Vesicoureteral Reflux (VUR) for over 20 years.

- A minimally invasive option for treating fecal incontinence in patients who have failed conservative therapy
- A nonsurgical approach to improve the bulk and thickness of the anal walls that can be administered in your office.[1]
- Administered through 4 injections into the wall of the anal canal, therefore providing more control of bowel movements. Anesthesia is not always necessary.[1]

Improved quality of life

- Studies show improvement in each sub-scale of the FIQL and a reduction in symptom burden, based on the CCFIS from baseline through 36-months post-treatment[13]

Solesta's proven efficacy

SIGNIFICANT IMPROVEMENT FOR PATIENTS[3]

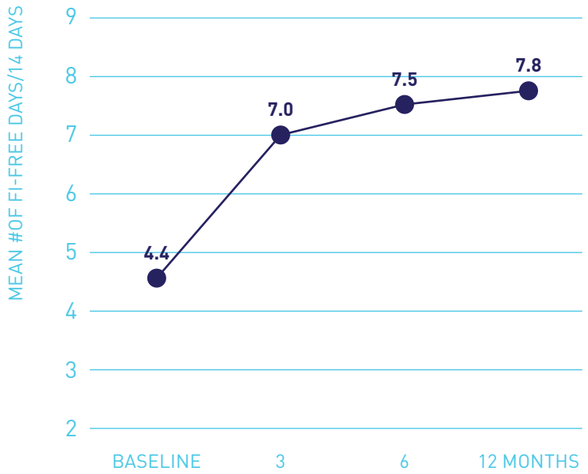
Clinical data supporting the safety and effectiveness of Solesta are available from four clinical studies.

- **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.
- **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.
- **Post Approval Study:** conducted per FDA post-marketing surveillance requirements to evaluate long-term efficacy of Solesta. A single-arm, multi-site study of 283 patients over 36 months, showing Solesta provided significant and long lasting improvements to quality of life.

SOLESTA EFFICACY HIGHLIGHTS

~2X	Increase of incontinence free days through 36 months[3,10]
3X	Greater improvement in FIQL Lifestyle score for patients receiving Solesta vs. sham[3]
53.3%	Reduction in the median number of FI episodes through 36 months[3]
>80.0%	of patients did not require additional intervention for up to 36 months[12]

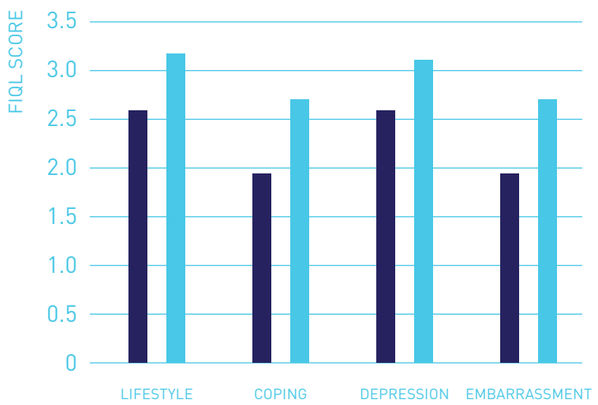
MEAN # OF FI-FREE DAYS INCREASES THROUGH 12 MONTHS (n=136:Pivotal Study) [3,9]



INCREASED FI-FREE DAYS

- ~2x increase of incontinence free days [3,10]
- All studies show an increase 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]

AT 36 MONTHS, SOLESTA PATIENTS REPORTED SIGNIFICANT IMPROVEMENT ON ALL FIQL SUB-SCALES AND ON THE CCFIS [12]



