



Surpass™ Surgical Lead Manual

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NEVRO CORP.

All questions or concerns about Nevro products should be forwarded to:

Nevro Corp.

1800 Bridge Parkway

Redwood City, CA 94065, USA

Tel: +1.650.251.0005

Fax: +1.650.251.9415

info@nevro.com

EC REP

MDSS GMBH

Schiffgraben 41

D-30175 Hannover,

Germany

Australian Sponsor

Emergo Australia

Level 20, Tower II, Darling Park

201 Sussex Street,

Sydney, NSW 2000

Australia

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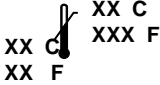








CE Mark effective on 4 May 2010

Nevro hereby declares that the Senza® System is in compliance with the essential requirements and other relevant provisions of the Radio Equipment Directive (2014/53/EU).

IMPORTANT: Changes or modification to any component of the Nevro® Spinal Cord Stimulation system, unless expressly approved by Nevro Corp., could void your authority to operate this product.

CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.

Explanation of symbols. Refer to the product for symbols that apply.

Symbols	Description		
SN	Serial number		
LOT	Batch code		
	Date of Manufacture		
	Manufacturer		
	Caution		
REF	Catalog number		
	Temperature limitation (storage)		
<table border="1" data-bbox="142 987 410 1039"> <tr> <td>STERILE</td><td>EO</td></tr> </table>	STERILE	EO	Sterilized using ethylene oxide
STERILE	EO		
	Use by		
	Do not use if package is damaged		
	Do not reuse		
	Do not re-sterilize		
	Keep dry		
R_x ONLY	Prescription only		
 www.nevro.com	Consult Electronic Instructions for Use		
	Non-sterile		
	Non-ionizing radiation		



Type B Applied Part



Type BF Applied Part



Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations.



Conditional

MR Conditional



MR unsafe



CE Marking of Conformity



Authorized representative in the European Community

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Device Description

The Surpass™ Surgical Lead is intended to be used with a Nevro Implantable Pulse Generator (IPG) or Trial Stimulator for use in delivering stimulation. These leads are implanted surgically, are intended for single use, and interface with an IPG, Lead Extensions, OR Cable, and associated accessories.

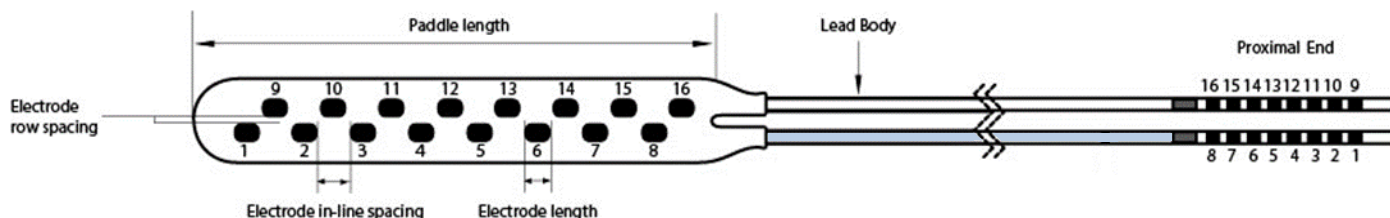


Figure 1: Surgical lead with electrodes facing up

The distal end of the lead is molded out of Silicone material and has 16 distal electrodes, arranged in 2 columns. The distal electrodes are made out of Platinum / Iridium alloy. The Nevro surgical lead is provided in 3 configurations. The design, materials and manufacturing are identical on all three configurations with the exception of the offset between the two electrode columns.

The proximal end of the lead has two legs each with 8 contacts. The isodiametric proximal legs attach to a Nevro IPG, Lead Extension or OR cable and are made out of Pellethane® material. Each proximal leg has eight low impedance cables that conduct signals from a proximal contact to a distal electrode. One proximal leg is blue in color with connections to electrodes 1-8, while the other proximal leg is clear with connections to electrodes 9-16.

The components included in the Surgical Lead kit are:

- Surgical lead
- Silicone Anchors

Device specifications for Surgical Lead models

Description	Model LEAD3005-xx*(B)	Model LEAD3015-xx*(B)	Model LEAD3025-xx*(B)
Connector	Octapolar, in-line	Octapolar, in-line	Octapolar, in-line
Shape	Contoured	Contoured	Contoured
Conductor resistance	<18 Ω	<18 Ω	<18 Ω
Length (includes paddle)	30 to 90 cm	30 to 90 cm	30 to 90 cm
Lead body diameter	1.3 mm	1.3 mm	1.3 mm
Distal end			
Number of electrodes	16	16	16
Electrode shape	Rectangular	Rectangular	Rectangular
Electrode size (width x length)	1.25 mm x 3.0 mm	1.25 mm x 3.0 mm	1.25 mm x 3.0 mm
Electrode stimulating area	6.75 mm ²	6.75 mm ²	6.75 mm ²
Electrode span	57.4 mm	64.6 mm	71.9 mm
Electrode spacing (edge to edge)			
in-line spacing	4.25 mm	4.25 mm	4.25 mm
row spacing	1.0 mm	1.0 mm	1.0 mm
Paddle length	64 mm	71 mm	79 mm
Paddle width	10 mm	10 mm	10 mm
Paddle thickness	2.0 mm	2.0 mm	2.0 mm

