

QS

Quinacrine Informed Consent Form

You are considering a very serious decision. Please read and consider everything you have been given. Take your time and ask questions.

How does tubal sterilization occur?

One kind of sterilization occurs when there is no way for the egg and the sperm to meet. This happens when the Fallopian tube between the ovary and the uterus becomes blocked.

Although there can continue to be normal ovulation, the egg cannot pass through the tube and cannot meet a sperm. Occasionally this blockage happens after an infection causing unwanted infertility. It also happens intentionally when the tubes are cut during surgical sterilization.

What is Quinacrine?

Quinacrine is also known as Atabrine or Mepacrine. It is taken by mouth.

It was first introduced in the 1930s to prevent and treat malaria. Since then, doctors all over the world have prescribed it for millions of people who have malaria and also for treatment of giardiasis, lupus, tapeworm, and other medical conditions.

It is the only drug in the United States approved by the FDA (Food and Drug Administration) to treat giardiasis.

There has been a great deal of research on oral Quinacrine over the past 65 years. Oral use of Quinacrine is very safe, especially in doses under 3000 mg per month. Millions of Americans have taken as much as 36,500 to 52,000 milligrams of it by mouth each year. In some cases they have done so for years as an anti-malarial, with few lasting side effects.

What is Quinacrine Sterilization (QS)?

QS is a nonsurgical sterilization procedure for women. It cannot be reversed. **Do not** agree to have this procedure if you may want more children. On the other hand, although the QS method is intended to prevent

pregnancies permanently, it can fail and you could become pregnant.

Permanent sterilization results when pellets of Quinacrine are put into the uterus (womb). They dissolve and some of the liquid flows into the Fallopian tubes. The action of the Quinacrine that reaches the Fallopian tube causes scar tissue, which blocks the tube.

The QS method requires two doses of 252 milligrams of Quinacrine. They are to be inserted into the uterus one month apart.

What is the history of QS?

The QS method was first developed in Chile in 1977. Since then, over 130,000 women in 30 countries have undergone the procedure.

Even though Quinacrine is an FDA-approved drug for giardiasis, the FDA has not approved its use for female sterilization. Using Quinacrine for this purpose is considered an "off-label" use. Off-label use of drugs is legal, acceptable, and common practice by providers. Treating lupus with Quinacrine is also an off-label use. The United States Pharmacopoeia, a national text, lists female sterilization as a use of Quinacrine.

What happens during the QS procedure?

QUINACRINE INSERTION

The pellets are inserted in the uterus the week after your menstrual period. This reduces the risk that you may be pregnant and not know it. It is also that part of the cycle when the endometrium is least proliferative.

Before insertions, Dr. Whitney will perform a pelvic examination. Its purpose is to determine the size, shape, and position of the uterus and to be sure that there are no contraindications. An instrument called a speculum will hold your vagina open so that the cervix (the



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entrance to the uterus) can be seen and you will probably feel its pressure throughout the insertion procedure.

The cervix is then cleaned with an antiseptic solution, a small amount of anesthetic may be injected, and an instrument called a tenaculum is attached to it. This instrument helps hold the uterus steady during insertion. A narrow instrument called a sound is then passed through the opening of the cervix into the uterus to measure its depth. You can expect to feel cramping similar to menstrual cramps as the sound is inserted and withdrawn.

Then Dr. Whitney will guide the inserter containing the Quinacrine pellets through the vagina and the cervix into the uterus. The pellets are ejected near the top of the uterus.

During insertion, you may have some pain or cramping. You may feel nauseated, weak or faint. After the inserter is removed from the cervical opening, the tenaculum and speculum will then be removed. Following the insertion, you will walk to recovery, and then rest for a time in a reclining position. After 30 minutes, an abdominal ultrasound will be done to show the dye position.

FOLLOW-UP PROCEDURES

For up to 24 hours after insertion, you will likely have a discharge that is bright yellow; tampons are ok to use. If you have any event that you read in the "Warnings" section, call immediately. You will have a follow-up appointment in a month for a second insertion. It may be necessary to repeat the insertion a third time.

There is currently no reliable test to learn if the blockage is complete. There is one test called a hysterosalpingogram (HSG), but when it is used, it can disturb the fresh scar tissue. It can reduce the effectiveness of QS.

CONTRACEPTIVE BACKUP METHODS

A good contraceptive method should be used starting before the first insertion for a total of at least 12 weeks. This ensures that during the period when the plug of scar tissue is forming, the chances of pregnancy will remain

low. If you have already been using a contraceptive method that you are comfortable with before you had your QS, you should keep using it for the required time.

