Adiana®

Permanent Contraception

Instructions for Use and Radiofrequency (RF) Generator Operator's Manual

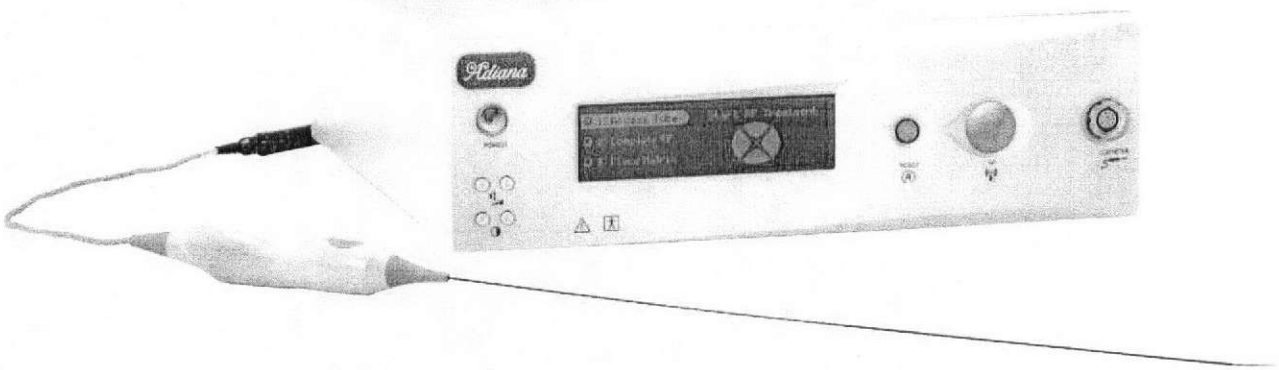

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Table of Contents

Instructions for Use

Hysterosalpingography (HSG) for Adiana Permanent Contraception

Radiofrequency (RF) Generator Additional Instructions

Adiana®
Permanent Contraception

Instructions for Use

Instructions for Use

IMPORTANT

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

This device should only be used by physicians who have prior training in hysteroscopy, have completed Hologic's Adiana® Permanent Contraception physician training program, and have read and understand these instructions for use. Completion of the Adiana physician training program includes proctoring in Adiana RF treatment and implantable matrix (matrix) placement for at least three cases.

IMPORTANT

The Adiana method should not be relied on for contraception until the patient has undergone hysterosalpingography (HSG) three months after the Adiana RF treatment / matrix placement procedure. The three-month HSG must demonstrate bilateral tubal occlusion before the patient may rely on Adiana Permanent Contraception for pregnancy prevention.

If the Adiana RF treatment / matrix placement cannot be performed bilaterally, the patient should not rely on this method of sterilization. The Adiana method has not been proven to be effective when the RF treatment / matrix placement procedure is performed unilaterally.

Adiana Permanent Contraception is intended to prevent pregnancy. It does not protect against either HIV infection or other sexually transmitted diseases.

This document provides instructions and information pertaining to the use of the Adiana Permanent Contraception System (Adiana System), including the radiofrequency (RF) generator, delivery catheter (catheter) and matrix.

The Adiana System is comprised of sterile and non-sterile components. The catheter, which includes the matrix, is provided sterile and the RF generator is provided non-sterile.

Refer to the "Radiofrequency (RF) Generator Additional Instructions" section of the operator's manual for further information on the RF generator.

Refer to the "Hysterosalpingography (HSG) for Adiana Permanent Contraception" document, which is provided separately and is included in the operator's manual provided with the RF generator, for details on performing HSG after the Adiana procedure.

It is important to carefully follow all instructions pertaining to the use of the Adiana System to ensure the system operates as intended. It is also essential to adhere to all instructions to ensure optimal results when placing the Adiana matrices and performing the HSG procedure.

MECHANISM OF ACTION

Overview

The Adiana method of permanent sterilization consists of four steps:

Step 1: Delivery of bipolar radiofrequency energy to create a superficial lesion within the fallopian tube. The creation of this lesion will initiate an acute wound healing response.

Step 2: Deployment of a matrix within the area of the superficial lesion. The tissue in-growth response will lead to occlusion of the fallopian tube along the length of the matrix.

Step 3: Patient must use a reliable form of contraception until bilateral tubal occlusion is confirmed by the Adiana HSG three months after placement of the Adiana matrices.

Step 4: Bilateral tubal occlusion must be confirmed by the Adiana HSG before the patient can be advised that she can rely on Adiana Permanent Contraception for pregnancy prevention.

The epithelial layer in a discrete section of the fallopian tube is ablated by the controlled application of bipolar electrical current (RF energy) through a catheter. Removal of the epithelium creates a superficial lesion which initiates an acute wound healing response. Following creation of the lesion, a biomaterial, which is a fully cured silicone matrix, is deployed into the tube. The matrix functions as a benign and permanent scaffold during wound healing. Within the region surrounding the solid core of the matrix, a porous architecture encourages a tissue in-growth response eventually leading to total occlusion of the tube. The tissue in-growth response can be described as a fibroblast infiltration into the pores of the matrix which occurs during the granulation tissue phase of the biomaterial process.

Catheter Placement

The catheter used to apply RF energy is introduced into the intramural section of the fallopian tube through a conventional hysteroscope, via a transvaginal and transcervical approach. Confirmation of correct catheter positioning within the intramural tube is achieved by means of direct visual assessment through the hysteroscope to confirm that the black positioning mark on the catheter has reached the tubal ostium. Confirmation of full tissue contact is communicated by the catheter, via the Position Detection Array (PDA), through the RF generator. The PDA consists of four small sensors circumferentially located in four quadrants around the catheter. When all four sensors detect tissue contact simultaneously, the RF generator signals that the catheter is correctly positioned within the fallopian tube.

Lesion Formation

Once the RF generator has signaled that the catheter is correctly positioned, the clinician activates the generator by pressing the RF button on the front panel. The clinician may also elect to activate the RF generator by depressing the footswitch. Following activation, the RF generator delivers bipolar RF energy (< 3 Watts) through the electrode array. The thermocouples in the catheter tip maintain a constant temperature of 64°C for 60 seconds, which creates a superficial lesion within the fallopian tube.

Matrix Deployment

Following creation of the superficial lesion, the display screen on the RF generator indicates that the delivery of RF energy is complete. The clinician then depresses the matrix release button on the catheter to deploy the matrix within the region of the lesion. The outer sheath retracts while the push rod keeps the matrix in place, deploying the matrix into the fallopian tube. The catheter is then removed and the procedure repeated with a new catheter on the contralateral tube.

Tissue In-Growth

The procedure results in a host response which is expected for soft tissue implants such as the matrix. The initial response is due to the actual surgical procedure itself, and is similar to any acute

healing mechanism. Acutely, there is an exudate and edema of the surrounding tissue, and cells such as neutrophils and leukocytes invade the space.

The acute response will give way to a chronic process which stimulates granulation tissue. During the chronic process, there is observed neo-vascularization, which is needed to support the granulation process. The dominant cell lines in this phase consist of macrophages and fibroblasts. Epithelial cells could be considered a marker of potential fistulization or re-canalization and are therefore undesirable. The macrophages fuse to form foreign body giant cells, which will cover the surface of the matrix. The granulation tissue settles into a steady-state and a durable fibrous tissue is formed. The neo-vascularization diminishes; there is less cellularity, consisting mainly of fibrocytes, and the extra-cellular matrix now contains more collagen. Integration of this fibrous tissue into the matrix is the expected end result which in turn results in tubal occlusion.

DEVICE DESCRIPTION

The Adiana System consists of two single-use, disposable catheters (each containing a matrix) and an RF generator (Figure 1).

