Medtronic

SenSight™ Directional Lead Kit

B33005
B33015

Implant manual

! USA Rx only

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Information available for the Deep Brain Stimulation Therapies:

The information for prescribers manual provides information about contraindications, warnings, precautions, adverse events, sterilization, and component disposal. The information for prescribers addendums contain indication-specific information. For customers in Japan, the appropriate package insert provides information about safety, contraindications, warnings, precautions, and adverse events.

The indications sheet provides information about indications and related information. For customers in Japan, the appropriate package insert provides information about indications.

The system eligibility and battery longevity manual describes programming considerations and provides battery longevity information to aid in the appropriate neurostimulator selection.

MRI guidelines provide information about any MRI conditions and MRI-specific contraindications, warnings, and precautions for MRI scans with the neurostimulation system.

Product manuals, such as programming guides, recharging guides, and implant manuals provide device descriptions, package contents, device specifications, product-specific warnings and precautions, and instructions for use.

! USA **The clinical summary provides information about the clinical study results for the neurostimulation system.**

Description

The Medtronic Models B33005 and B33015 SenSight™ directional leads are part of a neurostimulation system for deep brain stimulation (DBS).

Intended purpose

The lead is an implanted device intended to conduct electrical stimulation to the intended target as part of a DBS system.

Compatibility

⚠ **Warning:** Only use SenSight components with other SenSight components, unless specific compatibility is stated in this manual. Do not use incompatible components. Using incompatible components may result in component damage, intermittent or loss of stimulation, and require surgical replacement or revision.

Package contents

- 1 Lead (Model B33005 or B33015)
- 1 Straight stylet (preinserted in the lead)
- 1 Torque wrench (white)
- 1 Lead cap
- Product literature
- ! USA Warranty card
- ! USA Registration form

Device specifications

The lead has electrodes on the distal end; the proximal end fits into an 8-conductor connector. A stylet has been inserted into the proximal end of the lead to aid in positioning the lead and performing intraoperative test stimulation.

Electrode spacing and numbering

- The Model B33005 lead has narrow (0.5 mm) electrode spacing, or the spacing between each level of electrodes (Figure 1).
- The Model B33015 lead has wide (1.5 mm) electrode spacing, or the spacing between each level of electrodes (Figure 2).
- Electrode levels are numbered as 0, 1, 2, 3. Electrodes 0 and 3 are full annular electrodes. The six electrodes at levels 1 and 2 consist of electrode segments. When viewed from the proximal end of the lead, the electrode segments are alphabetically ordered counterclockwise, and identified as 1a, 1b, and 1c, and 2a, 2b, and 2c (Figure 3).

Bilateral markers

- Leads identified with the letter M after the length (eg, B3300533M), include 2 bilateral markers.
- Bilateral markers help differentiate between hemispheres when 2 leads are implanted.

Orientation markers

- The orientation markers visually aid in determining the direction of segmented electrodes during lead placement. They are visible on imaging including x-ray, fluoroscopy, CT, and O-Arm.
- The proximal orientation marker aligns with electrode segments 1a and 2a. The distal orientation marker aligns with electrode segments 1b and 2b. Electrode segments 1c and 2c do not align with the orientation marker, but the location of these electrodes can be determined when orienting to segments a or b.
- For examples of fluoroscopic images showing the orientation marker positions and electrode segment placement, refer to the **"Appendix" on page 16**.

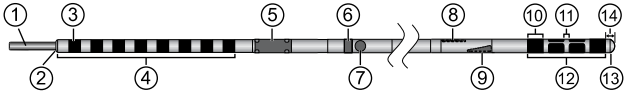

Figure 1. *Model B33005 marked directional lead.*

① Preinserted stylet
② Proximal end
③ Lead contact
④ Lead contacts total distance–17.5 mm
⑤ Setscrew fixation ring
⑥ Insertion marker
⑦ Bilateral marker (marked leads only)
⑧ Proximal orientation marker
⑨ Distal orientation marker
⑩ Electrode length–1.5 mm
⑪ Electrode spacing–0.5 mm
⑫ Electrodes total distance–7.5 mm
⑬ Distal end
⑭ Distal tip distance