How effective is the QS method?

QS is not as effective in the first year as surgical sterilization or as some temporary methods such as IUD, the Pill (when used correctly), and Depo-Provera.

QS is more effective than some well-known birth control methods such as condoms, the diaphragm, or spermicides (used alone).

Early studies reported that 9 out of 100 women who had QS became pregnant: 3 in year 1, 2 more in years 2 to 5, and 4 more in the next 5 years. **Changes in insertion procedure have improved effectiveness.**

To see how the failure rate of QS compares with all methods of birth control, see Table 1. A failure means that the woman has become pregnant in spite of using a particular method. Failures continue to occasionally occur throughout a woman's reproductive years with QS because the body never stops striving to repair itself, just as we see in women who have been surgically sterilized. With surgery, about two women out of 100 will become pregnant in the first 10 years.

There is a chance of pregnancy. It is strongly recommended that women who are faced with post QS pregnancy obtain an abortion as soon as arrangements are made. If you are opposed to abortion for yourself, QS may not be a good choice for you. You should consider either surgical sterilization or temporary contraception methods. You should be prepared to be faced with either of these circumstances before deciding on the QS method.



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Typical Failure Rates for All Methods During the First Year of Use	
Oral Contraceptives	Less than 5%
ParaGard® T 380A (IUD)	Less than 1%
Diaphragm + Spermicide	18%
Vaginal Sponge	18 - 28%
Condom (Alone)	12%
Periodic Abstinence	20%
Injections (Depo)	Less than 1%
Surgical Sterilization	Less than 1%
QS	1 - 3%

TABLE 1.

What are the permanent sterilization choices?

- **SURGICAL STERILIZATION**
The most common method is surgical (various techniques).
- **QUINACRINE STERILIZATION**
- **OTHER**
There are a few other experimental methods. The safety and the effectiveness of these methods are not yet established. In early 2003, the EOA approved a new hyteroscopically placed spring into the tubal junctions (where QS scar tissue develops).

What are the risks and discomforts to be considered?

DEATH

In over 130,000 Quinacrine Sterilizations, no deaths have been reported.

Surgical sterilization (various methods) requires surgery and anesthesia. In industrialized countries, the death rate for surgical sterilization is 1-2 for 100,000 women. In less developed countries, the death rate for surgical sterilization can be as high as 20 per 100,000 women.

It is also much less risky to have a QS than to become pregnant, carry a child to full term, and give birth.

POTENTIAL FOR REGRET

Some women regret getting sterilized. This regret is almost always due to changing circumstances, usually divorce or remarriage. QS is not reversible. Surgical sterilization is sometimes reversible. If you believe there is any chance that you may regret your decision, QS might not be your best option. Surgical sterilization or a temporary method would be more appropriate for you. Before agreeing to be sterilized, you should be comfortable with your decision. Ask yourself these questions:

- Am I sure that I never want any more children?
- What action would I take if I found myself pregnant?
- Would temporary methods or a surgical sterilization be better for me?
- Is my family or a clinician or anyone else pressuring me to get sterilized?
- Why am I choosing QS?

ECTOPIC PREGNANCY

An ectopic pregnancy is one in which the fertilized egg implants in the tube or outside of the uterus. This can be extremely dangerous.

Were the tube blockage incomplete after QS and were an egg to be fertilized, the scar tissue in the tube would interfere with its trip into the uterus. The fertilized egg could then implant in the tube.

Although QS (and surgical sterilization) prevents many ectopic pregnancies, a greater percentage of the pregnancies that do occur are ectopic.

If you ever had an ectopic pregnancy, you have increased risk of having another one. You also have an increased risk of an ectopic pregnancy if you have ever had certain types of infections. These infections include pelvic inflammatory disease (PID) or any venereal disease (VD) or sexually transmitted disease (STD) caused by, for example, gonorrhea or chlamydia.

Ectopic pregnancy can cause death, so it is very important to know these symptoms!

- Vaginal bleeding or a missed period
- Lower abdominal and/or shoulder pain



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- Dizziness, weakness, and/or fainting

If you have any of these symptoms or suspect that you may be pregnant because of a missed period, you must immediately contact your doctor or us, or go to a hospital to find out if it is an ectopic pregnancy. Ectopic pregnancy may require surgery to save your life.

SERIOUS PROBLEMS REQUIRING HOSPITALIZATION

QS also has fewer serious complications that require hospitalization than surgical sterilization. The QS rate is 0.03% (3 per 10,000) compared to 1.7% (1.7 per 100) for laparoscopic sterilization. The risks of complications with the surgical method are even greater for women with certain health problems such as respiratory disease, diabetes, and obesity, or if they have had abdominal or pelvic surgery.

