Gynecare Interceed

In your care, she is protected...

ETHICON
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

Shaping the future of surgery

...for all her tomorrows

The adhesion barrier that conforms for control you can count on

GYNECARE INTERCEED® Absorbable Adhesion Barrier is easy to handle, and conforms to pelvic organs

- Does not crack, tear, or stick to gloves
- May be rolled or folded to aid in placement. Final placement should be flat (not folded or rolled)
- Pliability allows it to contour to organs of varying shapes and sizes for full coverage

Easy to use right out of the box

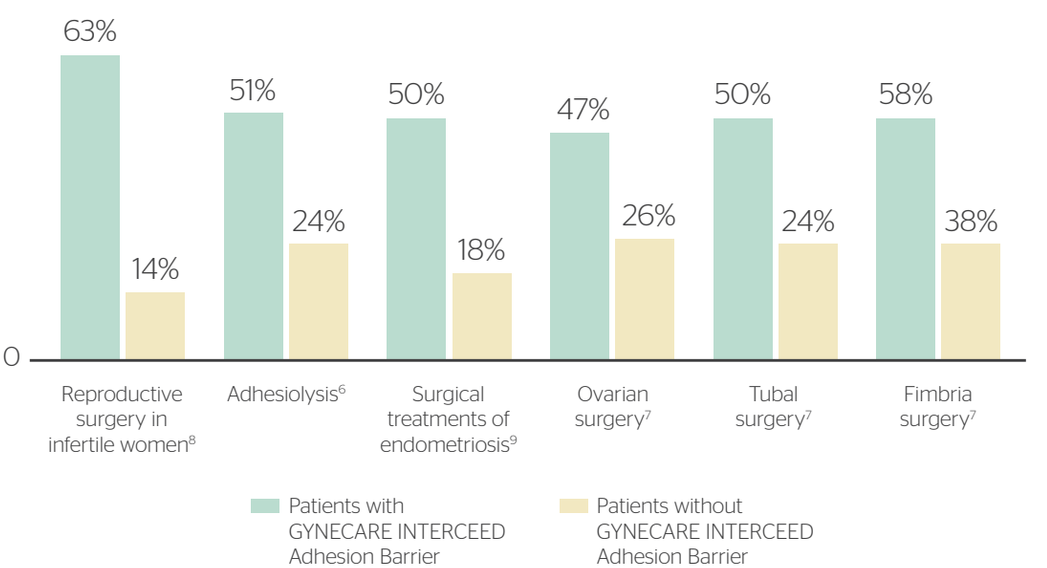
- Must be applied dry to traumatized tissues, after meticulous hemostasis has been achieved[1]
- Forms a continuous protective coating during the critical 5-7 day peritoneal healing period[2]

Proven safe and effective in gynecologic procedures

GYNECARE INTERCEED Adhesion Barrier has been shown in various gynecologic studies to:

- Significantly and safely reduce the incidence of both new and reformed adhesions[3,4]
- Be clinically effective across multiple gynecological procedures[3]
- Be up to 2 times more effective than good surgical technique alone in achieving an adhesion-free outcome[5]

Percent of adhesion-free outcomes[6-9]



Choose the adhesion barrier that matters

Ordering information

For more information or to order product, contact your Ethicon representative for GYNECARE INTERCEED® Absorbable Adhesion Barrier

Product	Ordering Code	How Supplied
GYNECARE INTERCEED Adhesion Barrier 3x4	4350	10 sheets per box 3 in x 4 in 7.6 cm x 10.2 cm
GYNECARE INTERCEED Adhesion Barrier 5x6	4350XL	10 sheets per box 5 in x 6 in 12.7 cm x 15.2 cm

Essential product information

Indications:
GYNECARE INTERCEED 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 Adhesion Barrier is contraindicated in the presence of frank infection. GYNECARE INTERCEED Adhesion Barrier 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 Adhesion Barrier application if adjacent tissues (eg, ovary and tube) and structures are coated or conjoined by the device, or if GYNECARE INTERCEED Adhesion Barrier is folded, wadded or layered. Care must be taken to apply GYNECARE INTERCEED Adhesion Barrier in single layers, interposed between adjacent anatomic structures at risk for adhesion formation.

