



SandShark Injectable Anchor System

Intended Use: The SandShark Injectable Anchor System is intended to be an accessory to the stimulator component of the Curonix Freedom Spinal Cord Stimulator (SCS) System to secure the stimulator to the fascia or interspinous/supra-spinous ligament. Refer to the Freedom SCS System literature for safety information.

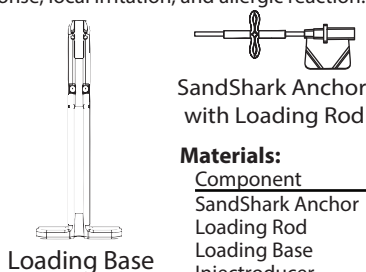
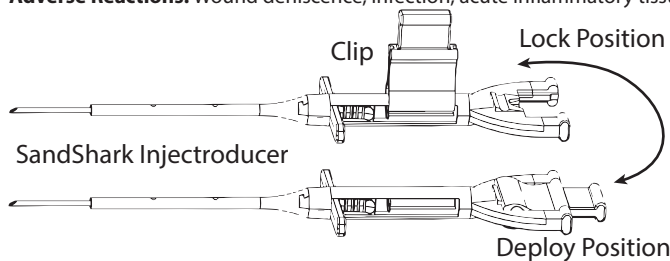
Contraindications: The use of the SandShark Injectable Anchor System is contraindicated in patients who: have local or systemic infections, bleeding disorders, or anatomical derangements that may prevent procedural success.

Warnings: This device is to be used only by appropriately trained personnel and only with the Freedom SCS System. Do not use magnetic resonance imaging while the Injectroducer is in place. Inadvertent dural puncture may result in headaches and other neurological symptoms. Do not use if package is torn or damaged. Store in a cool, dry and dust free environment. Check placement of Injectroducer with Anterior-Posterior and Lateral fluoroscopy.

Precautions: Unscrew the stylet handle and remove the stylet handle from the stimulator. Keep the stylet wire within the lumen of the stimulator to maintain rigidity while advancing the Injectroducer. If not already done, make a small incision around the stimulator to aid in advancing. Use care when advancing the Injectroducer to avoid deploying the anchor and from dislodging the position of the electrodes on the distal end of the stimulator. Check the targeted anchor location depth with a lateral fluoroscope to confirm the correct fixation before deploying the anchor. On the stimulator, the anchor should be deployed proximal to the flexible circuit board, but before the first marker band. Remove the stylet wire. Make sure clip is moved to the handle position and the most proximal end of the stimulator is pinched tight within the Injectroducer and Clip.

Pull back completely on plunger to deploy the anchor at the fixation location. Make sure to remove the clip before retracting the Injectroducer. Confirm anchor deployment and the final receiver stimulator placement with fluoroscopy.

Adverse Reactions: Wound dehiscence, infection, acute inflammatory tissue response, local irritation, and allergic reaction.



Package Contents:

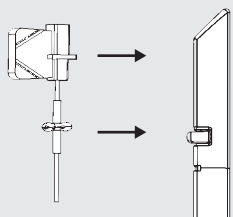
Package Contents	Quantity
SandShark Injectroducer	1
Loading Rod w/ Anchor	4
Loading Base	1

Materials:

Component	Material	Tissue Contact
SandShark Anchor	Carothane with barium sulfate	Yes
Loading Rod	Stainless steel and ABS plastic	No
Loading Base	ABS Plastic	No
Injectroducer	Stainless steel, PTFE, ABS plastic	Yes

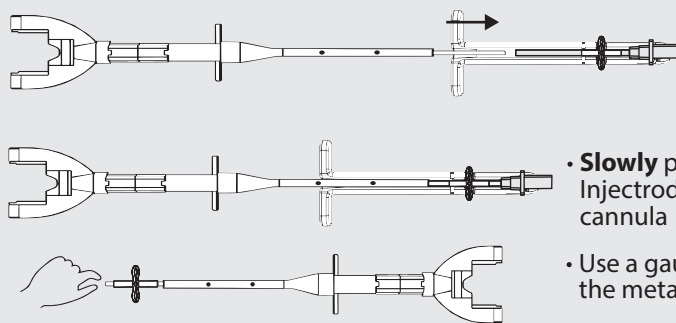
Instructions for Use:

1. Place Loading Rod in Loading Base



- Place Loading Rod and anchor in Loading Base
- Confirm Anchor wings are pinched in notch**

2. Load Anchor on Injectroducer

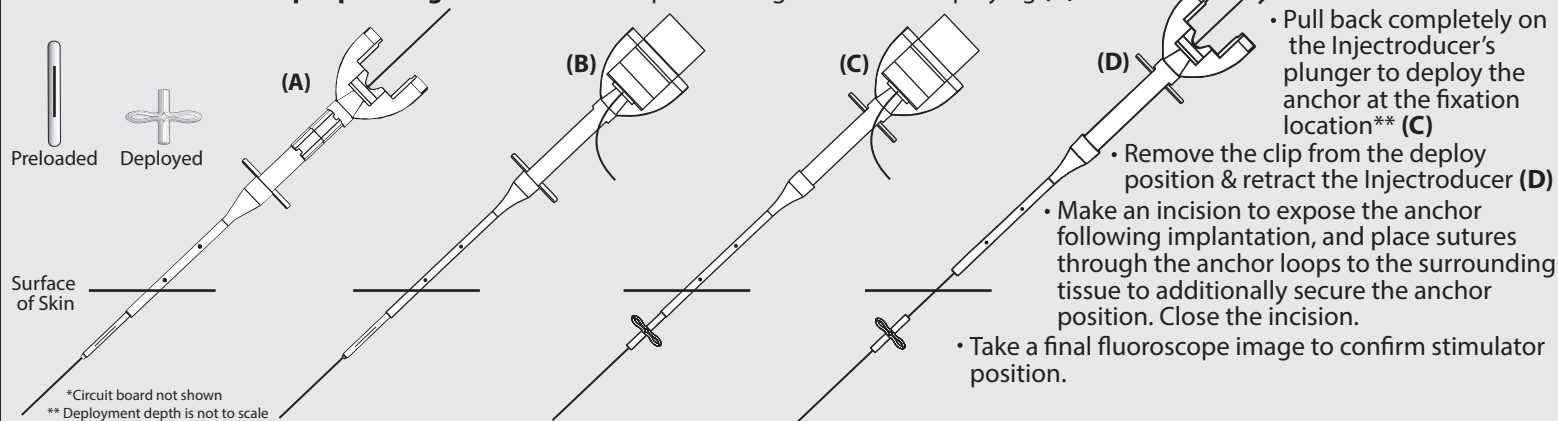


- Confirm clip is on Injectroducer shaft to prevent pre-mature deployment
- Place Injectroducer over Loading Rod

- Slowly push while twisting and rocking** Injectroducer to have anchor transfer onto metal cannula
- Use a gauze pad to grip and flatten Anchor on the metal cannula

3. Deploy Anchor

- Before removing the needle** used with the procedure, **use a scalpel to widen the incision**
- Remove the stimulator's stylet handle by unscrewing, but **keep the stylet wire within the stimulator**
- Place Injectroducer over the most proximal end of the stimulator and slide into place (A), the **Anchor should deploy at the depth of the interspinous ligament** proximal to the circuit board*
- Once Injectroducer and Anchor are in position, remove the stylet wire and move the clip from lock position to the deploy position (B)
- Ensure the sure the clip is pinching the stimulator** to prevent migration while deploying (B)



- Pull back completely on the Injectroducer's plunger to deploy the anchor at the fixation location** (C)
- Remove the clip from the deploy position & retract the Injectroducer (D)
- Make an incision to expose the anchor following implantation, and place sutures through the anchor loops to the surrounding tissue to additionally secure the anchor position. Close the incision.
- Take a final fluoroscopy image to confirm stimulator position.

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For device explant, make an incision with fluoroscopic assistance to the depth of the anchor. Cut any sutures or scarring around the implant. Slowly pull on the anchor or stimulator to remove the device.

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