IMPROVED QUALITY OF LIFE

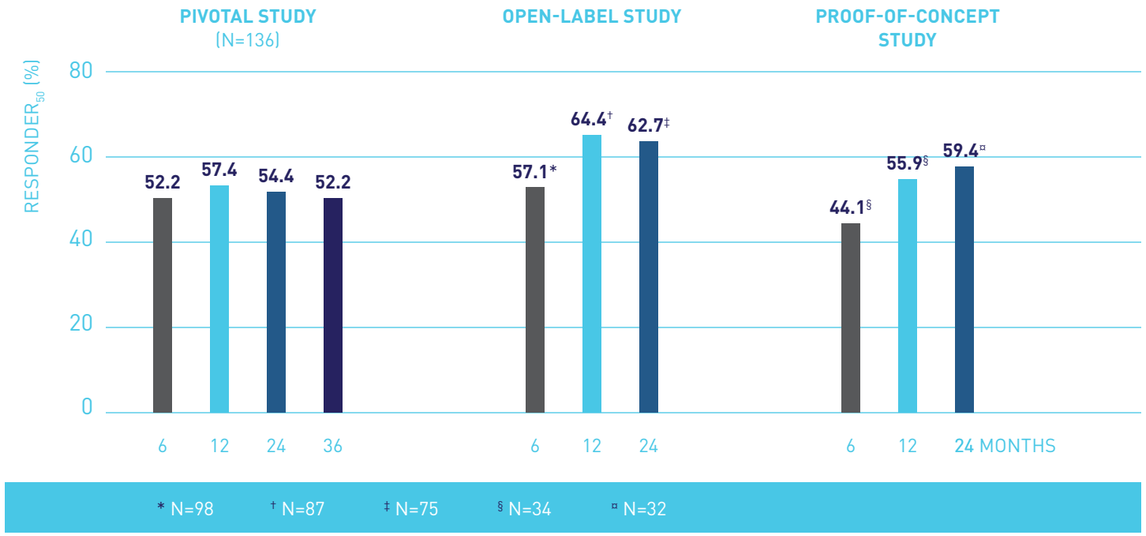
- 3x greater improvement in FI Quality of Life (FIQL) vs sham [3]
- >50% improved Embarrassment and Coping/Behavior scores [10]
- 80% of patients reported improved results at 6, 12, 24 and 36 months after treatment [10]
- No device-related restrictions that interfere with a patient's quality of life [3]

Fecal Incontinence Quality of Life Score: The FIQL score measures the effectiveness of therapy to correct fecal incontinence. FIQL is comprised of four categories: Lifestyle, Coping & Behavior, Embarrassment, Depression & Self-Perception

EFFICACY WITH SOLESTA WAS PROVEN OVER TIME IN THREE CLINICAL STUDIES AND VERIFIED THROUGH THE POST APPROVAL STUDY [3]

DEPENDABLE RESULTS WITHOUT SURGERY

- High response rates in all 3 clinical studies at 6, 12, 24 and 36 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

>72.0% of patients treated experienced some degree of relief from FI at 36 months.[12]

Solesta has been used to treat FI for more than 8,000 patients worldwide[4]

Over 80% of treated patients did not require further intervention for up to 36 months.[12]

Why administer Solesta?

SOLESTA IS SAFE, EFFECTIVE AND DURABLE[2]

- Significant reduction in fecal incontinence episodes
- Durable efficacy shown up to 36 months
- Measured impact on quality of life
- Dependable results without surgery
- Patients receiving Solesta experienced a 3x greater improvement in FIQL Lifestyle score

Patient preparation

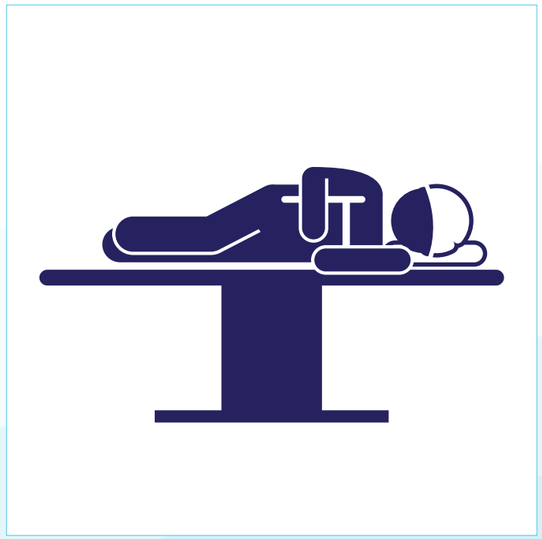
PRIOR TO INJECTING SOLESTA[1]

