ETHICON Women's Health & Urology

eClinical Compendium – Article Summary

Title	Interceed barrier in the prevention of post-operative adhesions following laparotomy: meta-analysis of its efficacy and safety
Author(s)	Franklin RR, Trout RJ, Marks MG, *et al*
Source	*Fertility & Sterility* (Program supplement): S227,19
Key Takeaways	In this meta-analysis, GYNECARE INTERCEED® Absorbable Adhesion Barrier was found to be between 1.6 to 2.5 times more effective than good surgical technique alone in preventing adhesions. Statistically ($p<.0001$) and clinically this confirms the effectiveness of GYNECARE INTERCEED Adhesion Barrier in reducing the incidence of adhesions after gynecologic surgery.

OBJECTIVE:

- A meta-analysis was conducted to assess the efficacy and safety of GYNECARE INTERCEED Adhesion Barrier for the prevention of post-operative adhesion formation following gynecologic surgery performed by laparotomy.

DESIGN:

- To be included in the analysis, studies had to meet the following criteria: (1) subjects underwent laparotomy for gynecologic procedures, followed by a second-look laparoscopy; (2) each patient had bilateral defects with the treatment side being randomly assigned; (3) each patient served as her own control; (4) the control side was treated by microsurgical technique only; (5) the treatment side used GYNECARE INTERCEED Adhesion Barrier; (6) the dependent measures that determined outcome were described; and (7) sufficient information was given to derive efficacy and safety.

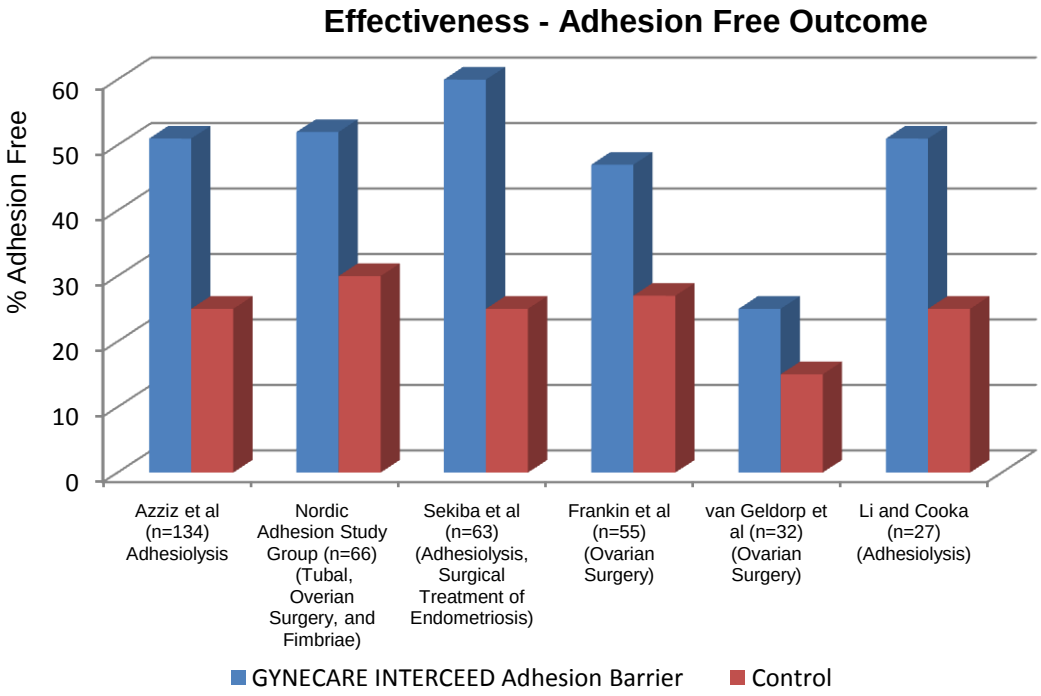
METHODS:

- Efficacy was assessed by the incidence of adhesion formation, the extent of adhesion formation, and the treatment effectiveness, defined as [(percent adhesion free sites treated with GYNECARE INTERCEED Adhesion Barrier)/(percent adhesion free control sites)]. Safety was evaluated by determining the number and severity of adverse events reported for each study.

RESULTS:

- Of the 10 clinical reports considered (483 patients), only 6 reports met the inclusion criteria for determining the incidence of adhesion formation (377 patients), and 5 reports for determining the extent of post-operative adhesions (311 patients). The study sites included ovaries (153 patients), sidewalls (224 patients), tubes (66 patients), fimbria (66 patients) and sites of endometriosis (28 patients) and endometriosis (14 patients).
- There was a mean reduction of 24.7 +/- 3.4 percent in the incidence of adhesions ($P<.0001$) between control sites and GYNECARE INTERCEED Adhesion Barrier treated sites.
- Treatment with GYNECARE INTERCEED Adhesion Barrie was 1.6 to 2.5 times more effective than good surgical technique alone in preventing adhesions.

