



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



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Hysterosalpingography (HSG) for Adiana Permanent Contraception

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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

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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-cannulization 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 an optional-use split introducer sheath and obturator.

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).

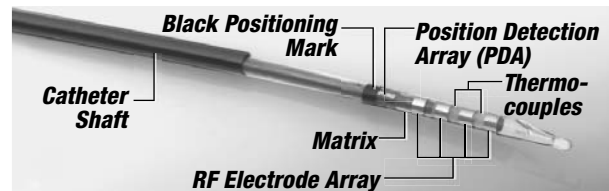


FIGURE 2: Catheter Tip (Detailed View)

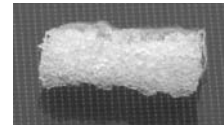


FIGURE 3: Matrix

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 six weeks 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

WARNING: Pregnancies (including ectopic pregnancies) have been reported among women with the Aadiana tubal implants (matrices) in place. Some of these pregnancies were due to patient non-compliance, which included failure to:

- use alternate contraception during the 3-month “waiting period” prior to confirmatory HSG;
- return for the confirmatory HSG to determine whether tubal occlusion is present; and
- use alternate contraception or undergo sterilization by another method if the confirmatory HSG reveals tubal patency. In this case, the clinician should inform the patient of the confirmatory HSG finding and counsel her not to rely on the Aadiana System for contraception.

Therefore, it is critical that clinicians properly counsel patients regarding the risk of pregnancy (including ectopic pregnancy) attributable to non-compliance during all stages of the Aadiana procedure.

WARNING: Physicians performing the Aadiana procedure must adhere to the confirmatory HSG protocol in the Aadiana Instructions for Use. The protocol for interpretation of the Aadiana confirmatory HSG is different from a standard HSG for infertility. In addition to patient non-compliance, incorrect interpretation of the confirmatory HSG has led to pregnancy with the Aadiana System.

- To allow for expected post-pregnancy anatomic changes, placement of the Aadiana matrices should be delayed a minimum of 6 weeks after delivery/termination. If involution appears to be delayed at any time prior to 12 weeks after delivery/termination, the clinician should consider waiting until 12 weeks post-pregnancy before placing the Aadiana matrices. The pivotal clinical trial of Aadiana required a minimum 12-week interval between the end of a pregnancy and the Aadiana procedure.
- Patients must use alternative contraception for at least three months post treatment and until bilateral tubal occlusion is confirmed by HSG.
- The Aadiana procedure should be considered irreversible. There are no data on the safety or effectiveness of reversing the procedure through surgery.
- The Aadiana 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 Aadiana RF treatment and matrix placement procedures. Ablation may cause intrauterine synechiae, which could compromise the results of the three-month Aadiana HSG. If bilateral tubal occlusion is not confirmed during this HSG, the patient cannot rely on Aadiana Permanent Contraception for pregnancy prevention.

- This product does not protect against HIV infection or other sexually transmitted diseases.
- Nonionic hysteroscopic distension 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 Aadiana 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.

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- 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 distension 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.

TABLE 5: Contraceptive Failure Rates

	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.

TABLE 6: Pregnancy Rates for Birth Control Methods (For One Year of Use)

Method	Typical Use* Rate of Pregnancy
Sterilization	
Male Sterilization	0.15%
Female Sterilization	0.5%
Hormonal Methods	
Implant (<i>Implanon</i> ®)	0.05%
Hormone Shot (<i>Depo-Provera</i> ®)	3%
Combined Pill and Progestin-Only Pill	8%
Vaginal Ring (<i>NuvaRing</i> ®)	8%
Patch (<i>Ortho Evra</i> ®)	8%
Intrauterine Devices (IUDs)	
Copper T	0.8%
LNG-IUS	0.2%
Barrier Methods	
Male condom (<i>used without spermicide</i>)	15%
Female condom	21%
Diaphragm (<i>used with spermicide</i>)	16%
Spermicides: (<i>foams, creams, gels, suppositories, films</i>)	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
- Nonionic hysteroscopic distension medium (e.g., 1.5% Glycine, 3% Sorbitol, 5% Mannitol) pre-warmed to body temperature to minimize fallopian tube spasm
- Large bore irrigation tubing
- Antiseptic swabs
- Gauze
- Sterile gloves
- Personal protective equipment (gown, eyewear, mask)
- Lithotomy drape with fluid collection pouch

Optional equipment:

- Cervical os finder
- Cervical dilation set
- Additional tenaculum
- Gimpelson tenaculum

Matrix Implantation Instructions

1. Turn on the RF generator by pushing the power switch located on the front panel.
2. The power switch illuminates to indicate the power is on.
NOTE: When the power switch is turned off in any mode, all power to the RF generator is terminated.
3. The RF generator performs an internal self test and displays the “Connect Catheter” message.
4. Employ sterile technique using universal precautions.
5. Position, prepare (prep) and drape the patient per standard practice.
6. Introduce a speculum to allow access to the cervix.
7. Prep the cervix according to standard practice. Consider numbing the cervix by applying or injecting a local anesthetic before placing the tenaculum for patient comfort.
8. Administer local anesthesia (i.e. paracervical block), with or without sedation, for procedural pain management. Allow adequate time for the local anesthetic to take effect before proceeding.
9. Perform cervical dilation only if necessary. Dilate only as much as required to insert the hysteroscope.
10. Open the inflow and outflow ports on the hysteroscope, and flush the hysteroscope of all air bubbles with the pre-warmed, nonionic, hysteroscopic distension medium (e.g., 1.5% Glycine, 3% Sorbitol, 5% Mannitol).
11. Insert the sheathed hysteroscope, with attached fiberoptic light source, camera and inflow and outflow tubing, into the uterine cavity and remove the speculum.

12. Adequate uterine distension must be achieved and maintained throughout the procedure to allow identification of and access to the fallopian tube ostia.
13. In order to reduce the risk of hypervolemia, monitor the procedure duration and total fluid volume applied.
14. The procedure should not exceed 30 minutes.
15. The procedure should be terminated if the fluid deficit exceeds 800 cc.
16. Rotate the hysteroscope to visualize and assess both tubal ostia to ensure the absence of pathology before opening the catheter package.
CAUTION: Do not use the catheter if the package is damaged or opened, or if the “Use by” date has passed.
17. Open the package and remove the catheter and split introducer sheath with obturator (optional) using sterile technique.
NOTE: Step 17 will require assistance.
18. If desired, insert the split introducer sheath with obturator into the hysteroscope working channel.
19. Connect the catheter to the connector cable on the RF generator.
NOTE: Step 19 will require assistance.
20. Verify that the RF generator display screen changes to the “Access Tube” mode and indicates “Position Catheter”.
21. Using sterile technique, carefully remove the yellow protective cap from the end of the catheter.
22. If using the split introducer sheath and obturator, remove the obturator from the split introducer sheath.
23. Gently insert the catheter into the hysteroscope working channel. If using the split introducer sheath, insert the catheter through the sheath. Remove the sheath once the catheter is in the hysteroscope working channel. Do not close the working channel port once the catheter has been inserted.
24. Visualize the tubal ostium and then use the catheter handle to guide the catheter tip into the tubal ostium.
25. Insert the catheter tip into the ostium until the black positioning mark located on the electrode sheath is at the utero-tubal junction.
26. Hold the catheter steady and slightly withdraw the hysteroscope to increase the panoramic image to visualize both the ostium and catheter shaft. This will help ensure that the catheter remains steady during the remainder of the procedure.
27. The RF generator will automatically sense the position of the catheter within the fallopian tube via the four-quadrant Position Detection Array (PDA) built into the catheter tip.

