

# **A New Method of Permanent Birth Control:**

The  
**essure™**  
Permanent Birth Control System

## **Patient Information Booklet**

**IMPORTANT**

This product is intended to prevent pregnancy.  
It does not protect against HIV infection and other sexually transmitted diseases.

This brochure is designed to provide important information regarding permanent female contraception using a device known as the **Essure Permanent Birth Control System**. Use of this medical device requires discussion with a qualified doctor. It is important that you read this booklet carefully and discuss its contents with your doctor.

## **The Essure? Permanent Birth Control System**

### **Your choice about permanent birth control**

You are reading this brochure because you are considering choices about permanent birth control (female sterilization). Sterilization is intended to prevent pregnancy for the rest of your life.

This brochure is about a new method of permanent birth control called **Essure**. Because it is intended to permanently prevent pregnancy, it is similar to other permanent birth control procedures such as tubal ligation ("having your tubes tied") or vasectomy.

**Essure** is a lower impact approach than incisional tubal ligation and is gentler on your body because it can be performed without general anesthesia, does not involve cutting through the skin and recovery is quick.

This brochure will provide you with information about **Essure** as well as the benefits and risks; however, this information is not intended to be comprehensive as all women have individual needs and concerns. Your doctor will advise you whether the procedure is appropriate for you with regards to your circumstances and medical history.

### **What is the Essure procedure?**

The **Essure** procedure involves placing a small, flexible device called a Micro-insert into each of your two fallopian tubes (the tubes where your eggs travel from your ovaries to your uterus). The Micro-inserts are made from materials that have been well studied and used successfully in the heart and other parts of the human body for many years. Once the Micro-inserts are in place, your body tissue grows into the Micro-inserts, blocking the fallopian tubes. Blocking the tubes is intended to prevent sperm from fertilizing the egg, thereby preventing pregnancy. Your doctor will be able to explain the procedure to you in more detail.

### **Is Essure right for you?**

The **Essure** procedure is only appropriate if you are sure you don't want any more children, would like to have permanent birth control and believe you will not change your mind. If there is any chance you may want to have children in the future, you should choose another form of birth control. You should avoid making this choice during times of stress, such as a divorce or after a miscarriage, and NEVER under pressure from a partner or others.

You should be aware that there are other methods of birth control, both temporary/reversible and permanent. The table on the following page shows pregnancy rates for various birth control methods. Your doctor will explain these alternative methods to you and advise you whether **Essure** is a suitable option for you. It is your right to decide what method suits you. If, at any time before the **Essure** procedure, you decide not to have it, you should tell your doctor and cancel the procedure. You do not have to provide any explanation or reason for your decision.

If you decide you want the **Essure** procedure, you will have a general examination and laboratory tests to confirm that you are a good candidate for the procedure. It may turn out that the **Essure** procedure is not an option for you.

## Pregnancy Rates for Birth Control Methods (For One Year of Use)

The following table provides estimates of the percent of women likely to become pregnant while using a particular contraceptive method for one year. These estimates are based on a variety of studies.

**"Typical Use"** rates mean that the method either was *not always used correctly* or was *not used with every act of sexual intercourse* (e.g., sometimes forgot to take birth control pill as directed and became pregnant), or was *used correctly but failed anyway*.

**"Lowest Expected"** rates mean that the method was *always used correctly with every act of sexual intercourse but failed anyway* (e.g., always took a birth control pill as directed but still became pregnant).

