

A QUICK NONSURGICAL TREATMENT

Do you have bowel control problems? Find out how you can manage accidents

Take control



Solesta[®]

What are bowel control problems?

Bowel control problems (doctors refer to this as “fecal incontinence,” or “FI”) happen when someone loses control of the passage of solid stool (waste matter). They can range from the loss of an entire solid bowel movement to the loss of a small amount of liquid waste.

ANY OF THE FOLLOWING MAY OCCUR:

- 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

Some people with bowel control problems have accidents every day. Others have them now and again. No matter how frequent they are, bowel control problems are always difficult to live with. They affect quality of life, limiting activities and impacting relationships. Some people with bowel control problems feel sad and depressed. They may not want to leave their house at all for fear of having an accident.

YOU ARE NOT ALONE

Recent research shows that up to 18% of the general population worldwide suffer from 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

Bowel control problems are not a normal part of aging- they affect men and women of all ages, races and backgrounds. FI is a medical condition that can be treated by a doctor- but many people are too ashamed to talk to their doctors about it.

SYMPTOMS SCORE

The Cleveland Clinic Fecal Incontinence Score (CCFIS) is the most commonly used scoring system in the U.S. to help patients assess severity with their doctors.³

To find your score, rate each of your symptoms by circling the number in the chart that best describes how often you experience it. Once complete, add up your total score to share and discuss with your doctor.

CLEVELAND CLINIC FLORIDA INCONTINENCE SCORE (CCFIS)³

	NEVER	RARELY	SOMETIMES	USUALLY	ALWAYS	YOUR SCORE
NEVER						
Solid Incontinence	0	1	2	3	4	
Liquid Incontinence	0	1	2	3	4	
Gas	0	1	2	3	4	
Wearing Pads	0	1	2	3	4	
Lifestyle Alterations	0	1	2	3	4	
Total Score						
RARELY	Less than 1 per month					
SOMETIMES	Less than 1 per week and 1 or more per month					
USUALLY	Less than 1 per day and 1 or more per week					
ALWAYS	1 or more per day					

Scores range from 0 (not incontinent) to 20 (more problematic). No matter your score, if accidents are impacting your life, talk to your doctor.

Starting the conversation.

Here are some suggestions to get the conversation started with your doctor

1. **Be honest and direct.** “Doctor, I’m having some difficulty controlling accidents.”

— Your doctor may ask whether the accidents are urinary or bowel related

2. **Discuss any previous medications or products you have tried to manage accidents.**

3. **Talk about how this condition has affected your life. Share this with your doctor.**

— How long have you been having accidents? How often do you have accidents? (e.g. 2 years; every 3 days)

— Describe your feelings after having an accident (e.g. shame, sadness, embarrassment)

— How have bowel control problems affected your social or family life? (e.g. travel and time with loved ones)

— How have bowel control problems affected your work life? (e.g. had to call in sick, missed meetings)

4. **Use the scoring system on page 1 of this brochure to help keep an accurate record to share with your doctor.**

— Your CCFIS score: _____

What are the treatment options for bowel control problems?

There are many treatment options available, but the first step in the treatment process is talking with a doctor.

Discussing bowel control problems may seem embarrassing, but it's worth it. A conversation about it can help your doctor make the right diagnosis and determine the right treatment options that can lead to a better quality of life.



CONSERVATIVE THERAPIES

Your doctor will usually recommend beginning with a first-step treatment option — commonly called “conservative therapies.” They include:

Changes in diet — adding or increasing fiber to a diet can make it easier to control stool. Sometimes, cutting out things like coffee, tea or chocolate can help as well.

Taking medication — some medicines help better regulate bowel movements. These include laxatives and other medicines that slow down the movement of the stool through the bowel.

Bowel training exercises — strengthening exercises called Kegel exercises (or pelvic floor exercises) can help control leakage. They involve contracting and relaxing the muscles of the anus, buttocks and pelvis.