28. The PDA display on the RF generator will indicate when all four quadrants of the PDA are in contact with the fallopian tube. Figures 4 through 6 are examples of various PDA/fallopian tube contact states.

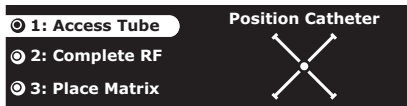


FIGURE 4: PDA senses no tubal contact

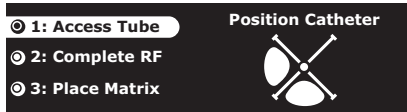


FIGURE 5: PDA senses partial tubal contact

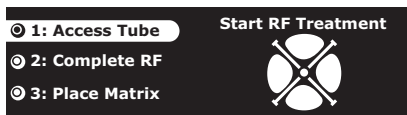


FIGURE 6: PDA senses full tubal contact

29. Once full contact with the fallopian tube is achieved, the RF generator display screen indicates “Start RF Treatment”.
30. Stabilize the hysteroscope and catheter prior to initiating RF energy delivery.

CAUTION: The hysteroscope and catheter must be held steady during the delivery of RF energy and deployment of the matrix to ensure proper matrix placement.

31. Ensure that the arm holding the hysteroscope is comfortably positioned, and stabilize the catheter within the hysteroscope by pinching the catheter between the thumb and index finger.
32. Position thumb within comfortable reach of the matrix release button to limit movement during the procedure.
33. Inform the patient that treatment will begin and that she should remain still until the procedure is completed.
34. Deliver RF energy by either pressing the RF button on the RF generator or by depressing the footswitch.

NOTE: Pressing the RF button in step 34 will require assistance.

35. The RF button illuminates to indicate RF energy is being delivered.
36. The RF generator display screen changes to the “Complete RF” mode, indicates “RF On...Hold Steady” and will count down from 60 seconds (Figure 7).

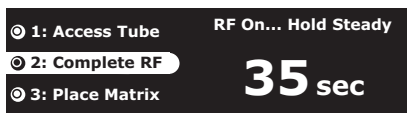


FIGURE 7

37. An audible tone will sound every five seconds during RF energy delivery.

If an error occurs during RF energy delivery, an error code will be displayed. Refer to the “Radiofrequency (RF) Generator Additional Instructions” section of the operator’s manual for a description of the error code and troubleshooting instructions.

WARNING: 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.

38. At the end of RF energy delivery, the display screen changes to the “Place Matrix” mode and indicates the “...Hold Catheter Steady” message (Figure 8).

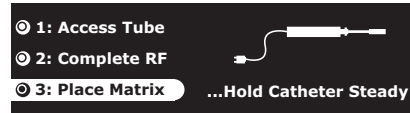


FIGURE 8

39. While ensuring that the catheter shaft and the black positioning mark are visible, press the matrix release button on the catheter handle, maintaining a steady position.
40. Upon matrix deployment, the electrode array and black positioning mark withdraw into the black shaft and a blue push rod can be seen.
41. A tone will sound indicating successful matrix deployment.
42. The RF generator display screen will indicate the “Remove and Disconnect” message (Figure 9). Matrix placement is complete. Remove the catheter from the hysteroscope.



FIGURE 9

43. Repeat the procedure on the contralateral fallopian tube with a new catheter.
44. After bilateral fallopian tube treatment, remove the hysteroscope.

Post-Treatment

Patients should be monitored and released following physician’s standard post-procedure and release methods.

Hysterosalpingography (HSG) for Adiana Permanent Contraception

- Following completion of bilateral matrix placement, the patient must use an alternate form of contraception for a minimum three-month waiting period, until bilateral fallopian tubal occlusion is confirmed by HSG.
- Only after HSG confirms bilateral tubal occlusion can the patient be advised to discontinue use of the alternate form of contraception and rely on Adiana Permanent Contraception.
- 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.

STORAGE AND HANDLING

Store catheters according to the following:

- Temperature range: -30°C to 50°C
- Humidity range: 10% to 90% RH, non-condensing

The shelf life of the catheter with matrix is one year from the date of manufacture. The “Use by” date is marked on the catheter packaging labels. Do not use product past its “Use by” date.

Handle all Adiana System components with care; improper handling can cause errors or damage.

TECHNICAL SUPPORT AND PRODUCT RETURN INFORMATION

Contact Hologic Technical Support if the Adiana catheter or RF generator fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number and biohazard kit if applicable.

Return used or opened catheters according to the instructions provided with the Hologic-supplied biohazard kit.

Return RF generators according to the instructions provided by Technical Support. Be sure to clean the RF generator before returning it and include all accessories in the box with the returned unit.

Hologic Technical Support

United States and Canada:

Phone: 1.800.442.9892 (toll-free) or 1.508.263.2900

Fax: 1.508.229.2795

SYMBOL DEFINITIONS

Symbols (Catheter and/or RF Generator)	
Caution, consult accompanying documents	
Manufacturer	
Catalogue number	
Batch code	
Serial number	
Use by	
Do not use if package is damaged	
Do not reuse	
Sterilized using steam	
Do not re-sterilize	
Temperature limitation -30°C to 50°C	
Humidity limitation 10% to 90% RH, non-condensing	
Left fallopian tube	
Right fallopian tube	
Delivery catheter (or catheter)	
Latex-free	

Symbols (RF Generator Only)	
Dangerous voltage	
Type BF equipment	
Date of manufacture	
Equipotential ground	
Fuse	
Footswitch	
Power	
Reset	
Radio frequency (RF) energy (non-ionizing radiation)	
Volume (audio speaker)	
Contrast (display screen)	
Increase (volume or contrast)	
Decrease (volume or contrast)	

Hologic, Inc.
 250 Campus Drive
 Marlborough, MA 01752
 USA
 Phone: 1.800.442.9892 (US toll-free) or 1.508.263.2900

www.adiana.com
www.hologic.com

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Hysterosalpingography (HSG) for Adiana Permanent Contraception

Hysterosalpingography (HSG) for Adiana® Permanent Contraception

This procedure should only be performed and results evaluated by physicians who are experienced in performing hysterosalpingography (HSG) and in interpreting radiographic images.

Following completion of bilateral matrix placement, the patient must use an alternate form of contraception for a minimum three-month waiting period until bilateral fallopian tube occlusion has been confirmed by HSG.

Only after bilateral tubal occlusion has been confirmed by HSG should the physician instruct the patient to discontinue use of alternate contraception and rely on Adiana Permanent Contraception for pregnancy prevention.

