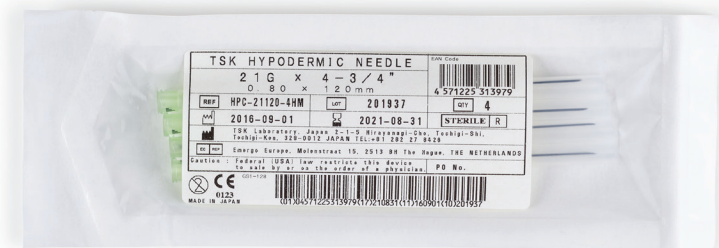
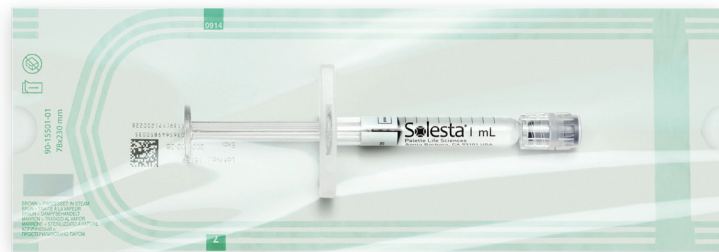


A QUICK NONSURGICAL TREATMENT

# Procedural Pearls



Solesta®



Solesta Kit

## Procedural Tools

### SOLESTA KIT CONTENT<sup>1</sup>

- **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 3/4 inches, 0.80 x 120 mm
- **Patient Record Labels**
- **Instructions for Use**

**Important:** 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.

### EQUIPMENT<sup>2</sup>

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 injection mucosa change.

## Syringe Preparation

### 4 SOLESTA SYRINGES SHOULD BE ASSEMBLED AHEAD OF PROCEDURE, UNDER ASEPTIC CONDITIONS

- Assemble all 4 syringes prior to patient procedure<sup>1</sup>
- Thumb and forefinger should be held firmly around the Luer-lock adapter on the glass syringe while attaching the needle to the syringe<sup>1</sup>
- DO NOT attach the needle by holding onto the glass barrel of the syringe<sup>1</sup>
- Firmly push and rotate the needle hub into the Luer-lock adapter<sup>1</sup>
- Slowly prime the needle until a small bead of Solesta appears at tip of needle<sup>2</sup>

**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 applied.<sup>1</sup>



# Patient Preparation

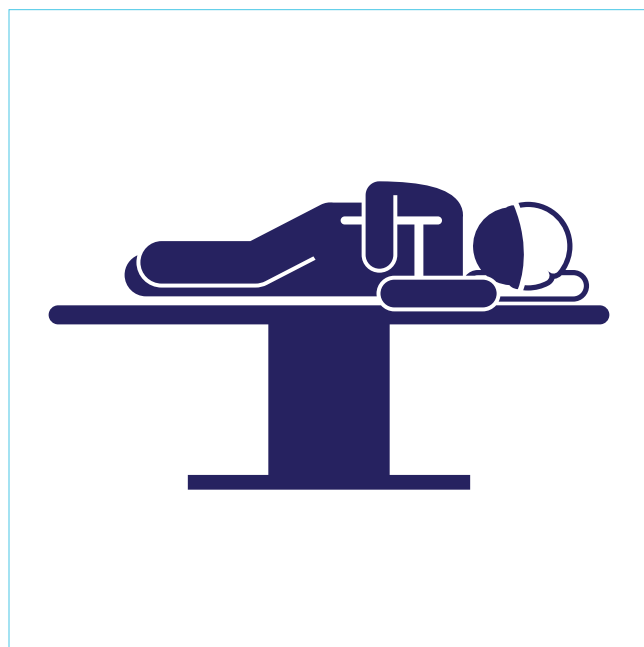
## PRIOR TO INJECTION<sup>1</sup>

- 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<sup>2</sup>

## PATIENT POSITIONING

Physician visualisation may be better from a sitting position

### Left Lateral Position<sup>3</sup>



### Prone Jackknife Position<sup>3</sup>



# Procedural Pearls

## INJECTION PEARLS<sup>1</sup>

- 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 capture<sup>2</sup>
- 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 line
- 3 If the patient indicates pain at the puncture, the injection site should be adjusted a few mm in the cephalic direction
- 4 If the puncture is painless, advance the needle further 5 mm approximately 30° to the axis of the rectum  
*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 gel
- 6 The four equally spaced injections are to be given in the following order:  
1) Posterior, 2) Left Lateral, 3) Anterior, and 4) Right Lateral

