



**Canadian Patient Information Brochure
Essure[®] System for Permanent Birth
Control**

January 2017



- **An Essure Confirmation Test should be performed three months after insert placement to evaluate insert retention and location. The patient must use alternative contraception until an Essure Confirmation Test demonstrates satisfactory results.**
- **There have been reports of perforation of the uterus and/or fallopian tubes, inserts located in the intra-abdominal or pelvic cavity, persistent pain, and allergy or hypersensitivity reactions in some patients. Some of these reported events resulted in insert removal that required abdominal surgery. Device removal may lead to improvement or resolution of symptoms when: the onset is shortly after placement, imaging indicates an unsatisfactory insert location, and other etiologies for these symptoms have been considered. This information should be shared with patients considering sterilization with Essure during discussion of the benefits and risks of the device.**

Read all of this leaflet carefully before you have Essure placed because it contains important information for you.

- **This information does not replace talking with your doctor.**
- **Keep this leaflet. You may need to read it again.**
- **You should have a consultation with your doctor to understand the risk/benefit of Essure. The Essure procedure has to be performed by a doctor who is trained and competent in the Essure placement procedure.**
- **If you have any questions about Essure or the placement procedure, ask your doctor.**
- **If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 6.**
- **You should read the Patient-Doctor Discussion Checklist at the end of this document. Reviewing and completing the checklist is an important step in helping you decide whether or not to have Essure implanted. The patient and physician must sign the checklist to acknowledge and document the discussion.**

What is in this leaflet

- 1. What Essure® is and what it is used for?**
- 2. What you need to know before you have the Essure procedure**
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1. What Essure® is and what it is used for?

Essure Model ESS 305 is a device for permanent birth control that works with your body to create a natural barrier against pregnancy. The Essure placement procedure involves using a delivery system that places a soft, flexible insert into your fallopian tubes. Over a period of about three months, tissue forms around the insert. The build-up of this tissue creates a barrier that stops sperm from reaching the eggs and prevents pregnancy. During the three month period after placement of Essure, you must either not have sex or continue using another form of birth control to prevent pregnancy until a doctor performs a test (the Essure Confirmation Test) to confirm that Essure is correctly placed and that you can rely on Essure for permanent birth control.

Components of the Essure System (insert)

The soft, flexible Essure inserts do not contain hormones. The Essure insert is made of Nitinol (nickel-titanium alloy), stainless steel, a type of polyester fibre (PET- polyethylene terephthalate), platinum and silver-tin (*see section 2*).

2. What you need to know before you have the Essure procedure

Essure may be right for you if:

- You want permanent birth control
- You are sure you are done having children

Essure is not right for you if:

- You are uncertain about ending your fertility.
- You are pregnant or you think you are pregnant.
- Within the last 6 weeks, you have had a baby or have terminated a pregnancy after the third month.
- You currently have an infection in the vagina, cervix, uterus or fallopian tube.
- You have unexplained vaginal bleeding.
- You have suspected or known cancer of the female reproductive organs such as vagina, cervix, uterus or fallopian tube.



- Your doctor has told you that your fallopian tube(s) are closed or blocked.
- You have had your “tubes tied” (tubal ligation).
- You are allergic to contrast dye used during x-ray examinations.
- You are unwilling to undergo the Essure Confirmation Test.

Your doctor will delay your Essure procedure if:

- You are or have been pregnant within the past 6 weeks.
- You have an active or recent infection in the vagina, cervix, uterus or fallopian tubes.
- You are in the second half (weeks 3 and 4) of your menstrual cycle because during that time, there is an increased risk of being pregnant.

Tell your doctor if:

- You were born with uterine abnormalities (e.g. unicornuate uterus) or if you have had one of your tubes removed (salpingectomy).
- Pain (e.g. acute or persistent) of varying intensity and length of time may occur and continue following Essure placement. Women with a history of pain prior to placement of Essure are more likely to experience both acute and persistent pelvic pain following Essure placement. Not all pain will be related to the Essure insert. Other gynecological conditions (such as endometriosis) or non-gynecological conditions (such as irritable bowel syndrome) can cause pain. Contact your doctor if you are experiencing significant pain or if the pain persists.

