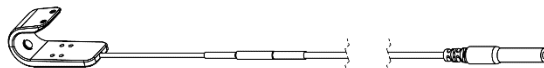


**Model: 9525**



Patents Pending [www.checkpointsurgical.com/patents](http://www.checkpointsurgical.com/patents)

**Nerve Electrode for use with Checkpoint Stimulators**

### **INSTRUCTIONS FOR USE**

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### INSTRUCTIONS FOR USE

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#### INDICATIONS FOR USE:

The CHECKPOINT® Guardian Intraoperative Lead is a single-use, sterile medical device accessory intended to be used with Checkpoint Stimulators to provide electrical stimulation of exposed motor nerves or muscle tissue to locate and identify nerves and to test nerve and muscle excitability.

#### PRECAUTIONS:

- Do NOT bend the connector of the lead.
- Do NOT use any lead that does not fit firmly onto the Stimulator probe or fails to connect electrically to the Stimulator.
- Do NOT use the lead if any metal surfaces other than the contact button are exposed.
- Avoid excessive force on the nerve while placing or removing the Lead.
- Single use only.
- Do not use if the sterile pouch is damaged.
- This device is an accessory to a Checkpoint Stimulator (REF 9094, 9095, 9394), and all contraindications, warnings, and precautions associated with the Stimulator use, as described in the Stimulator manual, are applicable.

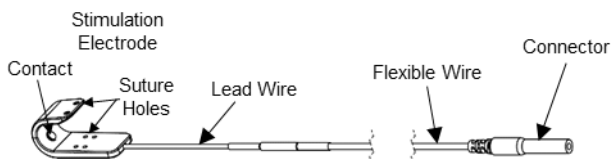
#### INSTRUCTIONS FOR USE:

##### 1. Prepare the Checkpoint Stimulator

- Refer to your stimulator's manual for all preparation instructions for use.

##### 2. Prepare the Lead

- Remove the sterile pouch from the box.
- Inspect sterile pouch for any damage.
- Do not use if sterile pouch or product appears damaged.
- Remove the lead from the sterile pouch.



##### 3. Place the stimulation electrode:

- Gently place the Stimulation Electrode around the targeted nerve ensuring the metal contact is touching the nerve.
- The lead wire proximal to the stimulation electrode body may be bent or formed as needed to aid in electrode placement.
- Suture holes may be used as needed to secure the lead to itself or surrounding tissue.

#### 4. Connect the stimulator

**NOTE: The stimulator must be turned ON BEFORE Lead connection.**



- Connect the probe end of the stimulator to lead connector.

#### **Additional notes:**

- Refer to the Checkpoint Stimulator's manual for stimulator setup, use, and indicator light meanings.


#### **End of use / disposal:**

- If sutures are used, cut off the sutures on the stimulation electrode.
- Carefully remove the stimulation electrode from the nerve.
- Disconnect the intraoperative lead from the stimulator probe and dispose of it in an appropriate biohazard container.








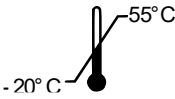




#### **WARRANTY and LIMITATIONS:**




Checkpoint Surgical, Inc. (CPS) warrants that this product has been manufactured, packaged, and tested with reasonable care and will be free from defects in workmanship and materials. CPS further warrants that the product will remain sterile for a period described on the product's label, provided the original packaging remains intact. This product is for single-use only and is not intended or designed for reuse. This warranty shall not apply to product that has been re-sterilized, repaired, altered, or modified in any way, or to products that have been improperly stored or operated. CPS will not be liable for any incidental, special or consequential loss, damage, or expense resulting, directly or indirectly, from the use of the product. The sole obligation of CPS shall be to refund or replace, at its option, any device that CPS determines was defective at time of shipment if notice thereof is received before expiration date described on such product label. Buyer assumes all liability, whether based upon warranty, contract, negligence, or otherwise, for damage resulting from the handling, possession, use or misuse (including reuse) of this product. Because CPS has no control over the operation, inspection, maintenance, or use of its products after sale and has no control over selection of patients, THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, AND OF ANY OTHER OBLIGATION ON THE PART OF THE SELLER. The remedies set forth in the Warranty and Limitations shall be the exclusive remedy available to any person. No agent, employee, or representative of CPS has any authority to change any of the foregoing or assume or bind CPS to any additional liability or responsibility in connection with this warranty. Buyer's use of this product shall be deemed acceptance of the terms and conditions of this Warranty and Limitations.

**CHECKPOINT (P/N 9525) SPECIFICATIONS:**

Nerve Electrode Size	 <p>Lead body width is 7mm</p>
Overall Length	850 mm
Electrode Body Material	Urethane
Contact Surface Area	3.8 mm <sup>2</sup>
Contact Material	304 Stainless Steel
Connection Type	Compatible with Checkpoint Stimulator probe
Operating Temperature	+16°C to +26°C (61°F to 79°F)
Relative Humidity	30% to 60%RH
Atmospheric Pressure	88kPA to 106kPa
Storage Temperature	-20°C to +55°C (-4°F to 131°F)

- Product has no user serviceable or repairable parts.
- Sterilized with Ethylene Oxide.
- Do NOT re-sterilize.

	<b>EN</b> Model Number
	<b>EN</b> Caution, consult accompanying documents
	<b>EN</b> Do not reuse
	<b>EN</b> Sterilized using ethylene oxide
	<b>EN</b> Lot number
 YYYY-MM-DD	<b>EN</b> Use by day DD of month MM of year YYYY
	<b>EN</b> Keep dry
 -20° C 55° C	<b>EN</b> Storage Temperature LOW- HIGH -20°C to +55 °C
	<b>EN</b> Manufacturer
	<b>EN</b> Do Not Use If Package Is Damaged
	<b>EN</b> Non-pyrogenic
	<b>EN</b> This system does not contain natural rubber (including natural rubber latex, dry natural rubber, synthetic latex and synthetic rubber that contains natural rubber in its formulation)
<b>Rx only</b>	<b>EN</b> Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

	<p><b>EN</b> Lead requires a Checkpoint Surgical stimulator.</p>
 <p>*+B13095251/          \$\$3yyMMdY3XX2*</p>	<p><b>EN</b> UDI barcode with Checkpoint LIC, part number, unit level (1: sterilized in pouch, 2: single unit sales carton), expiration date and lot number.</p>
	<p><b>EN</b> Refer to instruction manual/booklet.</p>



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