- **Prepare the rectum using an enema immediately prior to the procedure**
- **Prophylactic antibiotics are recommended**
- **Clean injection area with an antiseptic**
- **Talk patients through each step of injection**[2]

PATIENT POSITIONING

Physician visualization may be better from a sitting position

Left Lateral Position[3]



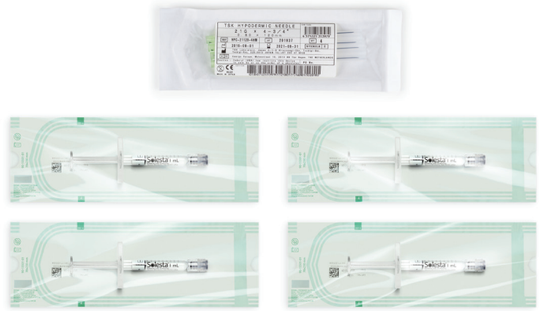
Prone Jackknife Position*

*Recommended by physicians, but not studied for the purposes of the Solesta IFU

Administering Solesta

SUPPLIED IN ONE KIT[3]

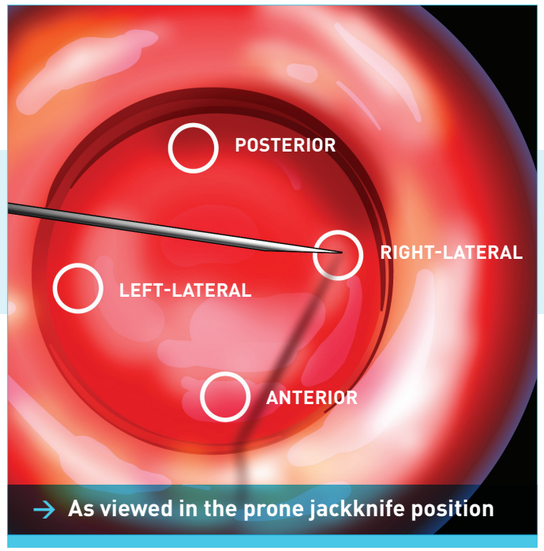
- 4 pouches with 1 mL prefilled glass syringes with a Luer-lock fitting
- Syringe is equipped with a plunger stopper, a plunger rod and a finger grip
- 4 sterile needles (21G x 4¾ inches, 0.80 x 120 mm)
- Patient record labels



A MINIMALLY INVASIVE, 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



As viewed in the prone jackknife position

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

Become a certified Solesta physician

SOLESTA CERTIFICATION AND TRAINING

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

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

Step 1: Watch the procedure video

Step 2: Review all relevant product safety information

Step 3: Create a physician locator profile for patients, by adding relevant practice details

Want more training?
Contact a representative for hands-on injection training using a simulator model

Get access to Solesta today

THERE ARE MULTIPLE OPTIONS TO INCORPORATE SOLESTA IN YOUR PRACTICE TODAY.

1. Buy and Bill product through Palette Life Sciences
   Purchase Solesta for a reduced rate and then bill patients' insurance
2. Submit through Specialty Pharmacy

Available now: Solesta reimbursement

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

→ Simply fill out the Service Request form available at MySolesta.com – for our expert assistance

For more information on the Solesta Reimbursement Assistance Program

Tel: 1-877-546-7150
Fax: 1-513-506-7361
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
→ **45335:** Diagnostic sigmoidoscopy

Solesta®

More information on indications, contraindications and warnings can be found in the Instructions For Use at www.mysolesta.com

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Palette LIFE SCIENCES

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

Palette Life Sciences
Medical Information Department

Tel 844-350-9656
Fax 510-595-8183
Email palettemc@dlss.com

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.