Surgery may be required to remove the insert. This may range from looking in the uterus (hysteroscopy), removal of the insert alone, or removal of the insert with the fallopian tube and/or uterus (hysterectomy). Device removal may lead to improvement or resolution of symptoms when: the onset is shortly after placement, imaging indicates an unsatisfactory insert location, and other etiologies for these symptoms have been considered.

- You have, or think that you have an allergy to nickel, titanium, stainless steel, polyester fiber (PET), platinum or silver-tin or you have had metal allergies. You may experience an allergic reaction to the insert. In addition, some patients may develop an allergy to nickel or other components of the insert following placement. Typical allergic symptoms such as hives, rash, swelling, and itching have been reported in patients who have had Essure placed. Talk to your doctor if you think you may have a nickel allergy and he or she will help to determine if Essure is right for you.
- You are taking or have received medicines that suppress your immune system. Examples include chemotherapy or corticosteroids, such as prednisone or other medicines used to treat inflammatory disorders such as rheumatoid arthritis. Medicines that suppress the



immune system may make Essure less effective for birth control. If you are taking medicines that suppress your immune system, your doctor will advise you of the type of confirmation test that is right for you.

Talk to your doctor about Essure and if it is right for you. Refer to the Patient-Doctor Discussion Checklist in this brochure and review it with your doctor.

IMPORTANT: Essure inserts do not protect against HIV or other sexually transmitted diseases.

Important factors you need to be aware when considering Essure

- The Essure procedure is irreversible and should be considered a permanent method of birth control. No method of birth control is 100% effective. There is a chance that you can become pregnant after having Essure placed.
 - While most pregnancies in women who have Essure have been reported as healthy deliveries, there have been reports of pregnancy loss, pre-term labor, premature delivery, stillbirth, and neonatal complications. You should contact your doctor immediately if you think you may be pregnant.
 - Women who have Essure placed may have an extrauterine pregnancy (ectopic pregnancy) if they get pregnant. The pregnancy usually happens in one of the fallopian tubes. Extrauterine pregnancy is very serious and can be life-threatening
 - If pregnancy occurs while Essure is in place, it cannot be relied on for future birth control and alternative birth control is needed to prevent pregnancy.
- Your doctor will schedule an Essure Confirmation Test which is part of the Essure procedure which should be performed about 3 months after the placement procedure. Your doctor will inform you on the options for the Confirmation Test including their risks and benefits. **YOU MUST SEE YOUR DOCTOR FOR THE ESSURE CONFIRMATION TEST BEFORE YOU CAN RELY ON ESSURE FOR BIRTH CONTROL. YOU MUST CONTINUE TO USE ANOTHER FORM OF BIRTH CONTROL TO PREVENT PREGNANCY UNTIL YOUR DOCTOR TELLS YOU THAT YOU CAN RELY ON ESSURE FOR BIRTH CONTROL.**
- Part of an Essure insert may perforate the wall of the uterus or fallopian tube during the procedure. This occurred in 1 out of 50 women in the original premarket study for Essure. A perforation may lead to bleeding or injury to bowel or bladder, which may require surgery. If removal of the insert is necessary, surgery will be needed. In that case, your doctor may tell you that you must use another form of birth control to prevent pregnancy. This surgery may range from looking in the uterus (hysteroscopy), removal of



the insert alone, or removal of the insert with the fallopian tube and/or uterus (hysterectomy).

