

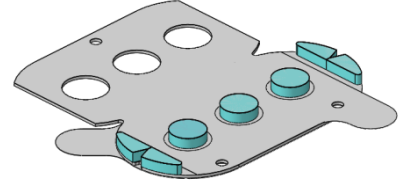
INSTRUCTION FOR USE

DEVICE DESCRIPTION

The TrialOn Fixation Device is a sterile adhesive fastener

INTENDED USE

The TrialOn Fixation Device is intended to secure Spinal Cord Stimulation (SCS) Leads during trials.



INDICATIONS FOR USE

The TrialOn Fixation Device is indicated to adhere to skin and secure a percutaneous Spinal Cord Stimulation (SCS) Lead to assist in minimizing movement of the leads during initial trials.

CONTRAINDICATIONS

- Use on patients with known allergies to tape or adhesive.
- Use with vascular catheters.

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Rx Only

PRECAUTIONS

- Read Instruction for Use thoroughly prior to use.
- Contents are provided sterile. Do not use if packaging is open or damaged.
- The device is for single patient use only. Do not reuse, reprocess or resterilization as this may damage the device and/or lead to device failure which may lead to patient injury, illness or death. Reuse, reprocess or resterilization of this device may also increase the risk of patient infection or cross-infection such as transmission of infectious disease from one patient to another.
- Do not use after expiration date.
- Store in a cool and dry location.

INSTRUCTION FOR USE

To ensure effective adhesion, the skin surface must be thoroughly cleaned and dry. Application instructions are illustrated below.

1. Remove the bottom release liner.
2. Move the device over to where the lead exit the skin and Position the lead into one of the grooved ends.
3. Press the device down onto the skin surface and apply even pressure.
4. Remove the top release liner.
5. Thread the lead down through the groove, around the posts and out the other end.
6. Fold over the remaining side and press the surfaces together securing the lead.

