V. Mueller® Neuro Patties

Catalog Numbers

23275-310, 23275-330, 23275-340, 23275-350, 23275-510, 23275-520, 23275-530, 23275-540, 23275-550, 23275-560, 23275-570, 23275-580

Important Information

Please read all instructions and warnings before use. Correct application is essential for proper functioning of product.

Indications

V. Mueller® Neuro Patties are intended to be used to protect neural tissue during surgery by providing moisture and absorbing fluids.

How Supplied

This product is disposable, supplied sterile and intended for single use only. Prior to the expiration date, contents are sterile if the package has not been opened or damaged. Do not resterilize.

Warnings

- Product should not be used if sterile packaging is damaged or opened. If damage is found, remove the product from the operative area to prevent unintended use, and return to the manufacturer.
- This device is for single use only. It is not intended for disinfection and/or subsequent re-use, which can result in microbial contamination causing health deterioration of the patient.
- This device has not been evaluated for reprocessing or re-sterilization. Reprocessing and/or re-sterilization may damage the device, rendering it unusable and/or may lead to device failure, which could result in patient illness, injury or death.
- Failure to remove patties from the patient may result in a foreign body reaction.
- The 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. Only the radiopaque markers are visible on imaging. The size and position of the 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.
- 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.
- Devices shall be used in accordance with these Instructions for Use. Read all sections of this IFU prior to use. Improper use of these devices may cause serious injury.

Directions

1. **UPON OPENING PRODUCT PACKAGES** – Immediately verify count of patties when package is opened.
2. **MOISTEN BEFORE USE** – Moisten patties with sterile water or physiological saline before applying to tissue. Reapplication of fluids may be necessary during the procedure to keep patties moist.
3. **REMOVAL** – Replace patties on the accountability card (if applicable) as they are removed from the wound.
4. **PRIOR TO CLOSING WOUND** – Verify pattie count.

Storage Conditions

Do not store product at extreme temperatures or in a moist/damp environment; doing so may damage the product which could cause a device malfunction and/or injury to the patient.

Warranty

CareFusion products are warranted for one hundred and twenty (120) days from the date of shipment from CareFusion as to product quality and workmanship. CareFusion WRITTEN WARRANTIES ARE GIVEN IN LIEU OF ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Caution: Federal (USA) law restricts this device to sale by or on the order of the physician.

For single use only

Not made with natural rubber latex

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