THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

HELEN MCLAUGHLIN, Plaintiff, v. BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G., Defendants.	Civil Action No. 2:14-cv-07315-JP The Hon. John R. Padova
RUTH RUBLE, Plaintiff, v. BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G., Defendants.	Civil Action No. 2:14-cv-07316-ER
MELDA STRIMEL, Plaintiff, v. BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G., Defendants.	Civil Action No. 2:14-cv-07317-LFR

SUSAN STELZER, Plaintiff, v. BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G., Defendants.	:	Civil Action No. 2:14-cv-07318-ER
HEATHER WALSH, Plaintiff, v. BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G., Defendants.	:	Civil Action No. 2:15-cv-00384-GP

POST-ARGUMENT JOINT SUBMISSION
CONCERNING PLAINTIFFS' WARRANTY CLAIMS

At the direction of the Court, the parties discussed plaintiffs' warranty claims on January 12, 2016, and plaintiffs agreed to withdraw the following paragraphs without prejudice[1]:

103(a), (b) as to all plaintiffs except McLaughlin;
103(d);
103(h);
104(a) as to all plaintiffs except McLaughlin;
104(c) as to all plaintiffs except McLaughlin;
104(d) as to all plaintiffs except McLaughlin;
105;
106;
107 as to all plaintiffs except McLaughlin;
108(a), (b);
109;
111(d);
111(e);

[1] Paragraph numbers from the *McLaughlin* Amended Complaint.

111(f) as to all plaintiffs except McLaughlin;
112;
114;
116(a), (b), (c);
117;
118; and
119.

Attached hereto as Exhibit "A" is a chart of the remaining warranty claims. At the direction of the Court, defendants have noted where those warranty claims appear in FDA-approved statements including various iterations of the patient labeling ("Patient Information Booklet") or physician labeling ("Instructions For Use"). We have also indicated situations in which the statements came from FDA's Summary of Safety and Effectiveness Data or were intended for physicians or other parties and not consumers.

Attached hereto as Exhibit "B" is a chart containing Plaintiffs' position on the same.[2]

Respectfully submitted,

Dated: January 15, 2016

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[2] Defendants did not understand the Court to invite further argument on the warranties, and hence have not provided any further argument on those claims.

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EXHIBIT A: CHART OF REMAINING "FACTS AND WARRANTIES CLAIMS"

Complaint Paragraph[1]	**Contested Statement**	**FDA-Approved Source Language**
103(a)	"Only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials."	"As of October 15, 2004 (the date of the last data extract), 643 women with bilateral placement contributed effectiveness time, 194 in the Phase II study and 449 in the Pivotal Trial. In total, the 643 trial participants contributed 28,290 months of follow-up time with no (zero) pregnancies reported." Page 3, **2008 Instructions for Use, part of PMA Supplement 15, Approved June 10, 2008**[2] "None of the women who relied on *Essure* for contraception during the clinical trials became pregnant over the 1 to 2 years of follow-up." Page 5, **2002 Patient Information Booklet**[3]
103(b)	"There were zero pregnancies in the clinical trials"	"As of October 15, 2004 (the date of the last data extract), 643 women with bilateral placement contributed effectiveness time, 194 in the Phase II study and 449 in the Pivotal Trial. In total, the 643 trial participants contributed 28,290 months of follow-up time with no (zero) pregnancies reported." Page 3, **2008 Instructions for Use, part of PMA Supplement 15, Approved June 10, 2008** "None of the women who relied on *Essure* for contraception during the clinical trials became pregnant over the 1 to 2 years of follow-up." Page 5, **2002 Patient Information Booklet**

[1] All references are to the *McLaughlin* First Amended Complaint.

[2] Attached

[3] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452280.htm

103(c)	"Physicians must be signed off to perform Essure procedures"	"This Device should only be used by physicians who are knowledgeable hysteroscopists; have read and understood the information in the Instructions for Use and in the Physician Training Manual; and have successfully completed the Essure® training program. Completion of the Essure training program includes preceptoring in Essure placement until competency is established, which is typically expected to be achieved in 5 cases." Page 1 (Box warning), **2008 Instructions for Use, part of PMA Supplement 15, Approved June 10, 2008**
103(e)	"Worry free: Once your doctor confirms that your tubes are blocked, you never have to worry about unplanned pregnancy"	**"Essure may be right for you if:** • You are certain you do not want any more children. • You desire a permanent form of birth control. • You would like to stop worrying about getting pregnant." Page 4, **2014 Patient Information Booklet**[4] "After 3 months, your doctor will perform a special type of x-ray test called an HSG. This test will assure you that your tubes are completely blocked and you can rely on the Essure micro-inserts for birth control." Page 3, **2007 Patient Information Booklet, part of PMA Supplement 13, Approved September 19, 2006**[5] "Reliance can begin at 3 months when the Essure confirmation test confirms placement and blockage of the tubes." Page 9, **2007 Patient Information Booklet, part of PMA Supplement 13, Approved September 19, 2006**

[4] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452280.htm

[5] Attached.

103(f)	"Essure is the most effective permanent birth control available-even more effective than tying your tubes or a vasectomy."	2007 Patient Information Booklet (comparison chart showing effectiveness rates in vasectomy, tubal ligation, and Essure) Page 9, **2007 Patient Information Booklet, part of PMA Supplement 13, Approved September 19, 2006**
103(g)	"Correct placement .. .is performed easily because of the design of the microinsert"	Defendants cannot respond since Plaintiffs have not identified the alleged source of this statement.
103(i)	"the Essure training program is a comprehensive course designed to provide information and skills necessary to select appropriate patients, perform competent procedures and manage technical issues related to the placement of Essure micro-inserts for permanent birth control."	Plaintiffs have not identified the source of this alleged statement, but it appears directed to physicians and not patients.
103(j)	"In order to be trained in Essure you must be a skilled operative hysteroscopist. You will find the procedure easier to learn if you are already proficient in operative hysteroscopy and management of the awake patient. If your skills are minimal or out of date, you should attend a hysteroscopy course before learning Essure."	Plaintiffs have not identified the source of this alleged statement, but it statement appears directed to physicians and not patients. "This Device should only be used by physicians who are knowledgeable hysteroscopists." Page 1 (Box warning), **2008 Instructions for Use, part of PMA Supplement 15, Approved June 10, 2008**
103(k)	"Essure is a surgery-free permanent birth control"	"Essure is indicated for women who desire permanent birth control (female sterilization)…" Page 1, **2008 Instructions for Use, part of PMA Supplement 15, Approved June 10, 2008**

		"The Essure™ System provides permanent birth control without invasive surgery or general anesthesia, and their associated risks." Page 22, **FDA's Summary of Safety and Effectiveness Data for Essure (FDA Document)**[6]
104(a)	"Zero pregnancies" in its clinical or pivotal trials.	"As of October 15, 2004 (the date of the last data extract), 643 women with bilateral placement contributed effectiveness time, 194 in the Phase II study and 449 in the Pivotal Trial. In total, the 643 trial participants contributed 28,290 months of follow-up time with no (zero) pregnancies reported." Page 3, **2008 Instructions for Use, part of PMA Supplement 15, Approved June 10, 2008** "None of the women who relied on *Essure* for contraception during the clinical trials became pregnant over the 1 to 2 years of follow-up." Page 5, **2002 Patient Information Booklet**
104(b)	In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks.	Plaintiffs have not identified the source of this alleged statement, but it appears directed to physicians, not patients.
104(c)	No pregnancies have occurred after a successful confirmation test in the Essure clinical studies at 4 and 5 years of follow up.	"As of the final 5-year follow-up data extracts (phase II-January 6, 2006; Pivotal-December 5, 2007), 643 trial participants with bilateral placement (194 Phase II; 449 Pivotal) contributed 35,633 months of follow-up time with zero pregnancies reported." Page 4, **Current Instructions for Use**[7]

[6] http://www.accessdata.fda.gov/cdrh_docs/pdf2/p020014b.pdf

[7] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452280.htm

104(d)	"I don't want to worry about an unexpected pregnancy"	**"Essure may be right for you if:** • You are certain you do not want any more children. • You desire a permanent form of birth control. • You would like to stop worrying about getting pregnant." Page 4, **2014 Patient Information Booklet** "After 3 months, your doctor will perform a special type of x-ray test called an HSG. This test will assure you that your tubes are completely blocked and you can rely on the Essure micro-inserts for birth control." Page 3, **2007 Patient Information Booklet, part of PMA Supplement 13, Approved September 19, 2006** "Reliance can begin at 3 months when the Essure confirmation test confirms placement and blockage of the tubes." Page 9, **2007 Patient Information Booklet, part of PMA Supplement 13, Approved September 19, 2006**
107	Defendants' CEO stated: "Essure allows you to push away the constant worry about an unplanned pregnancy that's our message and that's our theme.	This statement appears to come from a Q4 2007 Essure Earnings Call Transcript; patients were not the intended recipients.
110(a)	Defendants warranted that Essure "allows for visual confirmation of each insert's proper placement both during the procedure and during the Essure Confirmation Test."	Defendants cannot respond since Plaintiffs have not identified the alleged source of this statement.
111(a)	"Worry free"	"• You would like to stop worrying about getting pregnant." Page 4, **2014 Patient Information Booklet**

111(b)	"The Essure inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place."	Defendants cannot respond since Plaintiffs have not identified the alleged source of this statement.
111(c)	"The Essure inserts are made from the same trusted, silicone free material used in heart stents."	"The micro-inserts are made from polyester fibers and metals (nickel-titanium and stainless steel), materials that have been studied and used in the heart and other parts of the human body for many years." Page 4, **2002 Patient Information Booklet**
111(f)	Step Two: "pregnancy **cannot** occur"; Step Three: The Confirmation	Defendants cannot respond since Plaintiffs have not identified the alleged source of this statement.
111(g)	"Essure **eliminates** the risks, discomfort, and recovery time associated with surgical procedures."	"The Essure™ System provides permanent birth control without invasive surgery or general anesthesia, and their associated risks. The majority of women returned to normal activities within one day or less after the procedure. The vast majority of women rated their comfort with wearing the Micro-inserts at one -week as 'good' to 'excellent'. The vast majority of women rated their overall satisfaction with the Essure™ System as 'very satisfied'." Page 22, **FDA's Summary of Safety and Effectiveness Data for Essure (FDA Document)**
113(a)	"The inserts are made from ... safe, trusted material."	"The micro-inserts are made from polyester fibers and metals (nickel-titanium and stainless steel), materials that have been studied and used in the heart and other parts of the human body for many years." Page 4, **2002 Patient Information Booklet**
115(a)	"This viewable portion of the micro-insert serves to verify placement and does not	Verbatim statement: Page 9, **2007 Patient Information Booklet, part of PMA Supplement 13, Approved**

	irritate the lining of the uterus."	**September 19, 2006**
115(b)	"there was no cutting, **no pain,** no scars ... "	Verbatim statement: Page 16, **2007 Patient Information Booklet, part of PMA Supplement 13, Approved September 19, 2006**

ESS305
Purple Handle

essure®

essure

English

Permanent Birth Control by Conceptus

INSTRUCTIONS FOR USE

IMPORTANT

- Caution: Federal law restricts this device to sale by or on the order of a physician. This device should only be used by physicians who are knowledgeable hysteroscopists, have read and understood the information in this Instructions for Use and in the Physician Training Manual, and have successfully completed the **Essure** training program. Completion of the **Essure** training program includes preceptoring in **Essure** placement until competency is established, which is typically expected to be achieved in 5 cases.

IMPORTANT

- The **Essure** micro-inserts should NOT be relied on for contraception until the patient has undergone an **Essure** Confirmation Test [hysterosalpingogram (HSG)] 3 months after micro-insert placement, which demonstrates **both** bilateral tubal occlusion **and** satisfactory location of the micro-inserts.
- If **Essure** micro-inserts cannot be placed bilaterally, then the patient should not rely on this method of sterilization. **Essure** micro-inserts have not been proven to be effective when it is placed unilaterally.
- This product is intended to prevent pregnancy. It does not protect against either HIV infection or other sexually transmitted diseases.

NOTE: A patient ID card is supplied with each Essure system. Please give this to your patient and ask that she carry it with her at all times and show it to other physicians involved in her present or future care.

I. OVERVIEW OF ESSURE PROCEDURE AND PRINCIPLES OF OPERATION

Using a transvaginal approach, one **Essure** micro-insert is placed in the proximal portion of each fallopian tube lumen. When the **Essure** micro-insert expands upon release, it acutely anchors itself in the fallopian tube. Subsequently, the **Essure** micro-insert elicits an intended benign, occlusive tissue response, resulting in tissue in-growth into the device that anchors the device and occludes the fallopian tube, resulting in permanent contraception.

II. DEVICE DESCRIPTION

The **Essure** system is comprised of the **Essure** micro-insert, a disposable delivery system, and a disposable introducer.

The **Essure** micro-insert is a dynamically expanding micro-coil that consists of a stainless steel inner coil, a Nitinol expanding, super-elastic outer coil, and polyethylene terephthalate (PET) fibers. The PET fibers are wound in and around the inner coil. The micro-insert, shown below in its wound-down and expanded configurations **(Figure 1a and Figure 1b, respectively)**, is 4 cm in length and 0.8 mm in diameter in its wound down configuration. When released from the delivery system, the outer coil expands to 1.5 to 2.0 mm in diameter to anchor the micro-insert in the varied diameters and shapes of the fallopian tube.

Figure 1a
Essure Micro-insert
Shown in its wound-down configuration, attached to release catheter
(NOT TO SCALE)

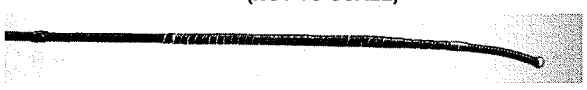
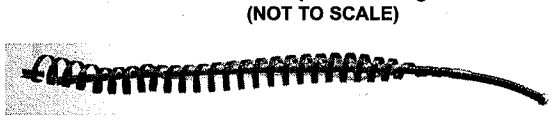


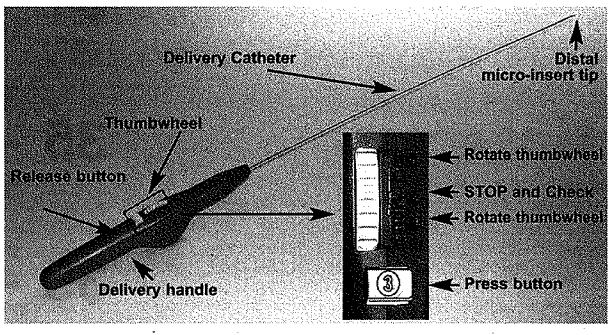
Figure 1b
Essure Micro-insert
Shown in its expanded configuration
(NOT TO SCALE)



The disposable delivery system, (shown in **Figure 2**), consists of a delivery wire, a release catheter, a delivery catheter and a delivery handle.

NOTE: The delivery wire and the release catheter are not visible in **Figure 2.**

Figure 2
Essure Delivery System
Showing detail of placement procedure symbols
(NOT TO SCALE)

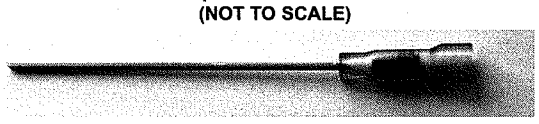


The **Essure** micro-insert is provided attached to the delivery wire, in a wound-down configuration. The delivery wire is composed of a nitinol core wire, which is ground at the distal end to result in a flexible, tapered profile. The device is constrained and sheathed by a flexible delivery catheter. A black positioning marker on the delivery catheter aids in proper placement of the device in the fallopian tube.

The delivery handle controls the device delivery and release mechanism. The thumbwheel on the delivery handle retracts the delivery catheter. The button allows the physician to change the function of the thumbwheel from retracting the delivery catheter to deploying the outer coils. The delivery wire is detached from the micro-insert by continuing to rotate the thumbwheel. To remind the physician of these placement procedure steps, symbols are located on the delivery handle (refer to **Figure 2**).

The introducer (**Figure 3**) is placed into the sealing cap of the working channel of the hysteroscope, and is intended to help protect the **Essure** micro-insert as it is being passed through the sealing cap of the hysteroscope working channel. Please see Section XIV.B, step #8, for a drawing showing how the **Essure** system is introduced through the introducer. Additional valved introducers are available from *Conceptus* as the **DryFlow™** introducer.

