

PROPOSED SURGICAL PROCEDURE

The Sponsor does not plan to provide detailed directions for carrying out spinal laminectomy, laminotomy or discectomy surgery; these techniques are well known by physicians who are trained in orthopaedic spine surgery. Instead, reference to *Surgical Procedure* will be made in the INSTRUCTIONS FOR USE of Oxiplex, as excerpted below:

INSTRUCTIONS FOR USE

A. Preparation

1. Remove tray containing the syringe and applicator from box.
2. The exterior of the tray is not sterile. Inspect the tray and lid to ensure they are not damaged or open. Do not use if the tray or lid have been damaged or opened.
3. The contents of the tray (syringe and applicator) are sterile. To maintain sterility, peel back the corner of the lid and place contents onto sterile field.
4. Using aseptic technique, remove syringe cap and discard.
5. Secure applicator to syringe.

B. Surgical Procedure

1. Follow standard technique for spinal laminectomy, laminotomy or discectomy surgery.
2. At the end of surgery and immediately prior to closing soft tissue incisions, achieve hemostasis.
3. Remove any hemostatic agent prior to applying Oxiplex.

C. Oxiplex Gel Application

1. Apply Oxiplex around exposed tissues, coating the dura and exiting nerve root along all surfaces (dorsal, ventral, medial and lateral).
2. Apply Oxiplex into the site of the laminectomy/laminotomy to fill the depth of the surgical site to the level of the ventral surface of the vertebral lamina.
3. Properly dispose of syringe and applicator after use.
4. Conclude the surgical procedure and close according to the standard technique of the surgeon.