ESSURE PERMANENT BIRTH CONTROL RECOMMENDED INFORMED CONSENT FOR PHYSICIANS

INITIALS

1. **Physician Opinion**

My doctor has advised me of his opinion regarding the Essure.

"Based on a thorough review of scientific literature and current available data, the Essure device is associated with unacceptably high rates of failure and complications even when optimally placed.

As compared to other forms of contraception and permanent birth control, less than 1% of all patients should consider having this device placed in their body as compared to traditional tubal ligation.

Only patients whose male partner cannot have a vasectomy for life threatening reasons; patients who cannot tolerate general, spinal or epidural anesthesia; and, patients who are at risk of life threatening complications from pregnancy, should be considered good candidates for the Essure as compared to traditional tubal ligation."

INITIALS

2. **Food and Drug Administration (FDA) BLACK BOX WARNING (BBW)**

- I have been advised by my doctor of the following BBW and draft guidance recommendations regarding the Essure.

  "WARNING: Some patients implanted with the Essure System for Permanent Birth Control have reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions. Some of these reported events resulted in device removal that required abdominal surgery. This information should be shared with patients considering sterilization with the Essure device during discussion of the benefits and risks of the device."

- I have been advised by my doctor that the ESSURE System is classified as a Class III, high risk device by the FDA. *"Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a* ***potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices."***

  http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/

- Due to its Class III classification, if the device were to cause any harm for reasons found to be associated with the device, I have been made aware that I would have little or no recourse to seek monetary compensation for injuries caused by the device from the manufacturer of the device, which is the Bayer Corporation.

INITIALS

3. I have been advised by my doctor that on September 24, 2015, an OBGYN advisory committee for the FDA recommended a number of changes to the current marketing and advertising of the ESSURE device to include additional data gathering regarding complications associated with the device such as autoimmune and chronic allergic reactions to the device.

INITIALS

4. I have been advised that, due to a significant number of complaints associated with the device, a Congressional bill, called the Fitzpatrick E-Bill, is currently in review in Congress in order to permanently ban the ESSURE device from use in the United States.

INITIALS

5. I understand that the Essure System is a permanent form of birth control (referred to as "sterilization") and that by electing to have the Essure device implanted in my fallopian tubes, I am deciding to permanently end my ability to become pregnant. I understand that sterilization must be considered permanent and not reversible.

INITIALS

6. I understand that the placement of the Essure System is performed as a **surgical procedure** using a special camera, called an operative hysteroscope, which is inserted through my vagina and cervix into my uterus to be able to see my fallopian tubes. The Essure device is then placed in my fallopian tubes.

INITIALS

7. I understand that this procedure can be performed using oral pain medication; under local anesthesia, IV or general anesthesia.

INITIALS

8. I understand the following concerning this surgical procedure:
   - It should take less than 10 minutes per side
   - When done awake under local anesthesia, some women have commented that insertion of the Essure devices causes excruciating pain.

INITIALS

9. I am aware that instead of choosing the ESSURE, I have the option of choosing from a number of temporary, highly effective methods of birth control that are available, which may allow me to bear a child in the future.

INITIALS

10. I have been advised of the risks, benefits, indications and alternatives of the following reversible forms of birth control by my doctor:
    - Mirena, 5 year IUD
    - Skyla, 3 year IUD
    - Paragard, 10 year IUD
    - Nexplanon, 3 year subdermal contraceptive implant
    - Depo Provera, 3 month intramuscular injection
    - NuvaRing, 3 week vaginal ring insert
    - Ortho Evra, 1 week dermal patch
    - Oral Contraceptive Pills
    - Barriers to include Condoms, Diaphragms, Cervical Caps, Dental Dam
    - Natural Family Planning
    - Withdrawal Method (Coitus Interruptus)
    - Emergency Contraception, i.e. Plan B

INITIALS

11. I have been advised by my doctor of the risks, benefits, indications and alternatives of the following permanent forms of birth control by my doctor:
    - Male Vasectomy
    - Postpartum Tubal Ligation (Tying of Tubes following delivery of a baby)
    - Laparoscopic Bilateral Tubal Ligation
    - Mini-Laparotomy Tubal Ligation
    - Filshie or Hulka Clips
    - Silastic Band Sterilization
    - Essure Permanent Birth Control

INITIALS

12. I have been advised by my doctor that any form of permanent birth control which intentionally causes injury or scarring to my fallopian tubes, such as the Essure System, may be associated with permanent changes in my menstrual cycle and other side effects commonly described as Post Tubal Ligation Syndrome (PTLS).