- If you are considering a gynecological procedure or (abdominal) surgery in the future, tell your doctor that you have had the Essure procedure.
- If you have already had, or are considering a procedure to reduce bleeding from the uterus (such as endometrial ablation) tell your doctor as it may affect the Essure procedure.
 - The ablation procedure should not be performed on the same day as your Essure placement procedure.
 - If you have Essure placed, your doctor must confirm that it is in a satisfactory location (via the Essure Confirmation Test) before performing an ablation procedure.
- The Essure procedure should be performed by a doctor who is trained and competent in the Essure placement procedure.
- The younger a woman is when she chooses to end her fertility, the more likely she is to regret her choice later
- If you have Essure placed, it does not prevent you from having an MRI of your pelvis . If you are prescribed such an examination, tell your radiologist that you have Essure in place.
- Read this Patient Information Brochure carefully and consult with your doctor before you decide if Essure is right for you.
- As with any procedure, the Essure procedure is NOT without risks. Talk with your doctor about the risks and benefits of Essure for you.
- Discuss and agree with your doctor on the adequate time to review and consider the information contained in this Patient Information Brochure before deciding whether to proceed with the Essure procedure.

3. Overview of the Essure Procedure

Step 1 – Having Essure placed

During the procedure, the doctor will place a tiny insert into your fallopian tubes. The inserts are soft and flexible, and are delivered through your vagina and cervix, and into your fallopian tubes. No incisions are needed.



Step 2 - Waiting for the natural barrier to form

Over the next 3 months, your body will form tissue around the Essure inserts. The tissue forms a natural barrier within the fallopian tubes. The barrier prevents sperm from reaching the eggs that are produced every month. During this initial 3-month period, you **must** either not have sex or continue using another form of birth control to prevent pregnancy.

Step 3 - Essure Confirmation Test

The Essure method for permanent birth control requires two distinct procedures in order to determine if it can be relied upon for permanent birth control. The first step is the placement of the insert(s) into the fallopian tubes and the second is the confirmation test. A satisfactory confirmation test performed **three months after the inserts are placed**, is required to determine that the Essure insert is in a satisfactory location and/or that the fallopian tubes are blocked and that you can rely on Essure for birth control. Your doctor will advise you of the type of test that is right for you. You may have pelvic X-Ray or an ultrasound that confirms that your Essure inserts are in a satisfactory location, or, your doctor may recommend a test that uses contrast dye and a special type of x-ray (modified HSG) to determine both that the insert is in a satisfactory location and that your fallopian tubes are appropriately blocked. Your doctor will advise you on which method or methods are best for you.

IMPORTANT:

YOU MUST SEE YOUR DOCTOR FOR THE ESSURE CONFIRMATION TEST BEFORE YOU CAN RELY ON ESSURE FOR BIRTH CONTROL. YOU MUST CONTINUE TO USE ANOTHER FORM OF BIRTH CONTROL TO PREVENT PREGNANCY UNTIL YOUR DOCTOR TELLS YOU THAT YOU CAN RELY ON ESSURE FOR BIRTH CONTROL.

FOR SOME WOMEN, IT MAY TAKE LONGER THAN 3 MONTHS FOR ESSURE TO COMPLETELY BLOCK THE FALLOPIAN TUBES, REQUIRING A REPEAT CONFIRMATION TEST AT 6 MONTHS.

Talk to your doctor about which method of birth control you should use for the 3 months after the placement procedure. Some women can continue using their current method of birth control.

4. What should I know about the Essure Confirmation Test

The Essure Confirmation Test verifies that the inserts are in a satisfactory location and sometimes tests whether the tubes are appropriately blocked. The Essure Confirmation Test can include pelvic X-ray, transvaginal ultrasound (TVU), or a special type of x-ray using a special



contrast dye in your uterus (modified HSG). Your doctor will advise you on which method or methods are best for you.

Some additional information on the confirmation tests that check the inserts are correctly placed is provided below:

- PELVIC X-RAY - test in which X-rays are used to obtain an image of the pelvis
- TRANSVAGINAL ULTRASOUND - test that uses sound waves to examine the genitals of a woman, including the uterus, ovaries and cervix. During this test, an ultrasound device will be placed inside the vagina. The ultrasound will create a picture that will enable your doctor to see the Essure inserts within your fallopian tubes and determine if the inserts are in the appropriate place.
- HYSTEROSALPINGOGRAM (HSG): test that consists of a special x-ray in which a contrast medium is used to view the uterus and fallopian tubes. During this test, a healthcare provider injects a special contrast dye into your uterus. The dye is visible on x-rays. This lets the doctor look at your fallopian tubes to confirm that the inserts are properly placed and that your tubes are appropriately blocked.