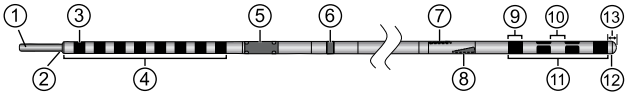

Figure 2. *Model B33015 directional lead.*

① Preinserted stylet
② Proximal end
③ Lead contact
④ Lead contacts total distance–17.5 mm
⑤ Setscrew fixation ring
⑥ Insertion marker
⑦ Proximal orientation marker
⑧ Distal orientation marker
⑨ Electrode length–1.5 mm
⑩ Electrode spacing–1.5 mm
⑪ Electrodes total distance–10.5 mm
⑫ Distal end
⑬ Distal tip distance

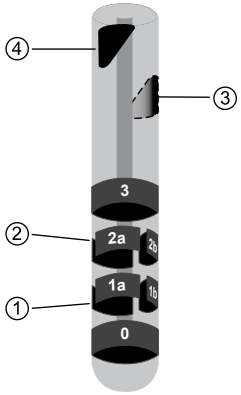

Figure 3. *Orientation markers and electrode numbering.*

① Segment 1c
② Segment 2c
③ Distal orientation marker
④ Proximal orientation marker

Table 1. Device specifications for the directional leads[a]

Description	Model B33005 or B33015
Expected lifetime	5 years
Conductor resistance [b,c]	Maximum 100 Ω for all lengths
Length	33 cm, 42 cm
Surface area	
33 cm length	13.55 cm²
42 cm length	17.26 cm²
Lead diameter	1.36 mm
Shape	Straight
Distal end	8 electrodes
Electrode shape	Cylindrical
Distal tip distance	1.0 mm
Proximal end	8 contacts, in-line
Lead contact spacing	2.2 mm
Stylet handle length	4.6 mm
Materials and substances to which the patient can be exposed[d,e]	Polyurethane, platinum iridium

[a] All measurements are approximate

[b] Electrical resistance of this device only.

[c] Electrical resistance is proportional to lead length: long lengths have higher resistance that may limit the amplitude.

[d] Discuss allergies or other intolerances related to the materials of construction with the patient before the procedure.

[e] Tested for category 1A or 1B carcinogenic, mutagenic, or toxic for reproduction (CMR) substances, and endocrine disrupting chemicals (EDC). No known CMRs or EDCs found for the materials and substances listed in this table.

Preparing for surgery

Implanting clinicians should be experienced in stereotactic and functional neurosurgery and deep brain stimulation procedures, as well as thoroughly familiar with all product labeling.

The deep brain stimulation system delivers electrical stimulation to selected targets in the brain. A test stimulation or mapping electrode may be utilized for further localization of the target. The DBS lead is not recommended for mapping.

Before opening the lead package, verify the model number, use-by date, lead length, and connector type.

Note: If the tip of the stylet is partially retracted, ensure the stylet is fully inserted into the lead before implanting.

Handling the components

⚠ **Warning:** Do not bend, kink, stretch, or twist the component. This can damage the component, resulting in intermittent or loss of stimulation, requiring surgical replacement or revision.

⚠ **Warning:** Do not implant a damaged component. If damage occurs to a component during the procedure, for example, breaking, cutting, nicking, flattening, stretching, etc., use a new component. Implanting a damaged component can result in intermittent or loss of stimulation, requiring surgical replacement or revision.

⚠ **Warning:** Use only rubber tipped forceps on the lead. Do not use sharp edged instruments on the lead, for example, a hemostat. Sharp edged instruments can damage or fracture the lead, resulting in intermittent or loss of stimulation, requiring surgical replacement or revision.

△ **Caution:** Do not use saline or other ionic fluids at the connections. Using saline or ionic fluids can result in a short circuit, or inadequate stimulation, requiring surgical replacement or revision. If necessary, use sterile water or a nonionic antibiotic solution to wipe connections. Wipe the lead connector and the extension connector with sterile gauze. Dry all connections.