Precautions

- The HSG requires the infusion of enough contrast medium to sufficiently achieve and maintain adequate distension of both uterine cornua, while minimizing patient discomfort.
- The use of abrupt or excessive force during the infusion of the contrast medium should be avoided as it could potentially disrupt the implanted matrices. Rapid increase in pressure could also cause excessive uterine cramping or a vasovagal reaction, whereby the patient may experience bradycardia, lightheadedness, sweating and/or fainting.
- The implanted matrices are not radiopaque. Tubal occlusion is confirmed if the contrast medium is seen proximal to the matrix placement site and does not flow into the isthmic portion of the fallopian tube or spill into the pelvis or abdomen on fluoroscopy and still radiographs.
- Improper radiologic interpretation of the HSG could result in pregnancy.
- A patient with a patent fallopian tube(s) or an inconclusive HSG result at three months post procedure must remain on an alternative form of contraception until the HSG is repeated after an additional three-month waiting period. If tubal occlusion is not established at six months post procedure, the patient must be advised not to rely on Adiana Permanent Contraception for pregnancy prevention.

Performing the HSG

- Physicians are advised to follow their customary HSG anesthesia and analgesia protocols.
- As with any HSG procedure, to ensure optimal results only an HSG catheter should be used. Do not substitute.
- The uterine cavity with respect to the fluoroscopy beam should be as close to the P/A projection as possible.
- The speculum should be removed prior to fluoroscopy to ensure that it does not block the view of a potential spill of the contrast medium into the cul de sac.
- A good cervical seal should be maintained during the procedure to ensure proper uterine distension. Do not dilate the cervix unless necessary.
- **NOTE:** In the Adiana pivotal clinical trial (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.

- Downward traction on the cervical tenaculum may be required to optimize fluoroscopic views.
- The uterine cavity silhouette must facilitate clear visualization of the cornua.
- A minimum of six still radiographs are necessary to perform the HSG and confirm tubal occlusion (see descriptions provided below). Left or right side markers should be used to differentiate the left and right cornua in the still radiographs.

Capture an image of the pelvis immediately prior to infusion of the contrast medium into the uterine cavity (see Figure 1).

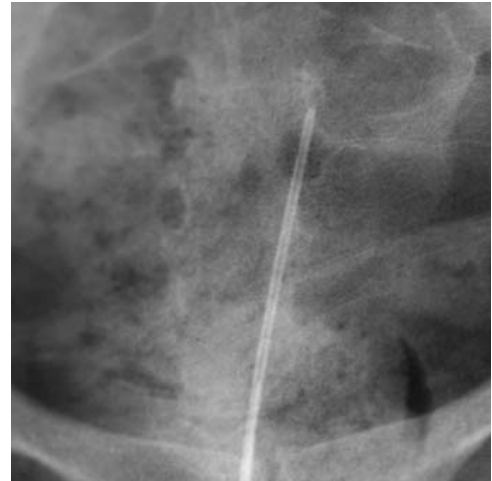


FIGURE 1: SCOUT RADIOGRAPH OF THE PELVIS

Begin to slowly infuse the contrast medium into the uterine cavity. Pay particular attention to the adequacy of the cervical seal. Ensure that the uterine cavity is in a P/A plane. If it is not, adjustment should be made by applying traction to the tenaculum and/or repositioning the patient.

Capture a minimal fill image (see Figure 2), which should demonstrate evidence of an adequate seal of the uterine cervix and the beginning of opacification of the uterine cavity. The contrast medium is not likely to have reached the uterine cornua in this radiograph.

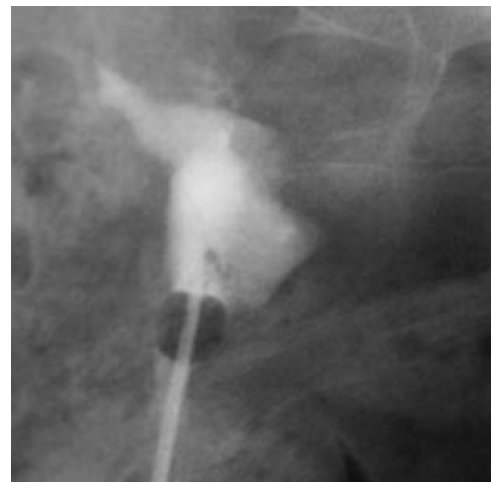


FIGURE 2: MINIMAL FILL OF THE UTERINE CAVITY

Capture a partial fill image (see Figure 3) when the uterine cavity is nearly full of the contrast medium or opacified to demonstrate filling

of the uterine cavity. The cornua may not yet have been adequately distended.



FIGURE 3: PARTIAL FILL OF THE UTERINE CAVITY

PRECAUTION: Avoid the use of abrupt or excessive force during the infusion of the contrast medium to produce the total fill image (see Figure 4), as it could potentially disrupt the implanted matrices. Rapid increase in pressure could also cause excessive uterine cramping or a vasovagal reaction.

Resistance on the plunger of the syringe is typically felt after infusing one or two milliliters of contrast medium, as long as an appropriate seal of the cervix has been achieved. If the cornua are opacified there is no need to continue depressing the plunger of the syringe. Maintain slight resistance on the plunger to ensure adequate cornual distension. Alternatively, cornual distension can be maintained by using a tenaculum to apply traction to the cervix.

Capture the total fill image (see Figure 4) when the uterine cavity is completely filled and each cornu distended, or to patient tolerance, whichever comes first. This image should provide clear visualization of the uterine cornua.

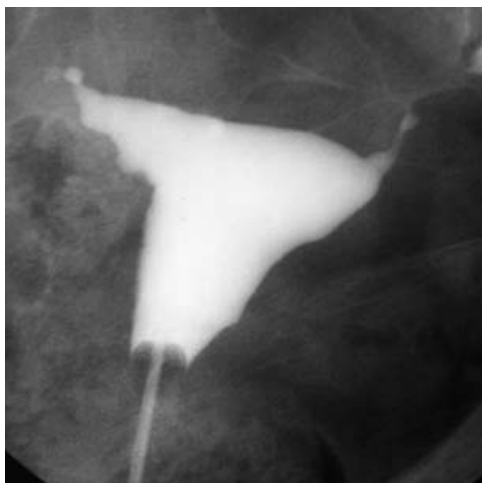


FIGURE 4: TOTAL FILL OF THE UTERINE CAVITY

Reposition the patient to obtain left and right oblique images (see Figures 5 and 6). This should improve the viewing angle, potentially optimizing visualization of the left and right cornua.