If you have any further questions on the Essure Confirmation Test, ask your doctor.

5. What to expect with Essure

Preparing for your procedure

Your doctor will schedule your Essure procedure for a time soon after the end of your menstrual period. Your doctor may give you medication to make it easier to see the openings of your fallopian tubes and place the inserts.

The day of your procedure

You will be asked to take a pregnancy test before or on the day of your procedure to ensure you are not pregnant. Your doctor may also give you medication before your procedure to reduce any discomfort. Talk to your doctor prior to the procedure about the types of medications that are right for you and the associated benefits and risks. Your doctor may recommend a local anesthesia, which numbs the cervix. Ask your doctor about the risks associated with this type of anesthesia.

During your procedure

Your doctor may first insert an instrument called a speculum inside your vagina. The speculum helps the doctor widen the opening of your vagina and see inside. Then your doctor will insert a narrow instrument (hysteroscope) through your cervix and into your uterus. A camera attached to the hysteroscope lets your doctor see the inside of your uterus. A salt water solution is used to expand the uterus. This makes it easier for your doctor to find the openings of your fallopian tubes.



The Essure insert is attached to the end of a small, flexible tube that passes through the hysteroscope and into your fallopian tube. Once the insert is placed, the flexible tube is removed.

IMPORTANT: Not all women will achieve successful placement of Essure inserts. In a recent post-marketing study, in only a few instances (about 1 out of 20 women), the doctor was unable to place one or both Essure inserts in the fallopian tubes. If this occurs, talk to your doctor about your contraceptive options.

After your procedure

Most women return to normal activities within one to two days following the procedure. Call your doctor if you experience pain, bleeding, fever, or vaginal discharge that worsen or do not go away following the procedure.

It takes about 3 months (sometimes longer) for your body to produce tissue around the inserts and form a barrier to prevent pregnancy. During that time you can still get pregnant.

IMPORTANT: YOU MUST SEE YOUR DOCTOR FOR THE ESSURE CONFIRMATION TEST BEFORE YOU CAN RELY ON ESSURE FOR BIRTH CONTROL. YOU MUST CONTINUE TO USE ANOTHER FORM OF BIRTH CONTROL TO PREVENT PREGNANCY UNTIL YOUR DOCTOR TELLS YOU THAT YOU CAN RELY ON ESSURE FOR BIRTH CONTROL.

Essure Confirmation Test

Your doctor will examine you **3 months after the placement procedure** to ensure that the inserts are correctly placed in your fallopian tubes. **This 3-month confirmation test (Essure Confirmation Test) is mandatory before you can rely on Essure for birth control** (see section 3 and 4).

Make sure you continue using another type of birth control until your doctor has reviewed your Essure Confirmation Test results and confirmed that you can rely on Essure for birth control.

6. Possible side effects and other Potential Risks

Like all methods of birth control, there are side effects and risks associated with the Essure procedure. These are described below, please also ask your doctor about them.

During the Essure placement procedure

- You may experience mild to moderate pain
- Your doctor may be unable to place Essure inserts correctly. If this happens a second attempt may be possible.



- Part of the Essure delivery system may break off. Although uncommon, if this happens, your doctor may remove the piece.
- The uterus or fallopian tubes can be perforated by the hysteroscope, Essure delivery system, Essure insert or other instrument. This occurred in 1 out of 50 women in the original premarket study for Essure. Most perforations do not result in symptoms. Some perforations may result in pain, bleeding or injury to the bowel, bladder or major blood vessel. You may have to have surgery to repair the perforation.
- Your body may absorb a large amount of the salt water solution used during the procedure which may make you feel short of breath.
- Your doctor may recommend a local anesthesia, which numbs the cervix. Ask your doctor about the risks associated with anesthesia prior to the placement procedure.