△ **Caution:** Do not reinsert the stylet, for example, if lead repositioning is required. Reinserting the stylet can damage the lead. Use a new lead.

Instructions for use

A variety of techniques may be used for the lead implant. Use of an insertion cannula is an approach for clinician consideration. The following procedure is presented as one possible approach.

Planning the lead placement

The deep brain stimulation system delivers electrical stimulation to selected targets in the brain. The target site may be localized using standard imaging techniques.

1. Use standard imaging and planning techniques to determine coordinates for target trajectory and frame placement.
2. Attach the desired frame with determined coordinates for the target trajectory.
3. Prepare the patient per stereotactic neurosurgical techniques.

Creating the burr hole

1. Mark the location of the burr hole and make an incision.
2. Create a 14-mm diameter burr hole in the marked location.
3. Secure the base of the burr hole device over the burr hole. Refer to the burr hole device instructions for use for complete information.

Assembling the frame and determining the target location

1. Confirm the frame coordinates for the target trajectory using preferred methods of surgical planning.
2. If using a microdrive, assemble it according to any instructions provided with the microdrive.
3. Using preferred methods, confirm the target location. If necessary, document the target location.
4. Determine the depth to place the lead and set the delivery system to the target depth.

Attaching the depth stop and advancing the lead

Note: Medtronic recommends the use of a depth stop. Refer to the instructions provided for the frame and the SenSight depth stop.

1. Attach the depth stop to the lead, ensuring the lead is aligned to the proper target depth for insertion. Refer to the depth stop instructions for use for complete information.

   Note: Depth stop placement on the lead will determine what size insertion cannula can be used:

   - If the depth stop is attached to the white section of the lead, an insertion cannula with minimum internal diameter of 1.57 mm can be used.
   - If the depth stop is attached to the clear section of the lead, an insertion cannula with a minimum internal diameter of 1.42 mm can be used.
2. Slowly advance the lead through the delivery system to the predetermined depth. Refer to any instructions provided with the selected lead delivery system.

Performing lead test stimulation

Refer to the lead test cable instructions for use for complete information.

1. To confirm proper lead placement, perform test stimulation that is appropriate for the intended indication.
2. When test stimulation is complete, disconnect the lead test cable from the lead.

Removing the stylet and stabilizing the lead

1. If an insertion cannula was used, retract the cannula until the lead can be seen between the burr hole and the cannula.
2. Carefully position the support clip of the burr hole device around the lead and into the base ring. Refer to the burr hole device instructions for use for complete information.
3. Gently hold the lead at a point above the support clip to maintain the lead position.
4. Close the support clip.
5. Raise the insertion cannula up to create enough space to pull the lead straight through the bottom of the cannula.
6. Remove the depth stop.

   △ **Caution:** Ensure that the depth stop is fully loosened before removing it from the lead. If the depth stop is not loosened completely before it is removed, lead damage and inadequate stimulation may occur, requiring revision surgery.

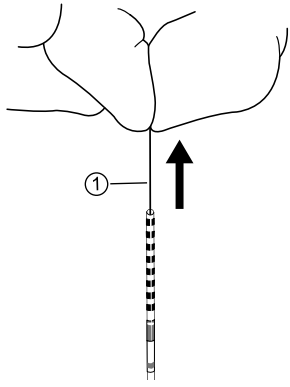

Figure 4. *Removing the stylet.*

① Hold the stylet

7. Remove the stylet from the lead (Figure 4).
8. Carefully pull the lead straight down through the bottom of the insertion cannula.
9. Move the frame assembly clear of the burr hole.

Securing the lead

1. Secure the lead using the burr hole device. Refer to the burr hole device instructions for use for complete information.

   ⚠ **Warning:** Do not use alternative anchoring methods to anchor or secure the lead. Use of other anchoring methods, for example, an incompatible model burr hole cover, tying ligatures, or using glues, cements, and surgical plates etc. may damage the lead, and cause lead movement. Lead damage or lead movement may result in intermittent or loss of stimulation, requiring surgical replacement or revision.

