ETHICON, a Johnson & Johnson company, is dedicated to providing innovative solutions for common women’s health conditions. Our goal is to provide you access to advanced technology and valuable, easy-to-understand information so that you can weigh your options, and along with your physician, make informed decisions.

What You Should Know About Pelvic Adhesions & Gynecologic Surgery

References


Did you know?

Studies show pelvic adhesions form in the majority of women after gynecologic pelvic surgery.¹ They are all too often an unfortunate result of an otherwise safe and effective procedure. It’s impossible to predict who will develop adhesions or whether they will occur.

Be sure to talk with your doctor before your surgery to discuss the steps that can be taken to help prevent adhesion formation.
What are adhesions?
Adhesions are bands or sheets of scar tissue that bind organs or tissues that are ordinarily separated. They tend to form after surgery in the pelvic area, the part of the body that contains the female reproductive organs, the uterus, ovaries and fallopian tubes. Adhesions can cause infertility, postoperative pelvic pain and small bowel obstruction. These complications can be serious, and you should speak with your doctor about what can be done to reduce the risk of their occurrence.

How common are adhesions?
Adhesions are a common occurrence after pelvic or abdominal surgery. They are also common in women who suffer from pelvic inflammatory disease (PID), endometriosis, or some sexually transmitted diseases.

The likelihood of adhesion formation and the consequences of adhesions vary based on a variety of factors (eg, type of surgery, number of previous surgeries, surgical technique and the predisposition of individual patients). Studies have consistently shown that adhesions form in the majority of women after gynecologic pelvic surgery.

Following pelvic surgery, adhesions form within 5-7 days. Diagnosis or clinical problems may arise within 6 months.

How do adhesions form?
All of the abdominal and pelvic organs, except the ovaries, are at least partially wrapped in a clear membrane called the peritoneum. Any surgery within the peritoneum, no matter how carefully performed, causes a certain degree of inflammation to the tissue. Inflammation is a normal part of the healing process, but it also contributes to adhesion formation by encouraging the development of bands of scar tissue.
Problems caused by adhesions

It is important to talk to your doctor about adhesion prevention before your surgery, so steps can be taken to help avoid these potential problems

Pelvic Pain – Adhesions are commonly associated with pelvic pain. That’s because they bind organs and tissues together - essentially “tying them down” - so that the stretching and pulling of everyday movements can irritate the surrounding nerves. Adhesions can also cause pain during intercourse

Infertility – Adhesions formed after surgery may make it more difficult to get pregnant again in the future. Adhesions involving the ovaries or fallopian tubes can block the passage of the ovum (egg) from the ovaries to the fallopian tubes. Adhesions around the fallopian tubes can also interfere with sperm transport to the ovum, increasing the risk of tubal pregnancies

Bowel Obstruction – A serious condition that can develop as a result of adhesions is called intestinal or bowel obstruction. It can occur a few days or many years after surgery. Symptoms of bowel obstruction can include pain, nausea and vomiting

Diagnosing adhesions

To determine whether adhesions are the cause of pelvic pain or fertility problems, your doctor may perform a laparoscopy. This is an exploratory procedure using a laparoscope (a narrow lighted telescope inserted through a small incision in the belly button) to inspect the abdominal cavity and pelvic structures

Treating adhesions

The only way to treat adhesions is to remove or separate them surgically. This procedure is called adhesiolysis (ad heez´ ee o lie sis). Studies have shown that patients with pelvic pain and severe adhesions can experience a marked reduction in symptoms after adhesiolysis

Unfortunately, this very surgery to treat your adhesions too often results in their reoccurrence. In fact, data confirms that adhesiolysis results in reformation of adhesions in 3 out of 4 women

What can be done to help prevent adhesions?

While adhesions cannot be prevented, your doctor can reduce the risk of adhesions by using careful surgical technique, including keeping the incision clean (lint free) and using less reactive suture materials (stitches)

In addition, your doctor can apply an adhesion barrier during your surgery to reduce the likelihood that adhesions will form

Adhesion barriers are physical barriers used to separate injured tissues involved in surgery from other tissues and organs during the healing process

Adhesion prevention should be a key topic to discuss with your doctor before your surgery
Talk to your doctor about your gynecologic surgery

Based on your condition, there are questions you might want to ask your doctor or surgeon. The more informed you are, the more comfortable you’ll be with the decision you, your family, and your doctor make together:

- Will you be doing the actual surgery? (If not, you might want to meet the doctor who will)
- How should I prepare for the procedure?
- What are the steps involved in the procedure?
- What risks are involved in having the procedure?
- Is it possible for adhesions to form as a result of this procedure?
- What will be done during the procedure to help prevent adhesions from forming?
- Can you use GYNECARE INTERCEED Adhesion Barrier to reduce the risk of adhesions?
- Are there symptoms of adhesions that I should watch for as I recover from surgery? What else should I watch out for as my incision heals?
- Are there any steps we can take to speed up my recovery?

Remember to learn all you can – and ask questions about the issues that are most important to you. This is the best way to feel confident that you are making the best decision possible.

GYNECARE INTERCEED® Absorbable Adhesion Barrier

GYNECARE INTERCEED® Absorbable Adhesion Barrier is a lightweight, tissue-like “fabric” that your surgeon can use to protect and separate the surfaces where adhesions are likely to form. It is naturally absorbed as the surgical site heals. GYNECARE INTERCEED Adhesion Barrier is clinically proven to be two times more effective than good surgical technique alone in achieving an adhesion free outcome.*

*While clinical studies have shown a reduction in adhesions, these studies have not measured the reduction in complications associated with adhesions, such as pelvic pain, infertility, and bowel obstruction.
What are the risks?

Like all absorbable adhesion barriers, the use of GYNECARE INTERCEED® Absorbable Adhesion Barrier presents some risks. They may include pain, infection, inflammation or foreign body reaction. While GYNECARE INTERCEED Adhesion Barrier has been shown to reduce the incidence of adhesions, some patients may still develop adhesions, despite product usage. Talk to your doctor about whether GYNECARE INTERCEED Adhesion Barrier is right for you.

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 (e.g., 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.