

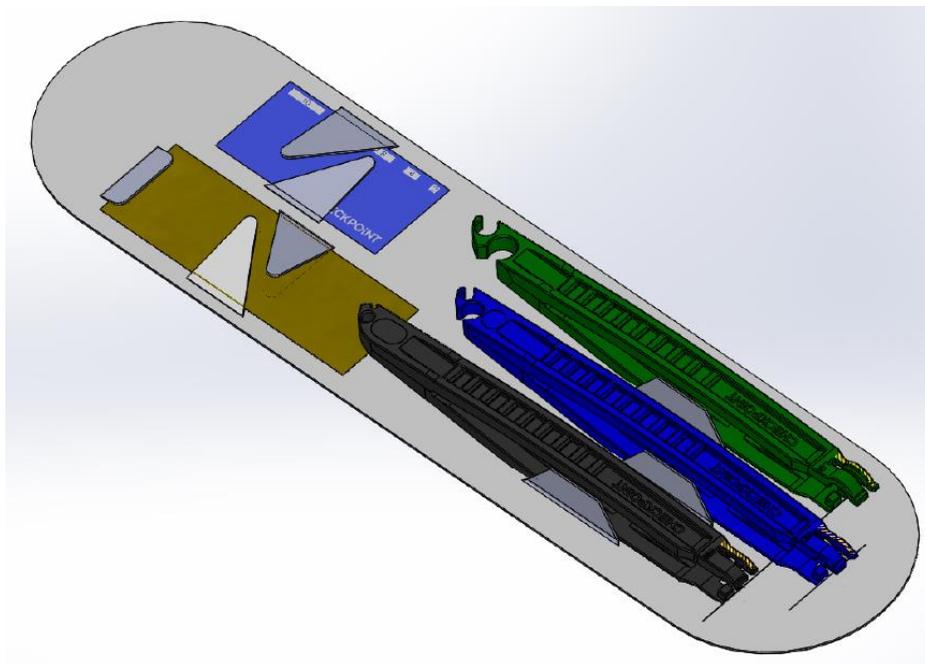
Model: 9250

Contents: SMALL GRAY Circumferential Nerve Forceps
MEDIUM BLUE Circumferential Nerve Forceps
LARGE GREEN Circumferential Nerve Forceps
Checkpoint Edge Nerve Micro-Surgical Background
SM69 Scalpel Blade*
10R Scalpel Blade*

* **Blade handles not included.**

Patents Pending - checkpointsurgical.com/patents

INSTRUCTIONS FOR USE



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INDICATIONS FOR USE:

The CHECKPOINT EDGE™ Nerve Cutting Kit is a single-use, sterile kit intended to provide surgeon aid in transecting nerve tissue for the purpose of nerve graft preparation, nerve repair, or removal of exposed nerve. The kit includes three circumferential nerve constraining forceps, two blades, and a silicone visibility background.

WARNINGS:

- Do NOT use the distal, constraining head of the nerve forceps for nerve sizing.
- Do NOT use in cerebrospinal fluid, brain, meninges, or spinal cord.
- Do NOT reuse with another patient. Patient cross-infection or pyrogenic reaction could occur.
- Handle the scalpel blade with care during assembly, use, and disposal.

PRECAUTIONS:

- The instruments included in the nerve cutting kit are intended for nerve transection. To ensure the cleanest and smoothest cuts, do NOT use the instruments within the nerve cutting kit for dissection.
- Be aware that the nerve forceps come in varying sizes with corresponding colors to constrain nerves of differing diameters.
 - SMALL GRAY Forceps: 1 – 3mm diameter nerves
 - MEDIUM BLUE Forceps: 3 – 5mm diameter nerves
 - LARGE GREEN Forceps: 5 – 7mm diameter nerves
- Each pair of forceps is equipped with a sizing guide (proximal end) and constraining head (distal end) with a sacrificial side, preserved side, and cutting slot (see Figure 2).
- Be aware that the sacrificial side of the forceps head, as indicated with caution lines, has a smaller aperture than the preserved side of the head (see Figure 2).
- To reduce the likelihood of compression injury to the nerve, use the sizing guide on the hinge end of the tool for estimating forceps' fit.
- The scalpel should be used with care in the cutting slot to prevent plastic shavings.
- To reduce the likelihood of injury to surrounding muscle and tissue, use the background provided and a fresh blade with a rounded/blunt tip such as those supplied within the nerve cutting kit.
- The proximal sizing guide of the forceps and linear dimension references on the background are approximate sizes. Measurements from the forceps and background should not be used for other intraoperative measurements.