Immediately following the placement procedure

- You may experience mild to moderate pain and/or cramping, vaginal bleeding, for a few days after the procedure. Some women experience headaches, nausea and/or vomiting or dizziness and/or lightheadedness/ fainting. These reactions may be treated with medication.
- Unusual pain or uterine bleeding may occur after the placement procedure. If this happens your doctor may investigate and may decide that the insert should be removed. This would require surgery. Device removal may lead to improvement or resolution of symptoms when: the onset is shortly after placement, imaging indicates an unsatisfactory insert location, and other etiologies for these symptoms have been considered.
- There are reports of an Essure insert being located in the abdomen and pelvis. If this happens, you cannot rely on Essure for birth control and surgery may be necessary to remove the insert.
- As with all procedures that use a hysteroscope (an narrow instrument used to view the inside of the uterus) there is a risk of infection. An infection could cause damage to the uterus, fallopian tubes or pelvic structures which may require antibiotics or rarely hospitalization or surgery (including hysterectomy).
- In some instances, an Essure insert may be expelled from the body. This is usually detected during the Essure Confirmation Test.



During the Essure Confirmation Test

- If your doctor performs an x-ray during the Essure Confirmation Test (pelvic X-ray or modified HSG) three months following insert placement, you will be exposed to very low levels of radiation which are consistent with most standard X-rays. The following additional risks are associated with the modified HSG: some women may experience nausea and/or vomiting, dizziness and/or fainting, cramping, pain or discomfort. In rare instances, women may experience spotting and/or infection which may require treatment with antibiotic and in rare cases hospitalization.
- The use of contrast dye, used to perform a modified HSG has been associated with allergic reactions in some patients. An allergic reaction can result in hives or difficulty breathing. Some allergic reactions can be serious.

Long term

- No birth control method is 100% effective. There is a possibility that you can become pregnant after completing the Essure procedure. In the most recent clinical trial, 1 out of 150 women became pregnant within the first year of relying on Essure. While most pregnancies in women who have Essure have been reported as healthy deliveries, there have been reports of pregnancy loss, pre-term labor, premature delivery, stillbirth, and neonatal complications. You should contact your doctor immediately if you think you may be pregnant.
- Women who have the Essure procedure may become pregnant and/ or may have an ectopic pregnancy. The pregnancy usually happens in one of the fallopian tubes. Ectopic pregnancy is very serious and can be life-threatening. If you think you are pregnant after you have had Essure placed, call your doctor.
- Pain. The following types of pain have been reported:
 - Pain (e.g. acute or persistent) of varying intensity and length of time may occur and continue following Essure placement. Women with a history of pain prior to placement of Essure are more likely to experience both acute and persistent pelvic pain following Essure placement. Not all pain will be related to the Essure insert. Other gynecological conditions (such as endometriosis) or non-gynecological conditions (such as irritable bowel syndrome) can cause pain. Contact your doctor if you are experiencing significant pain or if the pain persists.
 - Pain, abdominal or pelvic cramping (including during sexual intercourse or physical activity).



Surgery may be required to remove the insert. This may range from looking in the uterus (hysteroscopy), removal of the insert alone, or removal of the insert with the fallopian tube and/or uterus (hysterectomy).

- Bleeding between periods or heavier than usual bleeding during menstruation (this may be due to discontinuation of hormonal contraception).
- Risks of infection that may require medical treatment including surgery.
- Patients with a known hypersensitivity (allergy) to polyester fiber, nickel, titanium, stainless steel, platinum, silver-tin or any of the components of the Essure system may experience an allergic reaction to the insert. This includes patients who have had metal allergies. Some patients may develop an allergy to nickel or other components of the insert following placement. Typical allergic symptoms such as hives, rash, swelling and itching have been reported for this device. There is no reliable test to predict who may develop a reaction to the inserts.
- A woman may sometimes regret her decision to choose permanent birth control, and may experience mild depression or other emotional problems.

Risks Associated with Future Procedures

- If you have gynecological procedures including abdominal surgery in the future, tell your doctor that you have the inserts in your fallopian tube. The presence of the Essure inserts may need to be considered.
- If you have endometrial ablation, a procedure that removes the lining of the uterus to lighten or stop menstrual bleeding, after the Essure procedure, it is unknown if this will affect the blockage in your tubes, and effect your risk of pregnancy. Your doctor must confirm that the Essure insert is in a satisfactory location before performing this procedure.
- If you have Essure placed, it does not prevent you from having an MRI of your pelvis. If you are prescribed such an examination, tell your radiologist that you have Essure in place.