* xx represents the overall lead length

List of tissue contacting materials

Component	Material
Lead	
Electrodes	Platinum-iridium
Electrode paddle	Silicone rubber
Insulation	Polyurethane
Proximal connector	MP35N
Lead Anchors	Silicone rubber

Indications for Use, Contraindications, Warnings, and Precautions

For Indications for Use, Contraindications, Warnings, and Precautions for the Senza system, refer to the Physician Implant Manual.

Surpass surgical leads are MR conditional and therefore have demonstrated safety in the MR environment within defined conditions. Nevro recommends that patients implanted with Surpass surgical leads undergo MRI examination per the guidelines provided in *1.5 Tesla and 3 Tesla Magnetic Resonance Imaging (MRI) Guidelines for the Senza System* or *1.5 Tesla and 3 Tesla Magnetic Resonance Imaging (MRI) Guidelines for the Senza II Implantable Pulse Generator (IPG2000)* available on Nevro's website:

www.nevro.com/physicianmanuals

MR scans performed outside these guidelines may result in the MRI field interacting with implanted devices, potentially injuring the patient and damaging the implanted device. Due to risks associated with using an MRI with an implanted device, it is important to read, understand, and comply with these instructions to prevent potential harm to the patient and/or damage to the device.

Precautions Specific to the Surgical Lead Kit

Storage and Transport

The Surgical Lead kit should be stored in temperature regulated areas within the acceptable temperature range. Excessively hot or cold temperatures may damage the adaptor, particularly high heat. The storage temperature for the Surgical Lead kit should not exceed the range of 0°C - 45°C (32°F - 113°F). Do not expose the Surgical Lead kit to liquids or excessive moisture.

Sterilization

1. This device is for single use only and is not intended to be re-sterilized.
2. Prior to opening the sterile package, inspect the sterilization indicator and the sterile package.
3. Do not use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.
4. Do not use any component that shows signs of damage.
5. Do not re-sterilize the package or the contents. There is risk of infection and device malfunction.
Do not use if "Use by" date has passed.

Compatibility

The Nevro Surgical Lead is compatible only with Nevro Senza IPGs, Nevro Lead Extensions and Nevro OR cables. Use of stylets or components provided by other manufacturers may damage the Surpass Surgical Lead.

Instructions for Use

For complete directions for use of the Senza system, refer to the Physician Implant Manual.

The implanting physician must be experienced in epidural-access procedures and should be familiar with product labeling.

Warning: Use an appropriate imaging method to evaluate the geometry and suitability of the spinal canal. Ensure that the spinal canal can safely accommodate the insertion and placement of the surgical lead (paddle and body). Consideration should be given to the following items:

- Appropriate amount of space within the spinal canal
- Altered epidural anatomy due to medical conditions or surgical procedures
- Potential for post-implant tissue changes around the lead
- Changes in epidural space due to movement of the spine during routine activity

Implantation of a surgical lead in an inadequately spaced spinal canal may result in localized compression of the spinal cord, increasing the risk of spinal cord injury.

Warning: Safety and effectiveness of this lead has not been established for use with more than one IPG. Damage to nerve tissue may occur if this lead is connected to more than one IPG.

Caution: The surgical lead should not be implanted in anatomical locations that have a high degree of mobility. The stresses associated with such locations may reduce the functional survival time of the lead. The patient could require reprogramming and/or revision of the lead to restore effective therapy.

Cautions:

- Bending, stretching or kinking of the lead or extension may result in damage to the component.
- Only rubber-tipped forceps should be used to handle the lead. Sharp-edged instruments may damage the insulation.
- The use of saline or other ionic fluids at connections could result in a short circuit.
- Wipe off any fluids from the lead connector end before connecting it to any other component.

Percutaneous leads are suggested for temporary trial use when implantation of a surgical lead for permanent stimulation is planned.

a. Pre-op Instructions

- Before opening the packages, verify the use-by date and the description of the component, such as length and type.
- Do not use any component that shows signs of damage.

b. Lead Placement

1. Prepare the skin and drape the patient in the usual sterile fashion and follow appropriate pre-op antibiotic regiment.
2. Determine the appropriate vertebral level for surgical lead placement using fluoroscopic guidance.

