

Adiana Permanent Contraception Summary of Risks and Considerations

All methods of birth control, temporary and permanent, have benefits, warnings, precautions, and risks. Before making a final decision, you should discuss these thoroughly with your doctor.

Not all women are candidates for Adiana Permanent Contraception.

You can NOT have the Adiana procedure if you:

- Have already had a tubal ligation (“had your tubes tied”). The fallopian tubes are accessed during the Adiana procedure. This will not be possible if you have had a tubal ligation.
- Are taking immunosuppressive medicines (any drugs that prevent or block the activity of your body’s natural defenses). These drugs might interfere with the natural healing process. As a result, your tubes would not be blocked.
- Have an allergy to contrast fluid (the fluid used in the 3-month Adiana Hysterosalpingogram (HSG) Confirmation Test). You have to use an alternate form of birth control until you have confirmation that your tubes are completely blocked. You cannot receive this confirmation if your body cannot tolerate the HSG procedure.
- Have something abnormal about your uterus that could prevent your doctor from performing the procedure. Every woman’s body is different and this procedure may not be safe for those with uterine abnormalities.
- Cannot have the procedure done in both fallopian tubes (even if one tube is thought to be blocked or you have only one tube). There is no clinical data to support the safety or effectiveness of doing so.
- Have any personal doubts about ending your fertility. The Adiana procedure prevents pregnancy for the rest of your life and is not considered reversible.

You must delay having the Adiana procedure if you:

- Are pregnant, or suspect you might be pregnant. The risks to you and the fetus are not known.
- Have been pregnant or given birth in the last 3 months. Your body needs time to heal after a pregnancy, and the risks of this procedure are not known if it has been less than 3 months since your last pregnancy.
- Now have clinical evidence of a pelvic infection, or have recently had a pelvic infection. The bacteria from an infection could damage your fallopian tubes. You should be fully healed from a pelvic infection before undergoing a procedure that affects your fallopian tubes.

Other considerations:

Permanent contraception means forever.

- Adiana Permanent Contraception is meant to prevent pregnancy for the rest of your life. As with any major decision, there is always a chance you will regret the decision later. This risk is higher with younger women. That’s why it’s important to consider your options very carefully.
- The Adiana procedure is considered irreversible. There are no data on the safety or effectiveness of reversing the procedure through surgery.

No method of birth control is 100% effective.

- Once your doctor confirms that your tubes are completely blocked, there is a 1.6% chance that the procedure will fail to prevent pregnancy*. Also, there is a small chance that you will not be able to rely on the Adiana inserts for permanent contraception.
* Based on 3 years of clinical data.
- If you do become pregnant following the Adiana procedure, the risks to you and the fetus—both from continuing the pregnancy and from childbirth—are not known.

Adiana Permanent Contraception is among the newest methods of permanent birth control.

- Because Adiana Permanent Contraception is a newer procedure, it has not been studied in as many women, or for as long a time, as other methods*. This means there could always be risks that have not yet been identified.
- Adiana Permanent Contraception has only been used by women ages 18 to 45. There is no information available on its safety or effectiveness for women under the age of 18 or over the age of 45.

* Three-year clinical study data is available. Continued follow-up of women participating in the clinical study will provide more data in the future.

You must use an alternate form of birth control for 3 months after the procedure.

- Talk to your doctor before the Adiana procedure about what method of birth control you will use after the procedure. You will need to use temporary birth control (such as condoms, a diaphragm, or birth control pills) for 3 months until you have the Adiana HSG Confirmation Test and your doctor confirms that your tubes are completely blocked.

There's a small chance the procedure could take longer than 3 months to work.

- Your 3-month Adiana HSG may show that one or both of the inserts has not yet completely blocked the fallopian tubes. If this happens, you would need to keep using an alternate form of birth control for another 3 months, and then repeat the Adiana HSG.

There's a small chance that the procedure might not be successful.

- In the clinical study of 645 women, the inserts were placed in both fallopian tubes in 95% of the women. Thirty-four women (5%) could not have the inserts placed in one or both fallopian tubes and could not rely on the Adiana inserts for permanent contraception.
- In the clinical study, less than 6% of women had fallopian tubes that were not blocked following the HSG. These women could not rely on the Adiana inserts for permanent contraception.

Additional warnings, precautions, and risks.

- Women who do become pregnant following the Adiana procedure (or any other method of permanent birth control, including tubal ligation) are more likely to have an ectopic pregnancy. This is a pregnancy outside the uterus, usually in one of the fallopian tubes. Ectopic pregnancy can be a dangerous and even life-threatening condition. After the procedure, if your period is ever more than 5 days late, or if you suspect for any reason that you might be pregnant, contact your doctor immediately.
- This product does not protect from HIV infection or other sexually transmitted diseases. If you are sexually active, the best protection from HIV and other sexually transmitted diseases is the use of a latex condom.
- Sensitive electronic equipment, such as an external pacemaker or internal cardioverter defibrillator, may be adversely affected by the use of the instrument (RF Generator) that supplies the power for the Adiana procedure.
- A very rare complication that could happen during the procedure is absorbing too much of the fluid used to expand the uterus. This can lead to complications including nausea and vomiting, headache, confusion, or lethargy. Please consult with your doctor to understand all of the risks involved.
- The Adiana procedure should be performed during the first half of your menstrual cycle, before ovulation. This will reduce the risk of an undiagnosed pregnancy at the time of the procedure, and will also make it easier for your doctor to see the openings of your fallopian tubes. Your doctor will give you a pregnancy test before the procedure to confirm that you are not pregnant.
- You should refrain from moving during energy delivery and placement of the inserts. This part of the procedure takes approximately 60 seconds. Keeping very still will increase the likelihood of successful placement of the inserts.
- In the clinical study, no women had their uterus or fallopian tubes perforated (punctured) as a result of placement of the inserts, however, if that should occur, laparoscopic or other surgery could be needed to remove the inserts. Another type of tubal sterilization procedure may also be needed for permanent contraception.

- Anesthetics are medicines that may be used to prevent pain during the procedure. There are risks associated with the use of any medicines, even local anesthetics. Talk to your doctor about the risks of the particular anesthetic recommended for you.
- 645 women participated in the clinical study. Some of these women reported that they experienced the following symptoms during or immediately after the procedure:
 - o Mild to moderate cramping (26%)
 - o Vaginal spotting (12%)
 - o Post-procedure bleeding (10%)
 - o Pelvic pain (9%)
 - o Back pain (8%)
 - o Nausea (5%)
- 625 women in the clinical study were contacted after one year and reported the following side effects that may be related to the Adiana procedure:
 - o Cramping unrelated to menstrual periods (6%)
 - o Painful menstruation (5%)
 - o Vaginal bleeding (4%)
 - o Pelvic pain (3%)
 - o Back pain (3%)
 - o Vaginal spotting (1%)
 - o Painful sexual intercourse (1%)
 - o Nausea (1%)
 - o Unusually heavy or long-lasting menstrual periods (1%)
 - o Headache (1%)
- There are certain risks associated with the HSG test. This test is necessary to confirm that the fallopian tubes are blocked. These risks may include infection, spotting, allergic reaction to the dye (contrast fluid), and exposure to low levels of radiation. Please ask your doctor about these and other risks associated with the HSG test.
- No women in the clinical trial had allergic reactions to the Adiana inserts, and no women had their inserts removed due to pain or for any other reason.

Most of these symptoms were mild and resolved quickly, without any treatment. Some women took oral medication for relief of pain.

For complete patient information, please refer to the
Adiana Patient Information Booklet available at www.adiana.com