Figure 3
Conceptus Valved Introducer
(NOT TO SCALE)

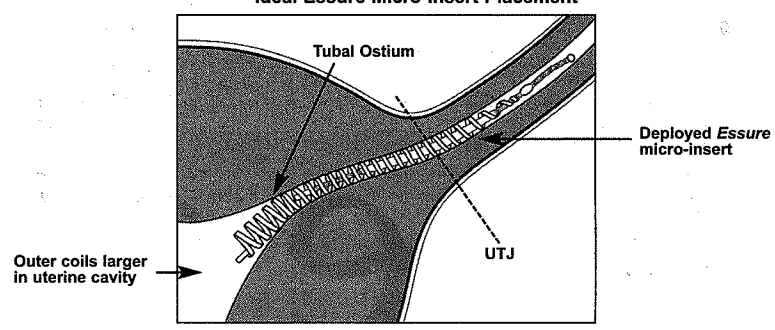


III. MECHANISM OF ACTION

A. Placement at Utero-Tubal Junction (UTJ)

The **Essure** micro-insert is intended for placement into the fallopian tube with the implant portion of the device spanning the utero-tubal junction (UTJ). For purposes of micro-insert placement, the UTJ is defined as the portion of the fallopian tube, just as it exits the uterus (refer to **Figure 4** for graphic representation of UTJ). This specific portion of the anatomy was chosen for the site of implantation so that devices would be placed far enough into the tube to prevent expulsion due to uterine contractions during menses, yet still proximal enough to allow a portion of the device to trail into the uterus (specifically, 3-8 coils or approximately 5-10 mm). It is desirable to have a trailing portion in the uterus to aid device anchoring. This anchoring is achieved by the greater outer diameter of the expanded coils that trail into the uterus, as compared to the outer diameter of the expanded coils within the fallopian tube. The outer diameter of the expanded coils trailing in the uterus is expected to be as much as two times the outer diameter of the expanded coils that are compressed by the walls of the fallopian tube at the UTJ (**Figure 4**). In addition, placement at the UTJ is expected to aid in anchoring since it most consistently represents the narrowest portion of the fallopian tube. Unacceptable rates of expulsions and failures with transcervical sterilization devices that were placed more proximally, at the ostial section of the fallopian tube, have been noted in the literature. In addition, expulsion of the **Essure** micro-insert has occurred when micro-insert placement was too proximal. Finally, if the device is placed without any trailing portion of the device in the uterus, then direct visualization of device location is not possible.

Figure 4
Ideal Essure Micro-insert Placement



B. Dynamic Anchoring

The **Essure** micro-insert is a dynamic, spring-like device, in that it is inserted into the fallopian tube at a reduced diameter, and then expands once deployed to conform to the fallopian tube. The spring-like mechanism is intended to provide the necessary anchoring forces during the acute phase of device implantation (3 months post-micro-insert placement), during which time the PET fibers are eliciting tissue in-growth into the coils of the **Essure** micro-insert and around the PET fibers.

C. Tissue In-Growth

The effectiveness of the **Essure** micro-insert in preventing pregnancy is believed to be due to a combination of the space filling design of the device and a local, occlusive, benign tissue response to the PET fibers. The tissue response is the result of a chronic inflammatory and fibrotic response to the PET fibers. It is believed that the tissue in-growth into the device caused by the PET fibers results in both device retention and pregnancy prevention.

The PET fibers were chosen for this application due to their success in causing tissue in-growth into devices used in other medical applications, such as prosthetic arterial grafts, percutaneous catheters, aneurysm coils, and other long-term implants.

D. Permanency of Tubal Occlusion (and Sterilization)

The long-term nature of the tissue response to the **Essure** device is not known. The majority of the clinical data regarding PET in the fallopian tube is based on 12-48 months of implantation, with little data at 60 months. Therefore, beyond 48 months, the nature of the cellular/fibrotic response and the ability of the response and the device to maintain occlusion are not known. Data for up to 5 years of wear will become available as participants in the clinical trials of safety and effectiveness continue to be followed. In addition, women who choose the **Essure** method of sterilization will be requested to notify the manufacturer if they have surgery in the future (such as hysterectomy) that will result in explantation of the devices. Also, the published failure rates for the device as a method of contraception will be updated as these patients continue to be followed to account for long-term sterilization failures.

IV. INDICATIONS FOR USE

The **Essure** system is indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes.

V. CONTRAINDICATIONS

The **Essure** system should not be used in any patient who is:

- Uncertain about her desire to end fertility
- Patients in whom only one micro-insert can be placed (including patients with apparent contralateral proximal tubal occlusion and patients with a suspected unicornuate uterus).
- Patients who have previously undergone a tubal ligation.

Or any patient with any of the following conditions:

- Pregnancy or suspected pregnancy.
- Delivery or termination of a pregnancy less than 6 weeks before **Essure** micro-insert placement
- Active or recent upper or lower pelvic infection.
- Known allergy to contrast media
- Known hypersensitivity to nickel confirmed by skin test (see Warnings section below for patients with suspected hypersensitivity to nickel.)

VI. WARNINGS

- The patient must use alternative contraception (cannot rely on the **Essure** micro-inserts for contraception) until an **Essure** Confirmation Test (HSG) performed three months post-micro-insert placement demonstrates satisfactory micro-insert location and tubal occlusion. During this time frame, the patient may be at an increased risk of ectopic pregnancy.
- The **Essure** procedure should be considered irreversible. There are no data on the safety or effectiveness of surgery to reverse the **Essure** procedure. Any attempt at surgical reversal will likely require utero-tubal reimplantation. Pregnancy following such a procedure carries with it the risk of uterine rupture and serious maternal and fetal morbidity and mortality.
- The effectiveness rates established for the **Essure** procedure and micro-insert were based on clinical data from women in whom micro-inserts were placed bilaterally. There is very little data on the effectiveness of unilateral **Essure** micro-insert placement in a unicornuate uterus or unilateral **Essure** micro-insert placement with presumed or confirmed contralateral proximal tubal occlusion (PTO).
- Micro-insert removal should not be attempted hysteroscopically once the micro-insert has been placed **and detached from the delivery wire**. The only exception is during the actual placement procedure when removal may be attempted if 18 or more coils of the **Essure** micro-insert are trailing into the uterine cavity. Because of device anchoring, however, removal may not be possible even immediately after placement. Attempted removal of a micro-insert having less than 18 coils trailing into the uterine cavity may result in fallopian tube perforation or other patient injury.
- In order to reduce the risk of hypervolemia, the procedure should be immediately aborted if the fluid deficit of the physiologic saline distension medium exceeds 1500cc. To further reduce the risk of hypervolemia, the hysteroscopic procedure time should not exceed 20 minutes.
- The **Essure** micro-insert will conduct energy if directly or closely contacted by an active electrosurgical device. If this occurs, then there is a risk of patient injury. Therefore, electrosurgery should be avoided in procedures undertaken on the uterine cornua and proximal fallopian tubes without either hysteroscopic visualization of the micro-inserts, or visualization of the proximal portion of the fallopian tube via open surgical procedures or laparoscopy. During Laparoscopically Assisted Vaginal Hysterectomy (LAVH) and other procedures in which electrosurgical instruments could contact the serosa of the fallopian tube, instruments should not be placed more proximal than the ampullary portion of the tube.
- Bench studies suggest that endometrial ablation using radio frequency (RF) energy will cause significant damage to surrounding tissue if an active RF instrument comes into direct contact with the **Essure** micro-inserts. Consequently, if using RF energy to perform endometrial ablation, direct contact with the **Essure** micro-inserts should be avoided. Global auto-ablative systems that employ RF energy should not be used in women with the **Essure** micro-inserts in place.
- DO NOT perform the **Essure** procedure concomitantly with endometrial ablation. Ablation causes intrauterine synechiae which can compromise (i.e. prevent) the 3-month **Essure** confirmation test (HSG). Women who have inadequate 3-month confirmation tests cannot rely on **Essure** for contraception.

  Bench and clinical studies have been conducted which demonstrate that balloon thermal (THERMACHOICE* Uterine Balloon System) and hydro-thermal (HTA** System) endometrial ablation of the uterus can be safely and effectively performed with the **Essure** micro-inserts in place. However, balloon thermal and hydro-thermal endometrial ablation should only be performed after the 3-month **Essure** confirmation test.
- There are no data regarding cryo-ablation techniques or the use of laser for endometrial ablation of the uterus with the **Essure** micro-inserts in place.
- There are also no data regarding the use of endometrial ablation devices that operate at microwave frequencies with the **Essure** micro-inserts in place. The use of microwave energy near metallic implants has been shown to pose significant risk of serious injury to patients. Use of microwave endometrial ablation devices near the **Essure** micro-inserts therefore should be avoided.

- Although not reported in the clinical trials of the Essure procedure and micro-insert, there is a theoretical increased risk of ectopic pregnancy in patients with the **Essure** micro-inserts, should they become pregnant.
- Placement of **Essure** micro-inserts into women who are undergoing immunosuppressive therapy (e.g., systemic corticosteroids or chemotherapy) is discouraged, because the immunosuppressive therapy is expected to negatively affect the tissue response to **Essure** micro-inserts that leads to tubal occlusion.
- To reduce the risk of uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilation, e.g. in the case of stenotic cervix.
- When introducing the **Essure** micro-insert into the fallopian tube, never attempt to advance the micro-insert(s) against excessive resistance. Refer to Section XIV. B. #10 (Directions for Use) for guidance on what constitutes "excessive" resistance.
- If tubal or uterine perforation occurs or is suspected, immediately discontinue the **Essure** device placement procedure, and work-up the patient for a perforation. A very small percentage of women in the **Essure** procedure clinical trials (1.8% or 12/682 patients) were identified as having device related tubal perforations. Retrieval of perforating micro-inserts, if necessary, will require laparoscopy or other surgical methods.
- A very small percentage of women in the **Essure** procedure clinical trials reported recurrent or persistent pelvic pain, and only one woman requested device removal due to pain; however, if device removal is required for any reason, it will likely require surgery, including an abdominal incision and general anesthesia, and possible hysterectomy.
- Patients with *suspected* hypersensitivity to nickel should undergo a skin test to assess hypersensitivity prior to an **Essure** placement procedure (see Contraindications section above for patients with known hypersensitivity to nickel).
- Patients may decide, in future years, to undergo *in vitro* fertilization (IVF) to become pregnant. The effects of the **Essure** micro-inserts on the success of IVF are unknown. If pregnancy is achieved, the risks of the micro-insert to the patient, to the fetus and to the continuation of a pregnancy are also unknown.

VII. PRECAUTIONS

- Women who undergo sterilization at a relatively young age are at greater risk of regretting their decision to undergo sterilization.
- **Essure** micro-insert placement should be performed during the early proliferative phase of the menstrual cycle in order to decrease the potential for micro-insert placement in a patient with an undiagnosed (luteal phase) pregnancy and to enhance visualization of the fallopian tube ostia. In women with menstrual cycles shorter than 28 days, the day of ovulation must be carefully calculated to reduce the potential of a luteal phase pregnancy. Micro-insert placement should NOT be performed during menstruation.
- Performing endometrial ablation immediately following placement of **Essure** micro-inserts may increase the risk of post-ablation tubal sterilization syndrome, a rare condition that has been reported in women with a history of tubal sterilization who undergo endometrial ablation.
- Do not continue to advance the **Essure** system once the black positioning marker on the catheter has reached the tubal ostium. Advancement beyond this point could result in unsatisfactory micro-insert placement and/or tubal/uterine perforation.
- Diagnostic procedures under direct visualization are optimal with the **Essure** micro-inserts in place. Blind insertion of instruments into the uterus with the micro-inserts in place should be undertaken with caution and care to avoid disruption of the micro-inserts.
- Any intrauterine procedure performed without hysteroscopic visualization following **Essure** micro-insert implantation could interrupt the ability of the **Essure** micro-inserts to prevent pregnancy. Following such procedures, device retention and location should be verified by hysteroscopy, X-ray, or ultrasound. In addition, the presence of the **Essure** micro-inserts could involve risks associated with intrauterine procedures that, at this time, have not been identified.
- 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. Test results at 1.5 tesla indicate zero magnetic force and radio frequency (RF) heating of 0.6° C in a phantom when a whole body specific absorption rate (SAR) of 1.3 W/kg was applied. The presence of the micro-inserts produces an MR artifact, which will obscure imaging of local tissue. The artifact is expected to be larger at higher field strength.
- As with all outpatient or office surgery procedures, appropriate equipment, medications, staff, and training should be in place to handle emergency situations, such as vaso-vagal response.
- Uterine or fallopian tube anomalies may make it difficult to place the **Essure** micro-inserts. Both tubal ostia should be identified and assessed hysteroscopically prior to proceeding to **Essure** micro-insert placement. No attempt should be made to place a micro-insert in one tubal ostium unless there is a reasonable expectation that the contralateral tube is accessible and patent. If it appears unlikely that successful bilateral micro-insert placement can be achieved, then the procedure should be terminated and potentially rescheduled. See Section XV regarding patient counseling in the event of failed placement.
- Do not advance the **Essure** system if the patient is experiencing extraordinary pain or discomfort. Terminate the procedure and work-up the patient for possible perforation.
- The **Essure** system is for single use only. Never attempt to resterilize an **Essure** micro-insert or delivery system.
- When using the introducer, there is a possibility that saline will be washed back through the operating channel of the hysteroscope. Proper eye and face protection should be utilized.
- An introducer must be used in order to avoid damage to the device tip.
- The working channel stopcock of the hysteroscope must remain in the open position to avoid damage to the micro-insert or to the introducer.
- Do not place more than one **Essure** micro-insert in a single fallopian tube.
- Do not use the **Essure** system if the sterile package is open or damaged. Do not use if the micro-insert is damaged.

VIII. ADVERSE EVENTS

A. Patient Population

Between November of 1998 and June of 2001, a total of 745 women underwent an **Essure** micro-insert placement procedure in two separate clinical investigations to evaluate the safety and effectiveness of the **Essure** system (227 in the Phase II study and 518 women in the Pivotal trial[1]). Some women underwent more than one procedure if successful bilateral placement was not achieved in the initial procedure. Placement of at least one **Essure** micro-insert was achieved in 682 women (206 in the Phase II study and 476 in the Pivotal trial).

B. Observed Adverse Events

Tables 1 and 2 below present adverse events that prevented reliance on **Essure** micro-inserts for contraception in the Phase II and Pivotal studies, respectively.

Table 1
Phase II Study
Adverse events that prevented reliance on Essure micro-inserts for contraception

Event	Number	Percent
Perforation	7/206	3.4%*
Expulsion	1/206	0.5%
Other unsatisfactory micro-insert location	1/206	0.5%
Initial tubal patency	7/200	3.5%**

*One patient relied on **Essure** micro-inserts for contraception for 31 months prior to laparotomy and cornual resection due to monthly pain associated with presence of the devices. The other 6 patients never relied on **Essure** micro-inserts for contraception.

Tubal patency was demonstrated in seven women at the 3-month **Essure Confirmation Test (HSG), but all seven women were shown to have tubal occlusion at a repeat **Essure** Confirmation Test (HSG) performed 6 months after **Essure** micro-insert placement.

Table 2
Pivotal Trial
Adverse events that prevented reliance on Essure micro-inserts for contraception

Event	Number	Percent
Expulsion	14/476	2.9%*
Perforation	5/476	1.1%
Other unsatisfactory micro-insert location	3/476	0.6%
Initial tubal patency	16/456	3.5%**

*Fourteen women experienced an expulsion, however nine of these 14 women chose to undergo a second micro-insert placement procedure, which was successful in all nine cases.

Tubal patency was demonstrated in sixteen women at the 3-month **Essure Confirmation Test (HSG), but all sixteen women were shown to have tubal occlusion at a repeat **Essure** Confirmation Test (HSG) performed 6-7 months after **Essure** micro-insert placement.

Other adverse events or side effects reported as a result of the hysteroscopic placement procedure are **shown in Tables 3 and 4** for the Phase II and Pivotal studies, respectively.

Table 3
Phase II Study
Adverse events reported on day of placement procedure
(N=233 procedures)

Event	Number	Percent
Band Detachment	3	1.3%
Vaso-vagal response	2	0.9%
Pain	2	0.9%

Table 4
Pivotal Trial
Adverse events and side effects reported on day of placement procedure
(N=544 procedures)

Event	Number	Percent
Cramping	161	29.6%
Pain	70	12.9%
Nausea/vomiting	59	10.8%
Dizziness/light headed	48	8.8%
Bleeding/spotting	37	6.8%
Vaso-vagal response/fainting	7	1.3%
Hypervolemia	2	0.4%
Band Detachment	2	0.4%
Other*	16	2.9%

*Includes: ache (3), hot/hot flashes (2), shakiness (2), uncomfortable (1), weak (1), profuse perspiration (1), bowel pain (1), sleepy (1), skin itching (1), loss of appetite (1), bloating (1), allergic reaction to saline used for distension (1).