Unknown Risks:

- The safety and effectiveness of restoring fertility following the Essure procedure are not known.
- The safety and effectiveness of Essure has not been established in women under 21 or over 45 years old.



- Other symptoms have been reported by women implanted with Essure, although they were not seen in the clinical trials supporting Essure approval. The more common of these symptoms include headache, fatigue, weight changes, hair loss and mood changes such as depression. It is unknown if these symptoms are related to Essure or other causes.

If you get any side effects, talk to your doctor including any possible side effects not listed in this leaflet.

7. Patient Identification Card

After your have had Essure placed, you will be given an ID card. The ID card tells doctors and others that you have Essure inserts in your fallopian tubes. Please ensure that you show the card when undergoing any procedure involving your abdomen, pelvis, uterus or fallopian tubes. This includes an MRI scan, dilation and curettage (D&C) - a procedure to remove tissue from inside your uterus, hysteroscopy, endometrial biopsy or endometrial ablation. The visibility of areas of the body near the inserts may be obscured when they are seen on x-rays, MRIs and other imaging.

8. Frequently Asked Questions to your doctor

If you are considering the Essure procedure as a permanent method of birth control, here are some questions you might want to ask your doctor:

- Is Essure the most appropriate method of birth control for my health and my expectations?
- What are the benefits and risks of this procedure?
- Where will this procedure be performed? How long will it take to place the inserts?
- What type of medications may be used before and/or during the procedure?
- Will the procedure require anesthesia? What are the risks of this?
- How should I prepare for the procedure?
- What are my options if inserts cannot be placed at the first attempt?
- What happens at the 3-month confirmation visit? When should I schedule it?
- Which birth control option can I use while I am waiting for confirmation that the procedure has been effective?
- Will someone need to take me home afterwards?

9. Methods of birth control

All methods of birth control have contraindications, precautions for use and side effects. For further information consult your doctor.

Of all of methods of birth control, only the condom (male or female) protects against HIV and most sexually transmitted diseases.



INTRA-UTERINE CONTRACEPTION

A device placed in the uterus with a T-shaped frame or other shapes. There are two types: progestin or copper. They are effective from 3 to 10 years depending on the models.

PERMANENT FEMALE CONTRACEPTION (STERILISATION)

Methods of birth control that cause a permanent and definitive blockage of the fallopian tubes, preventing conception. There are several types: tubal ligation, removal of the tubes, tubal clips performed by laparoscopy and the insertion of implants into the tubes.

INJECTABLE PROGESTINS

A synthetic progestin delivered with an intra-muscular injection every three months.

BIRTH CONTROL PILL

A pill taken daily at the same time for 21 or 28 days. There are two types: estrogen-progestin (two hormones), and progestin only (one hormone). The dose and the type of the hormones vary depending on the type of pill.

PATCH

A patch that the woman adheres to her skin once a week, renewed every week for 3 weeks; there is no patch in the 4th week, but protection is maintained. It contains two types of hormones.

VAGINAL RING

A flexible ring inserted by the woman into the vagina. It is left in place for 3 weeks (and removed at the start of the 4th week, though protection is maintained). Contains an estrogen and a progestin.

DIAPHRAGM

A dome-shaped silicone disc that the woman places in the vagina herself. Must be used in conjunction with a spermicide. It prevents sperm from reaching the uterus. It may be inserted a few hours before intercourse or just before. It must be left in place for 8 hours after intercourse. Re-usable.

FEMALE CONDOM

A sheath with a flexible ring at both ends, which is placed in the vagina. It may be put in place several hours before intercourse. It must be changed for every act of intercourse. Together with the male condom, the only method that protects against sexually transmitted diseases.

MALE CONDOM

A sheath placed over the penis that prevents passage of sperm. Applied immediately before intercourse and used only once. Together with the female condom, the only method that protects against sexually transmitted diseases.



