

The IMPACT of Adhesions



Oxiplex®/AP

Absorbable Adhesion Barrier Gel

*Adhesion Barriers
are a Proven Method
of Enhancing Good
Surgical Technique by
Reducing Post-Surgical
Adhesions*

Surgery Causes Adhesions in Spite of Best Efforts

93% Adhesions with prior laparotomy¹

88% Adhesions after laparoscopic myomectomy

Reduction of post-operative adhesion formation after laparoscopic ovarian cystectomy.²

Adhesions Cause Problems

Most women will develop adhesions after major gynecological surgery and some will develop clinical consequences³ such as:

- Bowel obstruction⁴
- Infertility⁴
- Chronic pelvic pain⁵
- Intraoperative complications⁶

~71% Adhesion-related complications following abdominal procedures⁴

Reducing Adhesions is Beneficial

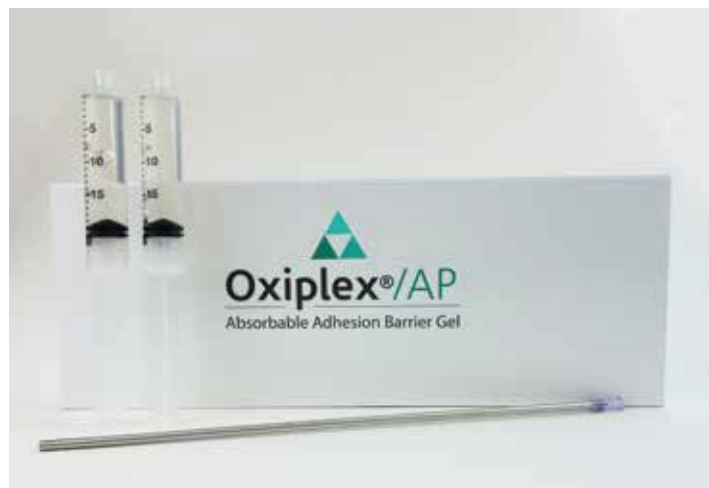
Enhanced Pregnancy Rate

~16% Not treated

~45% Treated

Treatment to reduce periadnexal adhesions (follow-up at 24 months)⁷

The EFFECT of Oxiplex®/AP



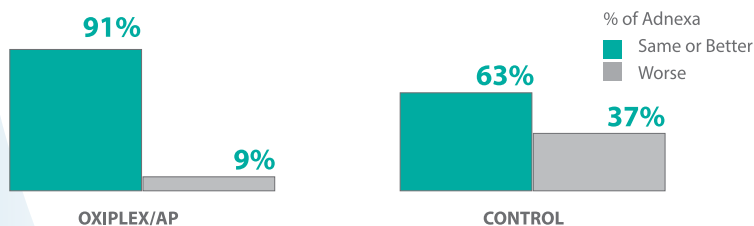
EFFECTIVE • EASY TO APPLY • PRECISE

EFFECTIVE

Consistent superiority in results as demonstrated by the American Fertility Society (AFS) adnexal score comparing patients with Oxiplex/AP vs. Control in 2 separate studies

- Prospective, randomized, third party blinded, parallel group multicenter studies
- Laparoscopic gynecological surgery with second look laparoscopy 6-10 weeks later
- American Fertility Society (AFS adhesion scores) quantified by blinded videotape review

Combined Data from Lundorff et al.⁹ and Young et al.¹⁰



Oxiplex/AP treated Adnexa AFS Category improved or did not worsen in 91% of cases, vs. only 63% in the control group (p-value=0,0001)

Additional Study Data^{11,12}

Di Spiezio Sardo et al used Oxiplex/AP following hysteroscopic surgery in a randomized study of 110 patients.¹¹

- Follow-up at one month showed that Oxiplex/AP treated patients had fewer 'de novo' adhesions (6% vs 22%) compared to control.
- Patients treated with Oxiplex/AP also demonstrated improvement in the degree of patency of the internal uterine ostium.

Fuchs et al. used Oxiplex/AP following hysteroscopic surgery in a randomized study of 52 women.

- Follow up at 20 months showed that Oxiplex/AP treated patients had fewer moderate to severe intra-uterine adhesions (4% vs. 16%) compared to control.
- Patients treated with Oxiplex/AP had an improved fertility rate (27% vs 14%) compared to controls.

EASY TO APPLY

Simple to apply in 1 single layer

PRECISE

Targeted protection of traumatized tissue creates a temporary barrier during healing

Oxiplex/AP is intended to be used as an adjunct to peritoneal surgery for reducing the incidence, extent and severity of post-operative adhesions at the surgical site.

REFERENCES

1. Menzies D, Ellis H. Intestinal obstruction from adhesions—how big is the problem? *Ann R Coll Surg Engl.* 1990 Jan; 72(1):60-3.
2. Keckstein J, Ulrich U, Sasse V, Roth A, Tuttlies F, Karageorgieva E. *Human reproduction.* 1996 Mar; 11(3):579-82.
3. Lower AM, Hawthorn RJ, Ellis H, O'Brien F, Buchan S, Crowe AM. The impact of adhesions on hospital readmissions over ten years after 8849 open gynaecological operations: an assessment from the Surgical and Clinical Adhesions Research Study. *BJOG.* 2000; 107:855-862.
4. Ellis H, Moran BJ, Thompson JN, et al. Adhesion-related hospital readmissions after abdominal and pelvic surgery: a retrospective cohort study. *Lancet.* 1999; 353:1476-1480.
5. Trew G. Consensus in adhesion reduction management. *Obstetrician & Gynaecologist* 2004; 6(2 Suppl):1-9.
6. Cheong YC, Laird SM, Li TC, Shelton JB, Ledger WL, Cookie ID. Peritoneal healing and adhesions formation/reformation. *HUM Reprod Update.* 2001; 7(6):556-566.
7. Tulandi T, Collins JA, Burrows E, Jarrell JF, McInnes RA, Wrixon W, Simpson CW. Treatment-dependent and treatment-independent pregnancy among women with periadnexal adhesions. *Am J Obstet Gynecol.* 1990 Feb; 162(2):354-7.
8. Sawada T, Nichizawa H, Nishio E, Kadowaki M. Postoperative adhesion prevention with an oxidized regenerated cellulose adhesion barrier in infertile women. *J Reprod Med.* 2000 May; 45(5):387-9.
9. Lundorff P, Donnex J, Korell M, Audebert AJ, Block K, di Zerega GS. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynaecological surgery by laparoscopy in Europe. *Hum Reprod.* 2005 Feb; 20(2):514-20. Epub 2004 Dec 9.
10. Young P, Johns A, Templeman C, Witz C, Webster B, Ferland R, Diamond MP, Block K, di Zerega G. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: a pilot study. *Fertil Steril.* 2005 Nov; 84(5):1450-6.
11. Di Spiezio Sardo et al. Efficacy of a polyethylene oxide-sodium carboxymethylcellulose gel in prevention of intrauterine adhesions after hysteroscopic surgery. *JMIG.* 2011 Apr; 18(4):462-9.
12. Fuchs N, Smorgick N, et al. Intercoat (Oxiplex/AP Gel) for preventing intrauterine adhesions after operative hysteroscopy for suspected retained products of conception: double-blind, prospective, randomized pilot study. *JMIG.* 2013 Jul; 21(1):126-130.

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