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# S8 Lead Adaptor Manual

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**R<sub>x</sub>**  
ONLY

**CE**  
0086

**NEVRO CORP.**

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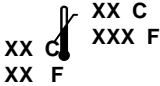






CE Mark effective on 4 May 2010

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:** Do not change or modify any component of the Nevro® Senza system, unless expressly approved by Nevro Corp.

**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		
<b>SN</b>	Serial number		
<b>LOT</b>	Batch code		
	Date of Manufacture		
	Manufacturer		
	Caution		
<b>REF</b>	Catalog number		
	Temperature limitation (storage)		
<table border="1" data-bbox="144 1081 410 1136"> <tr> <td><b>STERILE</b></td><td><b>EO</b></td></tr> </table>	<b>STERILE</b>	<b>EO</b>	Sterilized using ethylene oxide
<b>STERILE</b>	<b>EO</b>		
	Use by		
	Do not use if package is damaged		
	Do not reuse		
	Do not re-sterilize		
	Keep dry		
<b>R<sub>x</sub> ONLY</b>	Prescription only		
 <a href="http://www.nevro.com">www.nevro.com</a>	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

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The S8 Lead Adaptor allows a compatible St. Jude Medical (SJM) neuromodulation lead or extension to be connected to the Nevro's Senza Spinal Cord Stimulation (SCS) system to deliver stimulation using the compatible lead. This manual provides basic information for the operation of the S8 Lead Adaptor, model SADP2008-XXY (where  $1\text{cm} \leq \text{xx} \leq 60\text{cm}$  in increments of 1 cm and Y represents the cable color).

The components included in the S8 Lead Adaptor Kit are:

- S8 Lead Adaptor
- S8 Torque Wrench

## Indications for Use, Contraindications, Warnings, and Precautions

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

The following warning applies specifically to the S8 Lead Adaptor:

- If using the St. Jude Medical Penta lead, the clinician programmer will not allow programming parameters which result in excessive charge density.

### ***Storage and Transport***

The S8 Lead Adaptor 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 adaptor should not exceed  $0^{\circ}\text{C}$  -  $45^{\circ}\text{C}$  ( $32^{\circ}\text{F}$  -  $113^{\circ}\text{F}$ ). Do not expose the adaptor to liquids or excessive moisture.

### ***Sterilization***

1. Prior to opening the sterile package, inspect the sterilization indicator and the sterile package.
2. Do not use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.
3. Do not use any component that shows signs of damage.
4. Do not re-sterilize the package or the contents. There is risk of infection and device malfunction.
5. Do not use if "Use by" date has passed.
6. All implanted components are intended for single use only. Do not re-use.
7. Note:
  - The product is sterilized using ethylene oxide.
  - The product should not be re-sterilized.

## Compatibility

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The S8 Lead Adaptor is compatible with the following SJM lead and extension models:

- Octrode™ Lead Model numbers: 3183, 3186, 3189 and 3181.
- Lamitrode Exclaim™ Model numbers: 3224 and 3225.
- Lamitrode Tripole™ 16C Model numbers: 3214.<sup>1</sup>
- Lamitrode™ 44 Model numbers: 3244, 3262 and 3263.
- Lamitrode 44C Model numbers: 3245, 3264 and 3265.
- Lamitrode 88 Model number: 3288.<sup>1</sup>
- Lamitrode 88C Model number: 3289.<sup>1</sup>
- Lamitrode S8 Model numbers: 3283, 3286, 3268 and 3269.
- Single 8 Extension Model numbers: 3382, 3383 and 3386.
- Penta™ lead model number: 3228.<sup>1</sup>

<sup>1</sup> If using the St. Jude Medical Penta lead, the clinician programmer will not allow programming parameters which result in excessive charge density.