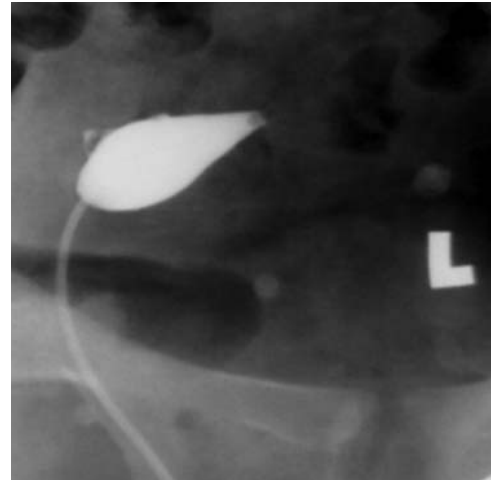


FIGURE 5: LEFT OBLIQUE IMAGE

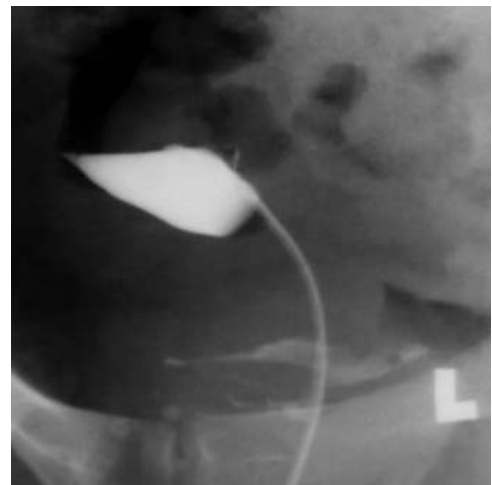


FIGURE 6: RIGHT OBLIQUE IMAGE

Evaluating the HSG

PRECAUTION: A patient with a patent fallopian tube(s) or an inconclusive HSG result at three months post procedure must remain on an alternative form of contraception until the HSG is repeated after an additional three-month waiting period. If tubal occlusion is not established at six months post procedure, the patient must be advised not to rely on Adiana Permanent Contraception for pregnancy prevention.

When evaluating the HSG it is important to confirm that the radiographs described above are provided and the cornua are clearly visualized on at least one image. The HSG will need to be immediately repeated if:

- The projection of the uterine cavity silhouette is fundal rather than P/A.
- The appropriate sequence of radiographs has been captured, but one or both uterine cornua are not clearly visualized.
- The appropriate sequence of radiographs was not taken and/or the uterine cornua are not clearly visualized or are otherwise obscured, making evaluation impossible or equivocal.

The Adiana matrix is delivered into the intramural portion of the fallopian tube and is located approximately 10 mm into the tube.

NOTE: The matrix is not radiopaque.

The following figures depict the implanted matrix location (Figure 7) and the HSG image (Figure 8):

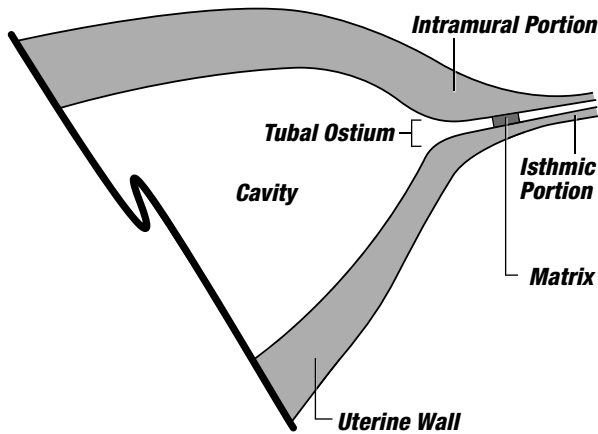


FIGURE 7: IMPLANTED MATRIX LOCATION

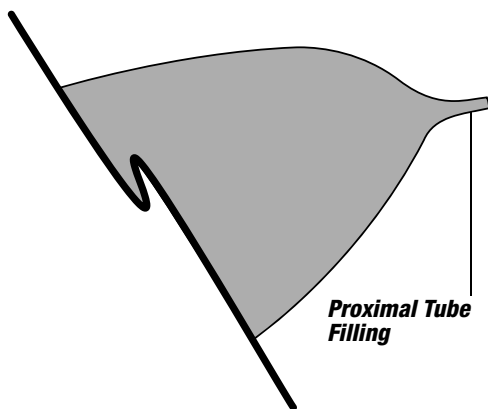


FIGURE 8: HSG IMAGE

Confirming Tubal Occlusion

Tubal occlusion is confirmed by verifying that there is a total blockage of contrast medium in the fallopian tube at, but not beyond, the implanted matrix. There should be no evidence of a flow of contrast medium within the isthmic portion of the fallopian tubes nor spill of contrast medium into the pelvis or abdomen.

Only after unequivocal tubal occlusion has been determined at the time of fluoroscopy and confirmed with still radiographs should the physician instruct the patient to discontinue use of alternate contraception and rely on Adiana Permanent Contraception for pregnancy prevention.



Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752
USA
Phone: 1.800.442.9892 (US toll-free) or 1.508.263.2900

www.adiana.com
www.hologic.com

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Radiofrequency (RF) Generator Additional Instructions

Radiofrequency (RF) Generator

Additional Instructions

RF Generator Warnings

- Explosion hazard. Do not use the RF generator in a flammable atmosphere or where concentrations of flammable anesthetics may occur.
- There is a potential to ignite endogenous gases.
- For patients with cardiac pacemakers or other active implants, a possible hazard exists due to interference that may damage the pacemaker or other active implants. Consult the respective manufacturer(s) for further information when the use of Aadiana Permanent Contraception is intended.
- Do not position the patient in direct contact with the RF generator or catheter cables.
- Do not position the patient in direct contact with grounded metal objects (e.g., surgical table frame, instrument table, etc.) during RF energy delivery.
- Do not use needle monitoring electrodes during the Aadiana procedure.
- Do not remove the cover of the RF generator as this would present an electrical shock hazard.
- Do not obstruct the activation light or disable the audible tone, as they are important safety features.
- Do not wrap the instrument cable around metal objects, as this may induce hazardous currents.
- Failure of the RF generator could result in an unintended increase in power output.
- Use of monitoring systems incorporating high frequency current-limiting devices is recommended.
- The Aadiana System is intended to be used with a hysteroscope; therefore, patient leakage currents may be additive. Also, care must be taken to avoid potential safety hazards that could result from the use of the hysteroscope with the Aadiana System. Refer to hysteroscope instructions for use for proper operation of the hysteroscope, including any applicable warnings or precautions.

RF Generator Precautions

To avoid potential damage to or malfunction of the RF generator:

- Avoid direct contact with any activated monopolar device during use of the Aadiana System.
- The voltage selector and the power entry module must be set to the same voltage to prevent malfunction of and potential damage to the RF generator. The voltage selector is factory set and should not be changed by the user.
- Connect the mains power cord of the RF generator to a properly grounded receptacle. Do not use extension cords and/or adapter plugs.
- Use only Aadiana catheters with the RF generator.
- Use only the power cord, footswitch and connector cable provided with the RF generator, and inspect them regularly for damage. The use of any cables or accessories other than those specified in these instructions may result in increased emissions or decreased immunity of the RF generator.
- The RF generator must be installed and put into service according to the guidance provided in these instructions to ensure its electromagnetic compatibility. Refer to the Electromagnetic

Emissions and Immunity tables in the Technical Specifications section.

- The RF generator has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
 - Reorient or relocate the receiving device.
 - Increase the separation between equipment.
 - Connect the equipment into an outlet on a circuit different from that to which the other device(s) is/are connected.
 - Contact Hologic Technical Support (or the manufacturer of the other equipment) for assistance.
- The RF generator should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the RF generator should be observed to verify normal operation in the configuration in which it will be used.
- Portable and mobile RF communications equipment can affect the RF generator. Refer to the Electromagnetic Immunity tables in the Technical Specifications section for recommended separation distances.
- Do not submerge electrical components or connections in water.
- Avoid subjecting RF generator components to extreme hot or cold temperatures. Refer to Environmental Specifications section.
- Contact Hologic Technical Support for RF generator service.