In addition, the majority of women experienced mild to moderate pain during and immediately following the procedure, and the majority of women experienced spotting for an average of 3 days after the procedure. Pain was managed in every case with oral non-steroidal anti-inflammatory drugs (NSAIDs) or oral narcotic pain reliever.

Table 5 summarizes all adverse events rated by the Investigators to be at least "possibly" related to the **Essure** micro-insert or the placement procedure during the first year of reliance on the **Essure** micro-inserts in the Pivotal trial (approximately 15 months post-device placement). The percentages presented reflect the number of *events* in the numerator and the number of *women in the trial* in the denominator. While a woman reporting numerous episodes of the same event is represented in the numerator as multiple reports of that event, she is only represented in the denominator once. Consequently, in some cases these percentages over-represent the percentage of *women* who have experienced that event.

Table 5
Pivotal Trial
Adverse events by body systems, first year of reliance*
(N=476 patients implanted with at least one device)

Adverse Events by Body System	Number	Percent
Abdominal:		
Abdominal pain/abdominal cramps	18	3.8%
Gas/bloating	6	1.3%
Musculo-skeletal:		
Back pain/low back pain	43	9.0%
Arm/leg pain	4	0.8%
Nervous/Psychiatric:		
Headache	12	2.5%
Premenstrual Syndrome	4	0.8%
Genitourinary:		
Dysmenorrhea/menstrual cramps (severe)	14	2.9%
Pelvic/lower abdominal pain (severe)	12	2.5%
Persistent increase in menstrual flow	9**	1.9%
Vaginal discharge/vaginal infection	7	1.5%
Abnormal bleeding – timing not specified (severe)	9	1.9%
Menorrhagia/prolonged menses (severe)	5	1.1%
Dyspareunia	17	3.6%
Pain/discomfort – uncharacterized:	14	2.9%

* Only events occurring in ≥ 0.5% is reported

** Eight women reported persistent *decrease* in menstrual flow

In the Phase II trial, 12/206 (5.8%) women with at least one micro-insert reported episodes of period pain, ovulatory pain, or changes in menstrual function.

C. Potential Adverse Events Not Observed in Clinical Studies

The following adverse events were not experienced by women who participated in clinical studies evaluating the **Essure** system but are still possible:

- Pregnancy and ectopic pregnancy in women relying on **Essure**[2] micro-inserts
- Perforation of internal bodily structures other than the uterus and fallopian tube.
- Adnexal infection/salpingitis.
- Adverse events associated with the hysterosalpingogram (HSG) or X-rays.
- 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.
- Adverse events associated with surgery attempting to reverse the **Essure** procedure, as well as adverse events associated with pregnancy following a reversal procedure or an IVF procedure.
- Adverse events associated with gynecologic surgical procedures (e.g. endometrial ablation).

D. Adverse Event Reporting

Any adverse event (clinical incident) involving the **Essure** system should be reported to *Conceptus* immediately.

To report an incident, call (877) Essure2 OR 877.377.8732.

IX. CLINICAL STUDIES

A. Purpose of the Study, Study Design, Primary Endpoints

Conceptus has conducted two clinical trials (a Phase II Trial and a Pivotal Trial) to demonstrate the safety and effectiveness of the **Essure** system in providing permanent contraception. Additionally, a third study was performed after pre-marketing approval to evaluate rates of bilateral **Essure** placement in newly trained physicians.

1. Phase II Study

The Phase II study was a prospective, multi-center, single-arm, non-randomized, international study of women seeking permanent contraception. The objectives of the study were to evaluate:

- The woman's tolerance of, and recovery from, the micro-insert placement procedure;
- The safety of the micro-insert placement procedure;
- The woman's tolerance of the implanted micro-inserts;
- The long-term safety and stability of the implanted micro-inserts; and
- The effectiveness of the micro-inserts in preventing pregnancy.

[1] In the Pivotal trial, 657 women initially enrolled in the study. Ninety-nine women subsequently changed their mind about participating. Twenty-three women were subsequently terminated because they did not meet the inclusion criteria, and 17 failed the screening tests. Therefore, 518 underwent the **Essure** placement procedure.

[2] One woman in the Phase II study who received a prior device design that was discontinued in 1998 (the Beta design of the STOP device) became pregnant after nearly two years of reliance on the device for contraception. That pregnancy is not included in the effectiveness rate calculations, since that device design was not subject of the Premarket Approval Application (PMA) that supported approval of the **Essure** system.

* Trademark of ETHICON, INC.
**Trademark of Boston Scientific Corporation

2. **Pivotal Trial**

The Pivotal study was a prospective, multi-center, single-arm, non-randomized, international study of women seeking permanent contraception. The study used findings from the U.S. Collaborative Review of Sterilization (CREST study) as a qualitative benchmark. The primary endpoints for the study included:

- Prevention of pregnancy;
- Safety of device placement procedure, and;
- Safety of device wearing.

The secondary endpoints for the study included:

- Participant satisfaction with device placement procedure;
- Participant satisfaction with device wearing;
- Bilateral device placement rate, and;
- Development of a profile for an appropriate candidate for the **Essure** procedure.

3. **Post Approval Study for Newly Trained Physicians**

The Post Approval Study for Newly Trained Physicians was a prospective, multi-center, single-arm, non-randomized study intended to document the bilateral placement rate for newly trained physicians in the United States. The primary endpoints for the study were:

- Rates of successful bilateral placement of the **Essure** System at first attempt, and;
- Identification of factors predictive of failure to achieve bilateral placement of the **Essure** System at first attempt.

B. Patients Studied

1. The study population of the Phase II and Pivotal studies combined consisted of 664 women in whom bilateral device placement was achieved after one or more attempts (200 in the Phase II study and 464 in the Pivotal trial). All study participants were between 21 and 45 years of age and were seeking permanent contraception prior to enrollment in the study. Additionally, all women had at least one live birth, had regular, cyclical menses and were able and willing to use alternative contraception for the first three months following **Essure** micro-insert placement.
2. The study population of the Post Approval Study for Newly Trained Physicians consisted of 370 women in whom micro-insert placement was attempted using the currently marketed **Essure** device. A total of 41 investigators performed the procedures at 39 US sites (74% community-based and 26% academic). All study participants were between 19 and 49 years of age and were seeking permanent contraception prior to enrollment. There were 6 women with known prior tubal surgery (tubal removal), 1 with known proximal tubal occlusion, 1 planned contralateral salpingo-oophorectomy, and 1 unicornuate uterus. Although these 9 subjects should not have undergone an attempt at device placement for the reasons listed above, they have been included as failures in calculating the bilateral placement rate. Excluded from the bilateral placement rate are 194 placement attempts using a previous generation **Essure** delivery catheter design that is no longer marketed and 21 placement procedure non-attempts (primarily caused by intrauterine visualization issues).

C. Methods

All study participants in the Phase II and Pivotal Trial were screened for eligibility to participate in the clinical study. A complete medical history was obtained. A physical examination, a pelvic examination and required laboratory tests (including a pregnancy test) were conducted.

An **Essure** micro-insert placement procedure was attempted on each fallopian tube. In the Pivotal Trial, a pelvic X-ray was performed within 24 hours following device placement to serve as a baseline evaluation of device location. Participants were instructed to use either a barrier contraceptive method or oral contraceptives for the first 3 months following the device placement procedure.

An **Essure** Confirmation Test [hysterosalpingogram (HSG)] was performed three months post device placement to evaluate device location and fallopian tube occlusion. If both fallopian tubes were occluded and both devices were satisfactorily placed within the fallopian tubes, the participant was instructed to discontinue use of alternative contraception and rely on the **Essure** micro-inserts for prevention of pregnancy.

D. Results

As of October 15, 2004 (the date of the last data extract), 643 women with bilateral placement contributed effectiveness time, 194 in the Phase II study and 449 in the Pivotal Trial. In total, the 643 trial participants contributed 28,290 months of follow-up time with no (zero) pregnancies reported. Adverse events that were reported in the clinical studies are provided in Section VIII B above, and events by study are provided below. **Tables 6 and 7** present the principal safety and effectiveness results and **Tables 8 and 9** present patient demographic information.

Table 6A
Micro-insert Reliance Rates
in the Phase II and Pivotal Clinical Studies

Outcome	Phase II N=227		Pivotal N=518	
	Number	Percent	Number	Percent
Reliance Rate:** *Among women with bilateral placement*	194/200	97%	449/464	97%

The reliance rate is the number of women who were able to rely on the **Essure for contraception divided by the number of women with bilateral micro-insert placement.

Table 6B
Micro-insert Placement Rate at first attempt in the Commercial Setting
Using the Essure System Model No. ESS205

Placement Status	Post Approval Study For Newly Trained Physicians	
	Number	Percent
Bilateral Placement:	350/370*	94.6%
Unilateral Placement:**	15/370	4.0%
No devices placed:	5/370	1.4%

* Excludes 194 placement attempts using a previous generation **Essure** delivery catheter design that is no longer marketed and 21 placement procedure non-attempts

** Includes 6 women with known prior tubal surgery (tubal removal), 1 with known proximal tubal occlusion, 1 planned contralateral salpingo-oophorectomy, and 1 unicornuate uterus

An analysis of predictors of bilateral placement rate was performed using tabular analysis and logistic regression. Placement rate tended to be higher (p values between 0.05 and 0.10) with higher gravidity, parity and vaginal births. Bilateral placement rate was lower in women that had prior tubal surgery (e.g., unilateral salpingectomy) and unicornuate uteri. Placement rate tended to be lower when concomitant procedures were performed after **Essure** placement. However, this probably results from a greater frequency of uterine pathology (e.g., menorrhagia) that necessitated the concomitant therapy. Although many factors were tested, there were no other significant factors predictive of micro-insert placement success or failure.

NOTE ON PLACEMENT RATES: The 94.6% bilateral placement rate at first attempt was determined in a Post Approval Study for Newly Trained Physicians using the ESSURE System Model ESS205. This placement rate is expected to be similar for the newer ESS305 model of the ESSURE System. Conceptus is investigating the bilateral placement rate at first attempt for this device in a large Post Approval Study. The results of the study will be used to revise this labeling upon completion or termination.

Table 7
Effectiveness Results as of December 2004

	CUMULATIVE FAILURE RATES		
	Phase II Trial	Pivotal Trial	Both Trials Combined
One-Year[C]	**0%** **N=193** (95% CI 0 - 0.35%) [A] (Adj 95% CI 0 - 0.49%) [A, B]	**0%** **N=441** (95% CI 0 - 0.19%) [A] (Adj 95% CI 0 - 0.21%) [A, B]	**0%** **N=634** (95% CI 0 - 0.12%) [A] (Adj 95% CI 0 - 0.15%) [A, B]
Two-Year[C]	**0%** **N=184** (95% CI 0 - 0.70%) [A] (Adj 95% CI 0 - 1.10%) [A, B]	**0%** **N=419** (95% CI 0 - 0.38%) [A] (Adj 95% CI 0 - 0.44%) [A, B]	**0%** **N=603** (95% CI 0 - 0.24%) [A] (Adj 95% CI 0 - 0.31%) [A, B]

Table 7 *continued*
Effectiveness Results as of December 2004

	CUMULATIVE FAILURE RATES		
	Phase II Trial	Pivotal Trial	Both Trials Combined
Three-Year[C]	**0%** **N=174** (95% CI 0 - 1.04%) [A] (Adj 95% CI 0 - 1.74%) [A, B]	**0%** **N=399** (95% CI 0 - 0.56%) [A] (Adj 95% CI 0 - 0.65%) [A, B]	**0%** **N=573** (95% CI 0 - 0.37%) [A] (Adj 95% CI 0 - 0.47%) [A, B]
Four-Year[C]	**0%** **N=169** (95% CI 0 - 1.39%) [A] (Adj 95% CI 0 - 2.19%) [A, B]	**0%** **N=91** (95% CI 0 - 0.75%) [A] (Adj 95% CI 0 - 0.85%) [A, B]	**0%** **N=260** (95% CI 0 - 0.49%) [A] (Adj 95% CI 0 - 0.61%) [A, B]
Five-Year[C]	**0%** **N=75** (95% CI 0 - 1.73%) [A] (Adj 95% CI 0 - 2.72%) [A, B]		**Not Applicable**

[A] 95% confidence intervals are based on a "constant-hazard" exponential failure-time model, whose parameter is determined by the total number of woman-months accumulated during the trial.

[B] Adjustment using indirect method, adjusted to CREST study population based on three age groups.

[C] The number of women "N" were considered to have completed follow-up at 1 year if patient contact occurred at ≥11 months, 2 years if contact occurred at ≥23 months, 3 years if contact occurred at ≥ 35 months, 4 years if contact occurred ≥ 47 months and 5 years if contact occurred at ≥ 59 months.

Although the effectiveness rate established in the clinical trials of the **Essure** procedure and micro-insert was 100%, no method of contraception is 100% effective, and pregnancies are expected to occur in the commercial setting.

While the effectiveness rates for the **Essure** procedure and micro-insert compare quite favorably to the effectiveness rate for other methods of tubal sterilization at these time points, longer-term data on the **Essure** procedure and micro-insert are not available and may not compare favorably to other methods once these data are obtained. Follow-up of the women in both the Phase II and Pivotal trials is ongoing, and will continue to 5 years of follow-up. As updated data regarding longer-term failure rates are included in the product labeling, they will also be posted on the *Conceptus* website: www.**essure**.com.

Table 8
Age Distribution

Study	<28 years old	28-33 years old	≥34 years old
Phase II (Average age: 35)	7%	23%	70%

Table 9
Patient Demographics

	Phase II N=227	Pivotal Trial N=518
Race	Not collected	
White/Caucasian		428
Latin		31
Black		24
Other		9
Gravidity	Mean=2.6 (0-10.0)	Mean=3.03 (1.0-11.0)
Parity	Mean=2.2 (0-5.0)	Mean=2.26 (1.0-6.0)
Body Mass Index (BMI) (kg/m²)	Mean=26 (17-57)	Mean=27 (16-52)

Table 10 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.

Table 10
Pregnancy Rates for Birth Control Methods
(For One Year of Use)

Method	Typical Use Rate of Pregnancy
Sterilization:	
Male Sterilization	0.15%
Female Sterilization	0.5%
Hormonal Methods:	
Implant (*Norplant™ and Norplant™ 2*)	0.05%
Hormone Shot (*Depo-Provera™*)	0.3%
Combined Pill (*Estrogen/Progestin*)	5%
Minipill (*Progestin only*)	5%
Nuva Ring	1.2%
Ortho Evra	1%
Lunelle	<1%
Intrauterine Devices (IUDs):	
Copper T	0.8%
Progesterone T	2%
LNg 20	0.1%
Barrier Methods:	
Male Latex Condom[1]	14%
Diaphragm[2]	17%
Cervical Cap[2]	17%
Female Condom	21%
Lea's Shield	15%
Spermicide: *(gel, foam, suppository, film)*	26%
Natural Methods:	
Withdrawal	19%
Natural Family Planning *(calendar, temperature, cervical mucus)*	25%
No Method:	85%

[1] Used Without Spermicide [2] Used With Spermicide

Data adapted from FDA's Uniform Contraceptive Table, and modified per FDA input based on new studies.

X. INDIVIDUALIZATION OF TREATMENT

The **Essure** system is available in one size only. The risks and benefits previously described in Section IX - CLINICAL STUDIES should be carefully considered for each patient before use of the **Essure** system. Patient selection factors to be assessed should include:

- Patient's certainty about her desire to end fertility,
- Gynecological co-morbidities (e.g., pelvic infection, cervicitis, undiagnosed vaginal bleeding), and
- Reproductive tract anatomical variants and/or pathology, such as a bicornuate uterus or a submucous leiomyoma which could make a patient unsuitable for transcervical delivery/placement of micro-inserts.

The decision to undergo treatment is at the discretion of the patient, with the advice of her physician.

A. Use in Specific Populations

The safety and effectiveness of the **Essure** system has not been established in patients with any of the following characteristics:

- Patients less than 21years old or greater than 45 years old
- Patients who delivered a baby or terminated a pregnancy less than 8-12 weeks before **Essure** micro-insert placement.

XI. PATIENT COUNSELING INFORMATION

IMPORTANT: Patients should be counseled that this product is intended to prevent pregnancy. It does not protect against either HIV infection or other sexually transmitted diseases.

