



Procedural Pearls

A quick nonsurgical treatment

Solesta®

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Procedural Tools

Solesta Kit Content¹

4 Syringes: Solesta is supplied in a disposable 1 mL assembled glass syringe with a standard Luer-lock fitting

4 Needles: SteriJect[®], 21G x 4 ¾ inches, 0.80 x 120mm

Patient Record Labels

Instructions for Use

Important¹

Store at a temperature up to 25°C (77°F) and protect from sunlight and freezing temperatures

Product is for single use. Do not use if damaged.



1. Solesta Package Insert. Santa Barbara, CA: Palette Life Sciences

Equipment¹

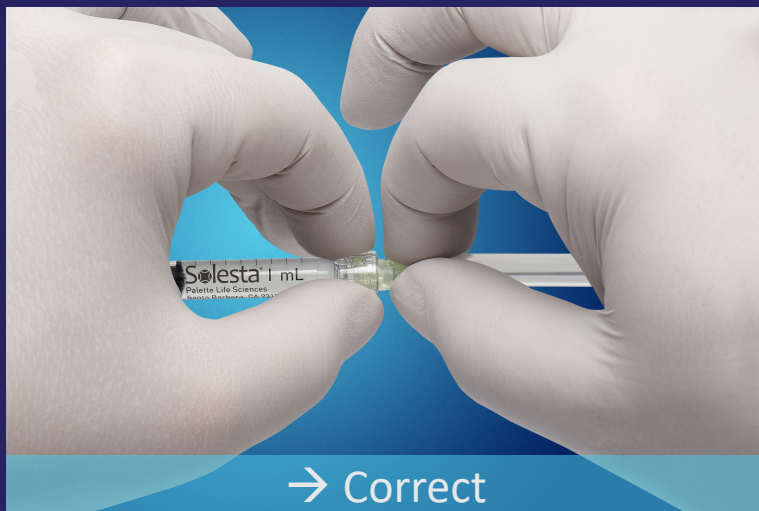
1. Side view anoscope with obturator
2. Maneuverable light source
3. Lubrication
4. Long swabs
5. Gloves
6. Gauze
7. Solesta x 4 mL
8. 4 Solesta needles
9. Extra Solesta kit on hand

Important: The light source should be maneuverable to illuminate the area of injection during patient movement and sequential mucosa change.

1. "Physician training and certification video." *Training and certification for administering Solesta*, Palette Life Sciences, Inc., www.mysolesta.com/solesta-training-and-certification.

Syringe Preparation

4 Solesta syringes should be assembled ahead of procedure, under aseptic conditions



→ Assemble all 4 syringes prior to patient procedure¹

→ Thumb and forefinger should be held firmly around the Luer-lock adapter of the glass syringe¹

→ DO NOT attach the needle by holding onto the glass barrel of the syringe¹

→ Firmly push and rotate the needle hub into the Luer-lock adapter¹

→ Slowly prime the needle until a small bead of Solesta appears at tip of needle²

→ *Important: The Luer-lock adapter is snapped onto the syringe and held in place with friction only. It can rotate freely or be pulled off should enough force be applied¹*



1. Solesta Package Insert. Santa Barbara, CA: Palette Life Sciences

2. "Physician training and certification video." *Training and certification for administering Solesta*, Palette Life Sciences, Inc., www.mysolesta.com/solesta-training-and-certification.

Patient Preparation



Bowel Preparation

Prepare the rectum using an enema immediately prior to procedure¹



Medication

Prophylactic antibiotics are recommended¹



Area Preparation

Clean injection area with an antiseptic¹

Talk patients through each step of injection²

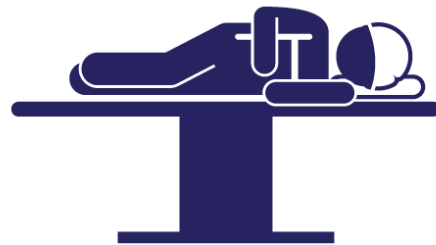
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Patient Positioning

Physician Visualization May be Better From a Sitting Position

Left Lateral Position¹



Jackknife Prone Position¹



1. Graf W, Mellgren A, Matzel KE, et al. Efficacy of dextranomer in stabilized hyaluronic acid for treatment of faecal incontinence: a randomized, sham-controlled trial. *The Lancet*. 2011;377:997-1003.