RF Generator Features

Front Panel: Contains control buttons, a display screen and a connector cable receptacle (refer to Figure 1 and Table 1).

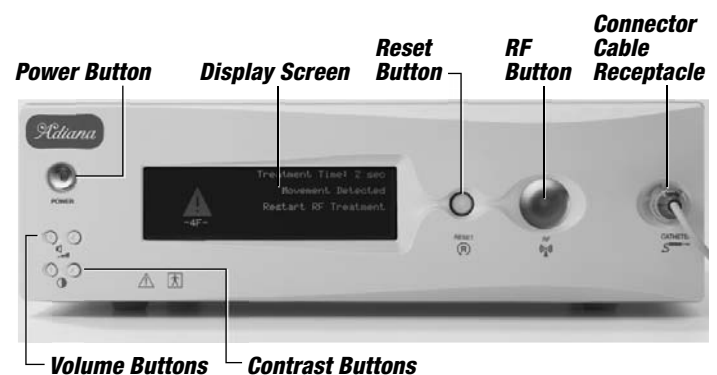


FIGURE 1: RF GENERATOR FRONT PANEL






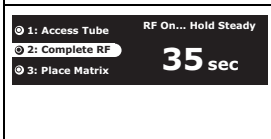

TABLE 1: RF Generator Front Panel	
 <p>POWER</p>	<p>Power Button Turns power to the RF generator on and off. The power button will illuminate (green) to indicate that power is on.</p>
	<p>Volume Buttons Left – Lowers the volume of the audio speaker. Pressing the button once lowers the volume by one increment. Pressing and holding the button lowers the volume continuously until the button is released or the minimum volume level is reached. Right – Raises the volume of the audio speaker. Pressing the button once raises the volume by one increment. Pressing and holding the button raises the volume continuously until the button is released or the maximum volume level is reached.</p>
	<p>Contrast Buttons Left – Decreases the contrast of the display screen. Pressing the button once decreases the contrast by one increment. Pressing and holding the button decreases the contrast continuously until the button is released or the minimum contrast level is reached. Right – Increases the contrast of the display screen. Pressing the button once increases the contrast by one increment. Pressing and holding the button increases the contrast continuously until the button is released or the maximum contrast level is reached.</p>

TABLE 1: RF Generator Front Panel	
 <p>RESET</p>	<p>Reset Button Resets the RF generator when in Error Mode (refer to Table 3 for Error Mode information). Pressing the reset button during RF energy delivery stops the energy delivery. The reset button flashes (red) if a system error occurs, indicating that the RF generator is in Error Mode.</p>
 <p>RF</p>	<p>RF Button Starts RF energy delivery. The RF button flashes (yellow) when the catheter Position Detection Array (PDA) senses complete (four quadrant) tissue contact. Pressing the flashing RF button initiates RF energy delivery. The RF button will steadily illuminate (yellow) during RF energy delivery and the light will automatically turn off after 60 seconds of energy delivery. Pressing the RF button during RF energy delivery stops the energy delivery.</p>
 <p>1: Access Tube RF On... Hold Steady 2: Complete RF 35 sec 3: Place Matrix</p>	<p>Display Screen (example) Provides RF generator status and instructional information during the Adiana procedure.</p>
 <p>CATHETER</p>	<p>Connector Cable Receptacle Receives the connector cable. (This receptacle is only for use with the connector cable provided with the Adiana RF generator.)</p>

Rear Panel: Contains a cooling fan, RS-232 port, footswitch receptacle, power entry module (with fuse housing), voltage selector and equipotential ground terminal (refer to Figure 2 and Table 2).

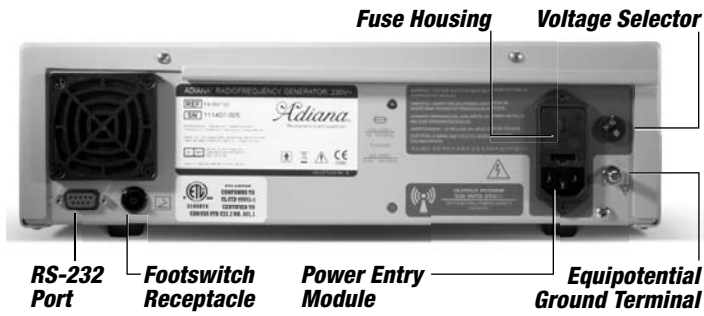







FIGURE 2: RF GENERATOR REAR PANEL

TABLE 2: RF Generator Rear Panel	
	Equipotential Ground Terminal Provides a means of securely linking the earth ground of the RF generator to that of other grounded equipment.
	RS-232 Port For Hologic service personnel only.
	Power Entry Module Receives AC power cord. Contains the fuse housing with viewing window to see either the '115' or '230' volt setting. Contact Hologic Technical Support for assistance before accessing the fuse housing.
	Voltage Selector Configures the RF generator to operate on either 110 or 220 volts. Contact Hologic Technical Support for assistance before changing this setting.
	Footswitch Receptacle Receives the footswitch connector.

Installation and Set-Up

Upon receipt, inspect the RF generator for any signs of physical damage to the front panel, chassis or cover. If any physical damage is found, do not use the unit; contact Hologic Technical Support for assistance (refer to the Technical Support and Product Return Information section).

Preparing RF Generator for Use

1. Place the RF generator on a cart or sturdy table.
2. Provide at least four inches (10 cm) of space around the sides and top of the RF generator for convection cooling. Under continuous use for extended periods of time, it is normal for the top and rear panel of the RF generator to be warm.

CAUTION: The voltage selector and the power entry module must be set to the same voltage to prevent malfunction of and potential damage to the RF generator. The voltage selector is factory set and should not be changed by the user.

3. Plug the power cord into the back of the RF generator and into a grounded electrical receptacle. Do not use extension cords and/or adapter plugs.
4. Connect the optional footswitch to the receptacle labeled "FOOTSWITCH" on the rear panel of the RF generator.
5. Insert the connector cable into the receptacle labeled "CATHETER" on the right front panel until an audible click is heard.

Periodic Maintenance

There are no periodic maintenance requirements for the Adiana RF generator.

Audible Tones

There are six audible tone categories that the RF generator produces to supplement the visual indicators on the display screen. These are described below:

1. Progress Tone:
 - A single tone that sounds when the RF generator is first turned on and when new information appears on the display screen.
 - It also sounds every five seconds during the delivery of RF energy.
2. Non-Progress Tone:
 - A double tone that sounds if an incorrect action occurs, such as when one or more quadrants of the catheter lose tissue contact during catheter positioning in the fallopian tube.
 - It also sounds when an inappropriate button is pressed (for example, pressing the RF button when it is not flashing).
3. Place Matrix Tone:
 - A triple tone that sounds at the end of the delivery of RF energy.
4. Matrix Placed Tone:
 - A double tone that sounds after the matrix has been released from the catheter.
5. Error Tone:
 - A double tone that sounds if an error is encountered during the procedure.
 - It is accompanied by an error message on the display screen.
6. Fault Tone:
 - A quadruple tone that sounds if the RF generator detects a problem during an internal self test.
 - It is accompanied by an error message on the display screen.

