

Introducer Kit Model SC-4365

Description

The Boston Scientific model SC-4365 Introducer Kit is intended to be used to prepare or preserve a path for a lead with a recommended outer diameter of up to 1.4 mm. This accessory kit contains two Introducer sheaths of different lengths.

Indications

The Boston Scientific model SC-4365 Introducer Kit is intended for the percutaneous introduction and placement of Spinal Cord Stimulation (SCS) leads.

Contraindications

Refer to the appropriate lead implant manual for a complete list of contraindications for SCS lead use

Sterilization and Handling

- This product has been sterilized with ethylene oxide (EtO).
- This product is intended for single use only. DO NOT reuse this product.

WARNINGS

- *Carefully examine all product packaging before use. If the product packaging is damaged, the sterile seal is broken, or the "Use by" date is past, DO NOT use the package contents.*
- *Do not cut the Introducer. Cutting the Introducer could cause sharp edges which may result in tissue damage.*
- *For a complete list of warnings associated with lead implantation, see the appropriate lead implant manual.*

Directions for Use

For detailed lead implant instructions, refer to the appropriate lead implant manual.

CAUTION:

Do not use excessive force when advancing the Introducer. Using excessive force may result in damage to the Introducer.

Replacement of Insertion Needle

1. Verify that the Introducer is the appropriate size and length for the lead being implanted.

Introducer Kit

2. After inserting the epidural needle into the epidural space, introduce the lead through the insertion needle. For detailed instructions, refer to the appropriate lead implant manual.
3. Using fluoroscopic guidance, advance the lead into the epidural space until the last contact is at least ½ vertebral body beyond the tip of the needle.

CAUTION:

To prevent lead damage, do not remove the insertion needle until the last contact is at least ½ vertebral body beyond the tip of the needle. Removing the needle while the stimulating contacts are in the needle may result in damage to the lead.

4. While holding the lead in place, gently withdraw the insertion needle over the lead, taking care not to remove the lead from the epidural space.
5. Place the Introducer over the proximal end of the lead. While holding the lead in place, advance the Introducer sheath over the lead until the proximal tip of the lead extends beyond the hub of the Introducer. Using fluoroscopic guidance, hold the proximal end of the lead and continue advancing the Introducer sheath until it is in the epidural space.

NOTE: Rotating the Introducer slowly may help ease advancement of the sheath.

6. Continue placing the lead under fluoroscopic guidance per the appropriate lead implant manual.

Replacement of Implanted Lead

1. Verify the Introducer is the appropriate size and length for the lead being removed.
2. Locate the epidurally-implanted lead and expose the proximal end. Remove any lead anchors or sutures that may interfere with the insertion of the Introducer into the epidural space.
3. Place the Introducer over the proximal end of the exposed lead. While holding the lead in place, advance the Introducer sheath over the implanted lead until the proximal tip of the lead extends beyond the hub of the Introducer. Then hold the proximal end of the lead and continue advancing the Introducer sheath to the desired location.
4. Carefully pull on the implanted lead until it is removed completely.
5. Insert the new lead into the hub of the Introducer.
6. Using fluoroscopic guidance, advance the new lead to the desired location.

7. Remove the Introducer by carefully pulling on the hub until the Introducer is completely removed from the epidural space.

CAUTION:

Use care to not move the lead in the epidural space once it is implanted.

8. To complete the lead implant procedure, refer to the appropriate lead implant manual.

Customer Service – USA

In USA, to order replacement parts, or for answers to any questions you might have, please contact the Customer Service Department:

- Phone: (866) 360-4747, +1 (661) 949-4747
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