Procedural Pearls

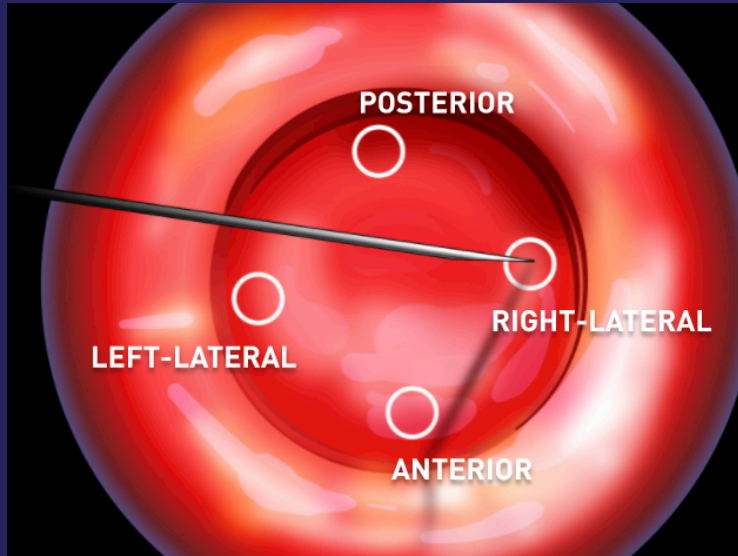
Injection Pearls

1. A side view lubricated anoscope should be used for visibility. Anoscope should be removed, obturator replaced, rotated 90° and reinserted with each injection to avoid tissue capture¹
2. Under direct vision, approximately 30° to the axis of the rectum, puncture the mucosa with the bevel of the needle facing the lumen of the rectum, 5 mm proximal to the dentate line²
3. If the patient indicates pain at the puncture, the injection site should be adjusted a few mm in the cephalic direction²
4. If the puncture is painless, advance the needle further 5 mm approximately 30° to the axis of the rectum²
Injections too close to the dentate line or at a depth greater than 5 mm may cause pain and/or lack of efficacy
5. The injections should be performed slowly with constant pressure to avoid stress on the Luer-lock connection and allow the tissue to adapt to the injected gel²
6. The four equally spaced injections are to be given in the following order²
 - 1) Posterior
 - 2) Left Lateral
 - 3) Anterior
 - 4) Right Lateral

Important: Injection should be stopped if excessive bleeding or pain occurs²

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Injection Pearls



**AS VIEWED IN THE PRONE
JACKKNIFE POSITION**

The four equally spaced injections are to be given in the following order¹

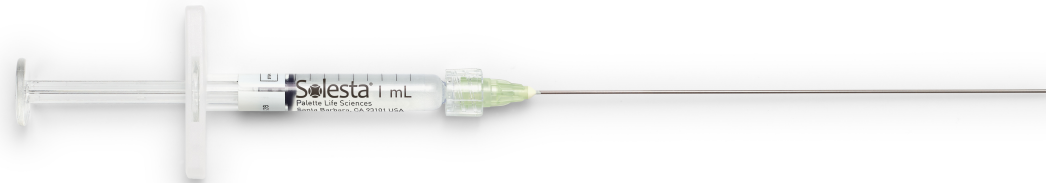
1. Posterior
2. Left Lateral
3. Anterior
4. Right Lateral

1. Solesta Package Insert. Santa Barbara, CA: Palette Life Sciences

Procedural Pearls

Needle Pearls

- A new needle should be used for each syringe and injection site¹
- The needle should be kept in position for 15-30 seconds to minimize leakage of Solesta¹
- There is a triangular mark on the needle hub that provides the orientation of the needle bevel to ensure the bevel is facing the lumen when needle is inserted¹
- The bevel of the needle opening is 2 mm long²