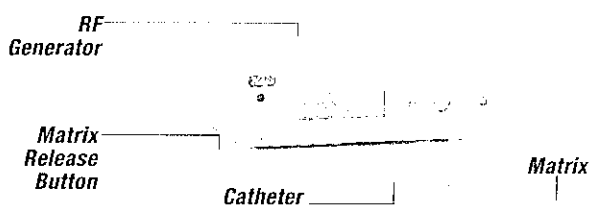


FIGURE 1: The Adiana System

Delivery Catheter (with Implantable Matrix)

The catheter is packaged with a split introducer sheath and obturator. The introducer sheath protects the catheter during insertion into the hysteroscope.

The catheter (Figures 1 and 2) has four electrode bands, which form the bipolar RF electrode array at its distal end. The catheter is attached to a handle at its proximal end.

A black positioning mark on the catheter aids in the proper positioning of the catheter in the fallopian tube ostium.

The gold position detection array (PDA) consists of four electrode sensors circumferentially located on the catheter (just proximal to the RF electrode array); the sensors detect tissue contact, which is communicated to the RF generator.

Thermocouples are placed within the catheter to provide feedback to the RF generator for temperature control.

The matrix is made of silicone and is comprised of a solid core surrounded by a porous architecture (Figure 3). It is approximately 3.5 mm in length and 1.6 mm in diameter, and is located directly under the bipolar RF electrode array (Figure 2).

A matrix release button, incorporated into the catheter handle, activates the release of the matrix following the delivery of RF energy (Figure 1).

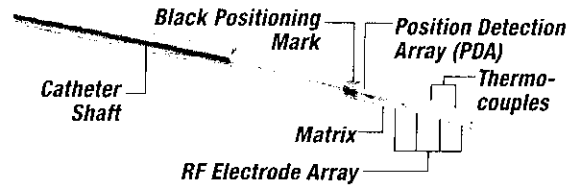


FIGURE 2: Catheter Tip (Detailed View)

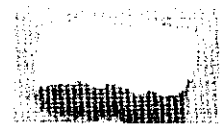


FIGURE 3: Matrix

RF Generator

The RF generator is designed to be used only with the Adiana catheter. It is supplied with a connector cable (for attachment to the catheter) and a power cord. An optional footswitch accessory is also provided to allow hands-free operation of the RF generator.

The RF generator is a microprocessor-controlled, bipolar, radiofrequency generator with automatic temperature control and a tissue contact sensor. It uses a menu-driven display to guide the operator through the procedure.

The RF generator provides continuous monitoring of catheter signals for determining proper catheter positioning, controlling lesion creation, ensuring matrix delivery and detecting error conditions.

There are no user-selectable controls for RF output, treatment time or treatment temperature. RF settings have been programmed in the generator software to ensure that the specified treatment temperature is achieved and maintained for the specified treatment duration. If necessary, the clinician can terminate treatment; however, no other physician control of output power is possible.

Refer to the "Radiofrequency (RF) Generator Additional Instructions" section of the operator's manual for further information on the following items pertaining to the RF generator: warnings and precautions, feature descriptions, specifications, installation and set-up instructions, error codes, troubleshooting instructions and cleaning and sanitizing instructions.

INDICATIONS FOR USE

Adiana Permanent Contraception is indicated for women who desire permanent birth control (female sterilization) by occlusion of the fallopian tubes.

CONTRAINDICATIONS

The Adiana System should not be used in a patient who:

- Is uncertain about her desire to end fertility
- Has clinical evidence of an active pelvic infection or history of a recent pelvic infection
- Has intra-uterine pathology which would prevent access to either tubal ostium or the intramural portion of either fallopian tube (such as large submucous fibroids, uterine adhesions, apparent uni- or bilateral proximal tubal occlusion, suspected unicornuate uterus, etc.)
- Is pregnant or suspects pregnancy
- Is currently less than three months since her last pregnancy

- Has previously undergone a tubal ligation
- Is currently taking immunosuppressive medications (e.g., steroids)
- Has a known allergy to contrast media

WARNINGS

IMPORTANT

In the Adiana pivotal clinical trial there were some patients who became pregnant as a result of not complying with instructions that they should not rely on Adiana Permanent Contraception for pregnancy prevention and that they should use either an alternate sterilization procedure or other reliable form of contraception. Therefore, it is important that patients be properly counseled during all stages of the Adiana procedure.

As with any tubal occlusion procedure, there is a risk of ectopic pregnancy. Ectopic pregnancies did occur during the Adiana pivotal clinical trial; however, the rate of occurrence was similar to or less than that reported for other tubal occlusion methods.

- Patients must use alternative contraception for at least three months post treatment and until bilateral tubal occlusion is confirmed by HSG.
- The Adiana procedure should be considered irreversible. There are no data on the safety or effectiveness of reversing the procedure through surgery.
- The Adiana pivotal clinical trial effectiveness rates were based on women in whom bilateral placement was achieved. Effectiveness has not been determined for women with unilateral placement in a unicornuate uterus or with presumed or confirmed contralateral proximal tubal occlusion.
- The safety and effectiveness of this procedure have not been demonstrated in patients under the age of 18 or over the age of 45.
- Women who undergo sterilization at a relatively young age are at greater risk of regretting their decision.
- Do not perform an endometrial ablation procedure concomitantly with the Adiana RF treatment and matrix placement procedures. Ablation may cause intrauterine synechiae, which could compromise the results of the three-month Adiana HSG. If bilateral tubal occlusion is not confirmed during this HSG, the patient cannot rely on Adiana Permanent Contraception for pregnancy prevention.
- This product does not protect against HIV infection or other sexually transmitted diseases.
- Nonionic hysteroscopic distention medium (e.g., 1.5% Glycine, 3% Sorbitol, 5% Mannitol) intake and outflow should be monitored. Any system delivering high pressure inflow to a patient increases the risk for fluid absorption and electrolyte imbalance (hyponatremia). To reduce the risk of hypervolemia, the procedure must be terminated if the fluid deficit exceeds 800 cc. Additionally, the procedure time should not exceed 30 minutes.
- Matrix removal should not be attempted hysteroscopically once the matrix has been placed in the fallopian tube. Removal of the matrix will most likely require surgery.
- Sensitive electronic equipment, such as an external pacemaker or internal cardioverter defibrillator, may be adversely affected by use of the RF generator.
- Monitoring electrodes should be placed as far away from the catheter site as possible when the Adiana System and physiological monitoring equipment are used simultaneously on the same patient.
- If the procedure is repeated for any reason, ensure the cumulative RF energy delivery time for a single fallopian tube does not exceed 120 seconds.
- To reduce the risk of uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilation (e.g., in the case of stenotic cervix).
- Refer to the "Radiofrequency (RF) Generator Additional Instructions" section of the operator's manual for additional warnings specifically related to the use of the RF generator.

PRECAUTIONS

- This procedure should not be performed during menstruation. It should be performed during the early proliferative phase of the menstrual cycle to decrease the possibility of implantation in a patient with an undiagnosed (luteal phase) pregnancy and to facilitate visualization of the ostia.
- The catheter and split introducer sheath are provided sterile and intended for single use only. They should not be used beyond the "Use by" date printed on their package label.
- Do not use if the package seal is open or damaged. Inspect sealed package before opening.
- Do not use the catheter if it has been damaged. Inspect catheter before use.
- Use the split introducer sheath when passing the catheter into the hysteroscope to avoid damage to the catheter tip.
- Use eye and face protection during this procedure to minimize the risk of fluid splash-back.
- Visually identify both tubal ostia prior to attempting tubal access. Do not implant the matrix in one tube unless there is a reasonable expectation that the opposite tube can be accessed.
- Do not advance the catheter if the patient is experiencing excessive pain or discomfort.
- To avoid possible uterine perforation and potential damage to adjacent organs when introducing the catheter into the fallopian tube:
  - Do not advance the catheter without visual guidance.
  - Do not apply excessive force.
  - Do not advance the catheter such that the black positioning mark is past the ostium.
- In the event of a uterine perforation, immediately discontinue the Adiana procedure. Although not noted during the Adiana clinical trial, as with any other intrauterine procedure, uterine perforations may be possible.
- Avoid catheter and/or patient movement during RF energy delivery and matrix placement.
- Do not place more than one matrix into a single fallopian tube.
- Follow the hospital or office policy and procedure for handling and disposal of hazardous materials.
- If endometrial ablation is performed after bilateral tubal occlusion has been confirmed by HSG then, as with any tubal sterilization procedure, there is a risk of post-ablation tubal sterilization syndrome
- Ensure appropriate training, equipment, medications and staff are in place to handle emergencies, such as a vasovagal response, prior to performing the procedure.

