



Adiana Permanent Contraception: Frequently Asked Questions

Here are some commonly asked questions about Adiana Permanent Contraception.

Q: How long should it take my patients to make a full recovery?

A: On average most patients in the clinical trial were discharged one hour following the procedure. With no incisions to heal and no recovery time from general anesthesia, most women in the clinical trial returned to their normal activities within a day, and reported little or no discomfort.

Q: How long should the Adiana procedure take?

A: On average, the Adiana procedure takes less than 12 minutes.

Q: Can I use Adiana Permanent Contraception even though I'm not hysteroscopically trained?

A: While Adiana Permanent Contraception is easy to learn and use, the procedure should only be performed by physicians who have prior training in hysteroscopy, have read and understand the instructions for use, and have completed the mandatory Adiana Permanent Contraception Physician Training Program.

Q: What training do I need to perform the Adiana procedure and how do I get started?

A: The Adiana Permanent Contraception Physician Training Program provides detailed information regarding the procedure. Physicians must complete this program before performing the Adiana procedure. The program includes didactic training, hands-on training, and proctored cases. To get started, please contact your Hologic sales representative or call Hologic customer support at 800.442.9892 for more information on the Adiana Permanent Contraception Physician Training Program.

Q: Can I use NovaSure[®] Endometrial Ablation for my patients who have undergone the Adiana procedure?

A: Yes, however, NovaSure endometrial ablation must be performed after the patient has received HSG confirmation of tubal occlusion (at least 3 months after the Adiana procedure was performed). Unlike the other form of hysteroscopic sterilization, the Adiana matrices are non-conductive and do not protrude into the uterus, thereby eliminating potential interference with NovaSure Endometrial Ablation.

Q: Are there any age considerations when determining if a patient is appropriate for the Adiana procedure?

A: Adiana Permanent Contraception is indicated for women who desire permanent birth control (female sterilization) by occlusion of the fallopian tubes. The procedure has been studied in women ages 18 to 45.



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Q: Is the Adiana procedure appropriate for my patients who are poor candidates for surgery?

A: Adiana Permanent Contraception may be an ideal solution for women who desire permanent birth control and are poor candidates for surgery. Make sure to review the contraindications in the Adiana Instructions for Use (IFU) prior to performing the Adiana procedure.

Q: How safe is the Adiana procedure?

A: The silicone matrix is soft and biocompatible, eliminating the risk of chronic inflammation or painful perforations and expulsions associated with nickel coils. 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. Most adverse events reported on the day of the procedure were mild in nature and resolved within a short duration. Adverse events reported after the day of the procedure were generally mild. In the clinical trial, no patients discontinued the use of Adiana Permanent Contraception due to pain, allergies, discomfort, or any other reason.

Q: Will the use of RF energy pose any health risks for my patients?

A: In the clinical trial, there were no adverse effects due to RF energy. Additionally, the RF generator has been tested and found to comply with the requirements for medical devices as defined in IEC 60601.

Q: How will I know the biocompatible matrix is placed correctly since it is not radiopaque?

A: The Position Detection Array (PDA) provides a real-time sensing of tip position, via four discrete sensors arranged in quadrants around the tip. This facilitates consistent, accurate placement of the Adiana matrices.

Q: Why is the Adiana RF generator needed for the procedure?

A. The RF generator or Procedure Guidance System (PGS) delivers RF energy to the catheter tip, while also directing the operator through each step of the procedure via a simple menu driven interface, minimizing the potential for procedural errors.

Q: What are the advantages of using the silicone matrix in my patient's fallopian tubes?

A: The biocompatible implant is about the size of a grain of rice. The unique porous architecture wrapped around a solid center core provides a scaffold into which tissue ingrowth occurs, occluding the tube. Because of the size, the biocompatible implant remains completely inside the fallopian tubes. This means that there is nothing left in the uterus that may interfere if certain gynecologic tests or procedures are needed in the future.



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Q: My patients are quite comfortable with oral contraceptives. Why subject them to a hysteroscopic procedure?

A: While oral contraceptives may be an appropriate option for some patients, the typical use failure rate is approximately 8%¹. The 3-year failure rate shown in the clinical trial for Adiana Permanent Contraception, is 1.6%, which is comparable to tubal ligation. The Adiana hysteroscopic procedure is minimally invasive and requires no incisions or general anesthesia, allowing most patients to return to normal activities within a day. Adiana Permanent Contraception eliminates the burden of taking pills, including the hormonal side effects.

Q: I perform tubal ligations, why switch from what I know?

A: The Adiana hysteroscopic procedure is minimally invasive and requires no incisions or general anesthesia, allowing most patients to return to normal activities within a day. Tubal ligation can pose serious risk of complications, including anesthesia-related problems and damage to organs or blood vessels, including the potential to puncture the bladder or bowel. There is a rapid recovery period following the Adiana procedure, while tubal ligation may take as long as four to five days.

Q: How soon after the Adiana procedure can I perform the HSG confirmation test?

A: Following completion of bilateral matrix placement, the patient must use an alternative form of contraception for a minimum 3-month waiting period. This allows ample time for complete tubal occlusion to occur after the Adiana procedure.

Q: Is Adiana Permanent Contraception reimbursed?

A: Adiana Permanent Contraception is covered under the Current Procedural Terminology (CPT) code 58565 — hysteroscopic sterilization. Please refer to the Adiana Permanent Contraception coding and reimbursement guide for more information.

¹ Trussell J. "Contraceptive efficacy". In: Hatcher: RA, Trussell J, Nelson AL et al., editors *Contraceptive technology: 19th revised edition*. New York: Ardent Media, 2007 p747-826