**Important:** Injection should be stopped if excessive bleeding or pain occurs.<sup>1</sup>

## NEEDLE PEARLS<sup>1</sup>

- A new needle should be used for each syringe and injection site
- The needle should be kept in position for 15-30 seconds to minimise leakage of Solesta
- 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 the needle is inserted
- The bevel of the needle opening is 2 mm long<sup>2</sup>

## Visualisation

### DURING INJECTION

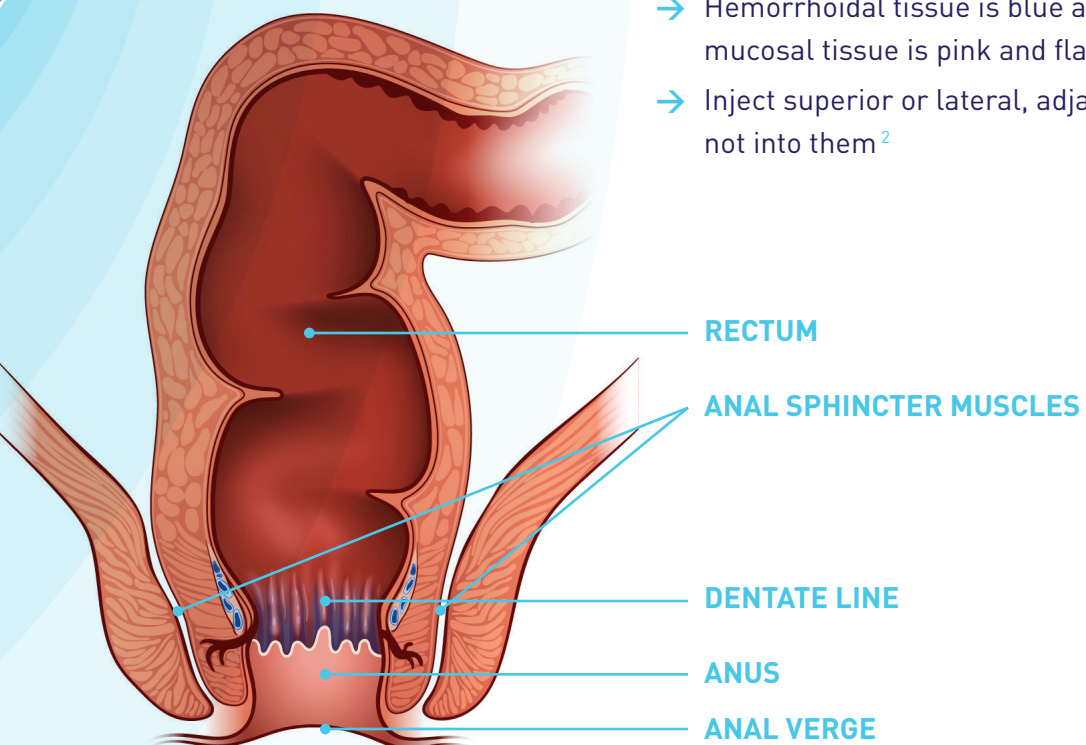
- The dentate line can vary due to anatomical variation, age, disease or overlapping rectal mucosa<sup>2</sup>
- The general area of injection is about 2 cm from the anal verge<sup>2</sup>
- If the patient feels pain, move the needle cephalad and proximal (towards the head and center) until no pain is reported<sup>1</sup>
- Bleeding may be stemmed with direct firm pressure and a long surgical swab<sup>2</sup>

### AFTER INJECTION<sup>2</sup>

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

### 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 them<sup>2</sup>



## Post-Procedural Instructions<sup>1</sup>

- 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.**

# Re-treatment

## NO SOONER THAN 4 WEEKS AFTER THE FIRST INJECTION<sup>1</sup>

- 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.

### References

- <sup>1</sup> Solesta Package Insert. Santa Barbara, CA: Palette Life Sciences.
- <sup>2</sup> "Physician training and certification video." *Training and certification for administering Solesta*, Palette Life Sciences, Inc., [www.mysolesta.com/solesta-training-and-certification](http://www.mysolesta.com/solesta-training-and-certification).
- <sup>3</sup> Graf W, Mellgren A, Matzel KE, et al. Efficacy of dextranomer in stabilised hyaluronic acid for treatment of faecal incontinence: a randomised, sham-controlled trial. *The Lancet*. 2011;377:997-1003.

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

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

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