Oxiplex®

ADHESION BARRIER FOR SPINE SURGERY

Manufactured by:

FzioMed
www.fziomed.com

FzioMed, Inc.
231 Bonetti Drive
San Luis Obispo, CA 93401 USA

FzioMed Australia Pty Ltd
Suite E316
3 Oracle Boulevard
Broadbeach QLD 4218
Australia

EC REP
OBELIS S.A
Bd. Général Wahis, 53
1030 Brussels
Belgium

CH REP
MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

STERILE

CE 0344

02285(L) EN

DESCRIPTION
Oxiplex® is a flowable gel. The gel is a sterile, absorbable, isotonic, combination of polyethylene oxide (PEO) and sodium carboxymethylcellulose (CMC) with calcium chloride and sodium chloride in sterile water for injection. Oxiplex is non-pyrogenic.

INTENDED USE
Oxiplex is intended for use as a mechanical barrier to adhesion formation.

INDICATIONS
Oxiplex is intended to be placed around neural tissues following spine surgery to reduce adhesion formation and related symptoms such as pain.

CONTRAINDICATIONS
Contraindicated for use in the presence of frank infection.

WARNINGS
Do not inject Oxiplex into blood vessels or allow it to enter blood vessels.

PRECAUTIONS
Oxiplex is supplied sterile. Do not use beyond the expiry date. 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. The use of Oxiplex in combination with pharmaceuticals, biologics, 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. 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. Oxiplex has not been studied at the site of bone fusion. Oxiplex has not been studied in the presence of surgical drains.

STORAGE AND HANDLING
Oxiplex does not require refrigeration and should be stored at room temperatures (2 °C - 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
PRE-PROCEDURE
Risk is inherent in the use of all medical devices. To minimize risk associated with the use of this device, it is recommended that the information for use be read by the physician and discussed with the patient prior to use of the device. Patients known to have a history of hypersensitivity to Oxiplex or its components should not be treated with Oxiplex.

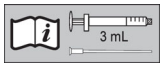
DEVICE PREPARATION
1. Remove packaging containing the Oxiplex-filled syringe and applicator from box.
2. Inspect packaging for any damage. Do not use if damaged or open. The exterior of the package is not sterile.
3. Oxiplex is for single use only. Do not reuse/re-sterilize.
4. Using sterile technique, introduce syringe and applicator into sterile operating field.
5. Remove cap from luer lock end of syringe and connect the gel applicator to the luer lock end of the syringe; rotate until firmly attached.

DEVICE PLACEMENT
IMPORTANT: Oxiplex is to be used by physicians only. Use Oxiplex according to the instructions for use.
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. Repair any dural defects.
4. Place Oxiplex around neural tissues where adhesions may form. Do not irrigate the site after application of Oxiplex. Apply gel as necessary to completely cover the tissue
5. The surgical procedure is concluded according to the standard technique of the surgeon.
6. Discard any opened or unused product. The used Oxiplex device may be a biohazard. Follow national, local or institutional guidelines for disposal of biohazard material.

CLINICAL INVESTIGATIONS
A U.S. multicenter, randomized, third-party blinded, controlled clinical trial to determine the safety and effectiveness of Oxiplex for the reduction of pain and symptoms following lumbar disc surgery was conducted. A total of 352 patients were randomized to receive surgery plus Oxiplex (Oxiplex group n=177) or surgery alone (Control group, n=175). The effectiveness of Oxiplex was evaluated by the Lumbar Spine Outcomes Questionnaire (LSOQ) and by physical evaluations to assess improvement in clinical outcome measures including leg pain, back pain and neurological symptoms.

