




Adhesion Barrier Gel for Intrauterine Surgery


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This product is protected by one or more of the patents listed on patentee's website ([www.fziomed.com](http://www.fziomed.com)).

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#### DESCRIPTION

Oxiplex/IU<sup>®</sup> is a clear, single use flowable gel. The gel is a sterile, absorbable combination of sodium carboxymethylcellulose (CMC) and polyethylene oxide (PEO) with calcium chloride and sodium chloride in water.

#### INTENDED USE

Oxiplex/IU is intended for use as a mechanical barrier to adhesion formation.

#### INDICATIONS

Oxiplex/IU is intended to be used as an adjunct to intrauterine procedures for reducing the incidence, extent, and severity of adhesions.

#### CONTRAINDICATIONS

Do not use Oxiplex/IU in the presence of infection.

#### WARNINGS

Do not inject intravenously.

#### PRECAUTIONS

Oxiplex/IU is supplied sterile. Do not use beyond the expiry date. Safety and efficacy of Oxiplex/IU 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/IU has not been studied in combination with other adhesion prevention products, in the presence of medicinal agents or hemostatic agents, or for use as a distention medium. Oxiplex/IU has not been evaluated in children or pregnant or nursing women. Therefore, patients should be advised to avoid conception during the first menstrual cycle after the application of Oxiplex/IU. Oxiplex/IU has not been evaluated in the presence of malignancies. Oxiplex/IU has not been evaluated following opening of the bowel, bladder, or other visceral organs. The gel has not been evaluated in the presence of bile. As with any implanted material, foreign body reactions may occur with Oxiplex/IU.

#### STORAGE AND HANDLING

Store at room temperature (2 - 25 °C).

#### HOW SUPPLIED

Oxiplex/IU is supplied sterile and consists of one 10mL syringe of gel and one gel applicator for vaginal use. The exterior of the package and outer contents are not sterile. Self-adhesive labels are provided for documentation purposes. The labels identify the product and production lot.

#### INSTRUCTIONS FOR USE

##### PRE-PROCEDURE

Oxiplex/IU is to be used by physicians only. Use Oxiplex/IU according to the instructions for use. Risk is inherent in the use of all medical devices. To minimize residual 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/IU or its components should not be treated with Oxiplex/IU. The gel serves as a barrier between tissues to prevent adhesions from forming. Tissue must be coated with gel for effective adhesion prevention.

##### DEVICE PREPARATION AND DISPOSAL

Oxiplex/IU is to be used for single use only. Do not reuse/resterilize.

1. Remove packaging containing the Oxiplex/IU filled syringe and applicator from box.
2. Inspect packaging for any damage. Do not use if damaged or open.
3. Using sterile technique, introduce syringe and applicator into the sterile surgical field.
4. Remove cap from luer lock end of syringe. Attach the syringe luer lock to the applicator; rotate until firmly attached.
5. After use, discard syringe, any remaining gel, and applicator. The used Oxiplex/IU device may be a biohazard. Follow national, local, or institutional guidelines for disposal of biohazard material.

##### INTRAUTERINE SURGERY

1. Apply gel at the conclusion of the procedure after aspiration of fluids and distention media.
2. Fill the applicator with gel by compressing the syringe plunger until gel appears at the tip end of the applicator.
3. Begin application of the gel at the fundus of the uterus. Gradually apply gel to fill the uterus and cervical canal by compressing the syringe plunger while slowly withdrawing the applicator. See Figure 1.
4. Conclude the procedure according to the standard technique of the surgeon.

##### ADVERSE REACTIONS

No device-related adverse reactions were reported in clinical studies.<sup>1-4</sup> Although not necessarily attributable to the use of Oxiplex/IU, the following adverse events have been reported in the postmarket phase following the use of the same gel that is intended for use in the peritoneal cavity: pain, fever, swelling, inflammation, foreign body reaction, and poor performance.

#### REFERENCES

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Ami, Zvi Vaknin, Yoseph Tovbin, Reuvid Halperin and Moty Pansky. "Intercoat (Oxiplex/IU Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorf P, J Donnez, M Korell, AJ Audebert, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

#### Contents

- 1 – Syringe 10 mL
- 1 – Vaginal applicator

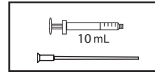


Figure 1.