BIRTH DEFECTS

In over 130,000 QS sterilizations, no birth defects have been reported in any infant exposed to Quinacrine in early pregnancy – that is, when a woman was not aware that she was pregnant at the time of Quinacrine insertion or when she became pregnant in the weeks following Quinacrine insertion.

POTENTIAL RISK OF CANCER

QS researchers believe that, if there is any risk of cancer with QS, that risk is very small. More than 100 million people have taken Quinacrine orally during its first 65 years of use, always in larger doses than for QS. There was never any mention that this drug might cause cancer because clinical experience did not indicate any link. No cancer clusters were ever reported in this vast human experience. One QS study in Chile, that has followed 1500 women for up to 20 years, has found no increase in the risk of cancer.

Some studies done on microscopic organisms in a laboratory caused some concern. Quinacrine caused some cells to mutate. Many other drugs including tetracycline, acyclovir, and metronidazole (Flagyl®), can also cause some cells to mutate in laboratory tests. Some mutagens cause cancer. Others, such as coffee and grilled hamburgers do not.

SEVERE ALLERGIC REACTION TO QUINACRINE

Severe allergic reactions that could be life threatening are known to occur occasionally with every drug used by humans. Quinacrine is no exception.

Thus far, two severe allergic reactions with QS have been reported, or one in more than 50,000 cases. Both women had the allergic reaction within an hour of use and fully recovered within a few hours.

UTERINE PERFORATION

Partial or total perforation through the wall of the uterus may occur when the Quinacrine is put in the abdominal cavity. Perforation could result in abdominal adhesions (scars), severe pain, and loss of contraceptive protection. Perforation has not resulted in serious illness or death.

SIDE EFFECTS

Side effects are those temporary and expected problems that accompany a treatment. Their severity ranges from almost nothing to severe, and they are not predictable.

Side effects in QS are common but they are almost always minor, temporary and easily managed. It is extremely important that you know about these possible side effects before you decide to have the procedure, so you will know what to expect.

If any of the following side effects severely bother you after QS is administered, you should contact us.

The following may occur during the insertion of the Quinacrine and shortly afterwards.

- Pain, usually uterine cramps, low backache, headache, dizziness, vaginal itching, or irritation and fever may occur at the time of insertion or shortly afterwards. If pain is severe, becomes worse, or persists, contact your clinician. Pain during sex is a rare side effect that disappears within a few months. Pain during urination is also rarely reported and disappears without treatment.



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- Dizziness or fainting may occur at the time of insertion.
- A small amount of bleeding occurs following insertion in some women. If the amount of blood is more than a teaspoon, the insertion must be repeated in the next cycle as an additional insertion. Blood in the uterus interferes with the action of the Quinacrine and will increase the risk of failure.
- Bleeding between menstrual periods may occur during the first two or three months after insertion. The first few menstrual periods after insertion may be heavier and longer than usual or they may be lighter and shorter. Some women will miss their period for as much as several months after the first insertion. If these conditions continue for longer than two or three months, consult your clinician.
- Occasionally, you may miss a menstrual period with QS. It is important to determine if you are pregnant; report this immediately to your clinician.
- You will experience a bright yellow discharge during the first 24 hours following insertion. The bright yellow color comes from the Quinacrine itself. This side effect is harmless but will stain clothing and bedding, as Quinacrine is also a dye.
- Cervical infection or pelvic infection (PID), which may result in surgical removal of your reproductive organs, including hysterectomy (unlikely, because Quinacrine is strongly antibacterial).
- Hematometra, accumulation of menstrual blood in the womb, an easily treated condition.
- Pregnancy. You must not be pregnant for QS to be performed. We will do a pregnancy test first.
- Infection – uterine or cervical – or active pelvic inflammatory disease (PID).
- Uterine bleeding.
- Tumor in the reproductive tract (severe fibroid, unexplained pelvic mass, etc.)
- Severe uterine distortion (bicornate uterus, etc.) that will not allow proper placement of the pellets.
- Psoriasis. Quinacrine may cause a severe attack of psoriasis.
- Porphyria. Quinacrine may cause this condition to worsen.
- Glucose-6-phosphate dehydrogenase (G6PD) deficiency.
- Use of primaquine.
- Use of hepatotoxic (liver damaging) drugs.
- **Use of alcohol or illegal drugs within 24 hours before the procedure.**

INFORMATION

There are many other conditions that we should know about in order to better understand your health.