3. Perform a laminotomy using the standard technique to introduce the surgical lead into the epidural space. Make the laminotomy width consistent with the lead's paddle width. Failure to do so may result in forcing the lead into the epidural space, which may damage the lead.
4. Bone wax or instrumentation should be used to ensure that the bony edge of the laminotomy is smooth. Sharp edges may damage the lead, resulting in intermittent or loss of stimulation.
5. Ensure that the contacts are facing towards the dura when inserting the surgical lead. Use the standard technique to introduce and advance the surgical lead to the desired vertebral level. Introduce the lead at a shallow angle. Using an angle that is too deep could cause contusion to the spinal cord.

Optional:

- Prior to introducing the surgical lead, a passing elevator may be used to ensure adequate space and proper location for the lead. Insert the passing elevator at a shallow angle to introduce the surgical lead, and then remove the passing elevator.
 - Caution:
 - Using excessive force with passing elevator or lead may cause patient injury.
 - Using an angle that is too deep could cause contusion to the spinal cord.
 - Insufficient space to accommodate the lead may result in localized compression of the spinal cord and potential neurological injury.
6. Confirm the lead position using fluoroscopy.
 7. Attach the OR Cables to the surgical lead and take impedance measurements as specified in the Physician Implant Manual.
 8. Anchor the surgical lead as specified in the Physician Implant Manual.
 9. If a Surgical Lead is being implanted for the purposes of conducting a permanent trial, the proximal ends of the lead should be connected to Extensions:
 - Wipe fluids (e.g. blood) from the proximal ends of the Surgical Lead. Then fully insert the proximal end of the lead into the lead extension's connector. Two extensions will be required for each Surgical Lead.
 - Conduct an impedance check.
 - Do not tighten the setscrew on the extension until all of the impedances are in the normal range.
 - Fully insert the torque wrench into the setscrew.
 - Rotate the torque wrench handle to turn the lead extension connector's setscrew clockwise until it clicks. Clicking indicates that it is fully tightened.
 - NOTE:
 - Ensure that the setscrew is not removed from the connector.
 - If the lead does not fully insert into the lead extension's connector, check to see whether the setscrew is impeding the progress of the lead. If it is, use the torque wrench to loosen the setscrew by turning it counter-clockwise and then re-insert the lead.
 - If the setscrew does not tighten smoothly, try the following:
 - Use the torque wrench to loosen the setscrew by turning it counter-clockwise and then re-tighten by turning it clockwise.
 - Check to see that the lead is fully inserted into the lead extension's connector before tightening.
 - The wrench is torque-limited and cannot be over tightened if you use the handle.
 - Use only the appropriate Nevro torque wrench to ensure that the proper torque is applied to the setscrews.
 - The Lead and Extensions should be tunneled in the following manner:

- Assemble the tunneling tool by screwing in one of the tips on the end of the shaft. Make sure the straw is on the shaft prior to screwing in the tip.
 - Plan the desired route of the tunnel and mark the route and the destination point at least 10-15 cm from the incision.
 - Give appropriate local anesthetic along the tunneling route.
 - Create a small incision at the planned extension exit site.
 - Insert the tunneling tool from the lead insertion site and create a subcutaneous tunnel to the extension exit site until the straw can be seen.
 - Hold the tunneling tip firmly and then unscrew and remove the tunneling tip. Take care not to drop the tunneling tip.
 - Remove the tunneling tool while leaving the straw in the tunnel.
 - Insert the proximal end of the lead extension(s) through the straw.
 - Push the lead extension(s) until they come out of the straw's other end.
 - Gently pull the extension(s) to get as much of the extension(s) that you need through the straw, and then withdraw the straw from the exit site. It is recommended that a strain relief loop is left in the dorsal wound.
 - Make sure that the lead location has not changed.
 - Connecting the Extensions to the Trial Stimulator:
 - Appropriate sterile dressings must be applied to the site where the lead extensions exit the body. Tape the extension securely to the skin.
 - Connect the extension to the OR Cable.
 - Create a loop of the OR Cable for strain relief and then tape the OR Cable to the skin.
 - Connect the OR Cable to the Trial Stimulator.
 - Using the lead location tool in the programmer, ensure that the proximal leg which is blue in color is connected to the lead port 1 of the TSM.
 - Program system as specified in the Clinician Programmer Manual.
10. If the Surgical Lead is being implanted for permanent stimulation, prepare the IPG implant site as specified in the Physician Implant Manual.
- Tunnel the lead or extensions to the IPG implant site as specified above.
 - Implant the IPG as specified in the Physician Implant Manual.
 - Using the lead location tool in the programmer, ensure that the proximal leg which is blue in color is connected to the lower port of the IPG.
 - Program system as specified in the Clinician Programmer Manual.

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