Oxiplex®

ADHESION BARRIER FOR SPINE SURGERY

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DESCRIPTION
Oxiplex® is a flowable gel. The gel is a sterile, absorbable combination of polyethylene oxide (PEO) and sodium carboxymethylcellulose (CMC). Calcium chloride and sodium chloride are added for stability. Oxiplex is non-pyrogenic.

INTENDED USE
Oxiplex is intended to be placed at sites of tissue injury in the epidural space following laminectomy, laminotomy, and/or discectomy to serve as a temporary mechanical barrier separating opposing tissue surfaces.

INDICATIONS
Oxiplex is intended to be used as an adjunct to posterior lumbar laminectomy, laminotomy, or discectomy procedures for reducing pain, radiculopathy, lower extremity weakness, and the incidence, extent, and severity of postoperative adhesions.

CONTRAINDICATIONS
Contraindicated for use in the presence of frank infection.

WARNINGS
Do not inject intravenously.

PRECAUTIONS
For professional use only.

Use Oxiplex according to the instructions for use. Oxiplex is supplied sterile and is for single use only. Do not use if the package is damaged or opened. Do not resterilize. Discard any opened or unused product. Safety and efficacy of Oxiplex have not been studied under conditions of reuse of device and/or applicator. Reuse may lead to immunological response and/or infection due to cross contamination, improper storage and/or handling.

Oxiplex is not a dural sealant. Any dural defects should be repaired prior to use.

The use of Oxiplex in combination with other adhesion prevention products or other medical devices has not been evaluated.

Oxiplex has not been evaluated in the presence of a malignancy in the spine.

Oxiplex has not been studied in the presence of hemostatic agents.

The use of Oxiplex has not been evaluated in children, or during pregnancy.

Preclinical reproductive toxicity studies have demonstrated the safety of Oxiplex in animals. No clinical studies have been conducted in women who have become pregnant in the first month after application of Oxiplex. Therefore, avoiding pregnancy during the first complete menstrual cycle after application of Oxiplex should be considered. The use of Oxiplex in nursing mothers should be avoided.

Foreign body reaction may occur as with any surgical adjuvant.

STORAGE AND HANDLING
Oxiplex does not require refrigeration and should be stored at room temperatures (2 °C to 25 °C). Product should not be exposed to elevated temperatures (26 °C to 39 °C) for more than 6 days and should never be exposed to temperatures greater than 39 °C.

INSTRUCTIONS FOR USE
Remove packaging containing the Oxiplex-filled syringe and applicator from box. Inspect packaging for any damage. Do not use if damaged or open.

The exterior of the package is not sterile. To maintain sterility, peel open packaging and place contents onto sterile field. Twist off syringe cap and secure applicator tip to syringe.

DEVICE PLACEMENT
Following the primary surgical procedure, and immediately prior to closing soft tissue incisions, use Oxiplex as follows:

1. Achieve hemostasis.
2. Remove any hemostatic agents prior to applying Oxiplex.
3. Using Oxiplex, coat the dura and exiting nerve root along both its dorsal and ventral surfaces.
4. Apply the gel into the site of the laminectomy/laminotomy to fill depth of the surgical site to the level of the ventral surface of the vertebral lamina.
5. After use, properly dispose of syringe and applicator.

The surgical procedure is concluded according to the standard technique of the surgeon.

Contents: 1 - Syringe 3 mL (luer lock)
1 - Applicator tip (luer lock)
1 - Instructions for use with product tracking labels