- Heart disease, murmur, or high blood pressure
- Hepatitis or severe liver disease
- Diabetes
- Leukemia or other cancer
- Fainting spells or seizures
- Migraine
- Steroid therapy
- Anemia or blood clotting problems
- Prior ectopic pregnancy (pregnancy outside the uterus)
- Sexual problems
- Bleeding between periods

What should you let the clinician know?

The clinician needs the truth. You will be interviewed and a checklist will be used for all of these points.

CONTRAINDICATIONS

There are 11 conditions that will prevent or delay your QS procedure. In some cases you can be treated for the condition and have the QS later.



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- Suspicious or abnormal Pap smear or previous cancer of the uterus (womb) or cervix
- IUD in place now
- Severe menstrual cramps
- Multiple sexual partners
- A sexual partner who has multiple sexual partners, or is at risk for acquiring HIV
- Genital sores or lesions
- All drugs you are taking
- Sexually transmitted disease (venereal disease), such as herpes, gonorrhea, chlamydia, or acquired immune deficiency syndrome (AIDS)
- Unexplained genital bleeding
- Uterine or pelvic surgery
- Unusual vaginal discharge
- Any drug abuse (oral, IV, sniff, or inhaled – this is confidential information!!)
- Alcoholism
- Nearly half of all women having this procedure complain of a side effect. The most common are lower abdominal pain, headache, dizziness, and backache. Sometimes users experience mild fever or vaginal itching. These symptoms usually stop a few hours or days after the treatment. Also, menstrual periods may be irregular for a few months after Quinacrine sterilization.
- Feminine protection should be used to prevent clothing stains from the bright yellow vaginal discharge.
- Quinacrine sterilization is still new, at least in the United States; there may be risks that are not yet known. Only one study has tried to establish long-term risks. For up to 19 years, it followed 1500 women who had QS. No long-term risks have been identified, but no definitive conclusions can be drawn from this research, which found no increased risk of cancer among Quinacrine pellet method users. A final answer to whether QS increases the risk of cancer can only come after a study of 30-40 years on many more women.

A Comparison of Advantages & Disadvantages

This is a list made by someone else. You may have your own considerations to add to this list.

ADVANTAGES OF QS

- Safe: less risky than surgical sterilization
- QS is an outpatient procedure. No hospitalization is needed. Usually you can leave the clinic or office in about a half hour after the pellets are inserted.
- No general anesthetic
- Less pain than with surgery
- Recovery is faster
- Many types of trained health care practitioners, not just doctors, can provide this method
- It is the least expensive contraceptive method
- It is permanent after the insertions are complete
- There is no visible scar
- It does not change the user's sex drive or interfere with her ability to feel sexual pleasure
- No ongoing use of hormones is required

DISADVANTAGES OF QS

It is not reversible; a woman cannot expect or hope to undergo another procedure that would make her fertile again.

- Life-threatening complications of QS are very rare. However, this does not mean that you will not experience a life-threatening complication. In such case, it is possible that you would have to undergo major surgery for some unforeseen reason, which could place you at risk of death. QS requires two, and possibly three, insertions one month apart.
- The failure (pregnancy) rate has been variously reported from 1-3% in the first year.
- You may become pregnant in a tube (ectopic pregnancy). This condition has also been reported more commonly for women who are using no contraceptive method or using temporary methods.
- It does not protect against AIDS or other sexually transmitted diseases.



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GLOSSARY

Adhesions – scarring within a body cavity or between organs in the abdominal cavity

Cervicitis – Infection of the cervix

Cervix – Lower portion of the uterus visible in the vagina

Contraceptive – Means of preventing conception

Ectopic or Tubal Pregnancy – Pregnancy outside the uterus

Endometrium – Lining of the uterus. The endometrium is shed every month and expelled during the menstrual period

Fallopian tubes – Tubes through which the egg passes from the ovary to the uterus

Fertilization – The process of the sperm penetrating the egg of the female

Genital – Referring to organs concerned with reproduction

Giardiasis – An intestinal infection caused by a protozoan parasite

HIV – Human Immunodeficiency virus that causes AIDS

Infection – Invasion of the body by microscopic (tiny) organisms, such as bacteria. Can cause illness

Intermenstrual Bleeding – Bleeding between periods

Intrauterine – Within the uterus

Menstruation – A woman's monthly period

Monogamous – Practicing sexual relations with only one partner

Mutagenic – The ability to cause genes to mutate (change)

Off-label Use – When a doctor prescribes a drug for a treatment that is not indicated on the drug's package insert or label. Any drug that is FDA-approved can legally be used in this way. Approximately 60% of all prescriptions are for off-label uses