BEHAVIORAL THERAPY

Biofeedback — using devices to help you learn how to do exercises to strengthen your pelvic floor muscles. New behaviors can be acquired through trial and error, with instant feedback provided by the device inserted into the rectum.

These options may be enough to help some people, but not everyone. Remember too, if the first treatment doesn't work, there are others to try. Just be sure to let your doctor know what works — and what doesn't.

What are additional treatment options?

NEXT STEP THERAPIES

Solesta® — a gel composed of two naturally occurring materials- dextranomer and hyaluronic acid (HA) - is administered by your doctor to improve the bulk and thickness of the anal walls. This is a quick, nonsurgical approach and the HA in Solesta has been used in more than 40 million procedures worldwide,⁴ often as a dermal filler for wrinkle correction.

Solesta has been proven to significantly reduce accidents and help patients achieve a better quality of life.⁵ Studies have shown that Solesta can help patients return to a more active lifestyle (socializing, going to work, etc.), and reduce overall depression and embarrassment associated with their bowel control problems.⁶

Solesta is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (e.g. diet, fiber therapy, anti-motility medications).

Surgery — there are a variety of surgical approaches to treat bowel control problems. Many of these approaches involve the repair or replacement of part of the anus or sphincter.

Electrical stimulation, also called sacral nerve stimulation, is another type of surgery. It involves placing electrodes in the nerves to the anal canal and rectum and continuously stimulating these nerves with electrical pulses. First, doctors will run a test phase to see if it works. If it does work, then another surgery will be performed to implant it permanently. Regular patient follow-up is necessary to ensure that the treatment is working, and to confirm that the device and its battery are functioning properly.

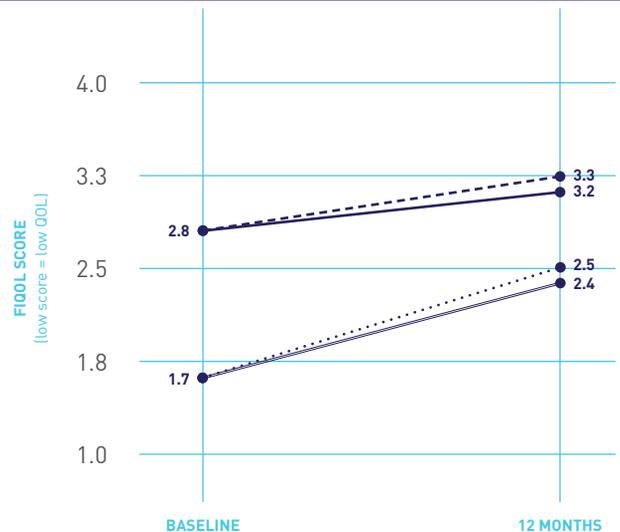
Potential considerations for surgery include prolonged recovery period, complications and risk of infection.

IMPROVED QUALITY OF LIFE WITH SOLESTA

Bowel control problems can have a dramatic impact on your quality of life – limiting your daily activities and affecting your relationships. However, some people avoid seeking treatment because of embarrassment or feeling that this is a part of growing older.

The Fecal Incontinence Quality of Life Scale (FIQOL) measures the impact fecal incontinence has on a patient's life.⁷ The scale consists of a questionnaire that measures four categories: Lifestyle, Coping & Behavior, Embarrassment and Depression & Self-Perception.

SOLESTA TREATMENT SHOWED SIGNIFICANT IMPROVEMENT OF ALL FOUR QUALITY OF LIFE CATEGORIES (n= 206 patients)⁶



Patients receiving Solesta experienced a 3X greater improvement in their FIQOL Lifestyle score than the control group.⁵

If your loved one has bowel control problems, here's how you can help.

If you have a loved one who is struggling with bowel control problems, this is a very stressful time for you both.

Many sufferers and caregivers don't realize there are treatment options. No one should "just have to live with" bowel control problems. There is hope and help for those who are suffering.

