



New Device Approvals

GYNECARE INTERGEL Adhesion Prevention Solution P990015

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: **GYNECARE INTERGEL® Adhesion Prevention Solution**
Manufacturer: **Lifecore Biomedical**
Address: **3515 Lyman Boulevard; Chaska, Minnesota 55318-3051**
Approval Date: **November 16, 2001**
Approval Letter: <http://www.fda.gov/cdrh/pdf/p990015a.pdf>

What is it and when is it used? GYNECARE INTERGEL® is a thick liquid (gel) made of sodium hyaluronate and iron. It is used during gynecological surgery to separate and protect tissues as they heal, preventing adhesions. The gel is supplied in a sterile, single-use bottle.

How does it work? After surgical procedures are finished, but before the abdominal cavity is closed, the inner tissues are coated with GYNECARE INTERGEL®. The gel lubricates the tissue surfaces and keeps them from sticking together (adhering) while they heal. After about a week, the tissues absorb the gel and it is passed out of the body.

What will it accomplish? GYNECARE INTERGEL® will reduce the chance that a woman will develop adhesions following surgery. Adhesions are a common complication of surgery on the female reproductive organs (ovaries, uterus, or fallopian tubes). They are bands of scar tissue that sometimes form during healing. Adhesions connect organs or tissues that should normally be separate. This can cause pelvic pain, bowel obstruction, or infertility. Once adhesions form, they can only be removed with surgery.

When should it not be used? GYNECARE INTERGEL® should not be used in patients who:

- have pelvic or abdominal infections
- are pregnant
- are undergoing laparoscopic surgery

Additional information: Summary of Safety and Effectiveness is available at:

<http://www.fda.gov/cdrh/pdf/p990015.html>

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Other:

- FDA Talk Paper: <http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01117.html>
- National Institutes of Health (NIH) MedlinePlus on pelvic adhesions:
<http://medlineplus.nlm.nih.gov/medlineplus/ency/imagepage/17118.htm>
- American College of Obstetricians and Gynecologists on Women's Health Issues:
<http://www.acog.com/>

(Updated 04-17-2002)