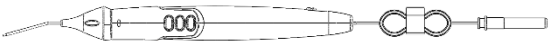
Model: 9894



Patents Pending www.checkpointsurgical.com/patents

Surgical Nerve Stimulator
INSTRUCTIONS FOR USE

CAUTION--Investigational device. Limited by Federal law to investigational use.

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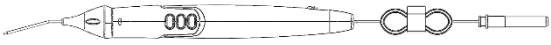

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INDICATIONS FOR USE:
The CHECKPOINT® Nerve Regeneration Stimulator is a single-use, sterile device intended to provide electrical stimulation of motor, sensory, or mixed peripheral nerves to promote nerve regeneration as an adjunct to surgical intervention following nerve injury, repair, or transfer.

WARNINGS:

- Effectiveness of therapy may be reduced by techniques or interventions that affect nerve conduction proximal to nerve injury or repair site. These include:
  - Prolonged tourniquet use may reduce nerve excitability distal to the tourniquet. Take down the tourniquet and allow time for re-perfusion before delivering therapeutic stimulation.
  - Local anesthetic nerve blocks prevent conduction to the cell body. Therapeutic stimulation should either be delivered proximal to the nerve block, or prior to use of nerve block.
- Do NOT apply stimulation across the patient's chest because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart.
- Direct stimulator contact may disrupt the operation of active implanted devices. Consult medical specialist before use.
- Do NOT use the Stimulator while delivering electrocautery. Electrocautery may interfere with or damage the Checkpoint Nerve Regeneration Stimulator.
- Do NOT use Stimulator in the presence of flammable anesthetics.
- Do NOT attempt to reuse with another patient. Serious patient cross-infection or pyrogenic reaction could occur.

PRECAUTIONS:

- Single use only. Once turned ON, the Stimulator will not turn OFF and will remain operational for approximately four (4) hours.
- Do NOT submerge or saturate the Checkpoint Nerve Regeneration Stimulator with fluid.
- The Stimulator may interfere with patient monitoring equipment in the operating room while stimulating.
- Portable and mobile Radio Frequency (RF) communications equipment can interfere with the Stimulator. Do not use such equipment while delivering stimulation.
- The Stimulator is not likely to cause any interference in nearby electronic equipment through Electromagnetic Interference (EMI) (complies with CISPR 11, Type A). The EMI Compliance tables can be found at http://checkpointsurgical.com/electromagnetic-guidance/.
- Be aware that using the device in the vicinity of certain nerves can have systemic effects (e.g. bradycardia, hypotension, laryngospasm).

INSTRUCTIONS FOR USE:

1. Prepare the Checkpoint Nerve Regeneration Stimulator and electrode for use

- Remove the sterile pouch from the package.
- Inspect sterile pouch for any damage.
- Do NOT use if sterile pouch or product appears damaged.
- Remove each product (stimulator and lead) from sterile pouch.
- Remove protective sleeve from probe, tape from return electrode cable, and cover from the needle return electrode.

Do NOT turn on until ready to use. Once turned ON, the device will not turn OFF and will remain operational for approximately four (4) hours.

2. Place the stimulation and return electrodes:

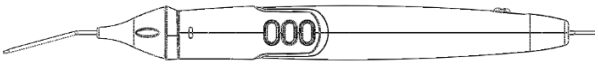
- Place stimulation electrode on the targeted nerve proximal to the site of injury or coaptation, as per lead manual.
- Place the needle return electrode in the sterile field but away from the area to be stimulated.

⊘ Do NOT cross midline of the body.

Effectiveness of therapy may be reduced by techniques or interventions that affect nerve conduction proximal to nerve injury or repair site. If using tourniquet, take down the tourniquet and allow time for re-perfusion before delivering therapeutic stimulation. If using local anesthetic nerve blocks, therapeutic stimulation should either be delivered proximal to the nerve block, or prior to use of nerve block.

3. Deliver stimulation

Probe ↓ ON/STANDBY Switch ↓



NOTE: The Stimulator must be turned ON BEFORE Lead connection.

- Turn ON the Checkpoint by moving the ON/STANDBY switch from the off position to any ON position (the switch provides two settings, ON and STANDBY, with 3 identical ON positions.). The visual indicator will turn FLASHING RED, indicating that the Stimulator is ON but the circuit is not complete.
- Connect the probe end of the stimulator to the stimulation lead.