- There was a mean difference of 1.6+/- 0.3 cm^2 in the extent of adhesions (*P*<.0001) between GYNECARE INTERCEED Adhesion Barrier treatment and control groups.
- No adverse events were reported in the studies used in the meta-analysis.



Efficacy- Improvement in Extent (cm^2)

Author [3]	n	GYNECARE INTERCEED Adhesion Barrier (mean +/- SEM)	Control (mean +/- SEM)
Azzia *et al.*	134	8.60 +/- 0.90	5.60 +/-0.5
Sekiba *et al.*	63	8.20 +/-2.10 [1]	2.90+/-2.00 [1]
Franklin *et al.*	55	4.97 +/-1.15	3.08+/-0.85
van Geldorp *et al* [4] *Center 1*	12	1.19+/-0.29	0.63+/-0.31
van Geldorp *et al* [4] *Center 2*	20	1.90+/-0.37	-0.65+/-0.33
Li and Cooke	27	3.70+/-0.49 [2]	2.37+/-0.52 [2]

(1) Determined from summaries at first and second looks
(2) These are on log scales and were reported at first and second looks
(3) Insufficient information was available for the Nordic Study Group to be included in this analysis
(4) Both centers from van Geldorp *et al* had responses that were positive and different enough in magnitude to prevent pooling

CONCLUSION:

- GYNECARE INTERCEED Adhesion Barrier is safe and effective for the reduction of post-operative adhesions in women undergoing gynecologic surgery.

PROFESSIONAL EPI

GYNECARE INTERCEED® ABSORBABLE ADHESION BARRIER

Essential Product Information

INDICATIONS:

GYNECARE INTERCEED® Absorbable Adhesion Barrier is indicated as an adjuvant in open (laparotomy) gynecologic pelvic surgery for reducing the incidence of postoperative pelvic adhesions after meticulous hemostasis is achieved consistent with microsurgical principles.

CONTRAINDICATIONS:

The use of GYNECARE INTERCEED® is contraindicated in the presence of frank infection. GYNECARE INTERCEED® is not indicated as a hemostatic agent. Appropriate means of achieving hemostasis must be employed.

WARNINGS:

The safety and effectiveness of GYNECARE INTERCEED® Adhesion Barrier in laparoscopic surgery or any procedures other than open (laparotomy) gynecologic microsurgical procedures have not been established.

Postoperative adhesions may be induced by GYNECARE INTERCEED® application if adjacent tissues (eg, ovary and tube) and structures are coapted or conjoined by the device, or if GYNECARE INTERCEED® is folded, wadded or layered. Postoperative adhesions may occur in the presence of GYNECARE INTERCEED® if meticulous hemostasis is not achieved prior to application. As with all foreign substances, GYNECARE INTERCEED® should not be placed in a contaminated surgical site.

PRECAUTIONS:

Use only a single layer of GYNECARE INTERCEED®, since multiple layers of packing or folding will not enhance the adhesion barrier characteristics and may interfere with the absorption rate of GYNECARE INTERCEED®. Care should be exercised in applying GYNECARE INTERCEED® to a pelvic organ not to constrict or restrict it. If the product comes in contact with blood prior to completing the procedure, it should be discarded, as fibrin deposition cannot be removed by irrigation and may promote adhesions formation. Ectopic pregnancies have been associated with fertility surgery of the female reproductive tract. No data exist to establish the effect, if any, of GYNECARE INTERCEED® on the occurrence of ectopic pregnancies. No adequate studies have been conducted in women who have become pregnant within the first month after exposure to GYNECARE INTERCEED®. No teratogenic studies have been performed. Therefore, avoidance of conception should be considered during the first complete menstrual cycle after use of GYNECARE INTERCEED®. The safety and effectiveness of using GYNECARE INTERCEED® in combination with other adhesion prevention treatments have not been clinically established. GYNECARE INTERCEED® is supplied sterile. As the material is not compatible with autoclaving or ethylene oxide sterilization, GYNECARE INTERCEED® must not be resterilized. Foreign body reactions may occur in some patients. Interactions may occur between GYNECARE INTERCEED® and some drugs used at the surgical site. Pathologists examining sites of GYNECARE INTERCEED® placement should be made aware of its usage and of the normal cellular response to GYNECARE INTERCEED® ‘to facilitate proper evaluation of specimens'.

ADVERSE REACTIONS:

The type and frequency of adverse events reported are consistent with events typically seen following surgery. Postsurgical adhesions may occur in the presence of GYNECARE INTERCEED®.