

Informed Consent

Solesta Treatment

Solesta is a bulking agent made of two biocompatible sugars used to treat fecal incontinence. Solesta is injected into each quadrant of the rectum through a small anoscope. Anesthesia is not necessary as no pain is felt in the region of injection. Some feeling of pressure and minor bleeding may happen during the procedure.

I CONFIRM:

INITIAL BELOW

- _____ The details of the procedure including the anticipated benefits and possible risks have been explained to me in terms I understand.
- _____ Alternative methods and therapies, their benefits, risks and disadvantages have been explained to me.
- _____ I have informed the doctor of all my known allergies.
- _____ I have informed the doctor of all medications I am currently taking including prescriptions, over the counter remedies, supplements, aspirin, recreational drugs and alcohol use.
- _____ I have been advised on whether I should avoid any of these medications on the days surrounding the procedure.
- _____ I understand that antibiotics may be prescribed before or after the procedure.
- _____ I understand that at least 1.5% of patients experience adverse events after Solesta injections which include but are not limited to: bleeding, pain/proctalgia, infection including abscess formation, bacteremia, fever, rectal discharge, vascular occlusion, pain and urgency with defecation, constipation, and nodules/cysts.
- _____ I have been informed on what to expect post-operatively and understand my recommended level of activity.
1. Avoid taking hot baths or engaging in physical activity for the next 24 hours.
 2. Avoid sexual intercourse or strenuous physical activity (such as horseback riding, bicycling and jogging) for one week.
 3. Avoid anti-diarrheal medications (such as Loperamide/Imodium, Lomotil) for one week.
 4. Avoid anal manipulation, such as insertion of suppositories or enemas, for one month.
 5. Avoid aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, Motrin, Advil, Aleve, diclofenac or naproxen for one week unless critical clinical need.
 6. I should contact the physician's office immediately if symptoms of rectal bleeding, bloody diarrhea, fever, tenesmus or problems with urinating occur.
- _____ I understand that Solesta may be felt on future rectal or vaginal exams and seen on radiographic images.
- _____ I am aware and accept that no guarantees about the results of the procedure have been made and that repeat Solesta injection may be necessary for adequate response.
- _____ I have an opportunity to ask questions and have those questions answered.

_____ I acknowledge that I understand and consent to the fact that other observers may be present during my procedure.

_____ I voluntarily consent to allow the physician. to perform the procedures described or referred to herein.

SIGNATURES

SIGNATURE OF PATIENT OR PERSON SIGNING ON BEHALF OF PATIENT

DATE

SIGNATURE OF WITNESS

DATE