⊘ Do NOT bend probe or apply excessive pressure

- The visual indicator will FLASH YELLOW indicating that stimulation therapy is being delivered until 10 minutes have elapsed.
- The stimulator delivers a continuous train of stimulation, for the duration of the therapeutic bolus.
- After 10 minutes of successful stimulation delivery, the visual indicator will change to groups of 3 yellow flashes, GROUP FLASHING YELLOW, to indicate that therapeutic dose is complete. No stimulation will be delivered while the indicator is GROUP FLASHING YELLOW.
- Inadequate current delivery, indicated by a FLASHING RED visual indicator, will not be counted in the elapsed therapy delivery time.

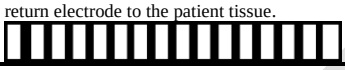
Additional notes:

- A FLASHING RED indicator means that stimulation has been requested, but adequate stimulus current is NOT being delivered because of poor connection of the stimulation electrode or the needle return electrode to the patient tissue.
  - Check needle return electrode contact and position.
  - Check stimulation electrode contact and position.
  - Check stimulator-lead connection at probe-connector interface.
  - Disconnect the probe from the lead connector and touch needle return electrode to probe tip and confirm stimulation delivery by observing FLASHING YELLOW indicator.
- Moving the ON/STANDBY switch to the STANDBY position will stop stimulation and the visual indicator will be illuminated SOLID YELLOW. It will also reset the therapy delivery bolus timer for additional therapy boluses.

End of use / disposal:

- After 4 hours, the Stimulator will automatically turn off and the visual indicator will not be illuminated. No further use of the Stimulator will be possible.
- At end of use, move the stimulus amplitude switch to the STANDBY position.
- Cut off and dispose of needle electrode in appropriate sharps / biohazard container.
- 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.
- Product is powered by two size N alkaline cells in series permanently sealed within the device. Use appropriate disposal methods per hospital guidelines.

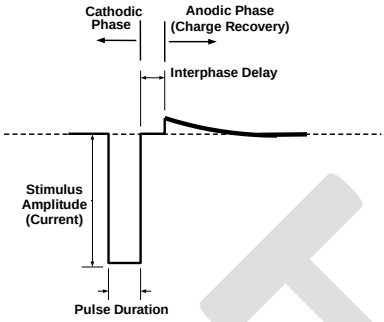
Indicator light status:

LIGHT	STIMULUS STATUS
Solid Yellow	The Stimulator has been turned on but the amplitude switch is now in the STANDBY position. Stimulation is NOT being delivered.
Continuous Flashing Yellow	Stimulation is being delivered (NOTE: the flashing rate does NOT correspond to the stimulus frequency or intensity).
Group Flashing Yellow	Simulation is complete when flashes are delivered in groups of three.
Flashing Red	Stimulation has been requested, but adequate stimulus current is NOT being delivered because of poor connection of the Stimulation Electrode or the needle return electrode to the patient tissue. 

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 9894) SPECIFICATIONS:

Stimulus Frequency	16Hz (+/- 1Hz)
Stimulus Amplitude	Fixed: 2mA (+/- 0.2mA) @ 100±4 µsec
Stimulus Waveform	Biphasic stimulus waveform with controlled current during the cathodic (leading) phase and no net DC current. Specified operation is ensured into any patient circuit load resistance up to 1,500Ω. 
Operating Life	Approximately four (4) hours of operation
Power Source	Two size N alkaline cells (permanently sealed within device)
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

- Product has no user serviceable or repairable parts.
- Sterilized with Ethylene Oxide.
- Protection against water ingress: Ordinary Equipment (IPX0).
- Do NOT resterilize.

DRAFT

	EN **OFF / Standby:** Before first use, this position indicates that the Stimulator is off. After the Stimulator is turned on, this position corresponds to Standby (no stimulus delivered)
	EN **ON:** Deliver a bolus of therapy. All switch positions with this symbol operate identically.
	EN **Accesssory Required** a lead is required for use with this device.
REF	EN **Model Number**
	EN **Caution**, consult accompanying documents
	EN **Do not reuse**
STERILE EO	EN **Sterilized** using ethylene oxide
LOT	EN **Lot number**
YYYY-MM-DD	EN **Use by day DD of month MM of year YYYY**
	EN **Keep dry**
55°C -20°C	EN **Storage Temperature LOW- HIGH -20°C to +55 °C**
	EN **Type BF applied part**
	EN **Manufacturer**

	EN **Do Not Use If Package Is Damaged**
	EN **Non-pyrogenic**
LATEX	EN **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)**
Rx only	EN **Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician or properly licensed practitioner.**

Symbols used in the Manual	
	EN **Prohibited Action**
	EN **Warnings**

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