## Instructions for Use

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

1. Confirm that the SJM lead that you wish to connect to is listed above.
2. Visually inspect the proximal end(s) of the St. Jude Medical lead to ensure that there is no damage.  
**Note:** SJM Lamitrode Tripole 16C, Lamitrode 88, Lamitrode 88C and Penta leads are designed to have 16 electrodes on the distal end and two proximal connectors, where each proximal connector corresponds to eight electrodes. Two S8 lead adaptors are needed to ensure that Nevro therapy can be delivered through all electrodes on these leads. The proximal connector with a differentiation band corresponds to electrodes 1-8 on these leads and the other proximal connector corresponds to electrodes 9-16.
3. Wipe fluids (e.g. blood) from the proximal end(s) of the lead.
4. Fully insert the proximal end(s) of the lead into the S8 Lead Adaptor's connector(s).
5. Take impedance measurements using Nevro OR cable (kit# ACCK4000) to ensure that the lead is fully inserted into the connector(s).
6. Fully insert the S8 torque wrench into the setscrew.

**Notes:**

- Ensure that the setscrew is not removed from the connector.
- If the lead does not fully insert into the S8 Lead Adaptor's connector, check to see whether the setscrew is not 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.

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<sup>1</sup> These SJM leads have 16 electrodes. For these leads, two S8 Lead Adaptors are needed to ensure Nevro therapy can be delivered through all electrodes.

- Check to see that the lead is fully inserted into the S8 Lead Adaptor's connector before tightening.
  - Use only the included S8 torque wrench to ensure that the proper torque is applied to the setscrews.
- 7. Rotate the torque wrench handle clockwise until it clicks.
 

**Note:** Clicking indicates that it is fully tightened. Do not try to tighten beyond the clicking as this could damage the lead.
- 8. Connect the proximal end of the S8 Lead Adaptor(s) into the Nevro IPG port(s).

**Notes:**

- For SJM Lamitrode Tripole 16C, Lamitrode 88, Lamitrode 88C and Penta leads, ensure that S8 Lead Adaptor connected to SJM lead's proximal leg with the differentiation band is inserted into the bottom port of the Nevro IPG. Connect the proximal end of the other S8 Lead Adaptor to the top port of the IPG.
- Tighten the IPG's setscrew using the torque wrench from the IPG kit. Clicking indicates that it is fully tightened. Do not try to tighten beyond the clicking as this could damage the lead.
- Do not use the S8 torque wrench to tighten the setscrew on the IPG. This may result in incomplete tightening of the setscrew.
- Typical connection configuration is illustrated below.