INSTRUCTIONS FOR USE:

1. Prepare the Nerve Cutting Kit for Use:

- Remove the sterile pouch from the sales carton and inspect the pouch. Remove the backer card with forceps, blades, and background from the sterile pouch.
 - Do NOT use if sterile packaging or product appears damaged.
- Remove kit contents from backer card prior to use.

2. Circumferential Nerve Forceps Selection:

- The surgical background may be used to estimate nerve diameter or length (Figure 1).

- Circumferential Nerve Forceps are sized and color-coded as follows:
SMALL GRAY Forceps: 1 – 3mm diameter nerves
MEDIUM BLUE Forceps: 3 – 5mm diameter nerves
LARGE GREEN Forceps: 5 – 7mm diameter nerves



Figure 1

- Nerve forceps include a sizing guide on the hinged, proximal end of the instrument corresponding to the smallest and largest size nerve diameter intended to be held by each forceps (Figure 2). Initial selection may be based on the estimated nerve diameter. Note the forceps' ranges overlap and are estimates. The sizing guide will be used to confirm appropriate forceps selection.

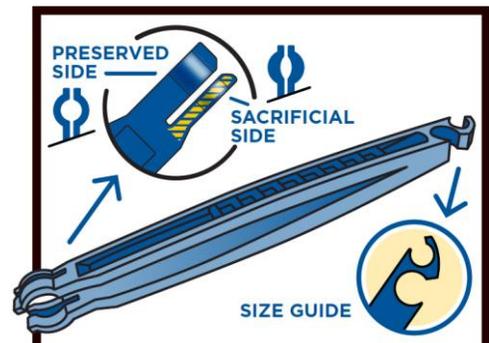


Figure 2

- To determine the appropriate nerve forceps to use, tension the nerve and place the maximum or minimum sizing guide cutout around the nerve.
 - If the nerve overflows within the maximum sizing guide cutout, the nerve is too large for the forceps selected (Figure 3, Too Large).
 - If there is a clearance within the minimum sizing guide cutout, the nerve is too small for the forceps selected (Figure 3, Too Small).
 - Upsize or downsize forceps as appropriate to achieve best match.

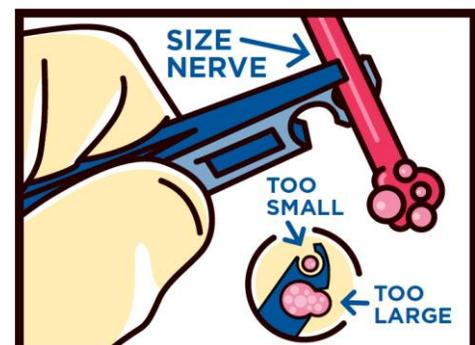


Figure 3

3. Blade Selection Recommendations:

- Checkpoint recommends the use of and includes:
 - an SM69 microblade (microsurgical handle not included), or
 - a 10R blade (No. 3 handle not included).
- A fresh blade with a rounded/blunt tip should be used when cutting nerves.
- Blades up to 1mm thick may be used with the circumferential nerve forceps.
- A cutting edge longer than the target nerve diameter is recommended.

4. Cutting Technique:

- The head of the nerve forceps includes a sacrificial and preserved side, separated by the cutting slot (recall Figure 2).
 - The sacrificial side has a smaller diameter aperture and a minimal nerve resection width (2mm).
 - This side of the forceps, identified with yellow striping, is to be placed on the side of and close to the nerve segment to be sacrificed and the larger diameter aperture of the nerve forceps, unmarked, is to be placed on the side of the nerve to be preserved (Figure 4).