- Do not attempt to use the catheter with any other RF generator, as it will not operate as intended.
- Do not attempt to use the RF generator without first reading the "Radiofrequency (RF) Generator Additional Instructions" section of the operator's manual, which includes additional precautions specifically related to the use of the RF generator.

ADVERSE EVENTS

Between November 13, 2002 and April 28, 2005, a total of 645 women underwent a procedure using the Adiana System in the pivotal clinical study, "A Multi-Center Prospective Evaluation of the Adiana System for Transcervical Sterilization Using Electrothermal Energy in Women Aged 18–45— The EASE Trial" (EASE study), to evaluate its safety and effectiveness. During the course of the study, any adverse events were recorded and evaluated.

Serious Adverse Events

During the first year of reliance one patient experienced an isthmic ectopic pregnancy, which was successfully resolved by treatment with medication. During the second year of reliance one patient experienced a left ampullary ectopic pregnancy, which was successfully resolved by salpingectomy. Also, during the second year of reliance another patient experienced a moderate to severe case of dysmenorrhea and endometrial polyp, which were successfully resolved by an out-patient polypectomy.

Other Adverse Events

Table 1 presents adverse events that occurred on the day of the placement procedure and were reported at a frequency greater than 0.5% (N=645).

Adverse Event	Percentage
Cramping	26%
Vaginal Spotting	12%
Post-procedural Bleeding	10%
Pelvic Pain	9%
Back Pain	8%
Nausea	5%
Headache	4%
Vomiting	2%
Post-procedural Pain	2%
Other	3%

All adverse events noted in Table 1 were mild in nature and resolved within a short duration. The majority of women in the clinical trial reported that the procedure was well-tolerated and that any discomfort or pain experienced during the procedure was the same as or less than they expected. Following the procedure, pain was managed with oral analgesics. One serious adverse event (not included in the table) that occurred on the day of procedure (hyponatremia) required intervention with medication prior to patient discharge on the same day. This case resulted from failure to properly monitor hysteroscopy fluid deficit (refer to the Warnings section for related warning).

Table 2 presents adverse events reported to be at least possibly related to the placement procedure or matrices during the first year of reliance on Adiana Permanent Contraception up to approximately 15 months post procedure and were reported at a frequency greater than or equal to 0.5% (N=625).

Adverse Event	Percentage
Cramping unrelated to menses	6%
Dysmenorrhea	5%
Vaginal bleeding	4%
Back pain	3%
Pelvic pain	3%
Dyspareunia	1%
Headache	1%
Menorrhagia	1%
Nausea	1%
Vaginal spotting	1%
Abdominal pain	<1%
Amenorrhea	<1%
Discomfort—uncharacterized	<1%
Pain—uncharacterized	<1%
Vaginal discharge	<1%
Vomiting	<1%

All adverse events noted in Table 2 did not prevent women from relying on Adiana Permanent Contraception.

The following adverse events were not experienced by women who participated in the clinical study to evaluate Adiana Permanent Contraception but are still possible:

- Perforation of the uterus or fallopian tube, or other internal body structures
- Adnexal infection/salpingitis
- Complications associated with hysterosalpingography (HSG)
- Complications associated with surgery attempting to reverse the procedure

CLINICAL STUDY

Some women underwent more than one procedure if successful bilateral placement was not achieved in the initial procedure. Overall, bilateral placement success was achieved in 95% of patients in the study.

Purpose of the Study

The EASE study was conducted to demonstrate the safety and effectiveness of Adiana Permanent Contraception. It was a prospective, single-armed, multi-center, multi-national study that used findings from the U.S. Collaborative Review of Sterilization (CREST) study as a qualitative benchmark.

Study Endpoints

Primary efficacy endpoint:

Pregnancy prevention rate after 12 months of reliance on Adiana Permanent Contraception

Secondary endpoints:

- Device placement rate
- Patient satisfaction and comfort with the placement procedure
- Patient satisfaction and comfort with device wearing
- Safety of device placement procedure
- Safety of device wearing

Patient Demographics

The intent-to-treat study population consisted of 645 women. All study participants were between 18 and 45 years of age and were seeking permanent contraception prior to enrollment in the study. Additionally, all women had been pregnant at least once, were sexually active, had regular, cyclical menses and were able and willing to use alternative contraception for the first three months following placement of the matrices.

Age (mean years)	31.5
Age group	
18–27 years	24.2%
28–33 years	47.7%
34–45 years	28.1%
Race	
Caucasian	488
Hispanic	98
African-American	47
Other	12
Gravidity (mean, range)	2.9 (1–9)
Parity (mean, range)	2.2 (0–7)
Weight (mean, range [lbs])	161.8 (98.0–355.0)
Height (mean, range [in])	64.7 (51.3–74.0)

Study Methods

All participants were screened for eligibility for inclusion in the clinical study. A complete medical history was obtained. A physical examination, pelvic examination and required laboratory tests (including a pregnancy test) were conducted.

NOTE: In the EASE study, the nonionic hysteroscopic distention medium used during RF treatment / matrix placement was 1.5% Glycine.

An Adiana procedure was performed on each fallopian tube. If bilateral placement was achieved, participants were instructed to use either barrier contraceptive method or oral contraceptives for the first three months following placement of the matrices.

Hysterosalpingography (HSG) for Adiana Permanent Contraception

HSG was performed three months post-placement of the matrices to confirm bilateral fallopian tube occlusion.

NOTE: In the EASE study, a pressure monitoring device was used while performing the HSG to ensure that adequate intrauterine pressure was achieved during infusion of the contrast medium and that excessive pressure (i.e., pressure >200 mm Hg) was avoided.

If both fallopian tubes were occluded, the participant was instructed to discontinue use of alternative contraception and rely on Adiana Permanent Contraception for prevention of pregnancy.

Results

Matrix Placement Rates

A total of 770 participants were enrolled in the EASE study, of whom 645 had RF treatment / matrix placement attempted. Successful bilateral placement of the matrices was achieved in 604/645 (94%) participants after the first procedure. Successful bilateral placement of the matrices was achieved in 611/645 (95%) participants after 7 participants underwent a successful second attempt. Thus, bilateral placement of the matrices was not achieved in 34 participants (unilateral placement = 14; no device placement = 20). Refer to Table 4.

Reliance Rates

Of the 611 participants with bilateral placement of the matrices, 604 were evaluated for tubal occlusion by HSG. A total of 570/604 (94%) participants were ultimately able to rely on Adiana Permanent Contraception. Tubal patency was identified by HSG in those participants that were unable to rely on Adiana Permanent Contraception. Refer to Table 4.

	Number	Percent
Bilateral Matrix Placement Rate *(After first attempt)*	604/645**	94%
Bilateral Matrix Placement Rate *(Includes second attempt)*	611/645**	95%
Bilateral Matrix Placement Reliance Rate***	570/604	94%
*Intent-to-Treat Reliance Rate****	570/645	88%

*These bilateral matrix placement rates are based on data from the Adiana pivotal clinical trial.

**Of these 645 women, 14 had unilateral matrix placement only, and 20 had no matrices placed.

***The Bilateral Matrix Placement Reliance Rate is the number of women who were able to rely on Adiana Permanent Contraception for pregnancy prevention divided by the number of women who were evaluated by HSG.

**** The Intent-to-Treat Reliance Rate is the number of women who were able to rely on Adiana Permanent Contraception for pregnancy prevention divided by the number of women who had RF treatment / matrix placement attempted.