SPERMICIDES

Takes the form of a gel or suppository, is placed in the vagina a few minutes before intercourse and destroys the sperm.

CERVICAL CAP

A very fine dome-shaped silicone disc that covers the cervix. May be inserted a few hours before intercourse or just before. It must be left in place for 8 hours after intercourse. Re-usable.

EMERGENCY CONTRACEPTION

Method of birth control that prevent unwanted pregnancy after unprotected or poorly protected intercourse. A corrective method, not designed to be used regularly.

VASECTOMY

Permanent birth control for men that involves cutting or blocking a segment of the vas deferens (the tubes that carry the sperm).



10. Patient-Doctor Discussion Checklist

To the patient considering the “Essure[®] System for Permanent Birth Control” (“Essure”):
The review and completion of this form is a critical step in helping you decide whether or not to have Essure implanted. You should carefully consider the benefits and risks associated with the device before you make that decision. After reviewing the Essure Patient Information Booklet, please read and discuss the items in this checklist with your doctor. You should not initial or sign the document, and should not undergo the procedure, if you do not understand each of the elements listed below.

Birth Control Options

I understand that Essure is a permanent form of birth control (referred to as “sterilization”) I understand that sterilization must be considered permanent and not reversible.

I was told about other permanent sterilization procedures, such as surgical bilateral tubal ligation (“getting tubes tied”), and their benefits and risks.

I am aware that there are highly effective methods of birth control which are not permanent and which may allow me to become pregnant when stopped.

Patient Initials _____

Requirements for Essure

I understand that I am not a candidate for Essure if:

- I am uncertain about ending my fertility.
- I have had a tubal ligation procedure (“tubes tied”).
- I cannot have my insert(s) placed because my fallopian tube(s) cannot be visualized or blocked.
- I am pregnant or suspect that I may be pregnant.
- I have delivered or terminated a pregnancy within the last 6 weeks.
- I have an active pelvic infection on the date of the scheduled implantation.
- I have unexplained vaginal bleeding.
- I have suspected or known cancer of the female reproductive organs.
- I have a known allergy to contrast dye used during x-ray procedures.

I understand that one or both inserts may not be able to be placed and my options if this occurs. I understand that if this is not possible in my case, I may need to undergo a repeat attempt at Essure placement or consider a different form of birth control.

I understand that the placement procedure is only the first step in relying on Essure for birth control. After placement I must:



- Use an alternative form of birth control until my doctor tells me I can stop (typically for 3 months).
- Schedule and undergo a confirmation test after three months to determine whether I may rely on Essure.

I understand that a satisfactory confirmation test is needed before I can rely on Essure alone. I also understand that after the confirmation test my doctor may inform me that I may not be able to rely on Essure. If this occurs, I will have to use an alternative form of contraception.

I understand that 8% of women who undergo attempts at Essure placement are not able to rely on the device.

Patient Initials _____

Pregnancy Risks

I understand that no form of birth control is 100% effective. Even if my doctor tells me I am able to rely on Essure, there is still a small chance that I may become pregnant. Based on clinical studies, the chance of unintended pregnancy for women who have been told they can rely on Essure is less than 1% at 5 years.

I understand that the risks of Essure on a developing fetus have not been established. If I become pregnant with Essure, there may be a risk for the pregnancy to occur outside of the uterus (“ectopic pregnancy”). This may result in serious and even life-threatening complications. I understand that I should contact my doctor immediately if I think I may be pregnant.

Patient Initials _____

What to Expect During and After the Procedure

I understand that in clinical studies supporting device approval, the following events were reported to occur during the Essure placement procedure and/or in the hours or days following placement:

- Cramping (Reported in 29.6% of procedures)
- Mild to moderate pain (9.3%) or moderate pain (12.9%)
- Nausea/Vomiting (10.8%)
- Dizziness/Lightheadedness (8.8%)
- Vaginal bleeding (6.8%)

If I experience worsening of any of the events listed above or I continue to have the symptoms, I understand that I should contact my doctor.

