CHECKPOINT GEMINI™ | BIPOLAR NERVE STIMULATOR

INSTRUCTIONS FOR USE

Model: 9092

Patented - www.checkpointsurgical.com/patents

CHECKPOINT GEMINI™ | BIPOLAR NERVE STIMULATOR

INSTRUCTIONS FOR USE

Model: 9092

Patented - www.checkpointsurgical.com/patents

INDICATIONS FOR USE:

The CHECKPOINT GEMINI™ Nerve Stimulator is a single-use, sterile device intended to provide electrical stimulation of exposed motor nerves or muscle tissue to locate and identify nerves and to test nerve and muscle excitability.

CONTRAINDICATION:

- Do NOT use this stimulator when paralyzing anesthetic agents are in effect, as an absent or inconsistent response to stimulation may result in inaccurate assessment of nerve and muscle function.

WARNINGS:

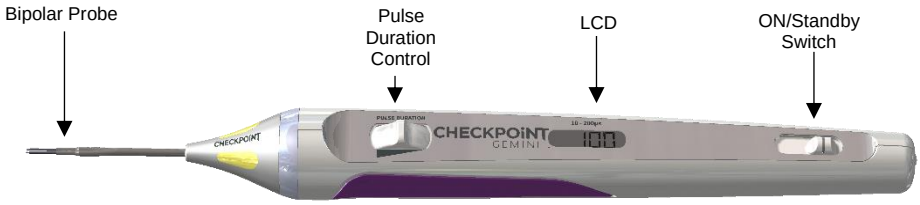
- Direct stimulator contact may disrupt the operation of active implanted devices. Consult medical specialist before use
- Use of a tourniquet may reduce nerve and muscle excitability distal to the tourniquet. If a decreased response to stimulation is observed, it may be necessary to take down the tourniquet and allow time for re-perfusion before testing with the stimulator.
- The bipolar probe, if exposed to fluid, may have fluid bridge between the probes and cause incorrect visual indicators when not stimulating. In this case, probe tips should be cleaned and device will return normal function.
- Do NOT use in cerebrospinal fluid, brain, meninges, or spinal cord.
- Do NOT use the stimulator in the presence of flammable anesthetics.
- Do NOT use the stimulator while simultaneously delivering electrocautery.
- Do NOT attempt to reuse with another patient. Patient cross-infection or pyrogenic reaction could occur.
- Do NOT leave the stimulator unattended in the surgical field.
- DO NOT attempt to use the stimulator after the device has been dropped or damaged.

PRECAUTIONS:

- Single use only. Once turned ON and used, the Checkpoint Gemini stimulator will not turn OFF and will remain operational for approximately seven (7) hours.
- Use the stimulator at 0.1mA initially and increase the amplitude as needed.
- Do NOT bend the probe, apply excessive pressure to the probe, or use the probe as a dissecting tool.
- Do NOT submerge or saturate the 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). For additional information on Electromagnetic Interference: http://www.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).
- Be aware that stimulating directly on muscle tissue with the Checkpoint Gemini stimulator may NOT elicit a muscle response.

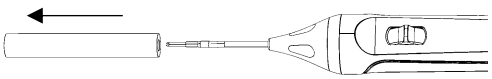
INSTRUCTIONS FOR USE:

The Checkpoint Gemini stimulator is an adjunctive tool for locating nerves and testing nerve and muscle excitability. It is not intended to replace good surgical techniques in locating and dissecting tissue. The surgeon is ultimately responsible for identifying exposed motor nerves and tissue**.**



1. Prepare the Checkpoint Gemini Stimulator for Use:

- Remove the sterile pouch from the sales carton and inspect it for damage. Remove the stimulator from the sterile pouch.
  - Do NOT use if the sterile pouch or product appears damaged.
- Remove protective sleeve from the probe by pulling it straight off.
- Only turn the stimulator on when ready to use. Once turned ON and used, the device will not turn OFF, and will remain operational for approximately seven (7) hours.