The physician should consider the following points when counseling the patient about this device:

- Details contained in the Patient Information Booklet regarding risks associated with placement and wearing of the **Essure** micro-inserts.
- The procedure is permanent, and irreversible.
- **Instruct the patient to use an alternative form of contraception (except an IUD or IUS) for the first 3 months following the micro-insert placement procedure until she has undergone the 3-month Essure** Confirmation Test (HSG). **Ensure that the patient is supplied with, or already has, contraception for this time frame. In addition, the patient should be counseled to use the most effective means of contraception for which she is a candidate. The patient should also be counseled that there is a theoretical increased risk of ectopic pregnancy during this time period, so compliance with her contraception regimen is critical.**
- Like all methods of birth control, the **Essure** procedure should not be considered 100% effective.
- Micro-insert placement may not be successful, resulting in either bilateral placement failure or only unilateral placement. Please refer to Section XV for directions on how to manage cases of unsuccessful micro-insert placement. Before conducting the **Essure** procedure, you should discuss with the patient a management plan that may be implemented in the event that successful placement is not achieved.
- Data regarding the effectiveness of the **Essure** procedure and micro-insert beyond 5 years is currently not available.

Conceptus recommends that the physician disclose to the patient (in written form) all risks associated with the **Essure** system, that the **Essure** procedure is permanent, and irreversible. Please also refer to the Patient Counseling section of the Practice Bulletin from the American College of Obstetricians and Gynecologists (ACOG) regarding female sterilization (ACOG Practice Bulletin Number 46, September 2003).

NOTE: A patient ID card is supplied with each Essure system. Please give this to your patient and ask that she carry it with her at all times and show it to other physicians involved in her present or future care.

XII. HOW SUPPLIED

Each **Essure** Permanent Birth Control System contains:

- Two (2) **Essure** devices
- Two (2) Valved Introducers
- One (1) Instructions for Use
- One (1) Patient Identification Card

STERILE: Each **Essure** system is sterilized using ethylene oxide and is supplied sterile for single use only. Do not reuse or resterilize. Resterilization may adversely affect proper mechanical function and could result in patient injury. Carefully inspect the sterile package for damage or defects prior to use.

STORAGE: Store in a cool, dry place.

XIII. PHYSICIAN TRAINING MANUAL

The **Essure** system Physician Training Manual contains detailed information not included in this Instructions for Use. Refer to the Physician Training Manual for additional information as required.

XIV. DIRECTIONS FOR USE

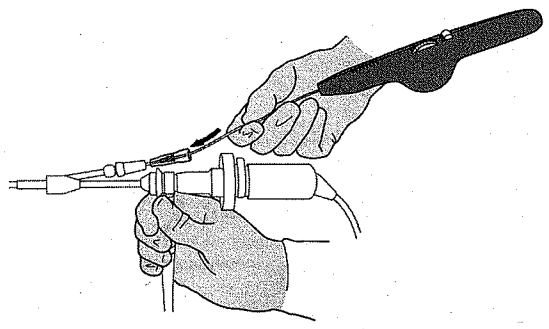
A. Prior to Micro-insert Placement Procedure

1. Micro-insert placement should be performed during the early proliferative phase of the menstrual cycle, in order to decrease the potential for micro-insert placement in a patient with an undiagnosed (luteal phase) pregnancy and to enhance visualization of the fallopian tube ostia. In women with menstrual cycles shorter than 28 days, the day of ovulation must be carefully calculated to reduce the potential of a luteal phase pregnancy. Micro-insert placement should NOT be performed during menstruation.
2. A pregnancy test administered by the physician or designee, should be conducted within 24 hours prior to the micro-insert placement procedure.
3. Administration of a non-steroidal anti-inflammatory drug (NSAID) is strongly recommended one to two hours before the micro-insert placement procedure, since clinical trial data demonstrate that the use of NSAIDs significantly increase the likelihood of placement success. If using only a paracervical block, an anxiolytic agent may also be offered 30 minutes prior to the procedure to reduce anxiety.

B. Essure Micro-insert Placement Procedure

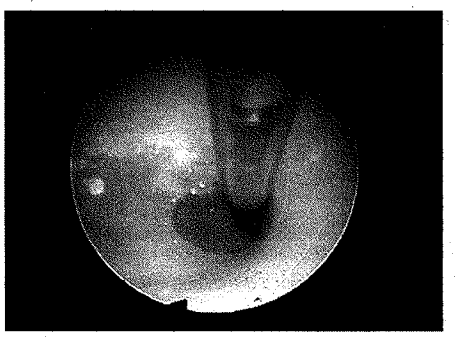
The **Essure** micro-insert placement procedure can be performed in an outpatient or office surgery setting. As with all outpatient procedures, appropriate equipment, medications, staff, and training should be in place to handle emergency situations, such as vaso-vagal response. Sterile technique should be used during the micro-insert placement procedure following universal precautions. Face and eye protective covering should be worn by the physician. The amount of time required to complete the hysteroscopic portion of the micro-insert placement procedure should not exceed 20 minutes.

1. Check all necessary equipment to ensure that there is no damage to equipment and that there are no missing parts.
2. Place the patient in the lithotomy position. An under buttocks drape with fluid control pouch is recommended for fluid management.
3. Introduce a speculum into the vagina to allow access to the cervix. Prep the cervix with betadine or other suitable antibacterial solution according to standard practice.
4. Local anesthesia (e.g. paracervical block), with or without IV sedation, is the preferred method for implantation of the micro-inserts, including implantation during preceptored cases conducted as part of the **Essure** training program.
5. Insert a sterile hysteroscope, with attached camera and operating channel (≥ 5 French), through the cervix into the uterine cavity. Do not perform cervical dilation unless necessary to allow hysteroscope insertion. If dilation is necessary, dilate only as much is required to insert the hysteroscope. In order to prevent uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilatation.
6. Uterine cavity distension should be accomplished with a physiologic saline infusion through the inflow channel of the hysteroscope. It is strongly recommended that the saline solution be pre-warmed to body temperature (but no greater than body temperature) and introduced under gravity feed to minimize spasm of the fallopian tubes and to reduce over-distension of the uterus. Adequate uterine distension must be achieved and maintained throughout the procedure in order to allow identification of and access to the fallopian tube ostia. Standard fluid monitoring procedures should be followed throughout the procedure. In order to reduce the risk of hypervolemia, the procedure should be immediately aborted if the fluid deficit of the physiologic saline distension medium exceeds 1500cc. To further reduce this risk related to hypervolemia, the hysteroscopic procedure time should not exceed 20 minutes.
7. Both tubal ostia should be identified and assessed hysteroscopically prior to proceeding to **Essure** micro-insert placement. No attempt should be made to place a micro-insert in one tubal ostium unless there is a reasonable expectation that the contralateral tube is patent.
8. Once the fallopian tube ostia have been identified, insert the introducer through the sealing cap on the hysteroscope working channel. The operating channel stopcock should remain in the open position (the device and/or introducer can be damaged if the stopcock closes on either device). Place the **Essure** delivery system through the introducer and advance through the operating channel of the hysteroscope. The introducer may remain in the operating channel throughout the **Essure** procedure.



Insert the introducer through sealing cap on the hysteroscope working channel, then place **Essure** *delivery system through the introducer.*

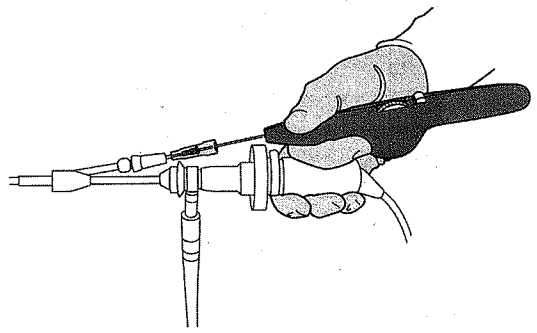
9. Advance the Essure delivery system into the proximal fallopian tube with gentle, constant forward movement to prevent tubal spasm. Advance the delivery system until the black positioning marker on the delivery catheter reaches the fallopian tube ostium. This visual marker indicates that the **Essure** micro-insert is spanning the intramural and the proximal isthmic segments of the fallopian tube, with the outer coil spanning the utero-tubal junction. This is the ideal placement for the **Essure** micro-insert.



Advance until black positioning marker is at tubal ostium. This is a visual indicator for proper position for deployment.

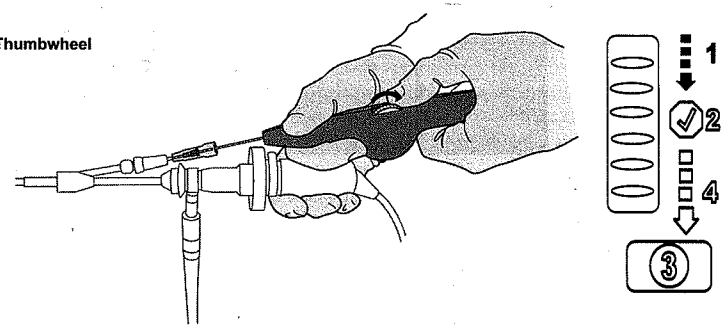
10. Proper concentric alignment of the delivery catheter with the tubal lumen is suggested by the ability to advance the catheter under direct visualization without undue resistance. Resistance to advancement is usually apparent if: 1) the black marker on the outside surface of the catheter is seen not to advance forward towards the tubal ostium, and/or 2) the delivery catheter bends or flexes excessively, thus preventing the physician from applying forward pressure on the catheter assembly. When such resistance to forward advancement of the catheter is observed, no further attempts should be made to place the micro-insert in order to avoid the possibility of uterine perforation or inadvertently placing the micro-insert in the uterine musculature rather than within the tubal lumen. A follow-up **Essure** Confirmation Test (HSG) should be undertaken to determine tubal patency.
11. If the tube is blocked or the catheter cannot be advanced to the black positioning marker, the case should be terminated. If micro-insert placement is not successful after 20 minutes of hysteroscopic procedure time, the case should be terminated and potentially rescheduled (see Section XV for management of cases with unsuccessful placement).
12. Only after the delivery catheter has been advanced to the black positioning marker should the micro-insert be deployed. To do so, first stabilize the handle of the **Essure** micro-insert against the hysteroscope or camera to prevent inadvertent forward movement of the **Essure** system during retraction of the delivery catheter. Please refer to the Physician Training Manual for specific instructions regarding techniques for stabilizing the handle.
13. Before proceeding with the **Essure** procedure, recall that two distinct operations will take place. The first is the retraction of the delivery catheter away from the micro-insert, prior to actual detachment of the micro-insert from the delivery and release wires. Retraction is accomplished by rotating the thumbwheel. Actual detachment is accomplished after full retraction (to the point where you cannot rotate the thumbwheel any further) by pressing the button which corresponds to the symbol ③ on the handle button and then continuing to rotate. Only after detachment of the micro-insert has occurred can you remove the delivery system.

    NOTE: Once you start rotating the thumbwheel, you cannot reverse the thumbwheel or undo the delivery catheter retraction operation. Once you push the button on the handle, you are committed. Therefore, DO NOT PUSH THE BUTTON ON THE HANDLE until you are certain that the delivery system is in the correct position for micro-insert placement.



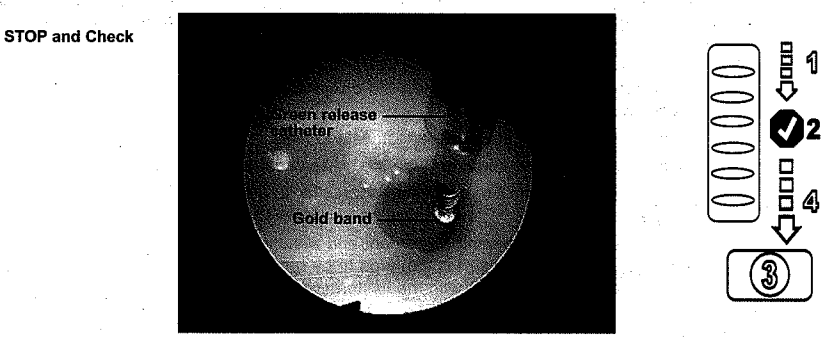
Stabilize handle against camera head or some other fixed object to prevent inadvertent forward movement of the **Essure** *system*

Being certain that the black positioning marker is at the fallopian tube ostium, rotate the thumbwheel on the handle toward you until the wheel no longer rotates. This operation corresponds to the symbol ①② on the delivery system handle. This action facilitates retraction of the delivery catheter exposing the wound down micro-insert. The black positioning marker will be seen to move away from the tubal ostium (towards the hysteroscope) and disappear into the operating channel. Approximately 1 cm of the micro-insert (wound-down coils) should appear trailing into the uterus when the delivery system is retracted.



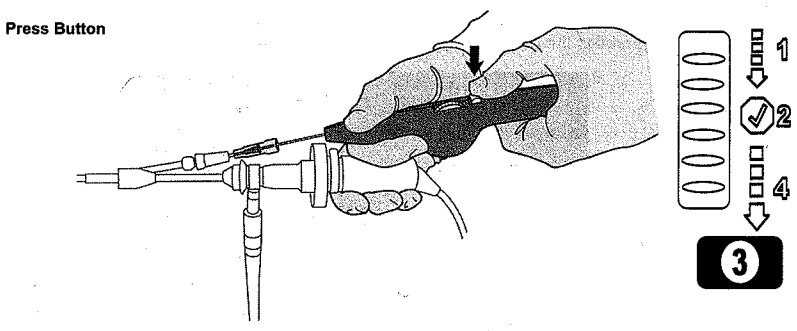
Rotate thumbwheel to retract delivery catheter exposing wound down micro-insert

14. To confirm proper positioning, place gold marker band just outside the ostium, which corresponds to the symbol ②③ on the delivery system handle. Visualization of the gold band just outside the ostium, as well as visualization of the distal tip of the green release catheter will confirm proper positioning. If more than 1 cm of the micro-insert is visible in the uterus, then the micro-insert should be repositioned by moving the entire system further into the tube, if possible, before proceeding to the next step.



Visualize gold band at ostium

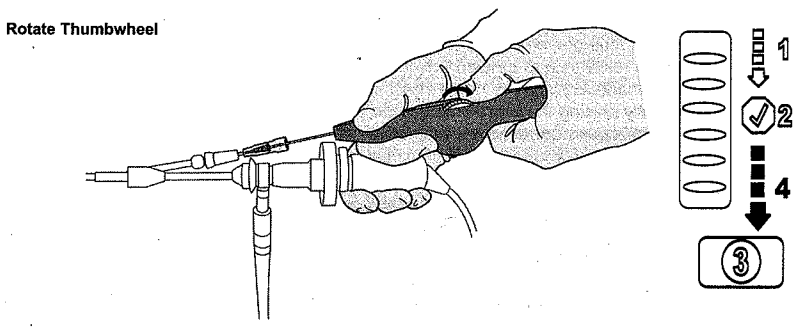
15. Press the button on the delivery handle to enable the thumbwheel to be further rotated which corresponds to the symbol ③ on the handle button.



Press button to enable the thumbwheel to rotate again

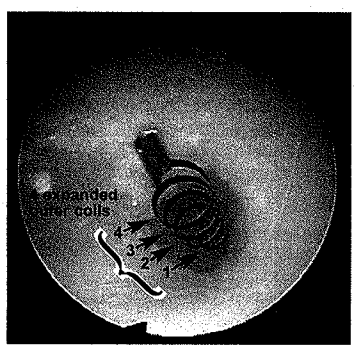
16. Continue to rotate the thumbwheel (symbol ④) towards you to the point you cannot rotate the thumbwheel any further. When the thumbwheel cannot be rotated any further and the expanded outer coils are visible, remove the delivery system.

    Note: Hold the valved introducer in place during removal of the delivery system as it may inadvertently be also withdrawn. If the introducer is removed, replace with a new introducer provided in the **Essure** system packaging.



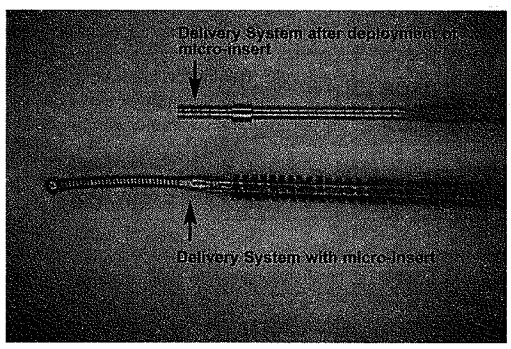
Rotate thumbwheel to allow the outer coils to expand and release the micro-insert from the delivery system

a. Once the delivery system has been removed, the position of the Essure micro-insert should be assessed. There should ideally be 3 to 8 expanded outer coils of the Essure micro-insert trailing into the uterus.