RF Generator Modes

The sequence of modes of operation for the RF generator are shown in the following flowchart (Figure 3) and presented in detail in Table 3 below.

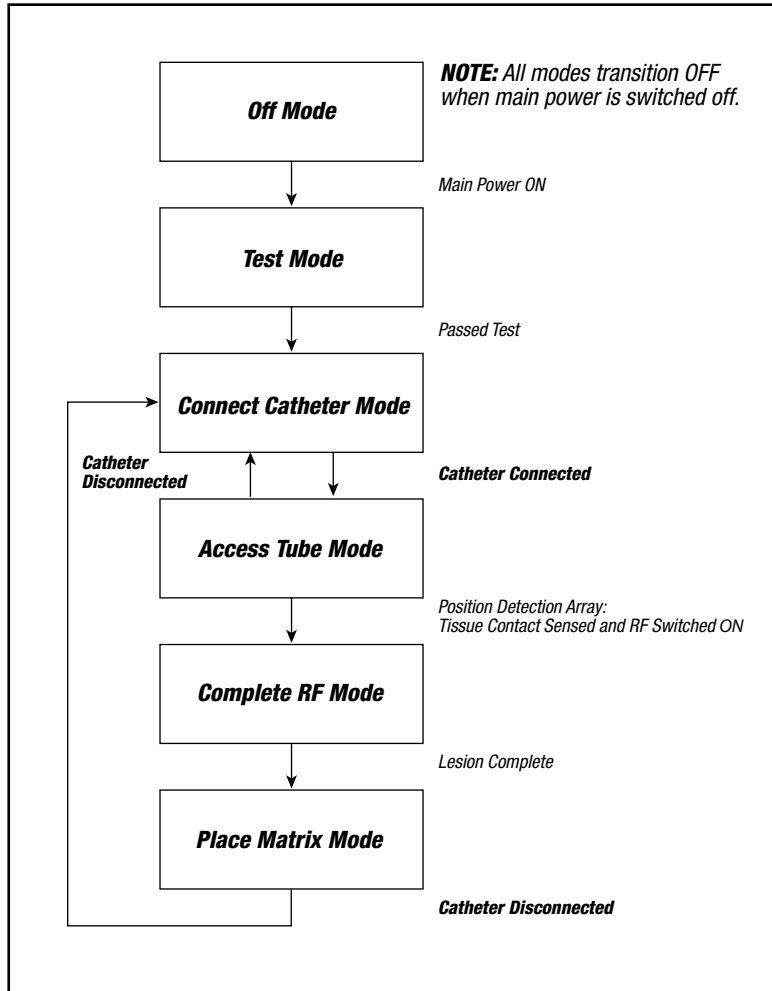


FIGURE 3: RF GENERATOR MODES FLOWCHART

TABLE 3: RF Generator Modes

Mode	Description	Indicator Light		Display Screen	Audible Tone
		RF Button	Reset Button		
Off Mode	Power to the RF generator is either turned off or the power cord is not connected to the RF generator or an electrical outlet.	OFF	OFF	Blank	None
Power On Self Test Mode	When the power button is turned on the RF generator performs an internal self-test. If the test fails, the system goes into Fault mode. If the test passes, the system goes into Connect Catheter mode.	ON	ON	Software version is displayed for approximately two seconds.	Progress Tone
Connect Catheter Mode	Indicates when the catheter is to be connected to the connector cable. Once the catheter is connected, the system goes into Access Tube mode.	OFF	OFF	“Connect Catheter...” message and Catheter symbol are displayed.	Progress Tone
Access Tube Mode	Indicates when to position the catheter in the tubal ostium. Once the catheter is in place, the “Start RF Treatment” message appears on the display screen. Pressing the flashing RF button (or the optional footswitch) transitions the system into the Complete RF mode.	OFF (until full tubal contact is established)	OFF	“Position Catheter” message and PDA symbol are displayed. One, two or three quadrants of PDA symbol will illuminate if partial tubal contact is established.	Progress Tone
		ON (flashes when full tubal contact is established)	OFF	“Start RF Treatment” message and PDA symbol are displayed (four quadrants of PDA symbol illuminated, indicating full tubal contact).	Progress Tone (Non-Progress Tone if full tubal contact is not maintained)
Complete RF Mode	Indicates when RF energy is being delivered. When the full 60-second RF energy delivery cycle has been achieved, the system goes into the Place Matrix mode.	ON (for the duration of RF energy delivery)	OFF	“RF On... Hold Steady” message and counter (indicating remaining RF energy delivery time) are displayed.	Progress Tone (every five seconds during RF energy delivery)
		OFF	ON (flashes until error condition is corrected and reset button is pressed)	If RF energy delivery is interrupted for any reason, the display will indicate an error message that includes the elapsed duration of RF energy delivery.	Error Tone
Place Matrix Mode	Indicates when to press the matrix release button on the catheter to deploy the matrix.	OFF	OFF	Catheter symbol and “... Hold Catheter Steady” message are displayed.	Place Matrix Tone
		OFF	OFF	After matrix is deployed, the Catheter symbol and “Remove and Disconnect” message are displayed.	Matrix Placed Tone
Error Mode	Indicates a recoverable error condition that occurs during any mode other than Fault mode.	OFF	ON (flashes until error condition is corrected and reset button is pressed)	Error message, including its associated error code, is displayed (refer to Table 4 for the full list of error codes).	Error Tone
Fault Mode	Indicates an unrecoverable error condition that occurs during any mode other than Error mode.	OFF	ON	Fault message, including its associated error code, is displayed (refer to Table 4 for the full list of error codes).	Fault Tone