Ovary – Almond-shaped organ. One ovary is located on each side of the uterus. Produces and releases human eggs

Ovulation – Release of an egg by the ovary

PID – Pelvic Inflammatory Disease

Porphyria – A metabolic disorder

QS – Quinacrine pellet method for nonsurgical female sterilization, or Quinacrine Sterilization procedure

Quinacrine (Atabrine) – A synthetic antiprotozoal drug. Originally used to treat malaria. When placed in the uterus, it can prevent pregnancy by scarring the Fallopian tubes

STD – Sexually transmitted disease, also called VD or venereal disease

Spermicide – Chemical that kills male reproductive cells (sperm)

Uterine Perforation – A tear, hole, or puncture of the uterus

Uterus (womb) – Pear-shaped organ, located deep in the pelvis, which contains and nourishes a fetus during pregnancy



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WARNINGS: CALL YOUR CLINICIAN IMMEDIATELY FOR ANY OF THE FOLLOWING REASONS

- A missed period; you may be pregnant
- Unexplained or abnormal vaginal bleeding or discharge. This could indicate a serious complication, such as an infection or ectopic pregnancy.
- A delayed period followed by scanty or irregular bleeding. You may have an ectopic pregnancy.
- Pelvic or lower abdominal pain or cramps or unexplained fever. An ectopic pregnancy or infection may have developed, requiring immediate treatment.
- Exposure to venereal disease (VD) also called sexually transmitted disease (STD).
- **QS does not prevent venereal disease.** If exposure to venereal disease is suspected, call for examination and prompt treatment. Failure to do so could result in serious pelvic infection. **QS does not protect against diseases transmitted sexually such as HIV (AIDS), chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.**
- If your relationship ceases to be mutually monogamous or if your partner becomes HIV positive or gets a sexually transmitted disease, you should report this change to your clinician immediately. It is advisable to use a condom as a partial protection against STDs.
- Genital sores or lesions, or fever with vaginal discharge. You may have an infection.
- Severe or prolonged menstrual bleeding.



Quinacrine Consent Form

You have contacted Family Planning, Inc. about permanent methods of contraception and decided that Quinacrine Sterilization is your preferred method. Prior to making your decision, you reviewed and understood information on the following (initial all that apply):

Initials Information Reviewed

- _____ Quinacrine Sterilization brochure
- _____ Quinacrine Sterilization Web pages
- _____ Quinacrine Sterilization information sheets
- _____ Quinacrine Sterilization video
- _____ Two other temporary contraceptive methods
- _____ One other surgical sterilization method

Please sign your initials to confirm that you have read and understand the following statements.

Initials

- _____ Sterilization is an irreversible contraceptive method. If you have any reservations about whether you might want to bear children in the future, you should not choose Quinacrine Sterilization.
- _____ Other than a full hysterectomy, no sterilization method is 100% effective. If you should become pregnant after having Quinacrine Sterilization, your only options would be abortion or childbirth. If you are opposed to both, you should reconsider your choice to have Quinacrine Sterilization.
- _____ Being sterilized does not protect you from sexually transmitted diseases, including Acquired Immune Deficiency Disease (AIDS), gonorrhea, chlamydia, syphilis, and others.
- _____ The FDA has not yet approved the use of Quinacrine for female sterilizations. It is, however, a legal use of the drug.
- _____ There is no money available from any source, including the doctor and this office, to cover additional costs incurred because of the Quinacrine Sterilization method. This includes any costs you may incur from complications.
- _____ You understand that there is no penalty for changing your mind and deciding against having Quinacrine Sterilization at this point in time.

You understand that you may sign this form and give your consent to have Quinacrine Sterilization only if ALL of the statements below are true:

Initials

- _____ No one has forced or pressured you to undergo sterilization. You are making this choice solely of your own free will.
- _____ You feel comfortable that the information you have reviewed and understood about the risks and benefits of, and alternatives to Quinacrine Sterilization is sufficient for you to choose this method.
- _____ You have had the opportunity to ask questions about Quinacrine Sterilization, other forms of sterilization, and other temporary contraceptive methods. All of your questions have been answered to your satisfaction.
- _____ You have answered all of the clinician's questions as truthfully, completely, and accurately as you can.
- _____ You have ingested no alcohol or illegal drugs in the past 24 hours.

After reading, understanding, and answering the above information, you still choose to be permanently sterilized by using the Quinacrine Sterilization method.

	Printed Name	Signature	Date
Patient	_____	_____	_____
Witness 1	_____	_____	_____
Witness 2	_____	_____	_____

R.B. Whitney, M.D.
Medical Director, QS Florida