Method	Typical Use Rate of Pregnancy	Lowest Expected Rate of Pregnancy
<b>Sterilization:</b>		
Male Sterilization	0.15%	0.1%
Female Sterilization	0.5%	0.5%
<b>Hormonal Methods:</b>		
Implant ( <i>Norplant™ and Norplant™ 2</i> )	0.05%	0.05%
Hormone Shot ( <i>Depo-Provera™</i> )	0.3%	0.3%
Combined Pill ( <i>Estrogen/Progestin</i> )	5%	0.1%
Minipill ( <i>Progestin only</i> )	5%	0.5%
<b>Intrauterine Devices (IUDs):</b>		
Copper T	0.8%	0.6%
Progesterone T	2%	1.5%
<b>Barrier Methods:</b>		
Male Latex Condom <sup>1</sup>	14%	3%
Diaphragm <sup>2</sup>	20%	6%
Vaginal Sponge ( <i>no previous births</i> ) <sup>3</sup>	20%	9%
Vaginal Sponge ( <i>previous births</i> ) <sup>3</sup>	40%	20%
Cervical Cap ( <i>no previous births</i> ) <sup>2</sup>	20%	9%
Cervical Cap ( <i>previous births</i> ) <sup>2</sup>	40%	26%
Female Condom	21%	5%
<b>Spermicide:</b> ( <i>gel, foam, suppository, film</i> )	26%	6%
<b>Natural Methods:</b>		
Withdrawal	19%	4%
Natural Family Planning ( <i>calendar, temperature, cervical mucus</i> )	25%	1-9%
<b>No Method:</b>	85%	85%

<sup>1</sup> Used Without Spermicide

<sup>2</sup> Used With Spermicide

<sup>3</sup> Contains Spermicide

Data adapted from: Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Stewart F, et al Contraceptive Technology: Seventeenth Revised Edition. New York, NY: Ardent Media, 1998.

## **THE ESSURE PROCEDURE: KEY CONSIDERATIONS**

### **The procedure should be considered irreversible**

There are no data on the safety or effectiveness of surgery to reverse the **Essure** procedure. It is only meant to be used by women who are certain they no longer want to have children. There are also no data on the safety or effectiveness of *in vitro* fertilization (IVF) after the **Essure** procedure has been performed.

### **Like all methods of birth control, the Essure procedure should not be considered 100% effective**

No method of birth control is 100% effective and there is a small chance you could become pregnant.

### **There is a waiting period after the procedure**

A pelvic x-ray will be taken three months after the procedure to determine the location of the Micro-inserts. Based on the results of the x-ray, your doctor will advise you whether the **Essure** Micro-insert can be relied on for permanent birth control. Because of this 3-month waiting period, you will need to talk to your doctor (before the procedure is performed) about alternative contraceptive options to cover this time.

### **The Essure procedure is newer than other procedures**

**Essure** is one of the newest methods of permanent birth control, so it hasn't been studied in as many women or for as long as most birth control methods.

### **As with all procedures, there are risks associated with Essure**

You should be aware of these risks and discuss them in detail with your doctor before you make your decision. There is a list of risks detailed in this brochure. Many of them are rare. You should talk to your doctor about the likelihood of these risks, particularly in relation to your own situation.

### **What is the Essure procedure like for women?**

Two separate trials of the effectiveness of the **Essure** procedure have been conducted in women from the United States, Australia, and Europe. This first trial involved approximately 200 women and the second trial involved approximately 500 women. Based on data from these trials, the **Essure** procedure is:

- effective
- quick
- highly rated by women

### **Effective**

If the **Essure** procedure is completed successfully, the one-year effectiveness rate is greater than 99.8%.

### **Quick**

The average procedure time was about 15 minutes in each trial.

### **Essure is highly rated by women**

- ? 88-89% of women rated their tolerance of the procedure as 'good' to 'excellent' in both trials.
- ? General anesthesia was not required, however 4% of patients or physicians elected to do the procedure under general anesthesia in the first trial. In the second trial, less than 1% of patients or physicians elected to do so.
- ? 92% of women missed only one day or less of work, not including the day of the procedure. After three days, 99% of women were back at work. This was evaluated in the second trial only.
- ? One year after the procedure, women rated the **Essure** Micro-inserts very highly. Overall, over 500 women have used the Micro-inserts for more than a year and 99% have rated their overall comfort as 'good' to 'excellent'.