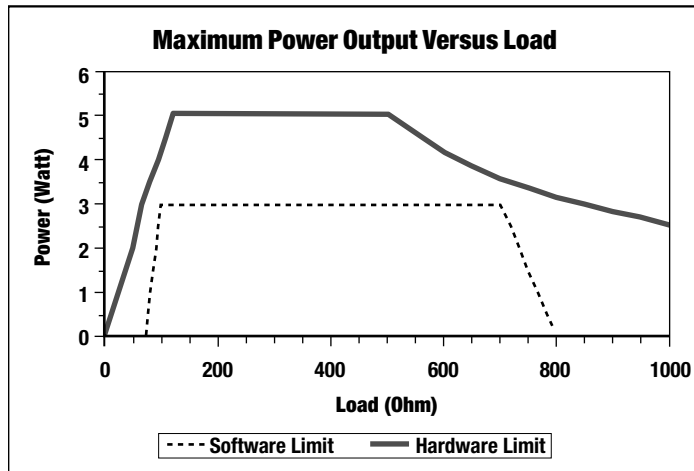
TABLE 4: Error Codes and Troubleshooting Instructions		
Error Code	Error Message on Display Screen	Troubleshooting Instructions
1A–F	System Error Turn Unit Off SEE INSTRUCTIONS	Disconnect the catheter and turn RF generator power off and then on. If the error recurs, contact Hologic Technical Support.
1G	Maintenance Recommended Press Reset to Continue	Press reset button and continue procedure. After completing the procedure, contact Hologic Technical Support.
1H–K	System Error Turn Unit Off SEE INSTRUCTIONS	Disconnect the catheter and turn RF generator power off and then on. If the error recurs, contact Hologic Technical Support.
2A	Bad Connection Replace Catheter or Cable	Disconnect catheter and connector cable from RF generator. Press reset button, and reconnect catheter and a new connector cable to RF generator to continue the procedure. If the error recurs, disconnect the catheter, press the reset button and connect a new catheter to continue the procedure.
2D	No Matrix Present Replace Catheter	Disconnect catheter. Press reset button and connect a new catheter to continue the procedure.
3A	Bad Connection Replace Catheter or Cable	Disconnect catheter and connector cable from RF generator. Press reset button, and reconnect catheter and a new connector cable to RF generator to continue the procedure. If the error recurs, disconnect the catheter, press the reset button and connect a new catheter to continue the procedure.
3B	Bad Connection Replace Catheter or Cable	Disconnect catheter and connector cable from RF generator. Press reset button, and reconnect catheter and a new connector cable to RF generator to continue the procedure. If the error recurs, disconnect the catheter, press the reset button and connect a new catheter to continue the procedure.
3D	Unexpected Matrix Ejection SEE INSTRUCTIONS	This refers to the condition when the matrix has been deployed while in Access Tube mode and RF energy has not yet been delivered. A) If the catheter was not positioned in the fallopian tube when the matrix was deployed, disconnect the catheter. Press reset button, connect a new catheter and repeat the procedure. B) If the catheter was positioned in the fallopian tube when the matrix was deployed, abandon the procedure.
3E	Bad Connection Replace Catheter or Cable or PDA Low Impedance	Press reset button and reposition the catheter in the tubal ostium to continue the procedure. If the error recurs, disconnect catheter and connector cable from RF generator. Press reset button, and reconnect catheter and a new connector cable to RF generator to continue the procedure. If the error recurs, disconnect the catheter, press the reset button and connect a new catheter to continue the procedure.
3G	System Error Turn Unit Off SEE INSTRUCTIONS	Disconnect the catheter and turn RF generator power off and then on. If the error recurs, contact Hologic Technical Support.
4A	Treatment Time: X sec Bad Connection Replace Catheter or Cable	Disconnect catheter and connector cable from RF generator. Press reset button, and reconnect catheter and a new connector cable to RF generator to continue the procedure. If the error recurs, disconnect the catheter, press the reset button and connect a new catheter to continue the procedure. WARNING: If RF energy delivery is interrupted for any reason before the completion of the 60-second delivery period, the elapsed RF energy delivery time will be presented on the display screen. Ensure the cumulative RF energy delivery time for a single fallopian tube does not exceed 120 seconds.
4B	Treatment Time: X sec Catheter Disconnected Restart RF Treatment	Press reset button and reconnect the catheter to continue the procedure. WARNING: If RF energy delivery is interrupted for any reason before the completion of the 60-second delivery period, the elapsed RF energy delivery time will be presented on the display screen. Ensure the cumulative RF energy delivery time for a single fallopian tube does not exceed 120 seconds.
4C	Treatment Time: X sec Bad Connection Replace Catheter or Cable	Disconnect catheter and connector cable from RF generator. Press reset button, and reconnect catheter and a new connector cable to RF generator to continue the procedure. If the error recurs, disconnect the catheter, press the reset button and connect a new catheter to continue the procedure. WARNING: If RF energy delivery is interrupted for any reason before the completion of the 60-second delivery period, the elapsed RF energy delivery time will be presented on the display screen. Ensure the cumulative RF energy delivery time for a single fallopian tube does not exceed 120 seconds.

TABLE 4: Error Codes and Troubleshooting Instructions		
Error Code	Error Message on Display Screen	Troubleshooting Instructions
4D	Treatment Time: X sec Bad Connection Replace Catheter or Cable	Check location of catheter. If confirmed or suspected that catheter moved out of fallopian tube during delivery of RF energy, press reset button, reposition catheter and continue the procedure. If error recurs, disconnect catheter and connector cable from RF generator. Press reset button, and reconnect catheter and a new connector cable to RF generator to continue the procedure. If the error recurs, disconnect the catheter, press the reset button and connect a new catheter to continue the procedure. WARNING: If RF energy delivery is interrupted for any reason before the completion of the 60-second delivery period, the elapsed RF energy delivery time will be presented on the display screen. Ensure the cumulative RF energy delivery time for a single fallopian tube does not exceed 120 seconds.
4E	Treatment Time: X sec Incomplete Treatment SEE INSTRUCTIONS	This refers to the condition when the matrix has been deployed during RF energy delivery. A) If the matrix was deployed in the fallopian tube, abandon the procedure. B) If it can be visually confirmed that the matrix was not deployed in the fallopian tube, disconnect the catheter. Press reset button, connect a new catheter and repeat the procedure. WARNING: If RF energy delivery is interrupted for any reason before the completion of the 60-second delivery period, the elapsed RF energy delivery time will be presented on the display screen. Ensure the cumulative RF energy delivery time for a single fallopian tube does not exceed 120 seconds.
4F	Treatment Time: X sec Movement Detected Restart RF Treatment	Press reset button and reposition the catheter to continue the procedure. WARNING: If RF energy delivery is interrupted for any reason before the completion of the 60-second delivery period, the elapsed RF energy delivery time will be presented on the display screen. Ensure the cumulative RF energy delivery time for a single fallopian tube does not exceed 120 seconds.
4G–K	Treatment Time: X sec Temperature Fault Restart Treatment	Press reset button and reposition the catheter to continue the procedure. WARNING: If RF energy delivery is interrupted for any reason before the completion of the 60-second delivery period, the elapsed RF energy delivery time will be presented on the display screen. Ensure the cumulative RF energy delivery time for a single fallopian tube does not exceed 120 seconds.
4L	Treatment Time: X sec Catheter Fault Replace Catheter	Disconnect catheter. Press reset button and connect a new catheter to continue the procedure. WARNING: If RF energy delivery is interrupted for any reason before the completion of the 60-second delivery period, the elapsed RF energy delivery time will be presented on the display screen. Ensure the cumulative RF energy delivery time for a single fallopian tube does not exceed 120 seconds.
4M	Treatment Time: X sec Bad Connection Replace Catheter or Cable	Disconnect catheter and connector cable from RF generator. Press reset button, and reconnect catheter and a new connector cable to RF generator to continue the procedure. If the error recurs, disconnect the catheter, press the reset button and connect a new catheter to continue the procedure. WARNING: If RF energy delivery is interrupted for any reason before the completion of the 60-second delivery period, the elapsed RF energy delivery time will be presented on the display screen. Ensure the cumulative RF energy delivery time for a single fallopian tube does not exceed 120 seconds.
4O	Treatment Time: X sec Treatment Halted by User Restart RF Treatment	Press reset button and reposition the catheter to continue the procedure. WARNING: If RF energy delivery is interrupted for any reason before the completion of the 60-second delivery period, the elapsed RF energy delivery time will be presented on the display screen. Ensure the cumulative RF energy delivery time for a single fallopian tube does not exceed 120 seconds.
5A	Catheter Disconnected Restart RF Treatment Before Placing Matrix	Reconnect the catheter, press reset button and repeat the procedure. WARNING: If RF energy delivery is interrupted for any reason before the completion of the 60-second delivery period, the elapsed RF energy delivery time will be presented on the display screen. Ensure the cumulative RF energy delivery time for a single fallopian tube does not exceed 120 seconds.
0A-Q	System Error Turn Unit Off SEE INSTRUCTIONS	Disconnect the catheter and turn RF generator power off and then on. If the error recurs, contact Hologic Technical Support.