Expanded outer coils of the **Essure** *micro-insert trailing into the uterus indicates ideal placement*

b. If there are no trailing coils visible subsequent to a placement attempt, the delivery system should be closely examined for presence of the micro-insert upon removal from the hysteroscope. The photograph below illustrates the difference in appearance between a delivery system with a wound-down micro-insert present and a delivery system in which the micro-insert has been deployed and is no longer attached.



Delivery systems showing absence of micro-insert after deployment (top) and with micro-insert attached (bottom)

IMPORTANT: If the micro-insert was inadvertently deployed in the uterine cavity and not into the tube, then the micro-insert should be removed from the uterus and another attempt made at micro-insert placement in the tube.

c. Micro-inserts showing 0-18 trailing coils should be left in place and evaluated via **Essure** Confirmation Test (HSG) three months post micro-insert placement.

WARNING: Micro-insert removal should not be attempted hysteroscopically once the micro-insert has been placed. The only exception is during the actual placement procedure when removal may be attempted if 18 or more coils of the Essure micro-insert are trailing into the uterine cavity. Because of micro-insert anchoring, however, removal may not be possible even immediately after placement. Attempted removal of a micro-insert having less than 18 coils trailing into the uterine cavity may result in fallopian tube perforation or other patient injury.

17. **If there are 18 or more expanded outer coils trailing into the uterus, then the micro-insert should be immediately removed from the uterus (as described in steps 1-5 below) and another attempt made at micro-insert placement in the tube. Micro-insert removal may not always be possible. Removal of a micro-insert should only be attempted during the same procedure in which the micro-insert was placed.**
    1. As necessary, administer analgesia/anesthesia to reduce or prevent patient discomfort.
    2. Introduce a grasping instrument through the hysteroscope working channel.
    3. Grasp the outer coil of the **Essure** micro-insert. Try to grasp the outer and inner coil of the micro-insert together.
    4. Slowly pull back on the grasping instrument and withdraw the hysteroscope at the same time. Since the *expanded* micro-insert is too large to be removed through the operating channel, the entire **Essure** system, together with the hysteroscope, should be removed from the uterus.
    5. The outer coil and/or the inner coil of the **Essure** micro-insert may stretch or elongate as micro-insert removal is being attempted.

    If complete micro-insert removal is accomplished, an attempt should be made to place another **Essure** micro-insert. If micro-insert removal is not accomplished, it should be left in place and no attempt should be made to cut the micro-insert. If the physician is not completely satisfied that the entire **Essure** micro-insert has been removed from the fallopian tube, another micro-insert should **NOT** be placed in that tube and a post-placement X-ray should be taken to determine if a micro-insert fragment remains *in vivo*.

18. Record the length of the micro-insert trailing into the uterine cavity, noting any issues with identifying or confirming either tubal ostium or any concern regarding potential perforation. These should be noted in patient records for subsequent reference when reviewing the 3-month **Essure** Confirmation Test HSG (See Section C below). Additionally, the following information should be noted in the patient records:
    - Concern, at the time of device placement, of possible perforation due to excessive force required on the delivery catheter, a sudden loss of resistance, or no visible trailing length in the uterus, as seen hysteroscopically after device placement.
    - The visible trailing length of the micro-insert at the conclusion of device placement, if less than 3 coils or greater than 8 coils. As stated, however, do not remove the micro-insert unless 18 or more coils are trailing into the uterine cavity.
    - Identification of the tubal ostium, at the device placement procedure, was compromised due to poor distension, poor illumination or poor visualization, secondary to endometrial debris.
19. Repeat the **Essure** micro-insert placement procedure in the contralateral fallopian tube. Utilize the other pre-packaged introducer as needed.
20. Remind the patient to use an alternative form of contraception (except an IUD or an IUS) for the first 3 months following the micro-insert placement procedure until she has undergone the 3-month **Essure** Confirmation Test (HSG). Ensure that the patient is supplied with, or already has, contraception for this time frame. In addition, the patient should be counseled to use the most effective means of contraception for which she is a candidate. The patient should also be counseled that there is a theoretical increased risk of ectopic pregnancy during this time period, so compliance with her contraception regimen is critical.
21. Provide the patient with the patient ID card and instruct her to carry it with her at all times and show it to physicians involved in her present and future care.

C. Patient Follow-up Requirements

Patients should be scheduled for an **Essure** Confirmation Test (HSG) 3 months following the **Essure** micro-insert placement procedure. The **Essure** Confirmation Test (HSG) is performed to evaluate micro-insert location and fallopian tube occlusion. If micro-insert location is satisfactory, and there is evidence of bilateral occlusion of the fallopian tubes, the physician will instruct the patient to discontinue use of alternative contraception and use only the **Essure** micro-inserts for pregnancy prevention.

XV. MANAGEMENT OF CASES WITH UNSUCCESSFUL MICRO-INSERT PLACEMENT

In the event of unilateral or bilateral micro-insert placement failure, the patient should be informed that her permanent contraception has not been completed. Patients who experience micro-insert placement failure should be counseled about the opportunity to undergo a second attempt at micro-insert placement, especially in the case of unilateral placement. Of the women in the Pivotal trial who underwent a second procedure following the follow-up **Essure** Confirmation Test (HSG), 83% achieved bilateral placement at the second procedure. If the patient chooses to undergo a second placement procedure, she must first undergo an **Essure** Confirmation Test (HSG) after her next menses (pre-ovulatory: day 7-14 where day 1 represents the first day of bleeding) to determine tubal patency. If tubal patency is observed, the physician may offer the patient a second attempt at micro-insert placement. If a second attempt at micro-insert placement fails, the patient is unlikely to have success with subsequent attempts. If the patient has one micro-insert left *in vivo* she should be counseled not to rely on the unilateral micro-insert for contraception. An attempt to remove a unilaterally placed micro-insert is not recommended unless the patient is experiencing an adverse event(s) with the micro-insert. If a patient undergoes a follow-up **Essure** Confirmation Test (HSG) in order to qualify for a second placement procedure, this **Essure** Confirmation Test (HSG) is NOT considered to be a substitute for the 3-month **Essure** Confirmation Test (HSG) described in Section XIV.C. of this document.

If the patient chooses laparoscopic sterilization (i.e., clip application or electrical cautery), both fallopian tubes should be clipped or coagulated even if one tube has the **Essure** micro-insert implanted in it. Clipping or coagulation of the tube or tubes should be performed distal or proximal to the **Essure** micro-insert. **Clipping or coagulation should not be performed adjacent to or over the Essure micro-insert.**

XVI. PERFORMING AND EVALUATING HYSTEROSALPINGOGRAMS THREE MONTHS POST- MICRO-INSERT PLACEMENT

Three months following the **Essure** micro-insert placement procedure, the patient should be scheduled for an **Essure** Confirmation Test (HSG). **Essure** Confirmation Test (HSG) is performed to evaluate: 1) micro-insert location; and 2) fallopian tube occlusion. Only if micro-insert location is satisfactory and there is evidence of bilateral occlusion of the fallopian tubes, may the physician instruct the patient to discontinue use of alternative contraception and rely on the **Essure** micro-inserts for pregnancy prevention.

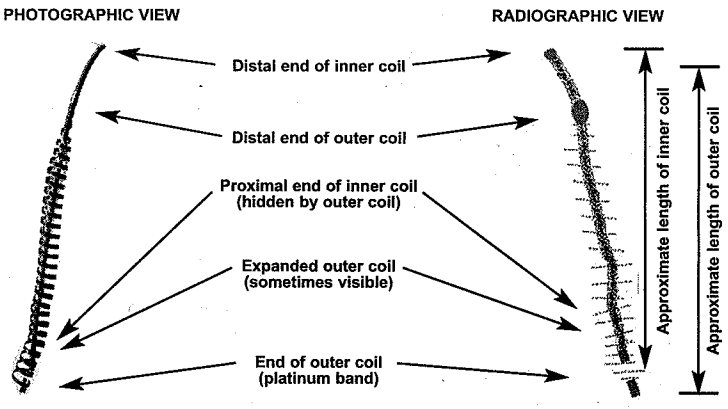
The following steps should be followed for performing and evaluating the **Essure** Confirmation Test (HSG).

A. Performing the Essure Confirmation Test (HSG)

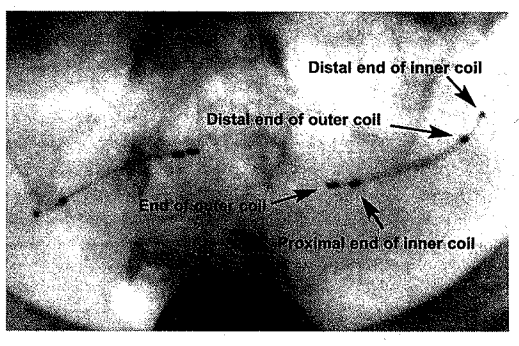
One objective of the **Essure** Confirmation Test (HSG) is to evaluate the relationship of the proximal end of the inner coil of the micro-insert to the uterine cornua, thus verifying that the micro-insert spans the UTJ. In order to achieve this, the following guidelines should be adhered to:

1. The uterine cavity silhouette must be clearly seen with good cornual filling.
2. The fluoroscopy beam with respect to the uterus should be as close to A/P projection as possible.
3. A good cervical seal should be maintained throughout the procedure to ensure good uterine distension. Accordingly, do not dilate unless necessary.
4. Downward traction on the cervical tenaculum may be required in patients having a midpositional uterus, to allow for ideal images of the uterine cavity. The speculum should be removed prior to fluoroscopy in order to assure the best possible visualization of uterine anatomy.
5. A minimum of six still radiographs should be taken to assess micro-insert location and tubal occlusion. A description of each radiograph is provided below with associated pictures.

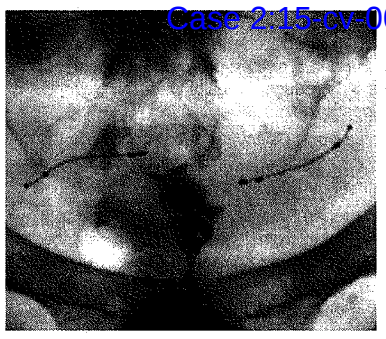
   NOTE: Assessment of the location of the micro-inserts on **Essure** Confirmation Test (HSG) is not the same as noted at hysteroscopy. Therefore, a correctly placed micro-insert may appear to be more distal on **Essure** Confirmation Test (HSG) than noted at the time of hysteroscopy.



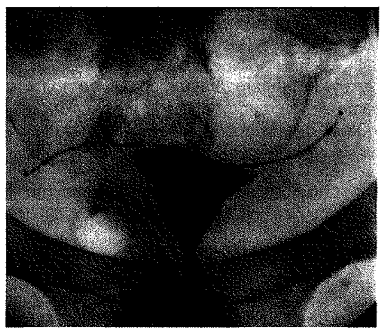
Corresponding radiographic view of the **Essure** *micro-insert.*



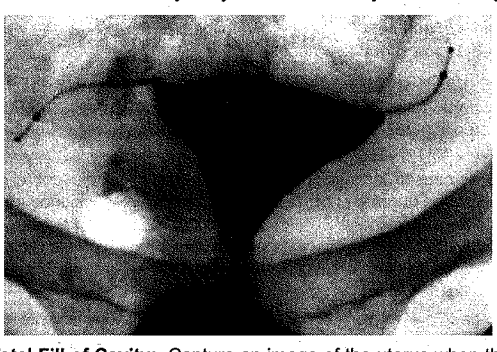
Radiograph 1 - "Scout Film": Capture an image of the uterus immediately prior to infusion of contrast into the uterine cavity. The **Essure** micro-inserts should be clearly seen. The lie and curvature of the micro-inserts should be noted.



Radiograph 2 - Minimal Fill of the Cavity: Capture an image of the uterus after a small amount of radioopaque contrast is instilled into the uterine cavity. This image should demonstrate evidence of an adequate seal of the uterine cervix and the beginning of opacification of the uterine cavity. In this radiograph, contrast material is likely not to have reached the uterine cornua. If the uterine cavity silhouette is not seen in a nearly A/P projection, the fluoroscopy beam and/or the patient need to be adjusted.



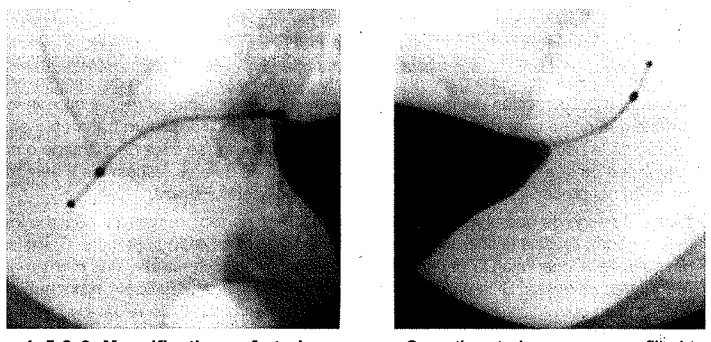
Radiograph 3 - Partial Fill of the Cavity: Capture an image of the uterus when it is nearly full of contrast or opacified. The cornua may not yet have been adequately distended. Proximal (uterine) portions of the **Essure** micro-insert may not yet be obscured by the advancing dye.



Radiograph 4 - Total Fill of Cavity: Capture an image of the uterus when the uterine cavity is completely filled to patient tolerance or maximal distension of the cornua has been achieved, whichever comes first. In this image, the advance of contrast (i.e., opacification) is likely to meet or obscure the proximal (uterine) portions of the **Essure** micro-inserts.

NOTE: An increase in volume of the intracavitary contrast, with resultant increase in intrauterine pressure, is often needed to allow for a satisfactory image.

CAUTION: An increase in intrauterine pressure beyond that needed to produce **Radiograph 4** serves no purpose and should be avoided, so as to avoid undue patient discomfort and the possibility of resultant vaso-vagal reaction such as profound bradycardia, lightheadedness, sweating and fainting.



Radiograph 5 & 6- Magnifications of uterine cornua: Once the uterine cornua are filled to maximum distension, magnified views of both right and left cornua should be obtained, highlighting the position of the micro-insert in reference to the uterine cornua.

B. Evaluating Essure Confirmation Test (HSG)s

When evaluating the **Essure** Confirmation Test (HSG), it is important to first confirm that the appropriate radiographs described above are provided, a good A/P image of the uterine silhouette is obtained, and the uterus is maximally distended in at least one view. The **Essure** Confirmation Test (HSG) will need to be immediately repeated if:

1. The appropriate sequence of radiographs has been captured but one or both uterine cornua are not maximally distended;
2. The projection of the silhouette is fundal rather than A/P;
3. The appropriate sequence of radiographs was not taken, and/or the uterine cornua are not distended or are otherwise obscured making evaluation of micro-insert position impossible or equivocal.

C. Micro-insert Location

In evaluating micro-insert position it is important to note the "markers" for the proximal end of the micro-insert (the end of the inner coil and the platinum band of the outer coil). Micro-insert position is then evaluated according to its relationship to the distended uterine cornua. **Ideal micro-insert location is when the inner coil of the micro-insert crosses the utero-tubal junction.**

The following scale should be used to categorize assessment of micro-insert location (please refer to the Physician Training Manual for sample **Essure** Confirmation Test (HSG)s that depict these categories):

1 - Micro-insert not present, OR more than 50% of the length of the inner coil of the micro-insert is trailing into the uterine cavity.

2 - Distal end of the inner coil is within the tube, with <50% of the length of the inner coil trailing into the uterine cavity, OR the proximal end of the inner coil appears to be up to 30 mm into the tube from where contrast fills the uterine cornua.

3 - Micro-insert is in the tube but proximal end of the inner coil appears to be more than 30 mm distal into the tube from the contrast filling the uterine cornua, OR the micro-insert is within the peritoneal cavity.

A patient with micro-insert location that is rated to be in categories 1 or 3 <u>should not rely</u> on the Essure micro-inserts for contraception.

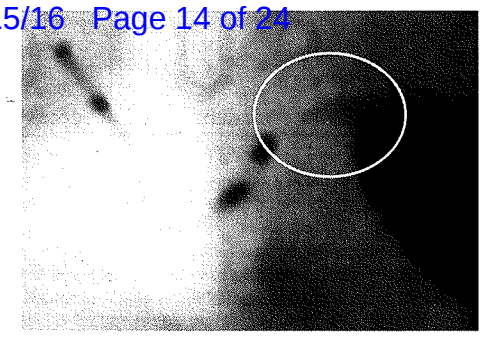
D. Occlusion

The most critical aspect of evaluating tubal occlusion is determining whether the contrast is visible in the tube beyond the micro-insert. It is also important to note any degree of proximal tubal filling with contrast even if the tube is occluded.