Pregnancy Prevention Effectiveness

Of the 570 participants relying on Adiana Permanent Contraception, 553 (97%) have been followed for at least 12 months, 510 (90%) have been followed for at least 24 months, and 481 (84%) have been followed for at least 36 months. During the one-year follow-up period, there were six pregnancies in those patients relying on Adiana Permanent Contraception, of which three were attributable to physician error (i.e., misinterpretation of HSG results). The two-year follow-up period revealed three pregnancies in relying patients, and the three-year follow-up period revealed no pregnancies. Table 5 presents the one-, two- and three-year contraceptive failure rates for the EASE study, as of July 31, 2008.

	Pregnancies - Cumulative Failure Rate*
One-Year	**1.1%** to (95% CI 0.6 to 2.1%)
Two-Year	**1.6%** to (95% CI 0.9 to 2.8%)
Three-Year**	**1.6%** to (95% CI 0.9 to 2.8%)

*The one-, two- and three-year failure rates for Adiana Permanent Contraception presented above are comparable to the failure rate for other methods of tubal sterilization at these time points.

** As of July 31, 2008, the date of the three-year data lock and analysis, 498 of the 513 (97%) evaluable subjects at the three-year point had completed three or more years of device wearing. The 498 subjects are comprised of those subjects who either completed or missed their three-year follow-up visit. A total of 15 subjects were not yet due for their three-year follow-up visit.

The data for years 4 and 5 are incomplete; however, as of February 2009 there have been two pregnancies reported during Year 4 of reliance and one pregnancy reported during Year 5 of reliance.

Follow-up of the women in the EASE study is ongoing, and will continue up to 10 years. Adiana Permanent Contraception labeling will be revised as necessary as follow-up data pertaining to longer-term failure rates become available.

Table 6 provides estimates of the percentage of women likely to become pregnant while using a particular contraceptive method for one year. These estimates are based on a variety of studies.

Method	Typical Use* Rate of Pregnancy
Sterilization	
Male Sterilization	0.15%
Female Sterilization	0.5%
Hormonal Methods	
Implant *(Implanon®)*	0.05%
Hormone Shot *(Depo-Provera®)*	3%
Combined Pill and Progestin-Only Pill	8%
Vaginal Ring *(NuvaRing®)*	8%
Patch *(Ortho Evra®)*	8%
Intrauterine Devices (IUDs)	
Copper T	0.8%
LNG-IUS	0.2%
Barrier Methods	
Male condom *(used without spermicide)*	15%
Female condom	21%
Diaphragm *(used with spermicide)*	16%
Spermicides: *(foams, creams, gels, suppositories, films)*	29%
Natural Methods	
Withdrawal	27%
Fertility-awareness-based methods	25%
No Method	85%

*Among *typical* couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason. Estimates of the probability of pregnancy during the first year of typical use for spermicides, withdrawal, periodic abstinence, the diaphragm, the male condom, the pill and Depo-Provera are taken from the 1995 National Survey of Family Growth corrected for underreporting of abortion; see the text for the derivation of estimates for the other methods.

Source: Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. *Contraceptive Technology: Nineteenth Revised Edition*. New York NY: Ardent Media, 2007.

CLINICAL USE INFORMATION

Physician Training

- This device should only be used by physicians who have prior training in hysteroscopy, have completed Hologic's Adiana Permanent Contraception physician training program and have read and understand these instructions for use.
- The Adiana Permanent Contraception physician training program provides detailed information regarding the procedure. Physicians must complete this program before initiation of their first procedure.

Patient Counseling

Important: Patients should be counseled that this product is intended to prevent pregnancy. It does not protect against either HIV infection or other sexually transmitted diseases.

The following should be considered in conjunction with the Adiana Permanent Contraception Patient Information Booklet when counseling patients prior to the procedure:

- The Adiana method of permanent sterilization consists of four steps: (1) delivery of RF energy to create a superficial lesion within the fallopian tubes; (2) deployment of a silicone matrix in the area of the superficial lesion within the tube; (3) reliance on a reliable form of alternative contraception for three months; and (4) an Adiana HSG to confirm bilateral tubal occlusion.
- The procedure is permanent and irreversible.
- Instruct the patient to use an alternative form of contraception for a minimum of the first three months following bilateral RF treatment and matrix placement, until she has undergone the three-month HSG to confirm bilateral tubal occlusion. Ensure that the patient is supplied with, or already has, contraception for this time frame. In addition, the patient should be counseled to use the most effective means of contraception for which she is a candidate. The patient should also be counseled that there is an increased risk of ectopic pregnancy after a tubal occlusion procedure, so compliance with contraception is critical during this three-month waiting period.
- Failure to return for the three-month HSG could lead to undesired pregnancy, including ectopic pregnancy.
- As with all other methods of birth control, Adiana Permanent Contraception should not be considered 100% effective.
- As with any tubal sterilization procedure, there is a risk of pregnancy, including ectopic pregnancy.
- There is a small possibility that bilateral placement of the matrix could be unsuccessful during the first attempt.
- Data regarding the effectiveness of Adiana Permanent Contraception beyond three years of treatment are not available.

HOW SUPPLIED

The catheter (with matrix) and split introducer sheath with obturator are supplied sterile and are intended for SINGLE USE ONLY. These items will remain sterile for the duration of the labeled shelf life as long as the packaging is not opened or damaged. The RF generator is supplied with a connector cable, power cord and an optional-use footswitch. The catheter and RF generator are supplied separately.

INSTRUCTIONS

Patient Preparation

- Administer a pregnancy test within 24 hours prior to the procedure.
- Administering a non-steroidal, anti-inflammatory drug (NSAID) may be considered one to two hours prior to the procedure. If using only a paracervical block, an anxiolytic agent may also be offered 30 minutes prior to the procedure to reduce anxiety.

Prior to Implantation

Refer to the "Radiofrequency (RF) Generator Additional Instructions" section of the operator's manual for further information on the following items pertaining to the RF generator: warnings and precautions, feature descriptions, specifications, installation and set-up instructions, error codes, troubleshooting instructions and cleaning and sanitizing instructions.

Necessary equipment and supplies:

- Two Adiana catheters
- Adiana RF generator
- Adiana connector cable
- Mayo stand and sterile drape
- Hysteroscope [continuous flow with a 5-French (minimum) working channel]
- Bivalve, open-sided speculum
- Single-toothed tenaculum
- Monitor, camera and fiberoptic light source
- IV Pole

