Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization: Guidance for Industry and Food and Drug Administration Staff

Appendix B: Patient Decision Checklist Example

To the patient considering the Essure System for Permanent Birth Control ("Essure"):
The review and completion of this document 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 information in this brochure, 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 Placement and Reliance
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 two inserts placed due to my anatomy.
- I am pregnant or suspect that I may be pregnant.
- I have delivered or terminated a pregnancy within the last 6 weeks.
- I have had a pelvic infection within six weeks prior to the date of the scheduled implantation.
- I have a known allergy to contrast dye used during x-ray procedures.

Essure works as intended only when the devices are successfully placed in both fallopian tubes. 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 payment for this test may or may not be covered by my insurance company.

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 based on clinical studies, approximately 8% of women who undergo attempts at Essure placement are not able to rely on the device for contraception.

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 an increased 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 after Essure placement, I should contact my doctor immediately if I think I may be pregnant.

Patient Initials _____

What to Expect During the Procedure and the Days Afterwards

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 up to 30% of procedures)
- Mild to moderate pain (Up to 9-10%) or moderate pain (Up to 13%)
- Nausea/Vomiting (Up to 11%)
- Dizziness/Lightheadedness (Up to 9%)
- Vaginal bleeding (Up to 7%)

If I experience worsening of any of the events listed above or I continue to have the symptoms 1 week after placement, 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 after Essure placement. I understand that I should contact my doctor if abdominal, pelvic or back pain continues for more than 1 week after placement or if I develop the onset of new pain more than 1 week after placement.

I understand that the Essure implants contain 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 reactions to the device 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 device.

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 devices removed by surgery.

I recognize that other symptoms have been reported to FDA 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 not.

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

I understand that there is a small possibility that the device could poke through the wall of the uterus or fallopian tubes ("perforation"), and/or move to other locations in the abdomen or pelvis ("migration"). The rate of perforation in studies has ranged from 1% to 4%. The rate for device migration into the abdomen or pelvis has not been determined but its occurrence is uncommon.

I understand that should one of these events occur, 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.

I understand that should my doctor and I decide that Essure should be removed after placement, a surgical procedure will be required. In complicated cases, my doctor may recommend a hysterectomy (removal of the entire uterus). I also understand that device removal may not be covered by my insurance company.

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 in this document 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.

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Patient Signature and Date

Physician: I acknowledge that I have discussed with the patient the benefits and risks of Essure as described in the Essure System Patient Information Brochure as well as this document. 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.

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Physician Signature and Date