The best thing you can do as a caregiver is to encourage your loved one to see a doctor who is knowledgeable about bowel control problems.

A doctor can offer treatment and support to help manage the condition. He or she may even be able to treat the condition directly in their office. If not, they can refer your loved one to a specialist.

ADDITIONAL RESOURCES

A doctor is the best person to talk to about bowel control problems. You can also find a lot of information online. Here are some websites that offer resources and tools to help manage a bowel control condition.

- **National Institutes of Health** (nih.gov)
- **International Foundation for Functional Gastrointestinal Disorders** (iffgd.org)
- **National Association For Continence** (nafc.org)
- **Cleveland Clinic** (my.clevelandclinic.org)

Unless otherwise indicated, Palette Life Sciences neither endorses nor is affiliated with these organizations.

IMPORTANT SAFETY INFORMATION ABOUT SOLESTA

It is important for you to know that SOLESTA® (hyaluronic acid/dextranomer) does not work for everyone and you may not benefit from SOLESTA treatment. It is also important for you to know that you may not experience immediate improvement after your first treatment with SOLESTA, and the full effects of SOLESTA may not be apparent until 3 to 6 months after treatment.

People who have an infection or who are currently experiencing bleeding in the rectum or anus should not receive SOLESTA. People who have problems in the rectum or anus, such as tumor, abnormal anatomy, large dilated blood vessels (hemorrhoids), or cracks in the tissue (anal fissures) should not receive SOLESTA. People who have active inflammation of their bowels (Crohn's disease or ulcerative colitis) should not receive SOLESTA. People who have trouble fighting off infection (immunodeficiency disorder such as HIV/AIDS) or who take medication to suppress the immune system, such as those used in cancer or organ transplant patients, should not receive SOLESTA. If you already have a device or material placed in your rectum or anus, or if you have had radiation treatments in your pelvic area before, you should not receive SOLESTA.

The most common risks of treatment with SOLESTA in the clinical study were mild or moderate pain or discomfort in the rectum or anus, and minor to moderate bleeding or spotting from the rectum following treatment. Some patients experience fever, abdominal pain, diarrhea, or constipation after treatment.

More serious risks, including infection and inflammation of the tissues in the anus, may occur but are not common.

You are encouraged to report negative side effects of SOLESTA to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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

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Tired of having accidents?

ASK YOUR DOCTOR ABOUT SOLESTA.

If you think you or someone you know may have bowel control problems, there is no need to suffer in silence. Discuss the symptoms with a doctor, and he or she can diagnose the condition and find the right treatment option.

For people who do not respond well to conservative or nonmedical therapies, Solesta may be an option. Ask your doctor if Solesta is the right treatment for you.

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References

- 1 Ng K, Sivakumaran Y, Nassar N, Gladman MA. Fecal incontinence: community prevalence and associated factors—a systematic review. *Dis Colon Rectum*. 2015;58(12):1194-1209.
- 2 Irwin T, Snow AR, Orton TS, Elliot C. Endoscopic, ultrasonographic, and histologic descriptions of dextranomer/hyaluronic acid in a case of fecal incontinence. *Case Reports in Pathology*. 2018.
- 3 Jorge JMN, Wexner SD. Etiology and management of fecal incontinence. *Dis Colon Rectum*. 1993;36:77-97.
- 4 Data on file.
- 5 Solesta [Package Insert]. Santa Barbara, CA: Palette Life Sciences.
- 6 Graf W, Mellgren KE, et al; for NASHA Dx study group. Efficacy of dextranomer in stabilised hyaluronic acid for treatment of faecal incontinence: a randomised, sham-controlled trial. *Lancet*. 2011;377(9770):997-1003.
- 7 Rockwood TH, Church JM, Fleshman JW, et al. Fecal incontinence quality of life scale: quality of life instrument for patients with fecal incontinence. *Dis Colon Rectum*. 2000;43:9-16.