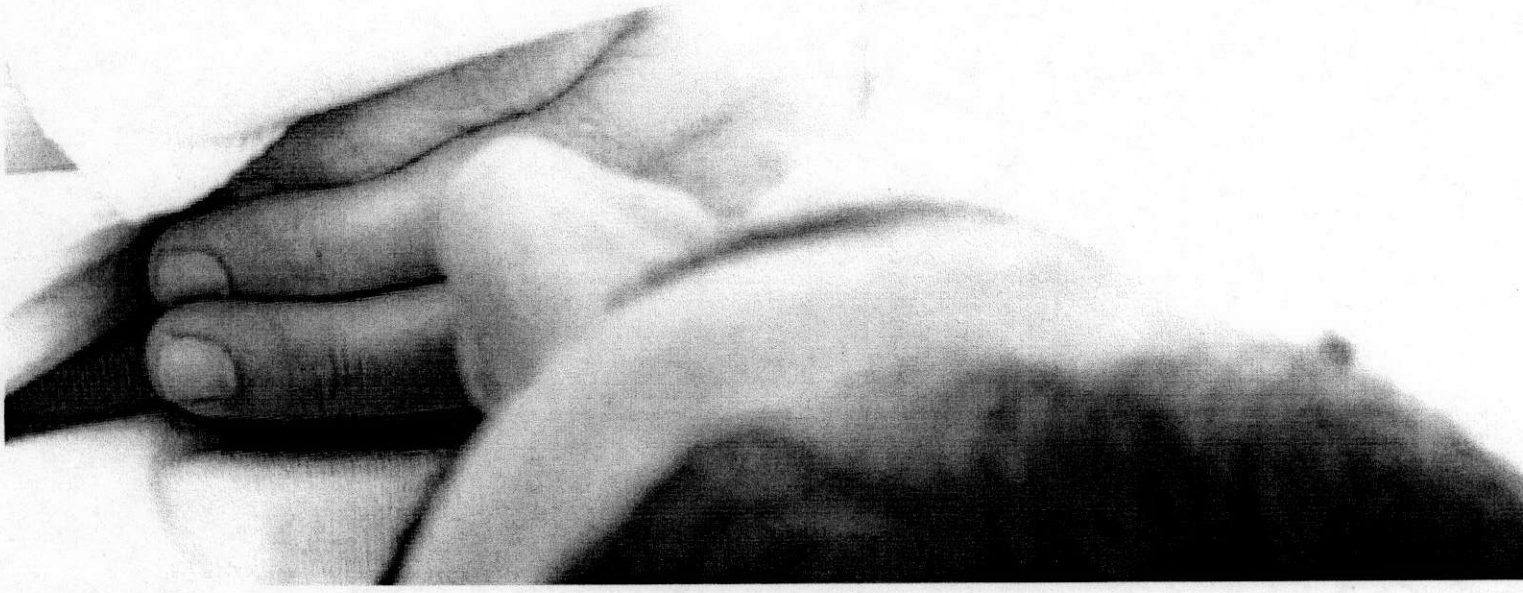
Adiana®
Permanent Contraception

Patient Information Booklet

Adiana Permanent Contraception is a procedure that works with your body to permanently prevent pregnancy.

HOLOGIC™
The Women's Health Company.

Table of Contents



This booklet is not meant to take the place of a consultation with your doctor. Your doctor can explain the benefits and possible risks of the procedure, and help you decide if Adiana Permanent Contraception is right for your specific personal and medical needs.

It's permanent

It's safe

It's effective

It requires no incisions

It uses no hormones or drugs

It's a simple procedure with a quick recovery

It leaves nothing in the uterus that might limit future gynecologic procedures

BIRTH CONTROL Preventing or lessening the likelihood of becoming pregnant.

CERVIX The narrow end of the uterus which has a small opening that connects the uterus with the vagina.

CONTRACEPTION The prevention of pregnancy by the use of birth control devices or agents.

CONTRAST FLUID The dye used in the Adiana HSG (hysterosalpingogram) Confirmation Test to confirm that the fallopian tubes are blocked.

DELIVERY CATHETER A slender, flexible instrument that helps the doctor place the Adiana inserts in each fallopian tube.

ECTOPIC PREGNANCY A pregnancy in which the fertilized egg does not implant in the uterine wall (usually in the fallopian tube, the ovary, cervix or the abdominal cavity).

ENDOMETRIAL ABLATION Procedure that controls heavy bleeding by removing the lining of the uterus.

FALLOPIAN TUBES Tubes through which an egg travels from the ovary to the uterus.

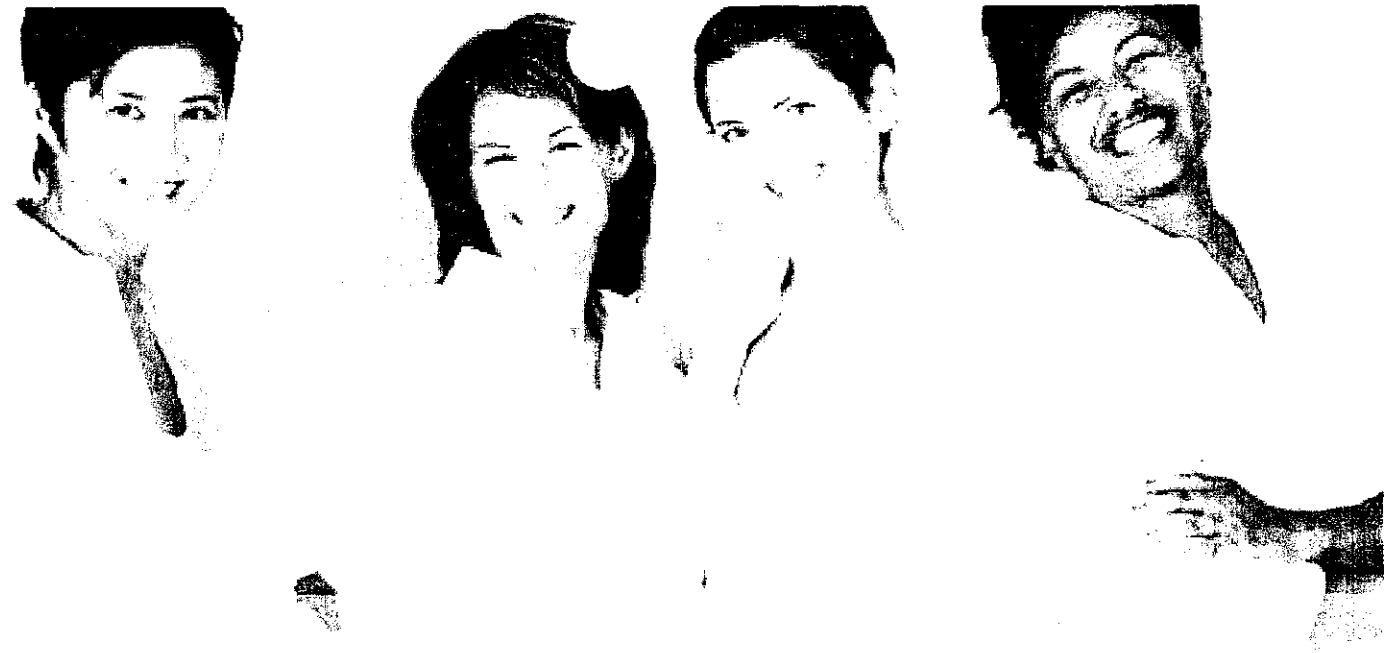
FERTILITY The ability to become pregnant through normal sexual activity.

GENERAL ANESTHESIA A drug given during surgery that acts primarily on the brain, resulting in a temporary loss of consciousness.

GYNECOLOGIC Relating to the diagnosis and treatment of disorders affecting the female reproductive organs. Also can refer to the routine medical care of the female reproductive tract.

HYSTEROSALPINGOGRAM (HSG) X-ray of the uterus and fallopian tubes. This test is used to confirm that the fallopian tubes are blocked after the Adiana procedure.

HYSTEROSCOPE A device that allows a doctor to see inside the uterus.



IMMUNOSUPPRESSIVE MEDICINES Drugs that inhibit or suppress the immune system.

INCISION A cut or a wound made by cutting with a sharp instrument.

LOCAL ANESTHETIC Medicine applied to the skin or given by injection that prevents the sensation of pain.

OVARIES The female organs that produce eggs and female hormones.

OVULATION The phase of the female monthly cycle when an egg is released from the ovary into the fallopian tube for possible fertilization.

PELVIC INFECTION An infection in the female reproductive tract.

PERFORATE Puncture (or create a hole).

PERMANENT CONTRACEPTION A procedure that prevents pregnancy for the rest of your life.

RADIOFREQUENCY ENERGY Energy that is delivered through the use of radio waves.

REVERSIBLE Capable of being "undone".

SILICONE A material used in many medical products, including surgical implants and dental impression materials.

STERILIZATION The process of permanently preventing pregnancy.

SUPERFICIAL LESION For the purposes of this information booklet this term is defined as "mild damage to surface tissue caused by applying heat".

TEMPORARY CONTRACEPTION A reversible process or method used to prevent pregnancy.

TUBAL LIGATION Permanent form of birth control in which a woman's fallopian tubes are surgically cut, tied, or burned to prevent pregnancy.

UTERUS The female organ in which a fetus grows, also known as the womb.

VAGINA The female organ that begins on the outside at the vaginal opening and extends about three to five inches inside, ending at the cervix.