### **Risks and adverse events of the Essure procedure and Micro-insert**

As with all procedures, there are risks associated with the **Essure** procedure and Micro-insert. The Safety Summary below includes detailed information on the known or possible risks associated with the **Essure Permanent Birth Control System**. There may be more risks that have not yet been identified. If you decide to have the procedure, your doctor will provide more detailed information about these risks and their likelihood for your particular circumstances. Many of these risks are rare.

This section is not intended to be a substitute for a thorough discussion with you doctor about whether this treatment is right for you. Please read this section carefully, then talk to your doctor.

## SAFETY SUMMARY

### Indications for Use

The **Essure Permanent Birth Control System** is indicated for permanent birth control (female sterilization) by occlusion of the fallopian tubes.

### Contraindications

The **Essure Permanent Birth Control System** should not be used if you are:

- ? Uncertain about your desire to end fertility.
- ? Currently taking systemic corticosteroids.

Or, if you have any of the following conditions:

- ? Pregnancy or suspected pregnancy.
- ? Delivery or termination of a second trimester pregnancy less than 6 weeks before **Essure** Micro-insert placement.
- ? Active or recent pelvic infection.
- ? Untreated acute cervicitis.
- ? Gynecological malignancy (suspected or known).
- ? Known abnormal uterine cavity or fallopian tubes that would make visualization of the tubal opening and/or catheterization of the proximal fallopian tube difficult or impossible.
- ? Known allergy to contrast media.
- ? Known hypersensitivity to nickel confirmed by skin test.

### Warnings

- ? Whenever possible, Micro-insert placement should be performed during days 7-14 of your menstrual cycle (where day 1 represents the first day of bleeding). This will help your doctor to see your fallopian tube openings and decrease the chance of your doctor placing the **Essure** Micro-inserts when you may have an undiagnosed pregnancy.
- ? You cannot immediately rely on the **Essure** Micro-inserts for contraception and must use alternative contraception until an x-ray performed three months after the **Essure** procedure demonstrates satisfactory Micro-insert location.
- ? You may, in future years, be offered intrauterine therapies that utilize electrical energy. Due to the presence of the **Essure** Micro-inserts, there may be risks associated with such procedures that, at this time, have not been identified.
- ? Any intrauterine procedure performed following the **Essure** procedure could interrupt the ability of the **Essure** Micro-inserts to prevent pregnancy. In addition, the presence of the **Essure** Micro-inserts could involve risks associated with such procedures that, at this time, have not been identified.

- ? There are no data on the safety or effectiveness of surgery to reverse the **Essure** procedure.
- ? In future years, you may decide to undergo *in vitro* fertilization (IVF) to become pregnant. You should know that the effects of the **Essure** Micro-inserts on the success of IVF are unknown. If pregnancy is achieved, the risks of the Micro-inserts to your health, to the health of your baby and to the continuation of your pregnancy are unknown.

### **Precautions**

Testing to ensure safety and compatibility with Magnetic Resonance Imaging (MRI) has been conducted using a 1.5 Tesla magnet. The **Essure** Micro-inserts were found to be MR safe at this field strength. However, the presence of the Micro-inserts produces an MR artifact which will obscure imaging of local tissue.

### **Risk/Benefit Analysis**

The information derived from the clinical investigation of the **Essure Permanent Birth Control System** indicates that the **Essure** procedure provides an adequate alternative means of permanent birth control with a reasonable assurance of safety and effectiveness. Following is a summary of known risks and benefits associated with use of the device.