The following scale should be used to categorize assessment of tubal occlusion:

1 - Tube is occluded at the cornua.

2 - Contrast seen within the tube but not past any portion of the length of the outer coil of the micro-insert (i.e., past the distal end of the outer coil, see **Radiograph 7**).



Radiograph 7 - Contrast seen within the tube but not past any portion of the length of the outer coil of the micro-insert.

3 - Contrast seen past the distal end of the micro-insert or in the peritoneal cavity.

If tubal occlusion is rated to be in categories 1 or 2 above, and micro-insert location is satisfactory (category 2 above), then the patient may be instructed to discontinue alternative contraception. If occlusion is rated as a 3 and micro-insert location is satisfactory at the 3 month **Essure** Confirmation Test (HSG), then the patient should remain on alternative contraception for 3 more months and have a repeat **Essure** Confirmation Test (HSG). **If occlusion is again rated as a 3, then she should be advised to not rely on the Essure micro-inserts for contraception.**

XVII. MANAGEMENT OF MICRO-INSERT EXPULSION OR UNSATISFACTORY MICRO-INSERT LOCATION

1. <u>Micro-insert is too proximal (> 50% of the inner coil trails into the uterine cavity):</u> The patient should be counseled not to rely on the **Essure** micro-insert (whether the tube appears occluded or not due to the increased risk for complete expulsion) and either continues alternative contraception or consider incisional sterilization.
2. <u>Micro-insert is too distal (proximal end of the inner coil is > 30 mm from the cornua):</u> If the tube is patent the patient may be considered for an additional micro-insert procedure to properly position a micro-insert in the patent tube. If the tube is occluded the patient should be counseled that there is a potential for a false positive diagnosis of tubal occlusion by **Essure** Confirmation Test (HSG). She should also be counseled about the option to have incisional sterilization or remain on alternative contraception.
3. <u>Unilateral or bilateral micro-insert expulsion:</u> If the **Essure** Confirmation Test (HSG) demonstrates tubal blockage in the tube(s) from where the micro-insert was expelled, the patient should be counseled that there is a potential for a false positive diagnosis of tubal occlusion by **Essure** Confirmation Test (HSG). She should also be counseled regarding the option to undergo incisional sterilization or remain on alternative contraception. If the **Essure** Confirmation Test (HSG) demonstrates patency in the tube(s) from which the micro-insert was expelled, the patient may be offered the opportunity to return for a repeat micro-insert placement procedure.
4. <u>Unilateral or bilateral micro-insert perforation:</u> If the **Essure** Confirmation Test (HSG) demonstrates tubal patency in the tube that should have been placed with a micro-insert, the patient may be offered the opportunity to return for an additional micro-insert placement procedure to re-attempt placement. She should also be counseled regarding the option to undergo incisional sterilization. If the **Essure** Confirmation Test (HSG) demonstrates occlusion in the tube that should have been placed with a micro-insert, the patient should be counseled that there is a potential for a false positive diagnosis of tubal occlusion by **Essure** Confirmation Test (HSG). She should also be counseled about the option to have incisional sterilization or remain on alternative contraception.
5. If a patient has opted for incisional sterilization following any of the above listed scenarios, both tubes should be occluded regardless of any remaining micro-insert that is in a satisfactory location. An attempt should be made to retrieve a micro-insert if the physician believes it can be done safely, however micro-insert retrieval may not be possible. Use of intra-operative fluoroscopy is recommended to identify the location of the micro-insert(s) prior to and during surgery. Attempted retrieval should not exceed 30 minutes.

XVIII. MICRO-INSERT REMOVAL

Micro-insert removal should only be attempted if a patient is experiencing an adverse event(s) with the micro-insert or if she demands micro-insert removal.

A cornual resection of the proximal fallopian tube may be required to remove the **Essure** micro-insert in some cases.

An **Essure** micro-insert can be removed with traditional linear salpingotomy or salpingectomy accomplished via laparoscopy or laparotomy.

1. To perform a linear salpingotomy, a small incision (approximately 2 cm in length) is made along the antimesenteric border of the fallopian tube, directly overlying the micro-insert.
2. Total or partial salpingectomy can be performed to retrieve the micro-insert along with, or independent of, the performance of a traditional tubal sterilization procedure.

Should micro-insert removal be deemed necessary, a transabdominal approach (i.e., laparotomy or laparoscopy) is required.

XIX. PATIENT INFORMATION BOOKLET AND PATIENT ID CARD

The Patient Information Booklet contains valuable information for patients considering treatment with the **Essure** system. Please be sure to provide a copy of this brochure to all patients considering treatment with the **Essure** system. Also, a patient ID card is supplied with each **Essure** system. Please provide one of these cards to any patient who receives implantation of an **Essure** micro-insert.

XX. REFERENCES

1. Peterson HB, Xia Z, Hughes JM, et al. The risk of pregnancy after tubal sterilization: Findings from the U.S. Collaborative Review of Sterilization. *Am J Obstet Gynecol* 1996: 174:1161-1170.

XXI. SYMBOL LEGEND

STERILE EO	Sterilized using ethylene oxide		Use by	CE 0050	Device complies with European Directive 93/42/EC
LOT	Batch code		Keep away from heat		Keep dry
	Do not reuse		Do not use if package is open or damaged	CONT	Content
REF	Catalog number				
⚠	Attention, See Instructions for Use	EC REP	Authorized European Representative		

Conceptus®

Conceptus Incorporated
331 East Evelyn Avenue
Mountain View, CA 94041
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Tel: 1.877.377.8732 or 1.650.962.4060
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www.conceptus.com www.essureMD.com www.essure.com

For product ordering or reporting of adverse events, please call (877) Essure2 or 877.377.8732.

essure
Permanent Birth Control

Patient Information Booklet

Essure Information Center
1-877-ESSURE1 • www.essure.com

For reorders: call 1-877-ESSURE2, prompt 2 (1-877-377-8732, prompt 2)
or visit www.essureMD.com Reorder Number CC-0475 31Oct06F

Laura,
Essure Woman

Essure®: A Simple Option for Permanent Birth Control

The *Essure* procedure is a method for permanent birth control (also known as sterilization). It is meant to prevent pregnancy for the rest of your life. This booklet will provide you with information about the *Essure* procedure, including its benefits and risks. This information, however, is not meant to take the place of a thorough talk with your doctor. All women have individual needs and concerns. Your doctor will advise you whether the *Essure* procedure is right for you with regard to your circumstances and health history. The *Essure* procedure is the first non-incisional permanent birth control procedure approved by the FDA.

Conceptus Incorporated, 331 East Evelyn Avenue, Mountain View, CA 94041

Essure and *Conceptus* are registered trademarks of *Conceptus Incorporated*. The *Essure* system is covered under the following US Patent Numbers: 5,601,600; 5,746,769; 6,145,505; 6,176,240; 6,526,979; 6,634,361; 6,679,266; 6,684,884; 6,705,323; 6,709,667; 6,763,833; 6,871,650. Other patents pending.

For reorders: call 1-877-ESSURE2, prompt 2 (1-877-377-8732, prompt 2), or visit www.essureMD.com

How Does the *Essure* Procedure Work?

During the *Essure* procedure, soft, flexible coils called "micro-inserts" are passed through the body's natural pathways (vagina, cervix, and uterus). They are then placed into each fallopian tube. The micro-inserts are made with materials that have been used in medical devices for many years. They do not contain or release hormones.

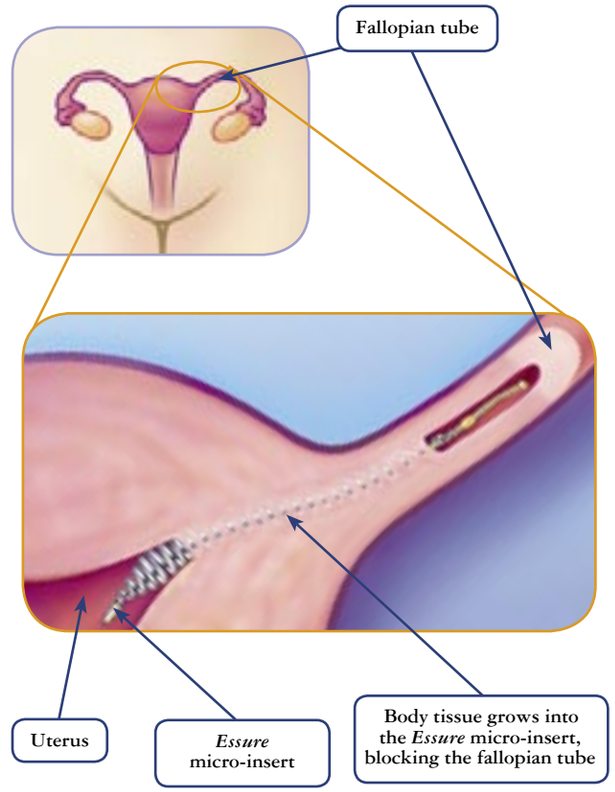
During the first 3 months following the procedure, your body and the micro-inserts work together to form a tissue barrier (like scar tissue) so that sperm cannot reach the egg. This prevents you from getting pregnant. You will need to use another form of birth control during this time. After 3 months, your doctor will perform a special type of x-ray test called an HSG. This test will assure you that your tubes are completely blocked and you can rely on the *Essure* micro-inserts for birth control.

Is the *Essure* Procedure Reversible?

The *Essure* procedure is not reversible. Women should be sure that they do not want to have any children in the future.

Does *Essure* Have Any Effect on Periods?

After an *Essure* procedure the ovaries will continue to produce eggs. The eggs will be absorbed by your body. Because the micro-inserts do not contain hormones, you will continue to have a period. However, some women do have temporary changes in their periods. They may have shorter or longer periods, heavier or lighter periods, or spotting between periods. Only a few women will experience permanent changes in their periods.



What Are the Benefits of the *Essure* Procedure?

Since FDA approval of the *Essure* system, tens of thousands of women worldwide have had the procedure. Two studies of the safety and effectiveness of the *Essure* Permanent Birth Control system were conducted in women from the United States, Australia, and Europe. Women who have had the procedure have reported the benefits outlined below.

Effective

- The *Essure* procedure is 99.80% effective at preventing pregnancy, based on 4 years of clinical data.

Covered by most insurance plans

- Many insurance plans cover the *Essure* procedure. When you have decided that the *Essure* procedure is right for you, please review your insurance coverage with your doctor. Confirm your insurance plan benefits before the procedure.

No cutting into the body

- The *Essure* procedure is unlike tubal ligation ("getting your tubes tied") or vasectomy (sterilization for men). It does not involve cutting or puncturing the body, and does not cut, crush, or burn the fallopian tubes.
- Because there is no cutting, the *Essure* procedure does not cause scars.

Rapid recovery

- On average, it takes 35 minutes to place the *Essure* micro-inserts. Most women are able to leave the medical facility 45 minutes after the procedure.
- Most women returned to normal activities within 1 to 2 days.
- Almost all women rated their comfort as "good" to "excellent" within 1 week of the procedure.

Can be done in an office setting

- The *Essure* procedure can be performed in the comfort and convenience of a doctor's office.

Confirmation of placement

- A confirmation test is done to check the placement of the *Essure* micro-inserts. This test confirms that you can rely on the micro-inserts for birth control. Knowing that this has been confirmed often gives women peace of mind.

High patient satisfaction

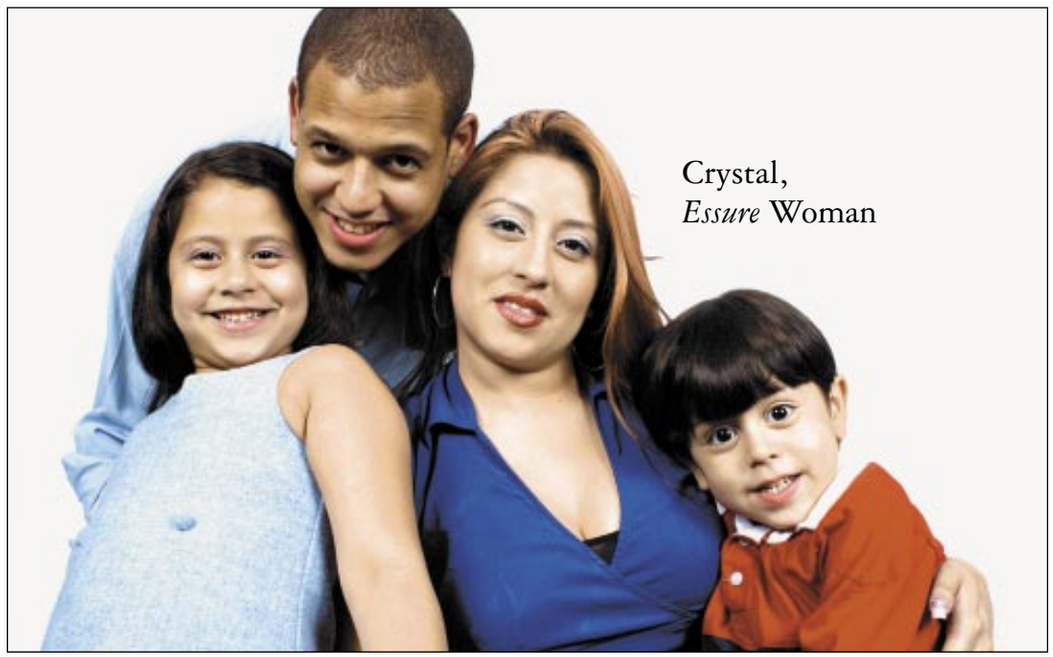
- Women consistently rate their overall satisfaction with the *Essure* micro-inserts as very high.

Hormone-free

- The *Essure* micro-inserts do not contain or release any hormones.

No general anesthesia required

- The *Essure* procedure can be performed with minimal anesthesia. Talk to your doctor if you have any questions.



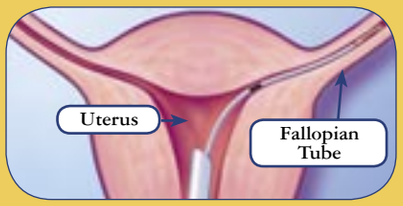
Crystal,
Essure Woman

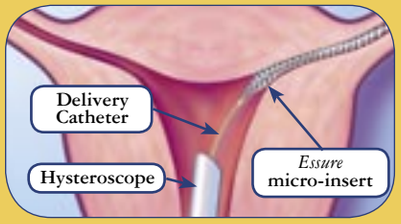
Before the Procedure

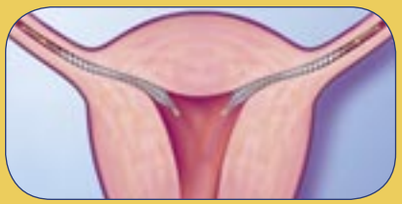
You are given medication to take 1 to 2 hours before the procedure. This medication helps to keep your tubes open and reduce cramping during the procedure. Before the procedure, talk to your doctor about what type of pain medication is best for you. General anesthesia is not required.

Note: The *Essure* procedure should be scheduled during the first half of your menstrual cycle. This will reduce the risk of having an undiagnosed pregnancy at the time of the procedure. It will also make it easier to see the opening to the fallopian tubes. Your doctor will give you a pregnancy test before the procedure to confirm that you are not pregnant.

During the Procedure







Once the procedure begins:

- An instrument called a speculum may be used to gently expand the opening of your vagina. The doctor then inserts a narrow telescope-like instrument called a hysteroscope through your vagina and cervix and into the uterus. The hysteroscope is attached to a video camera that sends pictures to a monitor. This lets the doctor see inside your uterus.
- Fluid (called normal saline or saltwater) flows through the hysteroscope and into your uterus. The fluid expands the uterus to let your doctor see the openings to your fallopian tubes clearly. You may feel some cramping during this time.
- A small, flexible tube (delivery catheter) is passed through the hysteroscope and into your fallopian tube. The micro-insert is attached to the end of this delivery catheter. The micro-insert is placed in the fallopian tube. When the micro-insert is in place, the delivery catheter is removed.
- A second delivery catheter and micro-insert is passed into your other fallopian tube, and the second micro-insert is placed. The delivery catheter is removed.
- After each micro-insert is placed, the doctor may take a picture of the opening of the fallopian tube into the uterus. A small piece of the micro-insert extends into this opening. By viewing this area, the doctor can check the location of the micro-insert.