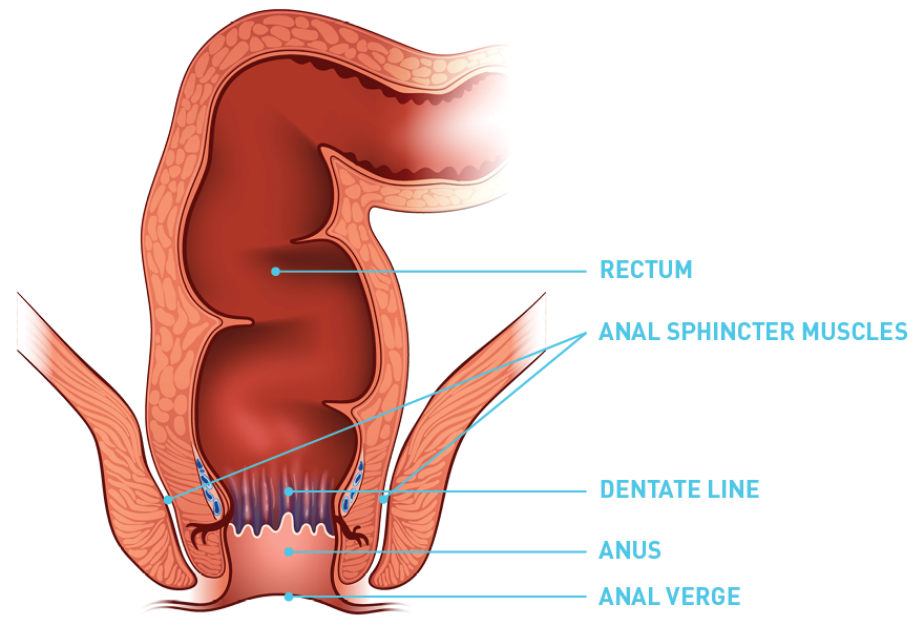


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Visualization

During Injection

- The **dentate line** can vary due to anatomical variation, age, disease or overlapping rectal mucosa²
- The general area of injection is about 2 cm from the **anal verge**²
- If the patient feels pain, move the needle cephalad and proximal (towards the head and center) until no pain is reported¹
- Bleeding may be stemmed with direct firm pressure and a long surgical swab²



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Visualization

After Injection

- A pillowing or slight bulging effect beneath the submucosal layer may be seen¹
- When properly placed submucosally, lack of 4 distinct bulges does not hinder effectiveness or indicate the injection was not performed correctly¹

Hemorrhoids

- Hemorrhoidal tissue is blue and bulging in appearance; mucosal tissue is pink and flat
- Inject superior or lateral, adjacent to the hemorrhoids and not into them¹

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Post-Procedural Instructions¹

1. Immediately after the procedure, the patient should rest at the clinic for 60 minutes
2. If no bleeding or other treatment-related symptoms are observed during this time, the patient may leave
3. Stool softeners may be used until the first defecation occurs
4. Analgesics other than nonsteroidal anti-inflammatory drugs (NSAIDs) may be prescribed, if needed
5. Inform of the risk of infection and bleeding
6. The patient should be instructed to avoid:
 - Hot baths during the first 24 hours
 - Physical activity for 24 hours
e.g., horseback riding, bicycling and jogging, etc.
 - Anti-diarrheal drugs for 1 week
 - Sexual intercourse for 1 week
 - Anal manipulation for 1 month
e.g., insertion of suppositories or enemas and rectal temperature recording
7. Patient should contact the clinic or physician's office immediately if symptoms of rectal bleeding, bloody diarrhea, fever, tenesmus or problems with urinating occur.

1. Solesta Package Insert. Santa Barbara, CA: Palette Life Sciences

Re-treatment¹

No sooner than 4 weeks after the first injection

- If the patient does not have an adequate response to Solesta after the first injection, a re-injection with a maximum of 4 mL Solesta can be performed
- Pre-treatment preparation and post-procedure patient instructions are the same
- Procedure technique is the same, except the point of injection should be made in between the initial injections, shifted one-eighth of a turn (left posterolateral, left anterolateral, right anterolateral, and right posterolateral)

Solesta is an injectable outpatient product 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).

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For more information on Solesta or to be certified
in the Solesta Treatment, please visit
[MySolesta.com](https://www.MySolesta.com)

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

[Palette Life Sciences](#)

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