VASECTOMY Permanent male sterilization in which the vas deferens (tubes that carry sperm) are cut, tied, cauterized (burned or seared) or otherwise permanently interrupted.

What is Adiana Permanent Contraception?

Adiana Permanent Contraception is a simple, safe procedure that works with your body to permanently prevent pregnancy.

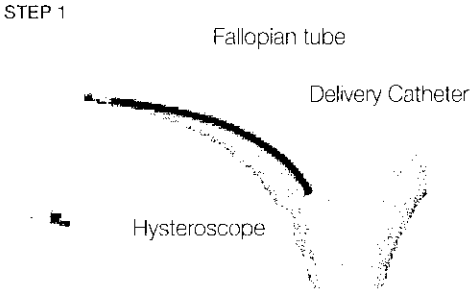
This procedure requires no incisions and can be performed under local anesthesia, usually in less than 12 minutes.

The tiny, soft Adiana insert measures 3.5mm in length, about the size of a grain of rice.

Here are the four steps of the Adiana procedure:

STEP 1: A slender, flexible instrument (delivery catheter) is passed through the body's natural openings (i.e., through the vagina and cervix and into the uterus) to deliver a low level of radiofrequency energy (i.e., energy that generates heat to create a superficial lesion) to a small section of each fallopian tube.

STEP 1



STEP 2: A tiny, soft insert - about the size of a grain of rice - is placed in each of your fallopian tubes, right where the energy was applied.

STEP 2

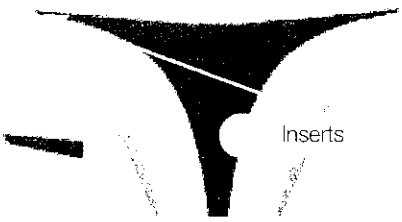
STEP 3: You must use another form of birth control over the next 3 months, while new tissue grows in and around the Adiana inserts, eventually blocking your fallopian tubes.

STEP 3

STEP 4: At 3 months, a special test is performed (hysterosalpingogram or HSG) to confirm that your tubes are completely blocked. This test will ensure that the procedure has been successful.

Your ovaries will continue to release eggs, however, these eggs cannot be fertilized since your fallopian tubes are completely blocked. Your unfertilized eggs will break down and be absorbed by your body.

STEP 4



If you are absolutely sure that you never want to have any children in the future, and would like the certainty and convenience of permanent birth control, then the Adiana procedure may be right for you.

Adiana Permanent Contraception isn't right for everyone.
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 and 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 HSG Confirmation Test). You have to use an alternate form of birth control until you have confirmation that your tubes are 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 be certain that you want to end your fertility before undergoing the procedure.

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 recently have 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.

It's permanent.

Unlike temporary methods of birth control such as birth control pills, diaphragms, condoms, and spermicides, the Adiana procedure is permanent. Once your doctor confirms that your fallopian tubes are completely blocked you will no longer have to rely on a temporary method of birth control.

No incisions.

The Adiana procedure avoids the risks and discomforts of more invasive surgical procedures. There are no incisions and no general anesthesia. The tiny, soft inserts used are made of medical-grade silicone, a material long known to be safe in the human body.

It's effective.

Adiana Permanent Contraception is 98.4% effective in preventing pregnancy* once your doctor confirms that your fallopian tubes are completely blocked. No method is 100% effective.

* *Based on 3 years of clinical data.*

There is, however, a small chance that your doctor will not be able to place the Adiana inserts in one or both fallopian tubes or that one or both tubes will not be completely blocked, at which point you will be told that you cannot rely on the Adiana inserts for permanent contraception (see page 11 for more information).

Quick recovery.

With no incisions to heal and no recovery time from general anesthesia, most women return to their normal activities within a day, and report little or no discomfort.

Uses no drugs or hormones.

The Adiana inserts do not use drugs or hormones that can disrupt your menstrual cycle or affect your natural body chemistry.

Leaves nothing in your uterus.

The Adiana inserts are completely contained inside the fallopian tubes leaving nothing in your uterus that might limit your options for future gynecologic tests or procedures.

Are there any potential risks with Adiana Permanent Contraception?

As with all medical procedures, there are some things to consider before deciding on the Adiana procedure. You should know what the following warnings, precautions, and risks are, and carefully discuss them with your doctor.

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 so 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 fallopian tubes are completely blocked, there is a 1.6% chance that the procedure will fail to prevent pregnancy*. There is a small chance that you will not be able to rely on the Adiana inserts for permanent contraception (see page 11 for more information).

** Based on 3 years of clinical data.*

- If you 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 of 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 and 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 (hysterosalpingogram), your doctor confirms that your tubes are completely blocked and the procedure has been successful.
- Three months after the Adiana procedure, you will need to have a special x-ray test called an Adiana HSG. This test will determine if your tubes are completely blocked.

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

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

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

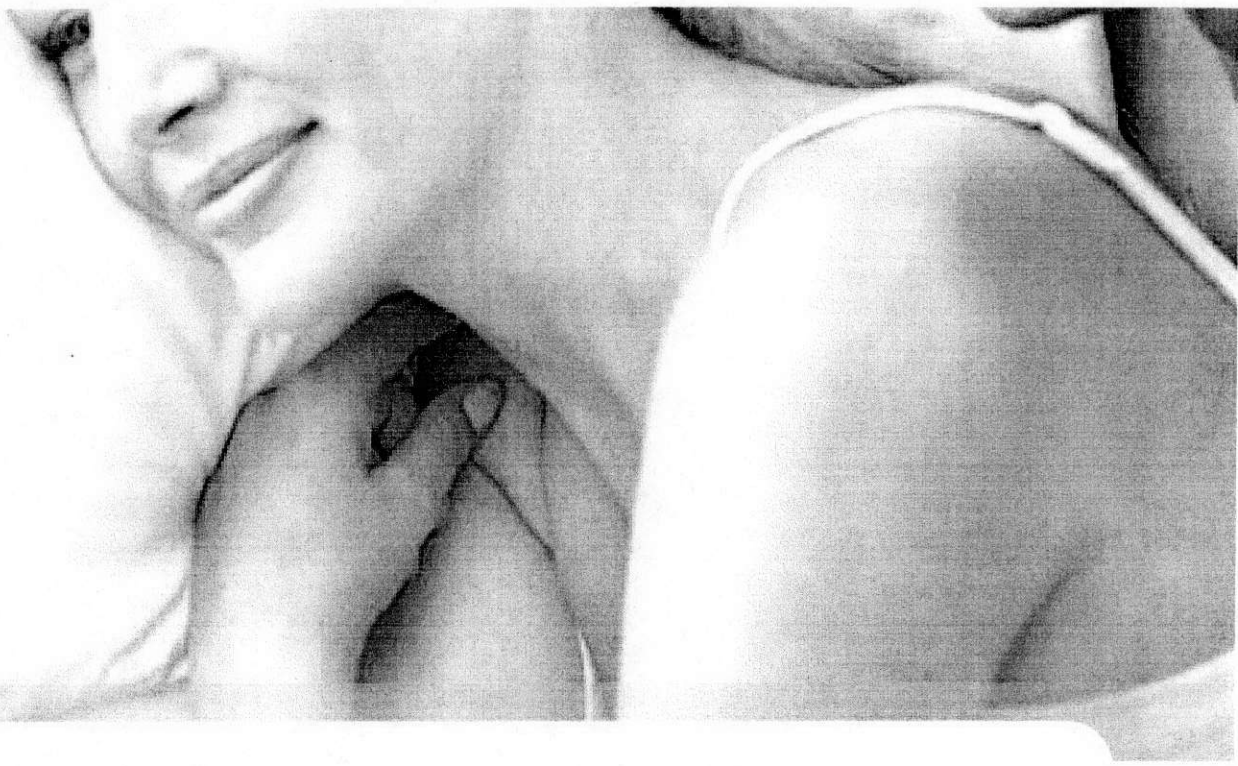
- In the clinical study of 645 women, the silicone inserts were placed in both fallopian tubes in 95% of the women. Thirty-four women (5%) could not have the silicone inserts placed in one or both fallopian tubes and could not rely on the Adiana inserts for permanent contraception.
- In the clinical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