After the Procedure

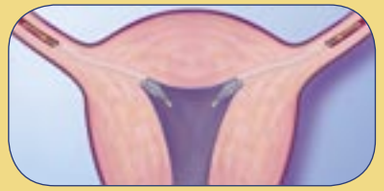
Most women are able to leave the doctor's office about 45 minutes after the procedure is completed. Most women return to normal activities within 1 to 2 days.
Note: Call your doctor if you notice unusual pain, bleeding, fever, vaginal discharge, or other symptoms.

The Next 3 Months

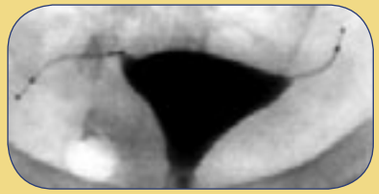
You will need to use another form of birth control during this period until your doctor confirms that the procedure has worked. During the time after your procedure, tissue will begin to grow into the micro-inserts. It will eventually block your fallopian tubes. The tissue barrier will keep sperm from reaching and fertilizing the egg. This will prevent you from getting pregnant.

Three months after the procedure, a special type of x-ray test called a hysterosalpingogram (HSG) is done. This test is required before your doctor can tell you whether you may begin relying on the *Essure* micro-inserts for permanent birth control. During an HSG, your doctor fills your uterus with a special fluid (dye) that shows up on x-rays. This test confirms two things. First, it verifies whether both of your *Essure* micro-inserts are in the correct location. Second, it shows whether both of your fallopian tubes are blocked.

Dye entering the uterus during the HSG.



In a successful HSG, the dye fills the uterus but does not enter the fallopian tubes.



X-ray image of the HSG showing that the dye does not go past the micro-inserts.

You should NOT use the *Essure* Permanent Birth Control system if you:

- Are not sure you want to become sterile.
- Cannot have an *Essure* micro-insert placed in both of your tubes (even if one tube is thought to be closed or you have only one tube).
- Have had a tubal ligation ("tubes tied") in the past.
- Have a known allergy to contrast dye (commonly used for x-ray [HSG] testing).
- Have a sensitivity to nickel as shown by skin testing.
- Are unwilling to have an HSG (confirmation test).
- Are unwilling to use alternative birth control.

Delay having the *Essure* procedure if you:

- Are pregnant or think you might be pregnant.
- Have been pregnant during the past 6 weeks.
- Have an active or recent pelvic infection.

Making the Decision

Don't make the decision to have permanent birth control during times of stress. Don't decide during a divorce or after a miscarriage. NEVER decide due to pressure from a partner or others.

If you are being treated for a medical condition that involves taking steroids or undergoing chemotherapy, ask your doctor whether the *Essure* procedure is right for you.

Kendra,
Essure Woman

Permanent Birth Control Options

	Tubal Ligation	Essure	Vasectomy
How is the procedure performed?	Usually performed as a laparoscopic procedure, under general anesthesia. Gas is used to expand the abdomen so surgical tools can be inserted. The fallopian tubes are blocked by one of these methods: • Clamping with metal clips or plastic rings • Cutting away a section of the tube • Burning a portion of the tube The clamps, rings, or clips remain in the body. Stitches or staples are used to close the cuts.	A soft, flexible micro-insert is delivered through the vagina and uterus and placed into each fallopian tube. The spring-like micro-insert expands during placement to fit the tube. A small trailing portion of the micro-insert remains in the uterus. This viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus. Scar tissue grows into the micro-insert (usually over 3 months) and forms a barrier so the sperm cannot reach the egg.	The scrotal area is shaved and cleaned with an antiseptic solution. An incision or puncture is made into the scrotum (the sac containing the testicles). The vas deferens tubes, one from each testicle, are tied in two places with permanent sutures. The tubes are severed between the ties by: • Cauterization (burning or searing of the tubes) • Cutting • Blocking with clips or clamps If an incision is made, it is then closed with stitches.
Effectiveness	99.45% at 1 year 98.82% at 4 years 98.15% at 10 years	99.95% at 1 year 99.80% at 4 years	99.26% at 1 year 98.87% at 5 years
Procedure Time	30–45 minutes	35 minutes	20–30 minutes
Recovery Time	4–6 days	1–2 days or sooner	2–3 days
Post-procedure pain/ discomfort	• Cramps • Discharge • Pain at the wound • Bloated abdomen and/or sharp pains in the neck or shoulder (due to gas used) • Bruising around the wound • Feeling tired and achy	• Cramps • Discharge	• Swelling • Bruising • Pain in the testicles (Ice packs and/or an athletic supporter may need to be used to decrease bruising and swelling.)
Reliance and Test	Immediate/no test	Reliance can begin at 3 months when the *Essure* confirmation test confirms placement and blockage of the tubes.	Reliance can begin at 3 months when a follow-up sperm test confirms no sperm is evident.

Temporary Birth Control Options*

(Pregnancy Rates for 1 Year of Use)

The following table provides estimates of the percent of women likely to become pregnant while using a particular contraceptive method for 1 year. These estimates are based on a variety of studies. For a complete list, visit the FDA website at www.fda.gov and search on *Birth Control Guide.*

Method	Description	Failure Rate	Some Risks	Convenience
Oral contraceptives–combined pill	A pill that suppresses ovulation by the combined actions of the hormones estrogen and progestin.	1–2%	Dizziness; nausea; changes in menstruation, mood, and weight. Rare: cardiovascular disease, including high blood pressure, blood clots, heart attack, and stroke.	Must be taken daily regardless of frequency of intercourse.
Oral contraceptives–progestin-only (minipill)	A pill containing only the hormone progestin that reduces and thickens cervical mucus to prevent the sperm from reaching the egg.	2%	Irregular bleeding, weight gain, breast tenderness, less protection against ectopic pregnancy.	Must be taken daily regardless of frequency of intercourse.
Injection (Depo-Provera)	An injectable progestin that inhibits ovulation, prevents sperm from reaching the egg, and prevents the fertilized egg from implanting in the uterus.	<1%	Irregular bleeding, weight gain, breast tenderness, headaches.	One injection every 3 months.
Injection (Lunelle)	An injectable form of progestin and estrogen.	<1%	Changes in menstrual cycle, weight gain (similar to oral contraceptives–combined pill).	Injection given once a month.
Vaginal contraceptive ring (NuvaRing)	A flexible ring about 2 inches in diameter that is inserted into the vagina and releases the hormones progestin and estrogen.	1–2%	Vaginal discharge, vaginitis, irritation (similar to oral contraceptives–combined pill).	Inserted by the woman; remains in the vagina for 3 weeks, then is removed for 1 week. If the ring is expelled and remains out for more than 3 hours, another birth control method must be used until the ring has been used continuously for 7 days.
The Patch (Ortho Evra)	Skin patch worn on the lower abdomen, buttocks, or upper body that releases the hormones progestin and estrogen into the bloodstream.	1–2% (Appears to be less effective in women weighing >198 lbs.)	Similar to oral contraceptives –combined pill.	New patch is applied once a week for 3 weeks. Patch is not worn during the fourth week, and woman has a menstrual period.
IUD (Intrauterine Device)	A T-shaped device inserted into the uterus by a health professional.	<1%	Cramps, bleeding, pelvic inflammatory disease, infertility, perforation of uterus.	After insertion, can remain in place for up to 1 or 10 years, depending on type.
Male condom (latex/ polyurethane)	A sheath placed over the erect penis blocking the passage of sperm.	11%	Irritation and allergic reactions. Oil-based lubricants weaken latex condoms and should not be used with these methods.	Applied immediately before intercourse; used only once and discarded. Polyurethane condoms are available for those with latex sensitivity.
Diaphragm with spermicide	A dome-shaped rubber disk with a flexible rim that covers the cervix so that sperm cannot reach the uterus. A spermicide is applied to the diaphragm before insertion.	17%	Irritation and allergic reactions, urinary tract infection. Risk of toxic shock syndrome, a rare but serious infection, when kept in place longer than recommended. Spermicide can cause irritation.	Inserted before intercourse and left in place at least 6 hours after. Can be left in place for 24 hours, with additional spermicide for repeated intercourse.
Female condom	A lubricated polyurethane sheath shaped similarly to the male condom. The closed end has a flexible ring that is inserted into the vagina.	21%	Irritation and allergic reactions.	Applied immediately before intercourse; used only once and discarded.
Spermicide alone	A foam, cream, jelly, film, suppository, or tablet that contains nonoxynol-9, a sperm-killing chemical.	20–50%	Irritation and allergic reactions, urinary tract infections.	Instructions vary; check labeling. Inserted 5 to 90 minutes before intercourse and usually left in place at least 6 to 8 hours after.
Periodic abstinence	Deliberately refraining from having sexual intercourse during times when pregnancy is more likely.	20%	None.	Requires frequent monitoring of body functions such as body temperature.

*Data adapted from FDA's Uniform Contraceptive Table (revised 9/17/98) and Birth Control Guide (12/03)

Please note: Not all temporary methods of birth control can be used during the 3-month waiting time following the *Essure* procedure. Please talk to your physician about what form of temporary birth control you should use during this time.

Key Considerations and Risks

Before you have the *Essure* procedure, you need to be sure it's right for you. Below are some considerations to think about. As with all procedures, there are risks associated with the *Essure* procedure. Know what these risks are and discuss them in detail with your doctor before you decide.

The *Essure* procedure is permanent (not reversible).

- There are no data on the safety or effectiveness of surgery to reverse the *Essure* procedure. Any attempt to reverse the *Essure* procedure will require surgery and has a poor chance for success. This surgery will require an abdominal incision and, most likely, general anesthesia.
- There are no data on the safety or effectiveness of in vitro fertilization (IVF) after the *Essure* procedure has been performed.
- The younger a woman is when she chooses to become sterile, the more likely she is to regret her choice later.

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

- No method of birth control is 100% effective. As with all permanent birth control procedures, there is a small chance that you can become pregnant even many years after the procedure.
- If you do become pregnant, the risk of the *Essure* micro-inserts to you, the continuation of the pregnancy, the fetus, or childbirth are not known.
- Women who have sterilization by the *Essure* procedure or incisional tubal ligation are more likely to have an ectopic pregnancy if they get pregnant. Ectopic pregnancy is when the pregnancy occurs outside of the uterus (womb). The pregnancy usually happens in one of the fallopian tubes. Ectopic pregnancies can be very serious, even life-threatening.

The *Essure* procedure is newer than other procedures.

- *Essure* is a non-incisional method of tubal sterilization that has been studied in clinical trials since 1997.
- The *Essure* product was approved in the U.S. in 2002. The follow-up clinical data (collected on women who have been relying on *Essure*) spans 5 years.
- Other incisional sterilization procedures, such as tubal ligation, have been used for over 50 years.

You must use another method of birth control for at least 3 months after the procedure.

- Before the procedure is performed, you will need to talk to your doctor about another birth control method to use with the *Essure* procedure during this time. During this 3-month period, intrauterine devices (IUDs) and intrauterine systems (IUSs) cannot be used.
- You will need to have a special type of x-ray test called an HSG 3 months after your *Essure* procedure. This test confirms two things. It verifies whether both of your *Essure* micro-inserts are in the correct location and whether both of your fallopian tubes are blocked.
- If you rely on the *Essure* micro-inserts for birth control before you complete the HSG test, you may get pregnant or have an ectopic pregnancy.

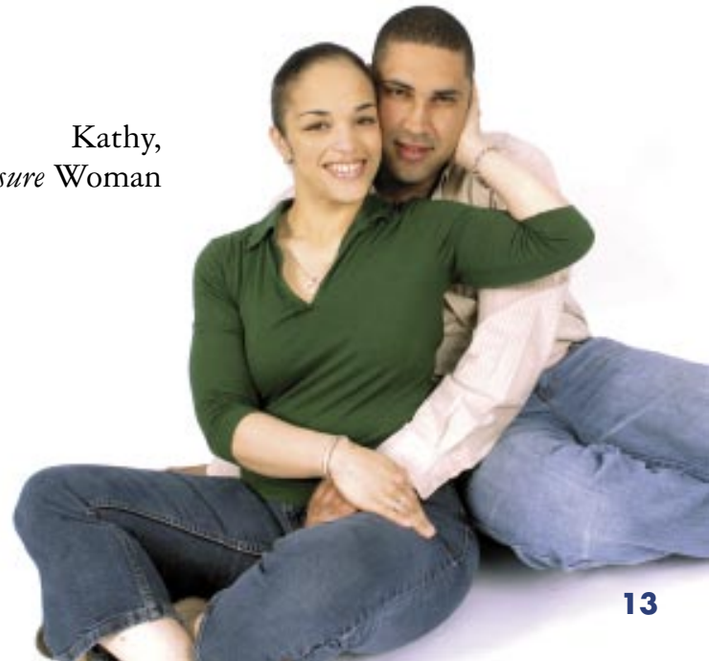
Not all women who have the *Essure* procedure will achieve successful placement of both micro-inserts.

- Approximately 1 out of 7 women were not able to have one or both of the micro-inserts placed.
- One or both of the *Essure* micro-inserts may not be in the right place or may fail to block the fallopian tubes by 3 months after the procedure. As a result, you may not be able to rely on the micro-inserts for birth control.
- A small percentage of women had fallopian tubes that were not fully blocked until 6 months after the *Essure* procedure.

If any of these situations occur, a woman can talk to her doctor about a second *Essure* procedure or confirmation test (HSG).

Important

- The *Essure* micro-inserts do not protect against HIV or other sexually transmitted diseases.
- If at any time you think you are pregnant, see a doctor immediately to help rule out the possibility that you have an ectopic pregnancy.



Kathy,
Essure Woman

As with all procedures, there are risks associated with the *Essure* procedure.

You should be well informed about these risks and discuss them in detail with your doctor before you make your decision. Below are complications that may occur during the *Essure* procedure.

- In the clinical studies, most women reported mild to moderate pain during the *Essure* micro-insert procedure.
- Rarely in the clinical studies, a portion of the *Essure* micro-insert broke off during the procedure.
- Women who have the *Essure* procedure or any other sterilization procedure during the second half of their menstrual cycle (after ovulation) are at an increased risk of being pregnant at the time of the procedure.
- Anesthesia (medicine to control sensation or consciousness) is used during the *Essure* procedure. Discuss with your doctor the risks of the anesthesia method recommended for you. Note that the *Essure* procedure doesn't require general anesthesia, which has a higher risk than other types of anesthesia.
- A small percentage (1.8%) of women in the clinical studies experienced tubal perforations related to *Essure* micro-insert placement. Most of these women underwent laparoscopic sterilization and about half had the devices removed. If it is necessary to remove *Essure* micro-inserts that perforate the uterus or fallopian tubes, major surgery may be required.

Below are complications that may occur after the *Essure* procedure:

- Many women reported mild to moderate pain and/or cramping and vaginal bleeding for a few days after the procedure.
- Some women in the clinical studies reported nausea and/or vomiting or fainting following the procedure.
- For a small percentage (2.9%) of women in the clinical studies the micro-inserts came out of the body (expulsion).
- Rarely, women in the clinical studies absorbed too much of the fluid used to expand the uterus during the procedure. If this condition occurs, it should be treated immediately to prevent serious complications.
- Some women in the clinical studies reported one or more episodes of pelvic, back, or abdominal pain.
- Problems with the HSG test are rare, but may include infection, spotting, and allergic reaction to the dye. You should also be aware that you will be exposed to very low levels of radiation.

Questions for Your Doctor

Choosing permanent birth control is an important decision. As you consider having the *Essure* procedure, here are some questions you might ask your doctor.

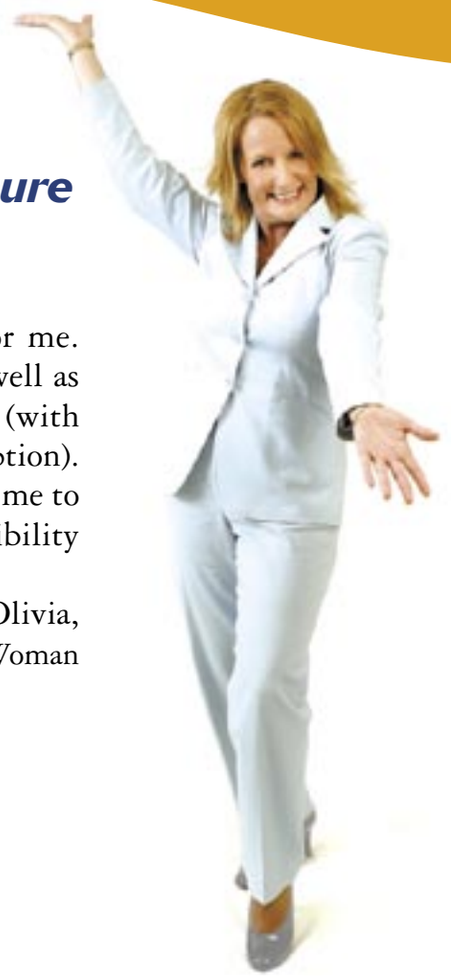
- Where will my *Essure* procedure be performed?
- What type of anesthesia will be used during my procedure?
- What do I need to do to prepare for the procedure?
- When is the best time of the month to schedule my procedure based on my menstrual cycle?
- What are my options if both micro-inserts cannot be placed on the first attempt?
- Can I continue to use my current method of birth control until my HSG confirmation test?
- Who will perform the HSG?

