

GYNECARE INTERCEED* (TC7) ABSORBABLE ADHESION BARRIER

Essential Product Information

Indications

INTERCEED 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 INTERCEED (TC7) Absorbable Adhesion Barrier is contra-indicated in the presence of frank infection.

INTERCEED Barrier is not indicated as a hemostatic agent. Appropriate means of achieving hemostasis must be employed.

Warnings

Postoperative adhesions may be induced by INTERCEED Barrier application if adjacent tissues (e.g., ovary and tube) and structures are coapted or conjoined by the device, or if INTERCEED Barrier is folded, wadded or layered. Care must be taken to apply INTERCEED Barrier in single layers, interposed between adjacent anatomic structures at risk for adhesion formation.

Postoperative adhesions may occur in the presence of INTERCEED Barrier if meticulous hemostasis is not achieved prior to application. INTERCEED Barrier must not be used if meticulous hemostasis has not been achieved or if blood contacts the product prior to its application.

As with all foreign substances, INTERCEED Barrier should not be placed in a contaminated surgical site. The performance of INTERCEED Barrier at such a site has not been determined.

Precautions

Use only a single layer of INTERCEED Barrier, since multiple layers of packing or folding will not enhance the adhesion barrier characteristics and may interfere with the absorption rate of INTERCEED Barrier. Care should be exercised in applying INTERCEED 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 adequate and well controlled studies have been conducted in women who have become pregnant within the first month after exposure to INTERCEED Barrier. No data exist to establish the effect, if any, of INTERCEED Barrier on the occurrence of ectopic pregnancies. No teratogenic studies have been performed. Therefore, an avoidance of conception should be considered during the first complete menstrual cycle after use of INTERCEED Barrier.

The safety and effectiveness of using INTERCEED Barrier in combination with other adhesion prevention treatments have not been clinically established.

INTERCEED Barrier is supplied sterile. As the material is not compatible with autoclaving or ethylene oxide sterilization, INTERCEED Barrier must not be resterilized. Foreign body reactions may occur in some patients.

Interactions may occur between INTERCEED Barrier and some drugs used at the surgical site. Pathologists examining sites of INTERCEED Barrier placement should be made aware of its usage and of the normal cellular response to INTERCEED Barrier¹ to facilitate proper evaluation of specimens.²

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 INTERCEED Barrier. Possible reasons for adhesion formation include failure to achieve meticulous hemostasis, or conjoining or coapting adjacent structures with INTERCEED Barrier.

*Trademark

References

1. Diamond, M.P., et al.: Interceed (TC7) as an Adjuvant for Adhesion Reduction: Animal Studies. In diZerega, G.S., Malinak, L.R., Diamond, M.P., Linsky, C.B. (Eds.): **Treatment of Postsurgical Adhesions**, pp 131-43, New York, Wiley-Liss, 1990.
2. Kershisnik, M.M., et al.: **American Journal of Clinical Pathology** 103:27, 1995.

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