Oxiplex/AP®

Absorbable Adhesion Barrier Gel

Manufactured by:

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DESCRIPTION
Oxiplex/AP is a clear, single use flowable gel. The gel is a sterile, absorbable combination of polyethylene oxide (PEO) and sodium carboxymethylcellulose (CMC). The gel is calcium stabilized, isotonic, and has been shown in preclinical studies to clear the peritoneal cavity within 30 days.

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

INDICATIONS
Oxiplex/AP is intended to be used as an adjunct to intrauterine or peritoneal surgery for reducing the incidence, extent, and severity of postoperative adhesions at the surgical site.

CONTRAINDICATIONS
Do not use Oxiplex/AP in the presence of infection.

WARNINGS
Do not inject intravenously.

PRECAUTIONS
Oxiplex/AP is supplied sterile. Do not use beyond the expiry date. Safety and efficacy of Oxiplex/AP 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/AP has not been studied in combination with other adhesion prevention products, in the presence of intraperitoneal medicinal agents or hemostatic agents, or as a distention medium. Oxiplex/AP 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/AP. Oxiplex/AP has not been evaluated in the presence of malignancies. Oxiplex/AP 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/AP. Application of multiple layers of gel in the peritoneal cavity increases the risk of gel becoming dislodged from the intended site of application, and in some of these cases, a small amount of residual gel was observed during the clinical study follow up procedure 6 to 10 weeks later. Residual gel was not associated with clinical sequelae.3,4

STORAGE AND HANDLING : Store at room temperature (2 - 25 °C).

HOW SUPPLIED
Oxiplex/AP is supplied sterile in a thermoform tray. The thermoform tray contains two 20mL syringes of gel and one gel applicator. 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/AP is to be used by physicians only. Use Oxiplex/AP 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/AP or its components should not be treated with Oxiplex/AP. The gel serves as a barrier between tissues to prevent adhesions from forming. Tissue must be separated by gel for effective adhesion prevention.

DEVICE PREPARATION AND DISPOSAL
Oxiplex/AP is for single use only. Do not reuse/re-sterilize.
1. Remove packaging containing the Oxiplex/AP filled syringe and applicator from box.
2. Inspect packaging for any damage. Do not use if damaged or open.
3. Using sterile technique, introduce syringes and applicator into the sterile operating field.
4. Remove cap from luer lock end of syringe. When using the applicator for peritoneal use, connect the gel applicator to the luer lock end of the syringe; rotate until firmly attached. (The same applicator is to be used for both syringes, if needed.)
5. After use, discard syringes, any remaining gel, and applicator. The used Oxiplex/AP 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 all fluids and distention media.
2. Attach the syringe luer lock to the hysteroscope. Fill the hysteroscope with gel by compressing the syringe plunger until gel appears at the tip end of the hysteroscope.
3. Begin application of the gel at the fundus of the uterus. Gradually apply gel to completely fill the uterus and cervical canal by compressing the syringe plunger while slowly withdrawing the hysteroscope. See Figure 1.
4. Conclude the procedure according to the standard technique of the surgeon.

PELVIC GYNECOLOGICAL AND PERITONEAL SURGERIES
1. Apply gel at the conclusion of the procedure after aspiration of all irrigation fluid. It is recommended that the patient be placed in a reverse Trendelenburg position for the most efficient removal of residual irrigation fluid.
2. Cover all anatomical sites where adhesion prevention is desired with a single layer of Oxiplex/AP.* Applicator dispenses the gel in a "ribbon." Only a single-layer gel ribbon (about 2 mm in depth) should be used to coat the tissue surfaces for which adhesion prevention is intended. See Figure 2.

3. Use only enough gel to place a single layer of gel on the tissues as described. It is not necessary to use all 40mL of gel.
4. Do not reposition gel with probes or other instruments once it has been applied. If gel falls into a pool of irrigation fluid, its ability to adhere to peritoneal tissues may be compromised. Therefore, it should be removed from the peritoneal cavity and new gel should be applied to the site.
5. Conclude the procedure according to the standard technique of the surgeon.

*Additional GEL APPLICATION INSTRUCTIONS: PELVIC GYNECOLOGICAL SURGERIES
1. Lift ovary away from pelvic sidewall and apply a single layer of gel to cover the ovarian fossa and posterior surface of the ovary.
2. Return ovary to normal anatomical position and apply a single layer of gel to cover the anterior portion of the ovary.
3. Apply a single layer of gel to cover the Fallopian tube, including the ampulla and the mesosalpinx.
4. Apply a single layer of gel to cover the lateral aspect of the uterus facing the adnexa.
Typically 15mL of gel is sufficient to cover a single adnexa and adjacent structures, including the ovarian fossa and lateral margin of the uterus.

ADVERSE REACTIONS
No device-related adverse reactions were reported in clinical studies.1-4 Although not necessarily attributable to the use of Oxiplex/AP, the following adverse events have been reported: 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, Reuvit Halperin and Moty Pansky. "Intercoat (Oxiplex/AP 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. Lundorff P, J Donnez, M Korell, AJ Audeburt, 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: 2 - Syringe 20mL
1 - Applicator tip

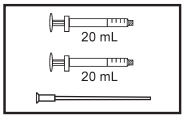


Figure 1

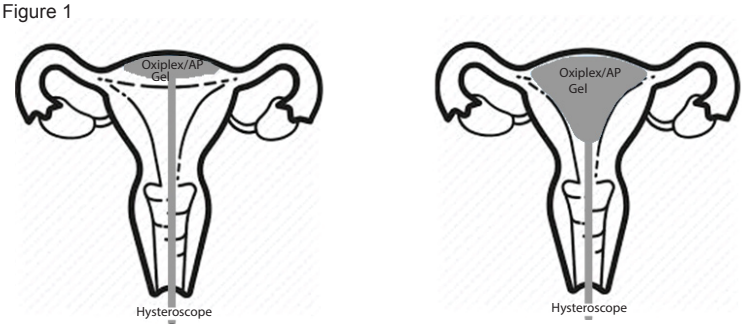
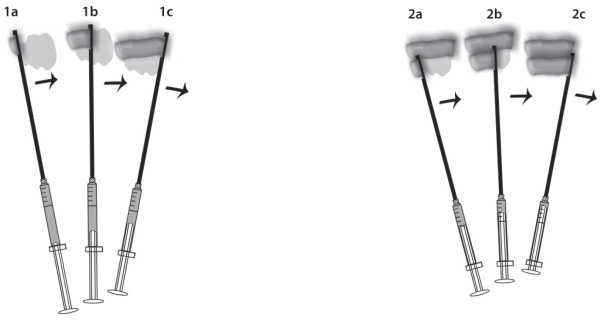


Figure 2



1a – Position the gel-filled applicator by aligning the applicator slot over a margin of the desired site.
1b – Sweep the applicator tip laterally over the site while depressing the syringe plunger to apply a 2 mm deep ribbon of gel.
1c – After completely covering the site once, do not apply additional gel to that site.
2a,b,c – If the site is not adequately covered by a single layer of gel, additional layers can be applied next to previously applied gel. Avoid applying additional layers of gel on top of one another.