Neutec®

NEUROSPONGES

by fabco®

Medsorb Dominicana, S.A.
Zona Franca Industriál • San Pedro de Macorís • R.D.

Manufactured for:

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1391-00000-00150 Rev. G

Neurosponges

(Please Read Prior to Use)

DESCRIPTION

Neutec Neurosponges are made of an absorbent material with x-ray detectable markers. Some sponges (patties) have a string attached for ease in location and accountability during the post-surgical verification process. Neutec Neurosponges are for use in the protection of neurological tissue during surgical procedures; tissues include the brain and other central nervous system tissues.

INSTRUCTIONS FOR USE

Step 1. **UPON OPENING PRODUCT PACKAGE -**
Verify count of sponges when package is opened.

Step 2. **MOISTEN BEFORE USE -**
Moisten sponge with physiological saline before applying to tissue.

Step 3. **REMOVAL -**
Replace sponges on the accountability card (if applicable) as they are removed from the wound.

Step 4. **PRIOR TO CLOSING -**
Verify sponge count.

PRECAUTIONS AND WARNINGS

- Do not use if individual packaging is damaged or open. As long as the individual package is not opened, damaged or beyond its expiration date, the product is sterile. Use proper aseptic techniques in all phases of handling.
- This product is for single use only; do not re-sterilize. Re-use can result in microbial contamination causing subsequent health deterioration of patient. FABCO will not be responsible for any product that has been re-sterilized and/or reused.
- Tissue contact of individual devices should be limited to <15 minutes.
- Do not leave sponges in situ. Failure to remove sponges from the patient may result in a foreign body reaction.
- Avoid cutting the patties because fragments without x-ray detectable material may enter the surgical site. Fragments left in the surgical site may result in an unintended adverse reaction.
- The locator string (if applicable) will not be visible by x-ray as it is not radiopaque. It is attached to the patties for location or identification purposes only. Avoid using the locator strings to remove the patties from the surgical site to prevent detachment.
- Count all devices before and after the procedure prior to surgical closure. In the event a device cannot be located, an x-ray can be used to locate the devices. Failure to perform count verification may result in additional procedures and/or extended surgery.
- Only radiopaque markers are visible on imaging. The size and position of radiopaque markers may impact their visibility.
- Small patties may be obscured from x-ray when behind bone or in morbidly obese individuals. It is recommended that at least three views, using the optimal parameters for the imaging (x-ray) equipment, at a variety of angles (e.g., 45 degrees, 22.5 degrees, and 0 degree angles) for anterior and posterior, or the appropriate plane, be taken and examined for a missing device. If there are concerns regarding visualization, consult with your local imaging expert to establish the optimal radiographic parameters (e.g., kVp, mAs) for visualization with the imaging equipment.
- The use and associated risks of solutions other than physiological saline, used to moisten the sponge, have not been evaluated by FABCO.
- Not intended for use as a wound dressing or general surgical sponge. This sponge is only intended for use in surgical procedures requiring protection of neurological tissue.
- The green X-ray (radiopaque) marker must be present and securely attached to the sponge. Do not use if x-ray marker is missing or not securely attached.

Phthalate Warning

The X-ray detectable material in this device contains phthalates, specifically Diisononyl phthalate (DINP). The results of certain animal experiments have shown phthalates to be potentially toxic to reproduction. Proceeding from the present state of scientific knowledge, risks for male premature infants cannot be excluded in the case of long-term exposure or application. Medical products containing phthalates should be used only temporarily with pregnant women, nursing mothers, babies and infants.

REF	LOT	STERILE EO				PHT
Reorder number	Lot number	Sterilized by Ethylene Oxide	Read Instructions	Do not reuse	Expiration date	DINP