Patient Initials _____

Long-Term Risks



I understand that some women may experience continued pain or develop new pain later after Essure placement. I understand that I should contact my doctor if abdominal, pelvic or back pain continues or worsens after placement or if I develop the onset of new pain..

I understand that the Essure inserts contain metals including nickel, titanium, stainless steel (iron, chromium, nickel), platinum and silver-tin, as well as a material called polyethylene terephthalate (PET). I understand that some women may develop allergic reactions to the inserts following implantation and have signs or symptoms such as rash and itching. This may occur even if there is no prior history of sensitivity to those materials. I also understand that there is no reliable test to predict ahead of time who may develop a reaction to the insert.

I understand that persistent or new pain, and/or allergic reaction may be a sign of an Essure-related problem which might require further evaluation and treatment, including possibly the need to have the inserts removed by surgery.

I recognize that other symptoms have been reported by women implanted with Essure, although they were not seen in the clinical trials supporting Essure approval. The more common symptoms reported include headache, fatigue, weight changes, hair loss and mood changes such as depression. It is unknown if these symptoms are related to Essure or other causes.

I understand that because Essure contains metals, I should tell all my doctors that I have the device before getting an MRI.

I understand there is a small possibility that the insert could poke through the wall of the uterus or fallopian tubes (“perforation”) during the procedure, and/or may be found in other locations in the abdomen or pelvis. The rate of perforation in the original premarket studies was 1.8%. The rate for an insert being found in the abdomen or pelvis has not been determined but its occurrence is uncommon. I understand that should one of these events occur, the insert may become ineffective in preventing pregnancy and may lead to serious adverse events such as bleeding or bowel damage, which may require surgery to address.

I understand that should my doctor and I decide that Essure should be removed after placement, an additional surgical procedure may be required. In complicated cases, my doctor may recommend a hysterectomy (removal of the entire uterus).

Patient Initials _____



CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the Essure Patient Information Brochure, and that I have had time to discuss the items in it and on this form with my doctor. I have had the opportunity to ask questions and understand the benefits and risks of the device and procedure, and understand that alternative methods of birth control are available.

Patient Signature and Date

Physician: I acknowledge that I have discussed the benefits and risks of Essure as described in the Essure System Patient Information Brochure as well as this form. I have also explained the benefits and risks of other birth control methods. Should device removal become necessary, I may perform the removal myself, or provide a referral to a physician who is willing and able to perform device removals. I have encouraged the patient to ask questions, and I have addressed all questions.

Physician Signature and Date



References

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Glossary

Anesthesia: Medically-induced partial or complete loss of sensation in all or part of the body. Loss of sensation may occur with or without loss of consciousness.

Cervix: The passageway that connects the vagina with the uterus.

Contraceptive: Any process, device, or method that reduces the likelihood of pregnancy.

Ectopic Pregnancy: The development of a fertilized egg outside the uterus, such as in a fallopian tube. Ectopic pregnancies can be dangerous and possibly life threatening.

Endometrial Ablation: A procedure that removes the lining of the uterus to lighten or stop your periods.

Essure Insert: The small, soft, flexible device that is placed in your fallopian tubes for permanent pregnancy prevention.

Fallopian Tubes: The tubes that carry the eggs from the ovaries to the uterus.

Hysteroscope: An instrument that is passed through the vagina and cervix to view the inside of the uterus.

Local Anesthesia: Medically-induced partial or complete loss of sensation of a certain part of the body.

Modified Hysterosalpingogram (modified HSG): An x-ray of the uterus and fallopian tubes after contrast dye has been given for the Essure Confirmation Test.

Occlusion: An obstruction or a closure of a passageway or a vessel.

Transvaginal Ultrasound (TVU): A test used to look at a woman's reproductive organs. An ultrasound device is placed into the vagina, and sound waves are used to see the uterus and fallopian tubes.

Tubal Ligation: A form of permanent birth control by means of cutting, tying, burning or clipping the fallopian tubes so that they are blocked.

Uterus: The womb, where a developing fetus grows.

Vasectomy: Permanent birth control for men that involves cutting or blocking a segment of the vas deferens (the tubes that carry the sperm).