2. If necessary, recheck stimulation after stabilizing the lead with the burr hole device.
3. Verify lead placement with standard imaging techniques (ie, record the settings and include a fluoroscopic image of the final lead position).

Implanting a second lead

1. To implant the second lead, repeat target localization, lead implantation, and test stimulation procedures. To help differentiate between the 2 leads, use a marked directional lead.
2. Use surgical methods to protect the excess lead wire (for example, a subgaleal pocket) during the implantation of a second lead.

Completing the lead implant

The remainder of the neurostimulation system may be implanted immediately after lead implant, or it may be implanted at a later date.

- If implanted immediately, prepare the patient for implantation of the remaining parts of the neurostimulation system.
- If implanted at a later date, cap the lead or leads until the remaining parts of the neurostimulation system may be implanted. Refer to "Capping the lead" for more information.

Capping the lead

1. Place the lead cap (provided in the lead kit or lead cap kit) over the exposed end of the lead.

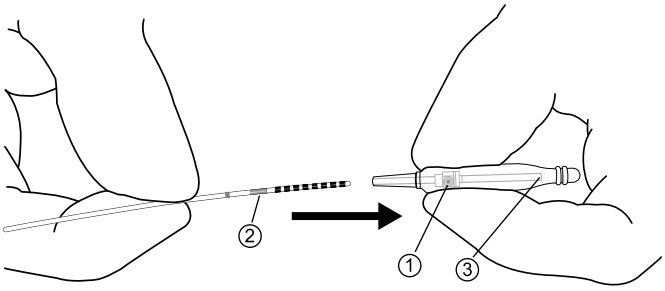

Figure 5. *Connecting the lead cap to the lead.*

① Setscrew connector block
② Setscrew fixation ring
③ Visual window to see full lead insertion

2. Position the setscrew connector block over the setscrew fixation ring on the lead. Use the visual window on the lead cap to confirm that the lead is fully inserted (Figure 5).

3. Use the torque wrench to tighten the setscrew, and hold the setscrew connector block firmly between thumb and forefinger to support the lead body and stabilize the connector block.

⚠ **Warning:** Do not reuse a torque wrench or use an incorrect torque wrench. Use only the white torque wrench provided. Using an incompatible torque wrench or reusing a torque wrench can damage the component, resulting in intermittent or loss of stimulation, requiring surgical replacement or revision.

⚠ **Caution:** Do not tighten the setscrew without stabilizing the setscrew connector block. Failure to stabilize the setscrew connector block can break or damage the lead, requiring surgical replacement or revision.

4. Tighten the setscrew onto the setscrew fixation ring by turning the torque wrench clockwise (Figure 6).

⚠ **Caution:** Ensure that the torque wrench is perpendicular to the setscrew axis, and tighten the setscrew until the torque wrench clicks at least once. Failure to hold the wrench perpendicular while tightening can result in an insufficiently tightened setscrew, or too loose of a setscrew, and require surgical replacement or revision.

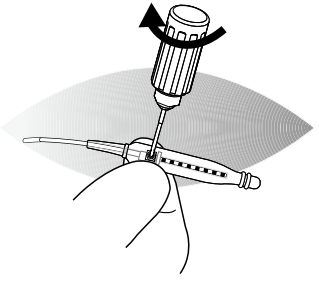

Figure 6. *Tightening the lead cap setscrew.*

5. Discard the torque wrench after making all connections.
6. Deliver the capped end of the lead to the desired temporary location, for example, a subgaleal pocket.

   ⚠ **Warning:** Be extremely careful when using sharp instruments around the lead body to avoid nicking or damaging the lead. A damaged lead can result in intermittent or loss of stimulation, requiring surgical replacement or revision.