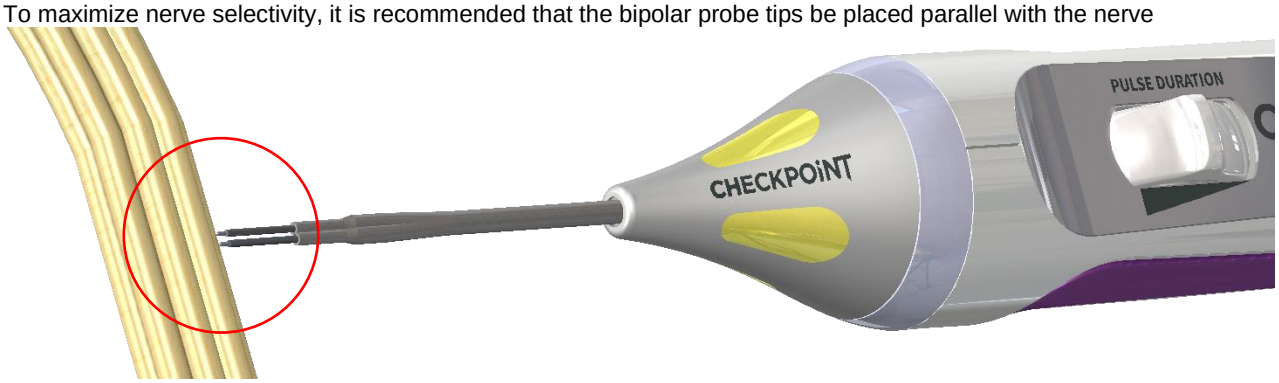


2. Prepare to Deliver Stimulation:

- Turn ON the stimulator by moving the stimulus amplitude switch from OFF/Standby to 0.1 mA before applying it to tissue.
  - The visual indicator will FLASH RED, indicating that the stimulator is ON and generating a stimulus output, but requested stimulus current is not being delivered.
- Once the probe is applied to tissue, the visual indicator will FLASH YELLOW to confirm the requested stimulation intensity is being delivered.

3. Suggested Stimulation Techniques:

- Stimulation intensity is adjusted by both the stimulation amplitude and pulse duration controls.
  - The amplitude switch provides coarse control of stimulation intensity: low (0.1mA), medium (0.5mA), and high (1mA) settings.
  - The pulse duration switch provides fine adjustment of stimulation intensity at each stimulation amplitude setting, from 10 µs to 200 µs in increments of 10 µs.
- The observed stimulation response is a tetanic or fused muscle contraction through continuous stimulation.
- Keep the probe in contact with tissue OR use a gentle sweeping motion rather than quickly tapping the tissue.
- Higher stimulation intensities can be used to stimulate groups of nerves.
- The Checkpoint Gemini Stimulator (model 9092) provides higher nerve selectivity than the Checkpoint Guardian Stimulator (model 9095).
- To maximize nerve selectivity, it is recommended that the bipolar probe tips be placed parallel with the nerve



- If a questionable response to stimulation is obtained from exposed motor nerves under test, move the probe to a known nerve and observe the results to confirm that the Stimulator is operating correctly.

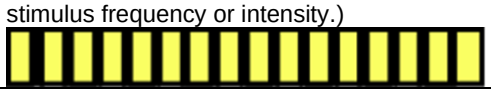
- Check that both probe tips of the bipolar probe are making contact at the same time. The visual indicator should flash YELLOW.
- Check stimulator settings.
- Verify that any paralytic agents used are no longer in effect. A tourniquet may prevent paralytic reversing agents from being effective.
- If a tourniquet is in use for a period of time, check for tourniquet effects on nerve and muscle response.

4. End of use / disposal:

- At the end of the 7 hour operational life, the Checkpoint Gemini stimulator will automatically turn off. The visual indicator will be SOLID RED, and the LCD will display END. No further use of the stimulator is possible.
- At end of use, move the stimulus amplitude switch to the OFF/Standby position.
- Product is powered by one size AAA alkaline cell permanently sealed within the device. Use appropriate disposal methods per hospital guidelines.
- Do NOT resterilize the device.