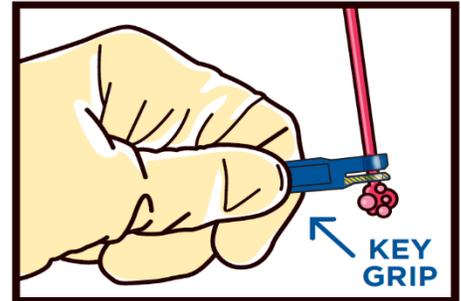


Figure 4

- The recommended grip to use on the forceps is the key grip which allows the user to firmly grasp the nerve (Figure 4).
- Using the forceps, apply tension in the direction of the sacrificial side sufficient to maintain the nerve and produce a clean cut (Figure 5).



Figure 5

- Insert blade carefully into the cutting slot to avoid damage to its cutting edge. With the blade in the cutting slot, use an oscillating movement under slight pressure and constant tension (Figure 6) to produce a straight, smooth resection of the nerve end (Figure 7).

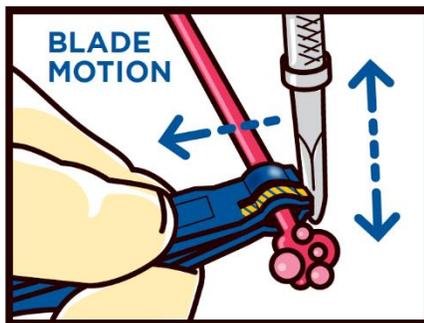


Figure 6

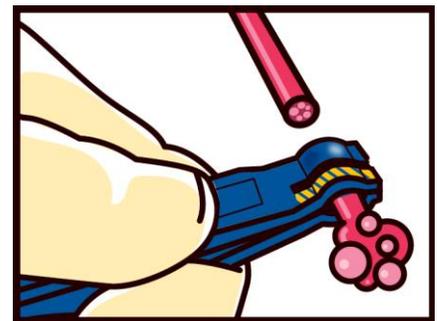


Figure 7

5. End of use / disposal:

- Dispose of scalpel blades in appropriate sharps/biohazard container.
- Dispose of nerve forceps and micro-background in accordance with local regulations.
- Do NOT re-sterilize.

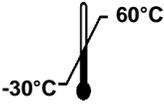
CHECKPOINT EDGE NERVE CUTTING KIT (REF 9250) SPECIFICATIONS:

Nerve Diameter Range	<ul style="list-style-type: none">• 1-3 mm [Small, Gray]• 3-5 mm [Medium, Blue]• 5-7 mm [Large, Green]
Nerve Resection Width	2 mm
Nerve Forceps Blade Compatibility	Max Blade Thickness: 1mm (0.039") Min Blade Length: > targeted nerve diameter
Nerve Forceps Sizing Guide Accuracy	+/- 0.5mm
Recommended Handle for SM69 Blade	Microsurgery Handle (See Part SF1 available from your Checkpoint Surgical field sales representative.)
Recommended Handle for 10R Blade	No. 3 Scalpel Handle
Microsurgical Background Scale Accuracy	+/- 1mm
Storage Temperature	-20°C to +55°C

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

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.

	EN Sacrificial Side of Forceps Head
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
 -30°C 60°C	EN Storage Temperature LOW- HIGH -30°C to +60 °C
	EN Manufacturer
	EN Do Not Use If Package Is Damaged
	EN Non-pyrogenic

	<p>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).</p>
<p>Rx only</p>	<p>EN Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician or properly licensed practitioner.</p>
 <p>*+B13092502/ \$\$3yyMMddY3XX+*</p>	<p>EN UDI barcode with Checkpoint LIC, part number, unit level (1: sterilized in Tray, 2: single unit sales carton), expiration date and lot number.</p>
	<p>EN Refer to instruction manual/booklet</p>



NERVES MATTER™

CHECKPOINT EDGE™ Nerve Repair Instruments



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