CHECKPOINT NEUROSHIELD™

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

CHECKPOINT NEUROSHIELD™ is a chitosan membrane used to provide non-constricting protection for peripheral nerves. Checkpoint NeuroShield is designed to be an interface between the nerve and the surrounding tissue to treat nerve injuries. When hydrated, Checkpoint NeuroShield is easy to handle, soft, pliable, non- friable, porous, and transparent.

INDICATION

Checkpoint NeuroShield is indicated for the repair of peripheral nerve injuries in which there is no gap or where a gap closure can be achieved by flexion of the extremity.

CONTRAINDICATIONS

No contraindications are yet known. There is no data on the use of Checkpoint NeuroShield in children.

STERILIZATION

Checkpoint NeuroShield has been sterilized with ethylene oxide gas.

STORAGE

Store Checkpoint NeuroShield in a clean, dry environment at room temperature.

PRECAUTIONS/PRECAUTIONARY MEASURES

- Checkpoint NeuroShield and its parts are designed exclusively for single use. Unused portions of Checkpoint NeuroShield should be disposed of. Do not re-sterilize or re-use. Re-using this product can potentially cause serious harm to the health of the patient. Examples of the dangers associated with re-using Checkpoint NeuroShield include significantly reduced product performance, cross infection, and contamination.
- Allergic reactions to medical products containing chitosan are not yet known. However, since chitosan is derived from shellfish, individuals with known shellfish allergies should exercise caution in the use of any product containing chitosan.
- Checkpoint NeuroShield is sterile as long as the packaging has not been opened or damaged. Please dispose of open, unused Checkpoint NeuroShield. Do not use if the sterile packaging is damaged.
- Do not use after the expiration date.

ADVERSE EVENTS

The adverse events listed below may occur following any surgery of injured nerves and can therefore also appear after the implantation of Checkpoint NeuroShield:

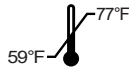
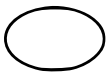
- Abnormal reddening of the operation scar,
- abnormal swelling at the site of the operation,
- temporary local irritation,
- delayed wound healing.

Risks such as infections, blood loss, healing disorders, and complications related to the anesthetic are associated with any surgical procedure. In the case of nerve reconstruction, adverse effects such as pain,

decreased sensitivity, and impairment of motor and sensory functions can occur. As with all procedures carried out on peripheral nerves, there is a risk of the nerve not regenerating.

CHECKPOINT NEUROSHIELD™ is a trademark of Checkpoint Surgical, Inc.

EXPLANATION OF THE SYMBOLS USED

	Expiration date: Year-Month-Day		Consult instructions for use
	Temperature limits for storage		Do not use if package is damaged
	Lot number		Do not re-sterilize
	Catalog number		Do not re-use
	Sterilized using ethylene oxide		Manufacturer
	Prescription only		Keep dry
	Non-Pyrogenic		Not made with natural rubber latex
	Single Sterile Barrier System		Double Sterile Barrier System
	Double Sterile Barrier System with Protective Packaging Outside	 *+B130NS40302/ $$3yyMMddC2-yymmnn/	UDI barcode with Checkpoint LIC, part number, unit level (1: double sterile pouch, 2: single unit sales carton), expiration date and lot number.
	NeuroShield is MR safe		

USE

Note: Instructions for use provide general information regarding the proper use of the device. Physicians should follow best clinical practices when performing peripheral nerve repair procedures. Clinical decisions are not affected by the information and references in these instructions for use.

When unpacking Checkpoint NeuroShield ensure that the internal pouch remains sterile. Do NOT use if sterile pouch or product appears damaged.

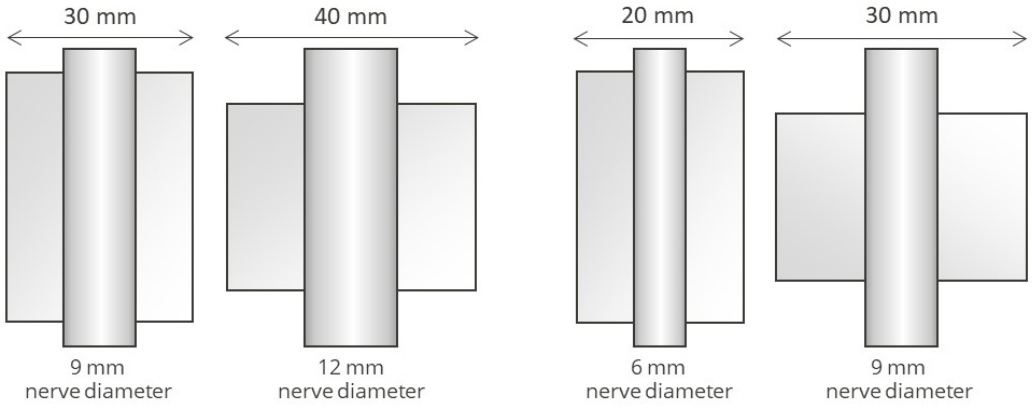
1. Remove Checkpoint NeuroShield and place in sterile, physiological saline or Ringer's solution to hydrate it until it's pliable (typically less than ten minutes). This will make Checkpoint NeuroShield flexible and facilitates folding, trimming, and suturing if needed.
2. Use anatomical forceps to grip Checkpoint NeuroShield.
3. If necessary, cut the membrane in half or trim to the desired size.
4. Apply Checkpoint NeuroShield between the nerve to be protected and/or repaired and the adjacent tissues.
5. Checkpoint NeuroShield may be fixed as necessary with sutures to prevent migration. If positioned around a nerve this may include placing running sutures along the longitudinal slit to

enclose the nerve, and/or stay-sutures placed through Checkpoint NeuroShield and the epineurium to anchor the device at each end. When securing the Checkpoint NeuroShield, allow room for the nerve to swell. Use non-absorbable monofilament suture material with a non-cutting needle. A USP 8-0 suture is recommended.

6. Dispose any unused portions of the device and packaging materials in accordance with clinical standards. Do not re-sterilize.
7. Close the wound.

CHECKPOINT NEUROSHIELD SPECIFICATIONS

NS4030	40mm x 30mm x 0.03mm
Max nerve diameter	9mm (using 30mm width) – 12mm (using 40mm width)
NS3020	30mm x 20mm x 0.03mm
Max nerve diameter	6mm (using 20mm width) – 9mm (using 30mm width)
Storage Temperature	59°F to +77°F



WARRANTY & 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 Surgical, Inc.
6050 Oak Tree Blvd, Suite 360
Independence, Ohio 44131 USA
Tel: 216.378.9107
checkpointsurgical.com

Patented: checkpointsurgical.com/patents

February 2023