



INFORMED CONSENT FOR ESSURE® HYSTEROSCOPIC TUBAL OCCLUSION

It is very important to Women's Health Center of Lebanon that you understand and consent to the treatment your doctor is rendering and any procedure your doctor may perform. You should be involved in any and all decisions concerning surgical procedures your doctor has recommended. Sign this form only after you understand the procedure, the anticipated benefits, the risks, the alternatives, the risks associated with the alternatives and all of your questions have been answered. Please initial and date directly below this paragraph indicating your understanding of this paragraph.

Patient's Initials or Authorized Representative

Date

I, _____, hereby authorize Dr. _____ and any associates or assistants the doctor deems appropriate, to perform the Essure procedure, which is performed by hysteroscopy.

The doctor has explained the benefits of the procedure(s) to me. However, I understand there is no certainty that I will achieve these benefits and no guarantee has been made to me regarding the outcome of the procedure(s). I also authorize the administration of sedation and/or anesthesia as may be deemed advisable or necessary for my comfort, well being and safety.

Proposed Procedure: Essure is a permanent form of birth control – it is not reversible. It is a bilateral tubal sterilization procedure performed under hysteroscopic guidance. Hysteroscopy is a surgical technique for looking inside the uterus using a thin telescope-like device inserted through the vagina and the cervix into the uterus. The hysteroscope is used to identify the openings of the fallopian tubes inside the upper portion of the uterus. Essure micro-inserts are inserted through the openings into the lower segments of the fallopian tubes and are held in place by an outer coiled spring. Over time, the fallopian tube tissues grow around the inserts, creating a blockage in the fallopian tubes. This blockage will prevent passage of sperm through the fallopian tubes and prevent fertilization of the eggs. This minor surgical procedure can be performed under local, regional, or general anesthesia.

Risks/Possible Complications: The doctor has explained to me that there are risks and possible undesirable consequences associated with any procedure including Essure hysteroscopic tubal occlusion procedures. These risks include, but are not limited to, adverse reactions to anesthesia (which will be explained to me by my anesthesiologist); bleeding with subsequent need for transfusion; pain in the pelvis, back or abdomen; infection of the uterus, tubes, peritoneum (abdominal lining); injury to or perforation of the uterus, bowel, or bladder; blood clot formation within the vascular system (DVT); death; loss of fertility; depression; loss of sexual pleasure; allergic reaction to medicines; damaged micro-inserts; failure to place the micro-inserts into the

correct position; over-absorption of fluids at the time of the procedure, which could lead to serious metabolic injury or loss of life; undiagnosed pregnancy at the time of the procedure resulting in pregnancy loss; long-term change in menstrual cycles.

I understand that tubal occlusion cannot be guaranteed following the Essure procedure. Failure to occlude (block) the fallopian tubes could lead to unintended pregnancy either within the uterus or an ectopic pregnancy (a pregnancy that develops in the fallopian tube or abdomen).

By signing this form, I am confirming that I do not have any known allergic reaction to x-ray dye or to nickel.

I have been advised that because tissue growth around the micro-inserts takes time to fully block off the fallopian tubes, I must use an alternative form of birth control for three (3) to six (6) months following the Essure procedure until an x-ray is performed which confirms tubal blockage.

I understand that there is a small chance that the micro-insert cannot be placed into the fallopian tubes at the time of surgery, which means the procedure would be abandoned and an alternative sterilization procedure would need to be performed in another setting at another time.

Alternative Procedures: The reasonable alternative(s) to the procedure(s), as well as the risks to the alternatives, have been explained to me. These alternatives include, but are not limited to, laparoscopic tubal ligation or reversible forms of contraception.

I understand the risks associated with the alternatives include, but are not limited to, incomplete closure of the tubes, ectopic pregnancy, injury to organs or structures due to surgical equipment, infection, and bleeding.

I hereby authorize my surgeon(s) and the hospital to dispose of removed tissues resulting from the procedure(s) authorized above.

I consent to the photographing or videotaping of the procedure(s) that may be performed, provided my identity is not revealed by the pictures or by descriptive text accompanying them.

I have been given the Essure Patient Information Booklet to review and have had any questions I had answered.

By signing below, I certify that I have had an opportunity to ask the doctor all my questions concerning anticipated benefits, material risks, alternative therapies, and risks of those alternatives, and all of my questions have been answered to my satisfaction.

_____/_____/_____
Date Time Signature of Patient or Authorized Rep. Relationship of Authorized Rep.

The Patient/Authorized Representative has read this form or had it read to him/her.
The Patient/Authorized Representative states that he/she understands this information
The Patient/Authorized Representative has no further questions.
The Patient/Authorized Representative has read the form in Spanish.

I certify that I have asked the patient/authorized representative the above questions and her responses were noted above.

Date Time Signature of Witness

CERTIFICATION OF PHYSICIAN:

I hereby certify that I have discussed with the individual granting consent, the facts, anticipated benefits, material risks, alternative therapies and the risks associated with the alternatives of the procedure(s).

Date Time Signature of Physician

USE OF INTERPRETER OR SPECIAL ASSISTANCE

An interpreter or special assistance was used to assist patient in completing this form as follows:

_____ Foreign language (specify)
_____ Sign language
_____ Patient is blind, form read to patient
_____ Other (specify) _____

Interpretation provided by _____
(Fill in name of Interpreter and Title or Relationship to Patient)

Signature (Individual Providing Assistance) Date Time