7. If preferred, use the cranial tunneler (provided in a separate kit) to tunnel a path to the intended lead-extension connection site. Refer to the cranial tunneler instructions for use for complete information.
8. Coil the excess lead to provide sufficient strain relief.
9. Close the incision.
10. Take an AP x-ray image to confirm the final lead orientation, and document the angle that corresponds to the proximal orientation marker. This angle will be used during programming.

    For examples of fluoroscopic images showing the orientation marker positions and electrode segment placement, refer to the **"Appendix" on page 16**.

Appendix

Fluoroscopic images showing the orientation markers

The following figures include examples of how to interpret and identify the angle of the electrode segments, when viewing the direction of the orientation markers on fluoroscopic imaging.

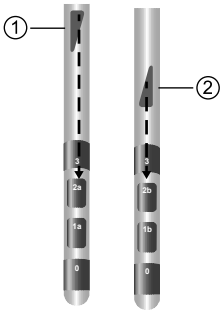

Figure 7. *Orientation markers*

① Proximal orientation marker ② Distal orientation marker

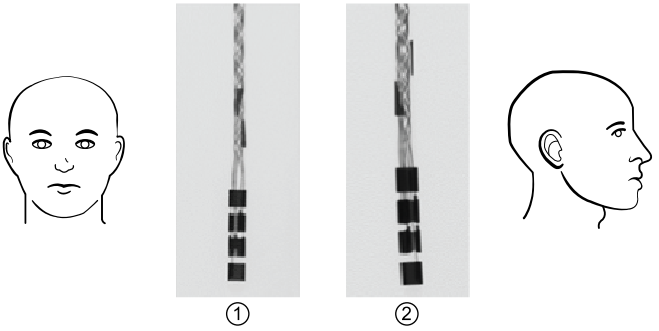

Figure 8. *Anterior proximal orientation marker direction*

① AP view ② Lateral view

Figure 9. *Posterior proximal orientation marker direction*

① AP view ② Lateral view

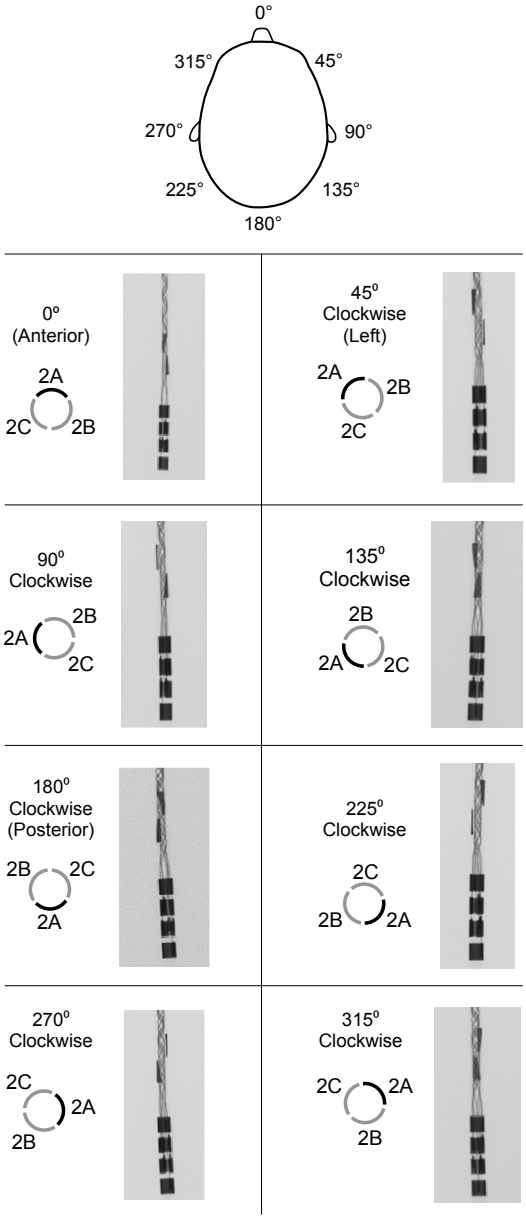

Figure 10. *AP imaging views*

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