Safety
There were no statistically significant differences in the number of subjects having serious adverse events (SAEs) or adverse events (AEs) or between the Oxiplex and Control groups. Serious adverse events related to the procedure or lumbar region in the treatment groups include cardiac disorders, gastrointestinal disorders, hepatobiliary disorders, cellulitis, pneumonia, wound infection, cerebral spinal fluid leakage, dural tear, hip fracture, incision site complication, nerve injury, wound secretions, muskoskeletal and connective tissue disorders, headache, migraine, syncope, psychiatric disorders, asthma, pulmonary embolism, cholecystectomy, spinal fusion surgery and deep vein thrombosis. Adverse events related to surgery include constipation, nausea, vomiting, chills, pyrexia, incision site complication, pain, vertebral disc protrusion, weakness, stiffness, myalgia, dizziness, headache, hypoesthesia, hyporeflexia, sensory loss, insomnia and pruritis. One (1) reoperation occurred in the Oxiplex group, while six (6) reoperations occurred in the Control group by 3 months (Fisher's Exact test P=0.0665).
Effectiveness
For each subject and for each follow-up evaluation period, measures were derived from the subjects' responses to the LSOQ: two pain severity measures (leg and back), leg weakness, physical symptoms, subject satisfaction, disability days, and activities of daily living. All subjects were treated surgically and showed substantial improvement as a result of surgery. The primary effectiveness outcome of improvement in leg pain at 1 month, 3 months and 6 months showed a statistically significant interaction between treatment and baseline back pain in the Intent-to-Treat (ITT) population (P=0.0113). Subjects with severe back pain at baseline showed significantly greater improvement (reduction from baseline) in leg pain in the Oxiplex group compared to subjects in the Control group. The most prominent gain in improvement in leg pain from baseline by Oxiplex subjects was observed at the 6-month visit (P=0.0507). Subjects with severe back pain at baseline showed greater improvement (P=0.0193). At 6 months, Oxiplex subjects with severe baseline back pain had significantly higher satisfaction scores (P=0.0456). Additional subgroup analyses demonstrated improvements across all subjects for each of the effectiveness measures: leg pain, back pain, leg weakness, physical symptoms, satisfaction, disability days, and activities of daily living. The mean improvement was higher for Oxiplex subjects than for Control subjects for all seven endpoints (P=0.008).

ADVERSE REACTIONS
General
Adverse events associated with surgery include: fever (within 36 hours postop), chills, pain, redness, swelling, itching, bleeding, bruising, hemorrhage, hematoma, seroma, wound secretions/drainage, cellulitis, weakness, stiffness, spasms, tightness at the surgical site, and death.
Spine Surgery
In addition, adverse events associated with spine surgery include: atelectasis/pneumonia, adjacent level disease, arachnoiditis, cavernous malformation, deep vein thrombosis, pulmonary embolism, dural tear, spinal fluid leak, fibrosis, facet fracture, wound infection, myocardial infarction, nerve injury, vascular injury, delayed union/non-union of fusion, spinal cord injury, paresis, myelopathy, including paralysis, additional surgery, failure of the surgical procedure to improve symptoms and/or function. Adverse events associated with cervical spine surgery also include: bone graft movement/graft dislodgement, cervical soft-tissue swelling, dysphagia, esophageal injury, axial neck pain, hardware failure, Horner’s syndrome, instability, kyphosis, pseudoarthrosis, stroke, trachea injury, upper airway obstruction, respiratory failure, and neurologic deficit. Adverse events associated with thoracic spine surgery also include: intercostal neuralgia (thorascopic procedure). Adverse events related to lumbar spine surgery also include: cardiac disorders, visceral injury, gastrointestinal disorders, hepatobiliary disorders, cellulitis, hip fracture, incision site complication, muskoskeletal and connective tissue disorders, headache, migraine, syncope, psychiatric disorders, asthma, cholecystectomy, ileus, constipation, nausea, vomiting, chills, pyrexia, procedural pain, arthralgia, back pain, intervertebral disc protrusion, myalgia, pain in extremity, dizziness, hypoesthesia, hyporeflexia, sensory loss, insomnia and pruritis. Adverse events reported but not necessarily attributable to the use of Oxiplex include pain, inflammation, hemotoma, infection, hypersensitivity reaction, and poor performance.



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