



INTRO

Accufix Medical LLC's StimFix™ device is a sterile, proprietary lead fixation system. It provides suture-free fixation for percutaneous Spinal Cord Stimulation trial leads. The market standardizing, cost and time saving, proprietary lead stabilizing device is specifically designed to stop trial lead migration and allow for more accurate outcome assessments of targeted stimulation SCS waveforms. **StimFix provides safe and secure fixation for up to 7 days.** (Can be increased based on IRB study)

Why choose the proprietary StimFix SCS trial lead Fixation Device?

- Maintains a secure locking system to provide a stable, safe and effective environment for your temporarily implanted SCS Trial leads.
- Minimize trial lead "anchoring" times
- Creates a more standardized environment for assessing outcomes
- Adds a layer of absorbable silver impregnated sponge at lead exit site
- Maintain comfortable yet secure adhesion

FEATURES

StimFix Suture-Free SCS Trial Lead Fixation Device Features

- **Suture-Free:** Non-invasive StimFix means no exposure to sharps or sharps related injuries and no painful suture skin pulling.
- **Secure:** Medical grade adhesive secures devices to patients skin for up to 7 days.
- **Stability:** SCS Trial leads secured up to 15 newtons of force using proprietary button lock technology.
- **Absorbent:** Silver Impregnated absorbable sponge provides the ability to absorb fluid leaking from the insertion site.
- **Easy:** Provides a time saving standardized anchoring system for physicians compared to the current standards of care.
- **Size:** Small comfortable footprint to be able to apply and maneuver easily.
- **Options:** Stimfix proprietary design allows for various positional options to allow for unilateral, bilateral or ipsilateral lead placements
- **Comfortable:** Pliable material allows for maneuverability for placement over various different skin contours

When to use SCS Trial lead anchoring device StimFix?

The StimFix proprietary fixation device is indicated to adhere to the skin and secure a percutaneous SCS Trial lead to help minimize migration and/or accidental removal.



HOW TO USE IT

StimFix User Manual

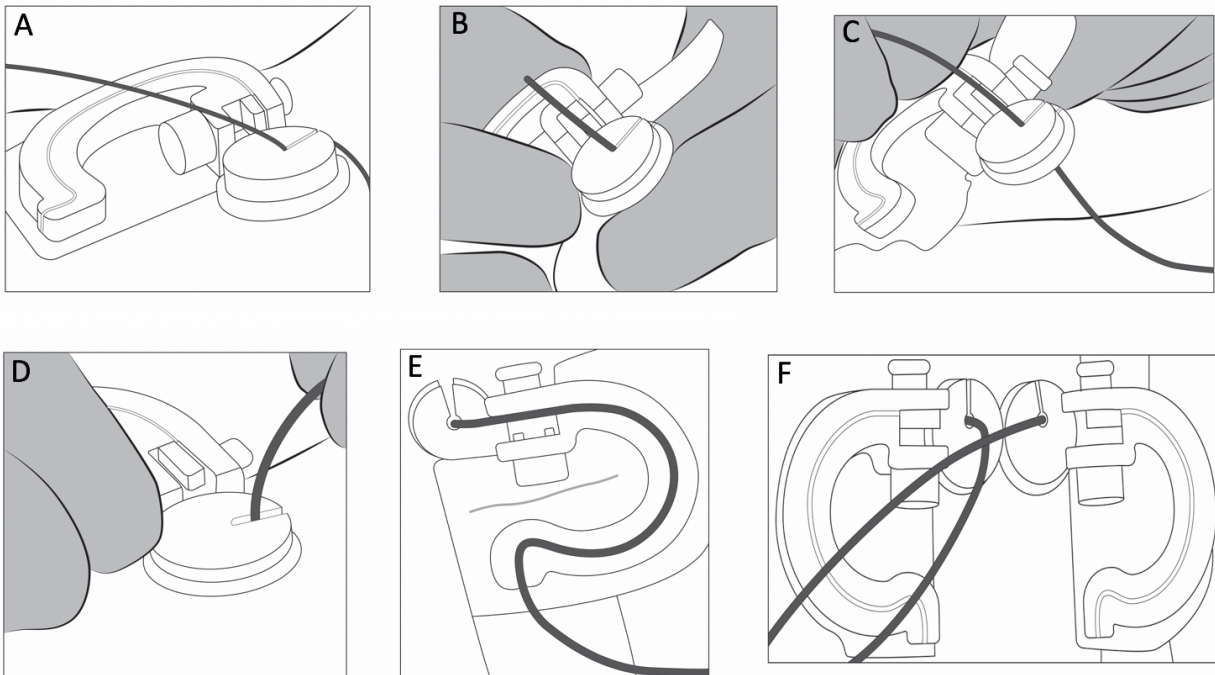
How to Use StimFix Fixation Device?

To adhere effectively, the StimFix Fixation Device must be applied to a clean, dry skin surface. Be sure to follow healthcare provider instructions for cleaning and managing the area where the SCS trial lead exits your body. Application instructions are illustrated below (Reverse instructions for removal):

Description of usage: Stimfix™ can be used in 2 ways as summarized by Figure 3.

First Method: As shown in the **Figure 3A** Stimfix™ can be directly anchored on to the skin by tucking the lead into the inlet.

Second Method: As shown in **Figures 3B-D** the lead can be anchored by feeding the lead from the small inlet and by gliding the Stimfix™ down until it anchors on the skin. After following either of the methods, under fluoroscopy guidance, an image is taken to make sure leads are still in place, and impedance is checked by the company clinical specialist. After the confirmation, the remaining lead is tucked into the locking system within the anchoring clip as shown in **Figure 3E**. Also, this Anchoring system can be used in ipsilateral leads as well, as shown in **Figure 3F**. Both



methods are followed by placing a taquederm on top of both anchors.

Figure 3 A-F. Overview of placement of StimFix using two methods in addition to ipsilateral placement.

Using the StimFix Fixation Device at Home:

- Stimfix Fixation Device should remain secure for up to seven days. After seven days or if the Stimfix device becomes loose please contact your health care provider.
- Inspect it daily to make sure that it is still holding the implanted device securely.
- If it becomes loose, please contact your health care provider immediately for instructions.
- Avoid touching the Fixation Device. Again, if it becomes loose, please contact your health care provider.

Precautions:

- Contents are sterile.
- Do not use if the packaging is opened, damaged, or broken.
- For single patient use only.
- Do not reuse, reprocess, or re-sterilize. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn may result in patient injury, illness, or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s)



from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

- Do not use after expiration date.
- Store in a cool, dry place.
- After seven (7) days please contact your health care provider on next steps.

Inspect the StimFix Fixation Device daily to make sure that

- It is still holding the SCS Trial Lead securely,
- Continues to stick to your skin, and
- Maintains its overall integrity

Contraindications:

- Use on patients with known tape or adhesive allergies.
- Use with other materials outside of percutaneous SCS leads.