CHECKPOINT GEMINI STIMULATOR INDICATOR LIGHT STATUS:

The lights located on the nose cone provide feeback on device operational status. The meaning of these indicators are described in the table below:

LIGHT	STIMULUS STATUS
Solid YELLOW	The Stimulator has been turned on, but the amplitude switch is now in the Off/standby position. Stimulation is NOT being delivered.
Flashing YELLOW	Stimulation is being delivered. (NOTE: the flashing rate does NOT correspond to the stimulus frequency or intensity.) 
Flashing RED	Stimulation has been requested, but adequate stimulus current is NOT being delivered because of poor connection to patient tissue with both tips of the bipolar probe simultaneously. 
Solid RED	Stimulation has turned off due to reaching end of life (7hrs), or the stimulator has detected an error if operated <7hrs. No stimulation output is being delivered.

CHECKPOINT GEMINI STIMULATOR LCD MESSAGES:

The LCD provides a secondary source of information on the stimulator status and settings. The display primarily shows the pulse duration setting (10-200µs) and shows stimulation amplitude for 2 seconds when the switch position is changed. The remaining display messages are described in table below:

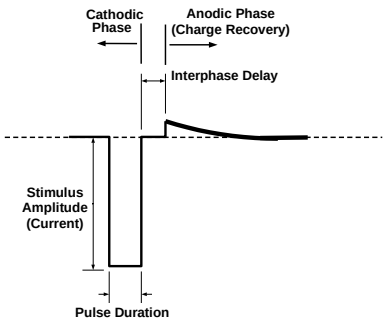
MESSAGE	MEANING
STBY	Amplitude switch is in Off/Standby position, stimulation is not being delivered.
END	Stimulator has reached end of life at approximately seven hours of operation
BATT	Battery depletion shutdown
ERR	Device has entered shutdown mode. Return to Checkpoint for evaluation.
0.1 mA 0.5 mA 1.0 mA	Pulse Amplitude, briefly displayed after changing stimulus amplitude switch.
10…200	Pulse Duration (in microseconds µs)

WARRANTY and LIMITATIONS:

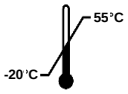
Checkpoint Surgical, Inc. (CPS) warrants that this product has been manufactured, packaged, and tested with reasonable care and will be free from defects in workmanship and materials. CPS further warrants that the product will remain sterile for a period described on the product's label, provided the 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 GEMINI STIMULATOR (P/N 9092) SPECIFICATIONS:

Stimulus Frequency	32 Hz (+/- 1Hz)
Stimulus Amplitude	User Selectable: 0.1 mA (+/- 0.01 mA) 0.5 mA (+/- 0.05 mA) 1.0 mA (+/- 0.1 mA)
Stimulus Pulse Duration	Adjustable in 10 µs increments from 10µs to 200µs
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 seven (7) hours of operation
Power Source	One (1) size AAA alkaline cell (permanently sealed within device)
Operating Temperature	+16°C to +26°C (61°F to 79°F)
Relative Humidity	30% to 75%RH
Atmospheric Pressure	70kPA 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.

	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 **Slide control** adjusts the pulse duration 10µs at the narrow end to 200µs (maximum stimulation) at the wide end.
	EN **Model Number**
	EN **Caution**, consult accompanying documents
	EN **Do not reuse**
	EN **Sterilized** using ethylene oxide
	EN **Lot number**
	EN **Use by day DD of month MM of year YYYY**
	EN **Keep dry**
	EN **Storage Temperature LOW- HIGH -20ºC to +55 ºC**
	EN **Type BF applied part**
	EN **Manufacturer**
	EN **Do Not Use If Package Is Damaged**
	EN **Non-pyrogenic**

	**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.**
 *+B13090921/ $$3yyMMddY3XX%*	**EN UDI barcode with Checkpoint LIC, part number, unit level (1: sterilized in pouch, 2: single unit sales carton), expiration date and lot number.**
	**EN Refer to instruction manual/booklet**

Checkpoint Surgical, Inc.
6050 Oak Tree Blvd.
Independence, Ohio 44131
Tel: 216-378-9107
www.checkpointsurgical.com

FEB 2022