INITIALS

13. I understand that I am **NOT** a candidate for the Essure System if:
    a. I am uncertain about ending my fertility.
    b. I may consider to having a baby in my future.
    c. I have had a tubal ligation procedure ("tubes tied").
    d. I have had previous surgery on my fallopian tubes.
    e. I cannot have two inserts, one in each of my tubes, placed due to my anatomy.
    f. I have a history of tubal injury or infection, to include a history of pelvic inflammatory disease (PID) or ectopic pregnancy
    g. I am pregnant or suspect that I may be pregnant.
    h. I have delivered or terminated a pregnancy within the last 6 weeks.
    i. I have been having unprotected intercourse for the past 30 days.
    j. I have a known allergy to contrast dye used during x-ray procedures.
    k. I suspect or am aware that I will not be able to have my Essure Confirmation Test (ECT) done in 3 months to confirm that the Essure procedure has closed my tubes.
    l. I suspect or am aware that I will not be able to pay for, or my medical insurance will not cover the cost of my 3 month Essure Confirmation Test (ECT)
    m. I will not be able or am unwilling to use effective birth control for at least 3 months following my Essure procedure.

INITIALS

14. I understand that successful placement of the Essure devices into both fallopian tubes may not be possible in some women. If that is the case with me, I may need to undergo a repeat attempt at Essure device placement or consider a different form of birth control, because the system works only when both Essure devices are successfully implanted.

INITIALS

15. I understand that having the insert procedure is only the first step in the process of the Essure System and that:
    - I must use an alternative form of contraception (e.g., intrauterine device (IUD), birth control pill or implant) until my physician tells me I can stop (typically for 3 months, but possibly longer).
    - I must schedule and undergo the Essure Confirmation Test (ECT) recommended by my physician after three months to ensure that my inserted Essure devices are in the proper location and that the fallopian tubes are blocked. I understand that:
        i. this is a critical part of the Essure System procedure and sterilization process
        ii. payment for this test may or may not be covered by my insurance company, especially if I have Medicaid
        iii. some patients have commented that the ECT is associated with excruciating pain when performed awake under local anesthesia.

INITIALS

16. I understand that even after the confirmation test, my physician may inform me that I may not be able to rely on the Essure System for permanent contraception. If this occurs, I will have to use an alternative form of contraception. In a recent study with the Essure device, over 90% of women who underwent attempts at device placement were able to rely on the device for contraception.

INITIALS

17. I understand that no form of birth control is 100% effective and that even if my physician tells me I am able to rely on the Essure System, there is still the possibility that I may become pregnant.
    - Based on currently available data, the chance of unintended pregnancy for women whose confirmation tests indicate that the devices have been successfully placed and the fallopian tubes have been blocked is between 1-9%.
    - **At least one study suggests that the Essure has a failure rate 15x higher than what has been documented with traditional tubal ligation.**

INITIALS

18. I understand that I should contact my physician immediately if I were to suspect or have any indications that I may be pregnant.

INITIALS

19. I understand that if I were to become pregnant, the effects of the Essure device on a developing conceptus, embryo, or fetus during pregnancy has not been established.

INITIALS

20. I understand that if I were to become pregnant, I have the choice of continuing with my pregnancy or terminating my pregnancy.

INITIALS

21. I understand that if I were to get pregnant, my risk of having a pregnancy outside of my uterus (ectopic pregnancy) could be has high as 50%.
    - In this type of pregnancy, the pregnancy cannot be saved.
    - I am at high risk of serious and even life-threatening complications
    - I am at increased risk of suffering from anxiety and depression associated with the required need to terminate my pregnancy

INITIALS

22. I understand that if I were to become pregnant, I am at increased risk of the following:
    - Having a spontaneous abortion
    - Having an Essure induced abortion (EUA)
    - Stillborn or fetal death
    - Premature Rupture of Amniotic Membranes (PROM) leading to, or requiring a premature delivery of my baby
    - Preterm delivery leading to developmental (physical and cognitive) delays

INITIALS

23. I understand that if I were to continue with my pregnancy, I would be considered to be a high risk pregnancy.

INITIALS

24. I understand that if I were to deliver my baby, the effects of the ESSURE device on a developing newborn or child have not been established.

INITIALS

25. I understand that if I were to become pregnant, this confirms the failure of the ESSURE device and I MUST use some other form of birth control to avoid becoming pregnant again.

INITIALS

26. I understand that I must have a 3 month post-insertion HSG done to support the diagnosis that my fallopian tubes are closed. However, even with a HSG confirming the closure of my tubes, I may still become pregnant.

INITIALS

27. I understand the following events were reported to occur during the Essure procedure and/or in the hours or days following insertion. The rates included below in parentheses were reported during the original Essure System studies:
    a. Cramping (Reported in up to 30% of procedures)
    b. Mild to moderate pain (Up to 9-10%) or moderate pain (Up to 13%)
    c. Nausea/Vomiting (Up to 11%)
    d. Dizziness/Lightheadedness (Up to 9%)
    e. Vaginal bleeding (Up to 7%)

    If I experience any of these events listed above, and they persist or worsen in the days to weeks following implantation, I understand that I should promptly consult my physician as they may be a sign of an Essure-related problem that needs prompt attention.