Additional warnings, precautions, and risks

- Women who 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 of 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 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 this 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 result in shortness of breath.
- 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 this should occur, laparoscopic or other surgery could be needed to remove the inserts. Also, another type of tubal sterilization procedure may be needed for permanent contraception.
- Anesthetics are medicines that may be used to reduce pain during the procedure. There are risks associated with the use of any medicines, even local anesthetics. Please 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 the following symptoms during or immediately after the procedure:

26% of women experienced mild to moderate cramping	12% of women experienced vaginal spotting
10% of women experienced post-procedure bleeding	9% of women experienced pelvic pain
8% of women experienced back pain	5% of women experienced nausea

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



- 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:

Cramping unrelated to menstrual periods (6%)	Painful menstruation (5%)
Vaginal bleeding (4%)	Pelvic pain (3%)
Back pain (3%)	Vaginal spotting (1%)
Painful sexual intercourse (1%)	Headache (1%)
Unusually heavy or long-lasting menstrual periods (1%)	Nausea (1%)

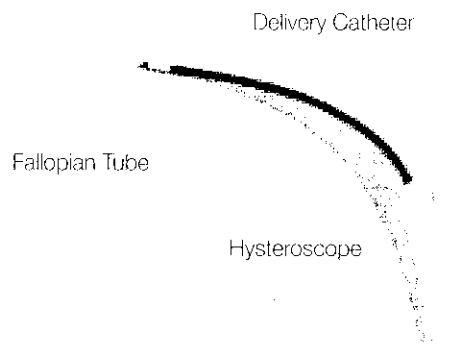
- There are certain risks associated with the Adiana HSG. This test is necessary to confirm that the fallopian tubes are completely blocked. These risks may include infection, spotting, allergic reaction to the dye (contrast fluid), and exposure to low levels of radiation. Please ask your doctor about these and other risks associated with the Adiana HSG.
- No women in the clinical trial had allergic reactions to the Adiana inserts, and no women had their inserts removed because of pain.

Before the procedure

- The procedure should only be scheduled during the first half of your menstrual cycle, before you ovulate, to reduce the risk that you might be pregnant and not know it. Your doctor will give you a pregnancy test before the procedure to confirm that you are not pregnant.
- You may be given an anti-inflammatory medicine to take an hour or two before the procedure, to reduce discomfort.

During the procedure

- Your doctor may inject a local anesthetic into the entrance of your uterus (cervix). No general anesthesia is required, so you will be awake during the procedure.
- A slender telescope-like instrument called a hysteroscope is inserted into your vagina and passes through the cervix and into the uterus. It lets the doctor see inside your uterus and see the openings of your fallopian tubes. To make this possible, your uterus will be expanded with fluid, so you may experience some cramping.
- Next, a narrow, flexible tube, called the delivery catheter, is passed through the hysteroscope and into your fallopian tube. Your doctor will ask you to lie still for 60 seconds while a low level of radiofrequency energy is applied. This will create a superficial lesion to a small section inside the fallopian tube.
- After the energy is applied, the delivery catheter places a tiny, soft insert in the area. This soft insert is made of silicone, and is about the size of a grain of rice.
- The procedure is then repeated in the other fallopian tube and the instruments are removed. The entire procedure usually takes less than 12 minutes.

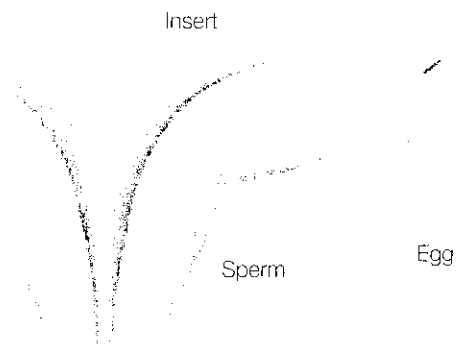


Right after the procedure

- Before you leave the doctor's office, you will receive discharge instructions. These instructions typically include the following information:
    - o After the procedure, you may experience mild cramping, very similar to menstrual cramps. Most women will be able to take an over-the-counter pain medicine to relieve any cramping or mild pain.
    - o Spotting or light bleeding is normal after the procedure. If you have heavy bleeding, serious pain, fever or vaginal discharge, call your doctor immediately.
    - o You must use an alternate form of birth control for the next 3 months. It is very important not to have unprotected intercourse until you receive the results of the Adiana HSG, confirming that your tubes are completely blocked, and you can no longer become pregnant.
- Please be sure to check with your own doctor to find out what your specific discharge instructions are.
- Most women in the clinical study reported only slight or moderate discomfort after the procedure. 90% of these women returned to their normal activities within one day or less after the procedure, and 98% within two days. 99% of these women rated their comfort level as "good" to "excellent" within one week of the procedure.

The 3 months following the procedure

- Over the next 3 months, your body goes through a natural healing process. In the area where the energy was applied, new tissue will begin to grow through the inserts. After 3 months, this tissue should completely block your fallopian tubes.
- During this 3-month healing time, you are still fertile. It is very important that you use another form of birth control during this time.
- At the end of 3 months, you will have a special x-ray test called an Adiana HSG (hysterosalpingogram). During the Adiana HSG, your uterus is filled with a contrast fluid, which is a dye that shows up in x-rays. Several x-rays are then taken of your uterus. Your doctor will study the images to make sure that the dye stops in the uterus and does not enter the fallopian tubes. This is how your doctor will know if your tubes are completely blocked.
- After your Adiana HSG is completed and your doctor confirms that your tubes are completely blocked, you can rely on Adiana Permanent Contraception for birth control.



Remember, the Adiana procedure is permanent and cannot be reversed. The new tissue blocking your fallopian tubes is expected to prevent pregnancy for the rest of your life.

Will I need to use any other birth control after 3 months?

After your Adiana HSG confirms that your tubes are completely blocked, you will not need to use any other form of birth control. Adiana Permanent Contraception is among the most effective forms of permanent contraception, with a 98.4% effectiveness rate for preventing pregnancy, based on 3 years of clinical data. This is comparable to tubal ligation (having your tubes tied).

What remains in my body after the Adiana procedure?

The only foreign material remaining after the procedure are 2 tiny, soft inserts. They are made of medical-grade silicone—a material used safely for many years in devices inside the body. Since the Adiana inserts don't contain metal, they won't present a problem for women who may be allergic to some metals. Since no part of the insert protrudes into the uterus, it is less likely to limit your options if gynecologic tests or procedures are needed in the future.

Will my periods stay the same?

Since the Adiana inserts do not contain any hormones, they don't affect your natural body chemistry, and your periods should return to the way they were before the procedure.

If heavy periods are a problem for you, staying on birth control pills or hormones is not the only option you have to control your bleeding. There is a safe and effective procedure you may want to discuss with your doctor called endometrial ablation. This is a treatment for the lining of the uterus that stops heavy bleeding (or may even stop your periods altogether), without hormones. If you choose the Adiana procedure for permanent contraception, you may also be able to have endometrial ablation at a later date to control your bleeding.

Will having Adiana cause early menopause?

No. After the Adiana procedure, your ovaries will still release eggs, and you will continue to have your period as usual. Your unfertilized eggs will break down and be absorbed by your body. You will, of course, go through menopause eventually — but not until it's your natural time to do so.

A note about ending your fertility.

Making a decision to end your fertility is complex, and deeply personal. If you know that you don't want more children right now, but think you could change your mind in the future, then do not choose permanent contraception. Use a temporary form of contraception instead.

If you do choose Adiana, but start to have doubts at any time before the procedure takes place, then just cancel the appointment. It's that simple. You will not need to give any reason for changing your mind.

Understanding Your Options

When considering a procedure like Adiana Permanent Contraception, it is important for you to consider other birth control options, including permanent and temporary methods. The tables on the pages to follow provide information on various permanent and temporary birth control methods.