Postoperative adhesions may occur in the presence of GYNECARE INTERCEED Adhesion Barrier if meticulous hemostasis is not achieved prior to application. As with all foreign substances, GYNECARE INTERCEED Adhesion Barrier should not be placed in a contaminated surgical site. Potentially contaminated surgical sites include hysterotomy following labor and/or prolonged rupture of membranes. The performance of GYNECARE INTERCEED Adhesion Barrier at potentially contaminated surgical sites has not been determined.

Precautions:
Use only a single layer of GYNECARE INTERCEED Adhesion Barrier, since multiple layers of packing or folding will not enhance the adhesion barrier characteristics and may interfere with the absorption rate of GYNECARE INTERCEED Adhesion Barrier. Care should be exercised in applying GYNECARE INTERCEED Adhesion Barrier 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 Adhesion Barrier 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 Adhesion Barrier. No teratogenic studies have been performed. Therefore, avoidance of conception should be considered during the first complete menstrual cycle after use of GYNECARE INTERCEED Adhesion Barrier. The safety and effectiveness of using GYNECARE INTERCEED Adhesion Barrier in combination with other adhesion prevention treatments have not been clinically established.

GYNECARE INTERCEED Adhesion Barrier is supplied sterile. As the material is not compatible with autoclaving or ethylene oxide sterilization, GYNECARE INTERCEED Adhesion Barrier must not be resterilized.

Foreign body reactions may occur in some patients.

Interactions may occur between GYNECARE INTERCEED Adhesion Barrier and some drugs used at the surgical site.

Pathologists examining sites of GYNECARE INTERCEED Adhesion Barrier placement should be made aware of its usage and of the normal cellular response to GYNECARE INTERCEED Adhesion Barrier '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 Adhesion Barrier.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

References:
1. GYNECARE INTERCEED® Absorbable Adhesion Barrier. Instructions for Use. Ethicon Inc. 2. Interceed Claims List INT-0057-09, Claim # 7. 3. Ten Broek RPG, Stommel MWJ, Strik C, et al. Benefits and harms of adhesion barriers for abdominal surgery: a systematic review and meta-analysis. *The Lancet* 2014;383(9911):48-59. 4. Ahmad G, Duffy JMN, Farquhar C, et al. Barrier agents for adhesion prevention after gynecological surgery. Cochrane Database Syst Rev 2008;(2):1-40. 5. Franklin RR, Trout R, Marks MG, et al. Interceed barrier in the prevention of post-operative adhesions following laparotomy: meta-analysis of its efficacy and safety. Poster Presentation: 1995 ASRM. 6. Azziz R. Microsurgery alone or with INTERCEED Absorbable Adhesion Barrier for pelvic sidewall adhesion reformation. The INTERCEED (TC7) Adhesion Barrier Study Group II. *Surg Gynecol Obstet*. 1993;177:135-139. 7. Nordic Adhesion Prevention Study Group. The efficacy of INTERCEED (TC7) for prevention of reformation of postoperative adhesions on ovaries, fallopian tubes, and fimbriae in microsurgicaloperations for fertility: a multicenter study. *Fertil Steril*. 1995;63:709-714. 8. Sawada T, Nishizawa H, Nisho E, et al. Postoperative adhesion prevention with an oxidized regenerated cellulose adhesion barrier in infertile women. *J Reprod Med*. 2000;45(5):387-389. 9. Sekiba K. Use of INTERCEED (TC7) absorbable adhesion barrier to reduce postoperative adhesion reformation in infertility and endometriosis surgery. *Obstet Gynecol*. 1992;79:518-522.

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