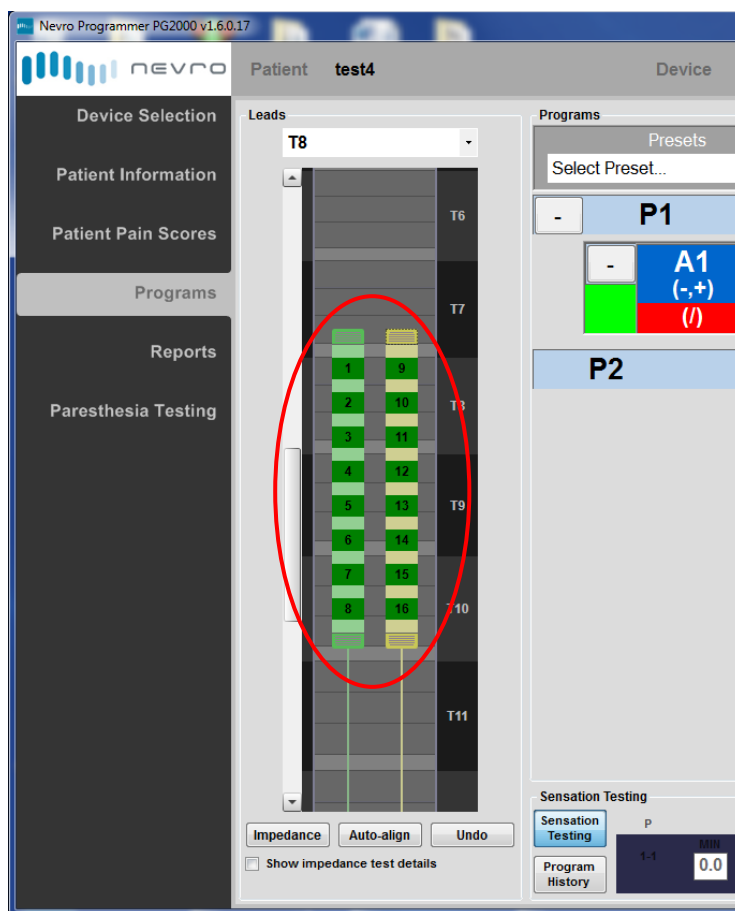


- 9. Conduct programming
  - Refer to the lead reference table below.
  - Program as shown in the Programmer manual.

**Notes:**

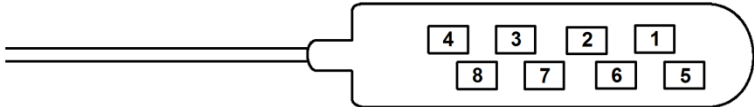
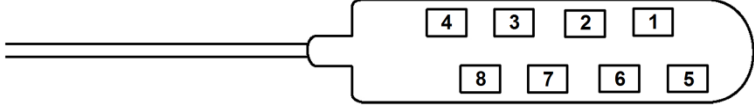
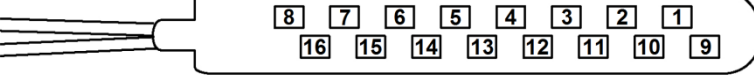
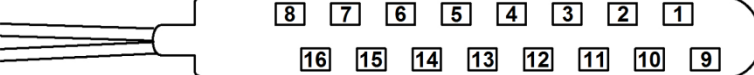
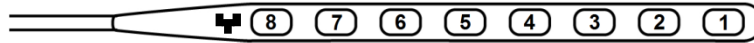
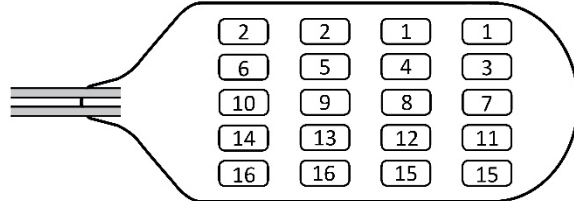
- As noted in the previous steps, the SJM leads will need to be connected to the Nevro IPG through the S8 Lead Adaptors.
- **If using the St. Jude Medical Penta lead, the clinician programmer will not allow programming parameters which result in excessive charge density.**
- It is important the connections are made properly as described above. Otherwise, the SJM electrode numbers shown in the diagrams below will not correspond to the electrode numbers in the programmer.
- A screenshot of the programmer shows the numbers from 1 to 16, which specifies the electrodes on the lead(s).





- The electrode numbers on the programmer corresponds to the electrode numbers in the diagrams of the SJM leads below. For example, programming electrode #1 in the programmer would control electrode #1 in the diagrams of the leads below.

Name	Model #	Electrode Configuration (All electrodes are shown face-down)
<ul style="list-style-type: none"> <li>• Octrode Lead</li> </ul>	3181 3183 3186 3189	
<ul style="list-style-type: none"> <li>• Lamitrode Exclaim Lead</li> </ul>	3224 3225	
<ul style="list-style-type: none"> <li>• Lamitrode Tripole 16C Lead</li> </ul>	3214	

Name	Model #	Electrode Configuration (All electrodes are shown face-down)
• Lamitrode 44 Lead	3244 3262 3263	
• Lamitrode 44C Lead	3245 3264 3265	
• Lamitrode 88 Lead	3288	
• Lamitrode 88C Lead	3289	
• Lamitrode S8 Lead	3283 3286 3268 3269	
• Penta Lead	3228	 <p>Note: If using the St. Jude Medical Penta lead, the clinician programmer will not allow programming parameters which result in excessive charge density</p>

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