TECHNICAL SPECIFICATIONS

RF Output

- The Aiana RF generator is a Class I, Type BF instrument, according to IEC 60601-1.
- RF energy: 460 KHz ± 10 KHz
- Maximum Power: 5 Watts
(software limited to 3 Watts at 250 Ohms)
- Maximum voltage: 50 V rms
- Maximum current: 0.2 A rms
- The output is isolated from earth ground and is intended for use with the bipolar catheter. No neutral electrode pad is used with this RF generator.
- The RF generator automatically adjusts its output level to the proper setting; there are no manual power control settings.



Electrical Specifications

- AC Ratings
 - Fusing: Two fuses: T1A250 V, 100–240 V~, 50/60 Hz
 - Current: 100–120 V~ / 50/60 Hz configuration: 1.0 Amp
220–240 V~ / 50 Hz configuration: 0.5 Amp

Mechanical Specifications

- Size: 14" (Width) x 18" (Depth) x 4.25" (Height)
(356 mm x 457 mm x 108 mm)
- Weight: 20 lb. (9 kg) maximum
- Footswitch Specifications: Air actuated

Environmental Specifications

- Operational Temperature Range: 10°C to 40°C
- Storage Temperature Range: –30°C to 50°C
- Operational Humidity Range: 20% to 80% RH, non-condensing
- Storage Humidity Range: 10% to 90% RH, non-condensing

Connectors Information


- Patient Connections
 - Isolated patient connection
 - 14-pin connector
- Mains Input
 - Standard IEC/UL power cable connection
- RF Output
 - Connection through catheter connector only

**Guidance and Manufacturer's Declaration—
Electromagnetic Emissions and Immunity**

The RF generator (models FA 007 01 and FA 007 02) is intended for use in the electromagnetic environment specified in the following tables. The customer or the user of the RF generator should assure that it is used in such an environment.

TABLE 5: Electromagnetic Emissions		
Emissions Test	Compliance	Electromagnetic Environment — Guidance
RF emissions CISPR11	Group 2	The RF generator must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR11	Class A	The RF generator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

TABLE 6: Electromagnetic Immunity			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% for 0.5 cycle 40% for 5 cycles 70% for 25 cycles <5% for 5 s	<5% for 0.5 cycle 40% for 5 cycles 70% for 25 cycles <5% for 250 cycles This condition causes the RF generator to shut down and then return to standby mode.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RF generator requires continued operation during power mains interruption, it is recommended that the RF generator be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

TABLE 6: Electromagnetic Immunity			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the RF generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.5 GHz	3 Vrms	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz <p>where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RF generator is used exceeds the applicable RF compliance level above, the RF generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RF generator.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the RF generator

The RF generator (models FA 007 01 and FA 007 02) is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RF generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RF generator as recommended in the following table, according to the maximum output power of the communications device.

TABLE 7: Recommended Separation Distance			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
	0.01	0.12	0.12
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CLEANING AND SANITIZING

The use of nonflammable agents for cleaning and sanitizing is recommended. Flammable agents or solvents for cleaning or sanitizing should be allowed to evaporate before use of the Adiana System.

The Adiana RF generator is not sterile. Cleaning should be done as needed using a mild detergent and water solution to wipe surface areas only. Do not immerse RF generator or components in liquid. Do not introduce liquid into the cooling vents or connection areas on the RF generator.

Do not sterilize the RF generator or any components.

PARTS LIST

TABLE 8: Ordering Information and Related Parts and Accessories	
Catalogue Number	Description
FA 007 01	RF Generator (115 volt)
FA 007 02	RF Generator (230 volt)
CS 228 01	Connector Cable
FS-1	Footswitch
A6000	Delivery Catheter (6 ea)
A1000	Delivery Catheter (1 ea)
328001	Biohazard Kit

WARRANTY INFORMATION

Hologic warrants to the original purchaser of the RF generator that it shall be free of defects in material and workmanship when used as intended under normal surgical conditions and in conformance with its instructions for use and maintenance instructions. The obligation of Hologic under this warranty shall be limited to the repair or replacement, each at no charge, at the option of Hologic within one year from the date of purchase, if examination shall disclose to the satisfaction of Hologic that the RF generator does not meet this warranty.

THIS WARRANTY IS MADE IN LIEU OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE AND ALL OTHER OBLIGATIONS AND LIABILITIES ON THE PART OF HOLOGIC. HOLOGIC NEITHER ASSUMES NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT ANY OTHER LIABILITY IN CONNECTION WITH THE SALE OF AN RF GENERATOR. THIS WARRANTY SHALL NOT APPLY TO AN RF GENERATOR OR ANY OTHER PART THEREOF WHICH HAS BEEN SUBJECT TO ACCIDENT, NEGLIGENCE, ALTERATION, ABUSE, OR MISUSE, NOR TO ANY RF GENERATOR THAT HAS BEEN REPAIRED OR ALTERED BY ANYONE OTHER THAN AN AUTHORIZED HOLOGIC SERVICE PERSON. HOLOGIC MAKES NO WARRANTY WHATSOEVER WITH REGARD TO ACCESSORIES OR PARTS USED IN CONJUNCTION WITH THE RF GENERATOR AND NOT SUPPLIED AND MANUFACTURED BY HOLOGIC. THE TERM "ORIGINAL PURCHASER", AS USED IN THE WARRANTY, SHALL BE DEEMED TO MEAN THAT PERSON OR ORGANIZATION AND ITS EMPLOYEES, IF APPLICABLE, TO WHOM THE RF GENERATOR WAS SOLD BY HOLOGIC. THIS WARRANTY MAY NOT BE ASSIGNED OR TRANSFERRED IN ANY MANNER.

TECHNICAL SUPPORT AND PRODUCT RETURN INFORMATION

Contact Hologic Technical Support if the Adiana catheter or RF generator fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number and biohazard kit if applicable.

Return RF generators according to the instructions provided by Technical Support. Be sure to clean the RF generator before returning it and include all accessories in the box with the returned unit.

Return used or opened catheters according to the instructions provided with the Hologic-supplied biohazard kit.

Hologic Technical Support**United States and Canada:**

Phone: 1.800.442.9892 (toll-free) or 1.508.263.2900

Fax: 1.508.229.2795



Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752
USA
Phone: 1.800.442.9892 (US toll-free) or 1.508.263.2900

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www.hologic.com

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Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752
USA
Phone: 1.800.442.9892 (US toll-free) or 1.508.263.2900

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