INITIALS

28. I understand that following Essure System placement, some women may experience adverse events including persistent pain, device puncture of the uterus and/or fallopian tubes ("perforation"), or movement of the device into the abdomen or pelvis ("intra-peritoneal migration").

INITIALS

29. The Essure System contains metals including nickel, titanium, iron, chromium, and tin, as well as a material called polyethylene terephthalate (PET).
    - I understand that some women may develop allergic or hypersensitivity reactions to the device following implantation, even if they have no prior history of sensitivity to those materials.
    - I also understand that there is no reliable test, to include a skin allergy test, to predict ahead of time who may develop a reaction to the device.

INITIALS

30. I understand that if I experience any of the following, I should contact my physician:
    a. Abdominal, pelvic or back pain that develops or persists more than 1 week following insertion. Clinical trial data suggest that for those women who do experience pain during and/or immediately after the procedure, most will have their symptoms resolve within a few days, and 99% will have their symptoms resolve within 1 week. However, survey data presented to the FDA and Manufacturer and Device Facility User Experience (MAUDE) suggest a much higher complication rate between 30-70%.
    b. Signs or symptoms consistent with an allergic or hypersensitivity reaction. These may include persistent changes in my skin (rash, itching) but may also include other persistent symptoms such as chest pain, palpitations, breathing difficulties or wheezing, and intestinal discomfort such as nausea, diarrhea, and vomiting. These types of events, although not reported in the clinical trials supporting device approval, have been reported by women implanted with the Essure System.
    c. Other signs or symptoms that continue or recur including joint or muscle pain, muscle weakness, excessive fatigue, hair loss, weight changes, and mood changes. These types of events, although not reported in the clinical trials supporting device approval, have been reported to FDA by women implanted with the Essure System.
    d. I understand that these may be signs of an Essure-related problem, which may require prompt evaluation and intervention, including possibly the need for Essure device removal by surgery.

INITIALS

31. I understand that in some patients, the Essure device can move after placement and:
    a. There is a possibility that the device could poke through the wall of the uterus or fallopian tubes ("perforation"), and/or travel to other locations in the abdomen or pelvis ("migration").
    b. The rate of perforation in the original Essure System study and several subsequent studies was 1% or less.
    c. Some studies have reported rates up to 3-4%. The rate for device migration into the abdomen or pelvis has not been determined.
    d. The device 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.

INITIALS

32. I understand that should my physician and I decide that the Essure System should be removed after placement, I will require a surgical procedure.

INITIALS

33. I understand that the surgical procedures that have been recommended for the removal of the Essure device are:
    a. Abdominal hysterectomy
    b. Laparoscopic Assisted Vaginal Hysterectomy (LAVH)
    c. Linear Salpingostomy
    d. Salpingectomy
    e. Cornual Resection

INITIALS

34. I understand that Essure device removal:
    a. May not be covered by my insurance company
    b. May be associated with retained fragments of the device
    c. May not resolve my symptoms, especially autoimmune symptoms

INITIALS

35. I understand that the Essure System may be associated with an increase risk of endometriosis and adenomyosis.

INITIALS

36. I understand that the Essure System may be associated with increased risk of dental caries, tooth fracture or tooth loss.

INITIALS

37. I understand that if I have an autoimmune condition, such as diabetes, hypo(hyper) thyroidism, rheumatoid arthritis, lupus, fibromyalgia, chronic fatigue syndrome or Sjorgen's Syndrome, my condition may get worse.

CONFIRMATION OF DISCUSSION OF RISKS

Patient: With my signature below, I acknowledge that I have received and read the Essure System for Permanent Birth Control Patient Information Brochure, and that I have had ample time to discuss the items contained within it and on this form with my physician. 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 contraception are available. I voluntarily choose to proceed with placement of the Essure device.

Patient's Signature | Name of Patient (Printed) | Date

Physician: With my signature below, I acknowledge the following:

1. I am proficient in operative hysteroscopy
2. I am Essure certified by Bayer
3. If placing the Essure device in an office setting, I am Advance Cardiac Life Support (ACLS) certified and my office meets the minimum standards for PO, IV and IM sedation.
4. I have discussed the benefits and risks of the Essure device and procedure as described in the Essure System for Permanent Birth Control Patient Information Brochure as well as this document.
5. I have also explained the benefits and risks of other contraceptive methods.
6. Should device removal become necessary, I am qualified to remove the Essure device or manage the complications associated with Essure removal. If not, I will provide a referral to a physician who is willing and able to perform device removals.
7. I have encouraged the patient to ask questions, and I have addressed all questions.
8. I have no monetary conflicts of interests associated with the promotion, sale or placement of this device.
9. I have discussed the facts that my patient should have the Essure Confirmation Test done two (2) months after the placement of her Essure devices.
10. I have confirmed that my patient will have insurance at her 3 month follow-up in order to pay for the Essure Confirmation Test.

Physician's Signature | Name of Physician (Printed) | Date