### **Risks**

The following risks are possible with the **Essure Permanent Birth Control System**:

- ? No placement or unsatisfactory placement of the Micro-inserts. In the clinical trials, approximately 8% of women were not able to have the Micro-inserts placed in at least one fallopian tube. At routine 3-month follow-up, an additional 4.5% were found to be incorrectly placed. These women could not *initially* rely on the **Essure** Micro-inserts for birth control. The types of improper placement include:
  - The Micro-insert placed in an unsatisfactory location
  - Perforation (e.g., a small hole in the wall of the fallopian tubes or uterus)
  - Movement of the Micro-insert after placement (including expulsion of the Micro-insert from the body due to improper placement)
- ? Breakage of the **Essure** Micro-insert
- ? Vaso-vagal response (e.g., nausea, sweating, slowness of the heartbeat, and rapid fall in blood pressure)
- ? Fluid over-absorption (absorption by the body of the saline used in the Micro-insert placement procedure in excessive quantities)
- ? Pain, cramping, vaginal bleeding
- ? Nausea/vomiting or fainting
- ? Regret
- ? Periods (menses) that are heavier or longer than normal, as well as bleeding between periods.
- ? Risks associated with anesthesia use
- ? Infection
- ? Pregnancy and ectopic pregnancy
- ? Women who undergo the placement procedure during the second half of their menstrual cycle (after ovulation) are at an increased risk of unknowingly being

pregnant at the time of the placement procedure. Therefore, the Micro-insert placement procedure should be scheduled during the first half of the menstrual cycle.

- ? Perforation (a small hole) in internal bodily structures other than the uterus and fallopian tube.
- ? Potential for pelvic inflammatory disease.
- ? Risks associated with the hysterosalpingogram or x-rays.
- ? The effect that the **Essure** Micro-insert could have on future medical procedures that involve the uterus or fallopian tube, especially those that might use electrosurgical energy (a form of electricity used in surgery).
- ? The effect of future medical procedures that involve the uterus or fallopian tubes on the ability of the **Essure** Micro-insert to provide protection against pregnancy.
- ? The risks and success of *in vitro* fertilization (IVF) with the **Essure** Micro-inserts in place.
- ? There are no data on the safety or effectiveness of surgery to reverse the **Essure** procedure.

### **Benefits**

The **Essure Permanent Birth Control System** is an effective means of permanent birth control (female sterilization). The **Essure Permanent Birth Control System** allows:

- ? A non-incisional alternative to incisional tubal ligation - the device is placed in the fallopian tubes using a delivery catheter, which is passed through the cervix.
- ? Avoidance of general anesthesia - General anesthesia (being asleep while surgery takes place) is not required, however a small percentage of patients or physicians have elected to do the procedure under general anesthesia.
- ? Fast Recovery - On average, patients are able to go home 45 minutes after the procedure and return to normal activities in an average of 1-2 days.
- ? Quick - Your procedure time should be about 15 minutes.
- ? No scars - You will not have any scars because it does not involve cutting into the skin.
- ? Rapid return to work - 92% of women treated in the clinical trial missed one day or less of work following the procedure (not including the day of the procedure).

## Glossary

**Anesthesia** - Partial or complete loss of sensation with or without loss of consciousness.

**Cervix** - The neck of the uterus.

**Contraceptive** - Any process, device or method that prevents conception (pregnancy).

**Delivery Catheter** - A long tube-like device that assists in the placement of the **Essure** Micro-inserts in the fallopian tubes.

**Ectopic Pregnancy** - Implantation of the fertilized egg outside of the uterus.

**Effectiveness** - Producing, or able to produce a desired effect.

**Expulsion** - To force something out.

**Fallopian Tubes** - The tubes that carry the eggs from the ovary to the uterus.

**Hysterosalpingogram** - An x-ray of the uterus and ovaries after filling the organs with dye.

**In vitro Fertilization** - Fertilizing an egg outside of the living body (in a test tube).

**Occlusion** - To close up or block off.

**Perforation** - Making a hole through something.

**Permanent** - Not able to change back and forth.

**Reversible** - Able to change back and forth.

**Tubal Ligation** - Permanent female sterilization by means of cutting and tying the fallopian tubes.

**Uterus** - An organ of the female reproductive system for containing and nourishing the embryo and fetus (baby) from the time the fertilized egg is implanted to the time of birth of the fetus.

**Vasectomy** - Permanent male sterilization by means of removal of all or a segment of the vas deferens (the tube that transports the sperm).

For more information on the Essure procedure, please speak to your doctor.

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