Questions for your doctor

1. Is Adiana Permanent Contraception a good choice for me?
2. When will my Adiana procedure be performed?
3. Where will I have the procedure performed?
4. What do I need to do to prepare for the procedure?
5. What type of anesthetic will be used during the procedure?
6. What can I expect after the procedure?
7. Can I keep using my current method of birth control for the 3 months after the procedure?
8. Will my appointment for my Adiana HSG be made for me before I leave your office after the procedure?
9. Are there any special risks I need to be aware of?

Permanent Contraception Methods

Adiana Permanent Contraception: A minimally invasive procedure that provides protection from pregnancy. It works by stimulating your body's own tissue growth around tiny, soft inserts placed inside your fallopian tubes.

Benefits/Advantages	Risks/Disadvantages	Failure Rate
One-time, permanent procedure Procedure makes no cuts through the skin, leaves no scars General anesthesia not required Most women return to their normal activities within a day Does not involve hormones	Post surgical pain/discomfort, risk of infection Not all women are candidates for the Adiana procedure Some risk of ectopic pregnancy No protection from STDs Risks associated with anesthesia	1.1%[1]

Tubal ligation: A surgical procedure that cuts through the abdomen to reach the fallopian tubes, which are then sealed off to prevent pregnancy. Also known as "having your tubes tied" or "female sterilization"

Benefits/Advantages	Risks/Disadvantages	Failure Rate
One-time, permanent procedure No need for temporary birth control afterwards Does not involve hormones	Post-surgical pain/discomfort, risk of infection Risks associated with general anesthesia Recovery time Some risk of ectopic pregnancy No protection from STDs	0.5%[2]

Vasectomy: A surgical procedure for men where an incision is made into the scrotum, and each tube that carries sperm out of the testes is sealed or blocked. Afterwards, a man can still achieve orgasm and ejaculate, but there is no sperm in the fluid, so it cannot fertilize a woman's egg.

Benefits/Advantages	Risks/Disadvantages	Failure Rate
One-time, permanent procedure Does not involve hormones	Post-surgical pain/discomfort, bleeding, risk of infection No protection from STDs	0.15%[2]

Temporary Contraception Methods

Oral Contraceptives (Birth control pills): Daily pill that either contains the hormones estrogen and progestin, or progestin only.

Benefits/Advantages	Risks/Disadvantages	Failure Rate
More predictable menstrual cycle May reduce menstrual bleeding in some women	Hormone side effects may include abdominal pain, acne, back pain, weight gain, breast tenderness, moodiness Increased risk of blood clots, heart attack and stroke. Risks are increased in women over age 35 who smoke Must be taken every day at a certain time No protection from STDs	8%[2]

Copper IUD: T-shaped copper device that is inserted into the uterus by a healthcare professional.

Benefits/Advantages	Risks/Disadvantages	Failure Rate
Long-term protection from pregnancy (up to 10 years, depending on type) Reversible at any time by removing No hormones	Risk of heavier/longer menstrual bleeding, cramps Risk of pelvic inflammatory disease Increased risk of ectopic pregnancy Risk of expulsion (the device becoming dislodged) No protection from STDs	0.8%[2]

IUC (LNG-IUS Mirena™): T-shaped plastic device inserted into the uterus that releases the hormone progestin, inserted by a healthcare professional. For use in women who have had a baby.

Benefits/Advantages	Risks/Disadvantages	Failure Rate
Long-term protection from pregnancy (up to 5 years) Reversible at any time by removing Hormones delivered locally, not systemically May result in lighter menstrual bleeding	Hormone side effects may include abdominal pain, acne, back pain, breast tenderness, moodiness Risk of irregular menstrual bleeding Risk of spotting between periods Higher risk of ectopic pregnancy Risk of expulsion (the device becoming dislodged) No protection from STDs	0.2%[2]

Patch (OrthoEvra™): Skin patch that releases the hormones estrogen and progestin only. A new patch is applied once a week for 3 consecutive weeks, and left off for one week per month.

Benefits/Advantages	Risks/Disadvantages	Failure Rate
Convenience Applied only once a week	Visibility May fall off, increasing risk of pregnancy Forgetting to change patch on correct day requires use of backup contraception Side effects may include nausea, skin irritation, breast tenderness, and mood swings Increased risk of blood clots, heart attack and stroke. Risks are increased in women over age 35 who smoke No protection from STDs	8%[2] (less effective in women who weigh more than 198 pounds)

Temporary Contraception Methods (Continued)

Implant (Implanon™): A small stick that releases the hormone progestin. It is inserted just under the skin of the upper arm by a healthcare professional and left in place for up to 3 years.

Benefits/Advantages	Risks/Disadvantages	Failure Rate
Long-term protection from pregnancy (up to 3 years) Reversible at any time by removing	Side effects may include irregular periods, weight gain, acne, headaches No protection from STDs	0.05%[2] (May be less effective in women who are very overweight)

Vaginal Ring (NuvaRing™): A flexible plastic ring inserted into the vagina once a month, slowly releasing the hormones estrogen and progestin.

Benefits/Advantages	Risks/Disadvantages	Failure Rate
Inserted only once a month	Side effects of ring may include vaginal infections, irritation Hormone side effects may include abdominal pain, acne, back pain, breast tenderness, moodiness Increased risk of blood clots, heart attack and stroke. Risks are increased in women over age 35 who smoke Risk of ring falling out. If it remains out for more than 3 hours, must use backup contraception No protection from STDs	8%[2]

Hormone shot (Depo-Provera™ injection): An injection of the hormone progestin given every 3 months.

Benefits/Advantages	Risks/Disadvantages	Failure Rate
Only needed once every 3 months May lessen menstrual bleeding	Hormone side effects may include irregular periods, spotting, weight gain, breast tenderness, headaches Prolonged use may result in bone loss—therefore not recommended for use for more than 2 years Possible delayed return to fertility after stopping the injections No protection from STDs	3%[2]

Male condom (latex): Disposable latex sheath placed on penis.

Benefits/Advantages	Risks/Disadvantages	Failure Rate
Best protection from STDs No hormones	May break Can only be used once Risk of allergic reactions	15%[2]

Temporary Contraception Methods (Continued)

Diaphragm w/ spermicide: Flexible, dome-shaped rubber cup used to cover the cervix. Spermicide is applied before insertion into the vagina. Must be fitted by a healthcare professional.

Benefits/Advantages	Risks/Disadvantages	Failure Rate
No hormones	Must be inserted correctly Must be left in place at least 6 hours after intercourse Additional spermicide must be used for repeated intercourse Risk of toxic shock syndrome if not removed within 24 hours No protection from STDs	16%[2]

Female condom: Similar to a male condom, inserted into vagina with a flexible ring at the closed top.

Benefits/Advantages	Risks/Disadvantages	Failure Rate
Some protection from STDs No hormones	Can only be used once Risk of allergic reactions May extend outside of vagina	21%[2]

Spermicide alone: A foam, cream, jelly, suppository, or film that contains nonoxynol-9, an ingredient that kills sperm.

Benefits/Advantages	Risks/Disadvantages	Failure Rate
Only used when needed	Less effective May cause irritation, allergic reactions, or urinary tract infections No protection from STDs	29%[2]

1 1-year pregnancy rate based on Adiana pivotal clinical trial data

2 1-year, typical use pregnancy rates (Adapted from: Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. Contraceptive Technology: Nineteenth Revised Edition. New York NY: Ardent Media, 2007.)

I'd like to learn more about Adiana Permanent Contraception. What's next?

- **Talk to your doctor**
  Your doctor can explain the various options for permanent contraception, and help you decide if Adiana Permanent Contraception may be right for you.
- **Visit www.adiana.com**
  Online information is also available for Adiana Permanent Contraception.

Adiana

Adiana Procedure	HSG Confirmation Test
Date:_____	Date:_____
Time:_____ AM/PM	Time:_____ AM/PM

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