Tia,
Essure Woman

Future Medical Care

After having the *Essure* procedure you will be given a patient identification card. You should keep this card with you at all times and show it to your doctors when discussing your medical care. Your doctor should be aware that you have the *Essure* micro-inserts in place before performing procedures that involve your uterus or fallopian tubes. Make sure your doctor knows you have micro-inserts before you undergo an MRI, a D&C, hysteroscopy, endometrial biopsy, or endometrial ablation. The *Essure* micro-inserts are MRI-safe but may cause an obscure image of tissue near or at the micro-inserts.

What Women Say About *Essure*



Essure was simply the only valid choice for me. *Essure* offered me everything I required, as well as the added bonus of very little recovery time (with 2 toddlers, this was an extremely attractive option). I love the complete freedom *Essure* has given me to move forward and no longer revisit the possibility of pregnancy.

—Olivia,
Essure Woman

I felt there were many positive benefits of the *Essure* procedure. I was happy there was no cutting, no pain, no scars, no uncomfortable gas, and same day recovery. I have been recommending the *Essure* procedure to all of my friends and they are all amazed when I tell them about it.

—Mari,
Essure Woman

I didn't want to keep taking birth control pills, so we decided my husband would have a vasectomy. I made an appointment with an Ob/Gyn who performed vasectomies. At the consultation, he was very informative of the *Essure* procedure. He made it perfectly clear that he was not trying to change our minds, but that *Essure* was less invasive and had less recovery time than a vasectomy. After thinking it over, my husband and I decided that the *Essure* procedure was the way to go for us.

—Angie,
Essure Woman

In the consultation, my doctor explained everything quite clearly and I decided *Essure* was right for me. I went to his office for the procedure and the whole thing took approximately 45 minutes. There was no general anesthesia, only the local numbing of the cervix. The actual procedure was slightly uncomfortable, but bearable. At the end of the procedure, they gave me a maxi pad to wear and told me to go home and take it easy. Well, I felt so good that I went shopping.

—Kelly,
Essure Woman

Glossary

- Anesthesia: Medically induced partial or complete loss of sensation, in all or part of the body, with or without loss of consciousness. General anesthesia is total loss of consciousness and sensation.
- Cervix: The passageway that connects the vagina to the uterus.
- Contraceptive: Any process, device, or method that reduces the likelihood of pregnancy.
- Delivery Catheter: A long tubelike device that helps the doctor place the *Essure* micro-inserts in the fallopian tubes.
- Ectopic Pregnancy: The development of a fertilized egg outside of the uterus, but inside the body.
- Expulsion: Forcing (expelling) something out.
- Fallopian Tubes: The tubes that carry the eggs from the ovaries to the uterus.
- Hysterosalpingogram (HSG): An x-ray of the uterus and fallopian tubes after they have been filled with dye (contrast medium).
- Hysteroscope: A telescope-like instrument that is used to view the inside of the uterus.
- In Vitro Fertilization (IVF): Fertilization of an egg outside of the body, followed by placement of the fertilized egg into the uterus.
- Intrauterine Device (IUD)/Intrauterine System (IUS): A medical device that is put into the uterus to prevent pregnancy.
- Local Anesthetic: Medicine that is applied to or injected in a certain spot in the body to cause a loss of sensation in that part of the body.
- Major Surgery: A procedure that requires general anesthesia and incisions in the body.
- Micro-insert: A small, flexible, coil-type device that is put into your fallopian tube for permanent pregnancy prevention.
- Occlusion: A closed or blocked part of a hollow tube.
- Perforation: Creation of a hole.
- Permanent: Not able to change back and forth.
- Reversible: Able to change back and forth.
- Tubal Ligation: Permanent female sterilization by means of cutting, tying, burning, or clipping the fallopian tubes.
- Uterus: The womb in which a developing fetus grows.
- Vasectomy: Permanent male sterilization by means of cutting or blocking a segment of the vas deferens (the tubes that carry the sperm).

EXHIBIT B: CHART OF REMAINING "FACTS AND WARRANTIES CLAIMS"

Complaint Paragraph	Contested Statement	FDA-Approved Source Language	Plaintiff's Position
103(a)	"Only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials."	"As of October 15, 2004 (the date of the last data extract), 643 women with bilateral placement contributed effectiveness time, 194 in the Phase II study and 449 in the Pivotal Trial. In total, the 643 trial participants contributed 28,290 months of follow-up time with no (zero) pregnancies reported." Page 3, 2008 Instructions for Use, part of PMA Supplement 15, Approved June 10, 2008[1] "None of the women who relied on *Essure* for contraception during the clinical trials became pregnant **over the 1 to 2 years of follow-up."** Page 5, 2002 Patient Information Booklet[2]	(1) Plaintiff's warranty is not based on the 2008 IFU or the 2002 PIB. (2) Plaintiff's warranty claim is based on a warranty off of Defendants' website which was never approved or even evaluated by the FDA per Defendants' CPMA. (3) Plaintiff's warranty is not the same as the alleged FDA-approved source language as it omits significant qualifiers and conditions. As such, even if it was approved, the FDA requires no deviations under *Riegel.* (4) Defendants' CPMA expressly states: "CDRH does not evaluate information related to contract liability warranties…" (5) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[3]

[1] Attached

[2] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirth Control/ucm452280.htm

[3] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

103(b)	"There were zero pregnancies in the clinical trials"	"As of October 15, 2004 (the date of the last data extract), 643 women with bilateral placement contributed effectiveness time, 194 in the Phase II study and 449 in the Pivotal Trial. In total, the 643 trial participants contributed 28,290 months of follow-up time with no (zero) pregnancies reported." Page 3, 2008 Instructions for Use, part of PMA Supplement 15, Approved June 10, 2008 "None of the women who relied on *Essure* for contraception during the clinical trials became pregnant **over the 1 to 2 years of follow-up."** Page 5, 2002 Patient Information Booklet	(1) Plaintiff's warranty is not based on the 2008 IFU or the 2002 PIB. (2) Plaintiff's warranty claim is based on a warranty off of Defendants' website which was never approved or even evaluated by the FDA per Defendants' CPMA. (3) Plaintiff's warranty is not the same as the alleged FDA-approved source language as it omits significant qualifiers and conditions . As such, even if it was approved, the FDA requires no deviations under *Riegel.* (4) Defendants' CPMA expressly states: "CDRH does not evaluate information related to contract liability warranties…" (5) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[4]

[4] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

103(c)	"Physicians must be **signed off** to perform Essure procedures"	"This Device should only be used by physicians who are knowledgeable hysteroscopists; have read and understood the information in the Instructions for Use and in the Physician Training Manual; and have successfully completed the Essure® training program. **Completion of the Essure training program includes** preceptoring in Essure placement until competency is established, which is typically expected to be achieved in 5 cases." Page 1 (Box warning), 2008 Instructions for Use, part of PMA Supplement 15, Approved June 10, 2008	(1) Plaintiff's warranty is not based on the 2008 IFU. (2) Plaintiff's warranty claim is based on a warranty off of Defendants' website which was never approved or even evaluated by the FDA per Defendants' CPMA. (3) Plaintiff's warranty is not the same as the alleged FDA-approved source language as it omits significant qualifiers and conditions . As such, even if it was approved, the FDA requires no deviations under *Riegel.* (4) Defendants' CPMA expressly states: "CDRH does not evaluate information related to contract liability warranties…" (5) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[5]

[5] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

103(e)	"**Worry free**: Once your doctor confirms that your tubes are blocked, you never have to worry about unplanned pregnancy"	"Essure may be right for you if: • You are certain you do not want any more children. • You desire a permanent form of birth control. • **You would like to stop worrying about getting pregnant**." Page 4, 2014 Patient Information Booklet[6] "After 3 months, your doctor will perform a special type of x-ray test called an HSG. This test will assure you that your tubes are completely blocked and you can rely on the Essure micro-inserts for birth control." Page 3, 2007 Patient Information Booklet, part of PMA Supplement 13, Approved September 19, 2006[7] "Reliance can begin at 3 months when the Essure confirmation test confirms placement and blockage of the tubes." Page 9, 2007 Patient Information Booklet, part of PMA Supplement 13, Approved September 19, 2006	(1) Plaintiff's warranty is not based on the 2007 PIB. (2) Moreover, Plaintiffs could not rely on a 2014 PIB because they were all implanted prior to the date. (3) Plaintiff's warranty claim is based on a warranty off of Defendants' website which was never approved or even evaluated by the FDA per Defendants' CPMA. (4) Plaintiff's warranty is not the same as the alleged FDA-approved source language as it omits significant qualifiers and conditions . As such, even if it was approved, the FDA requires no deviations under *Riegel*. (5) Eg. "Worry free" is not the same as "you would like to stop worrying about pregnancy." (6) Defendants' CPMA expressly states: "CDRH does not evaluate information related to contract liability warranties…" (7) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[8]

[6] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirth Control/ucm452280.htm
[7] Attached
[8] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

103(f)	"Essure is **the most effective permanent birth control available**-even more effective than tying your tubes or a vasectomy."	2007 Patient Information Booklet (**comparison chart** showing effectiveness rates in vasectomy, tubal ligation, and Essure) Page 9, 2007 Patient Information Booklet, part of PMA Supplement 13, Approved September 19, 2006	(1) Plaintiff's warranty is not based on the 2007 PIB. (2) Plaintiff's warranty claim is based on a warranty off of Defendants' website which was never approved or even evaluated by the FDA per Defendants' CPMA. (3) Plaintiff's warranty is not the same as the alleged FDA-approved source language as it omits significant qualifiers and conditions . As such, even if it was approved, the FDA requires no deviations under *Riegel.* (4) Eg. "Essure is the most effective permanent birth control available" is not the same as a comparison chart. (5) Defendants' CPMA expressly states: "CDRH does not evaluate information related to contract liability warranties…" (6) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[9]

[9] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

103(g)	"Correct placement .. .is performed easily because of the design of the microinsert"	Defendants cannot respond since Plaintiffs have not identified the alleged source of this statement.	(1) Plaintiffs have identified the source of the warranty ("Defendants' website"). (2) Notwithstanding Defendant's lack of a source for this warranty, the FDA stated that it does not evaluate information related to contractual warranties. (3) Correct placement is not easily performed as all of Plaintiffs' coils migrated. (4) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[10]

[10] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

103(i)	"the **Essure training program is a comprehensive course** designed to provide information and skills necessary to select appropriate patients, perform competent procedures and manage technical issues related to the placement of Essure micro-inserts for permanent birth control."	Plaintiffs have not identified the source of this alleged statement, but it appears directed to physicians and not patients.	(1) Plaintiffs have identified the source of the warranty ("Defendants' website"). (2) Notwithstanding Defendant's lack of a source for this warranty, the FDA stated that it does not evaluate information related to contractual warranties. (3) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[11]

[11] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

103(j)	"In order to be trained in Essure you must be a skilled operative hysteroscopist. You will find the procedure easier to learn if you are already proficient in operative hysteroscopy and management of the awake patient. If your skills are minimal or out of date, you should attend a hysteroscopy course before learning Essure."	Plaintiffs have not identified the source of this alleged statement, but it statement appears directed to physicians and not patients. "This Device should only be used by physicians who are knowledgeable hysteroscopists." Page 1 (Box warning), 2008 Instructions for Use, part of PMA Supplement 15, Approved June 10, 2008	(1) Plaintiffs have identified the source of the warranty ("Defendants' website"). (2) Notwithstanding Defendant's lack of a source for this warranty, the FDA stated that it does not evaluate information related to contractual warranties. (3) Plaintiff's warranty claim is based on a warranty off of Defendants' website, (not the 2008 IFU) which was never approved or even evaluated by the FDA per Defendants' CPMA (CDRH does not evaluate information related to (4) Plaintiff's warranty is not the same as the alleged FDA-approved source language as it omits significant qualifiers and conditions. As such, even if it was approved, the FDA requires no deviations under *Riegel.* (5) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[12]

[12] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

103(k)	Essure is a surgery free permanent birth control.	"Essure is indicated for women who desire permanent birth control (female sterilization)…" Page 1, 2008 Instructions for Use, part of PMA Supplement 15, Approved June 10, 2008.	(1) Plaintiff's warranty is not based on the 2008 IFU. (2) Plaintiff's warranty claim is based on a warranty off of Defendants' website which was never approved or even evaluated by the FDA per Defendants' CPMA. (3) Plaintiff's warranty is not the same as the alleged FDA-approved source language as it omits significant qualifiers and conditions . As such, even if it was approved, the FDA requires no deviations under *Riegel.* (4) Defendants' CPMA expressly states: "CDRH does not evaluate information related to contract liability warranties…" (5) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[13]

[13] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

104(a)	"Zero pregnancies" in its clinical or pivotal trials.	"As of October 15, 2004 (the date of the last data extract), 643 women with bilateral placement contributed effectiveness time, 194 in the Phase II study and 449 in the Pivotal Trial. In total, the 643 trial participants contributed 28,290 months of follow-up time with no (zero) pregnancies reported." Page 3, 2008 Instructions for Use, part of PMA Supplement 15, Approved June 10, 2008 "None of the women who relied on *Essure* for contraception during the clinical trials became pregnant **over the 1 to 2 years of follow-up."** Page 5, 2002 Patient Information Booklet	(1) Plaintiff's warranty is not based on the 2008 IFU or the 2002 PIB. (2) Plaintiff's warranty claim is based on a warranty off of Defendants' advertisement which was never approved or even evaluated by the FDA per Defendants' CPMA. (3) Plaintiff's warranty is not the same as the alleged FDA-approved source language as it omits significant qualifiers and conditions. As such, even if it was approved, the FDA requires no deviations under *Riegel.* (4) Defendants' CPMA expressly states: "CDRH does not evaluate information related to contract liability warranties…" (5) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[14]

[14] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

104(b)	In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks.	Plaintiffs have not identified the source of this alleged statement, but it appears directed to physicians, not patients.	(1) Plaintiffs have identified the source of the warranty (Defendants' advertisement). (2) Notwithstanding Defendant's lack of a source for this warranty, the FDA stated that it does not evaluate information related to contractual warranties. (3) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[15]

[15] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

104(c)	No pregnancies have occurred after a successful confirmation test in the Essure clinical studies at 4 and 5 years of follow up.	"**As of the final 5-year follow-up data extracts** (phase II-January 6, 2006; Pivotal-December 5, 2007), 643 trial participants with bilateral placement (194 Phase II; 449 Pivotal) contributed 35,633 months of follow-up time with zero pregnancies reported." Page 4, Current Instructions for Use[16]	(1) Plaintiff's warranty is not based on Current IFU. (this is especially true considering they were implanted in 2013 and prior.) (2) Plaintiff's warranty claim is based on a warranty off of Defendants' advertisement which was never approved or even evaluated by the FDA per Defendants' CPMA. (3) Plaintiff's warranty is not the same as the alleged FDA-approved source language as it omits significant qualifiers and conditions. As such, even if it was approved, the FDA requires no deviations under *Riegel*. (4) Defendants' CPMA expressly states: "CDRH does not evaluate information related to contract liability warranties…" (5) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[17]

[16]http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452280.htm
[17] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

104(d)	I don't want to worry about an unexpected pregnancy.	**"Essure may be right for you if:** • You are certain you do not want any more children. • You desire a permanent form of birth control. • You would like to stop worrying about getting pregnant." Page 4, **2014 Patient Information Booklet** "After 3 months, your doctor will perform a special type of x-ray test called an HSG. This test will assure you that your tubes are completely blocked and you can rely on the Essure micro-inserts for birth control." Page 3, **2007 Patient Information Booklet, part of PMA Supplement 13, Approved September 19, 2006** "Reliance can begin at 3 months when the Essure confirmation test confirms placement and blockage of the tubes." Page 9, **2007 Patient Information Booklet, part of PMA Supplement 13, Approved September 19, 2006**	(1) Plaintiff's warranty is not based on the 2014 PIB; (this is especially true considering McLaughlin was implanted in 2012 and prior) or the 2007 PIB (2) Plaintiff's warranty claim is based on a warranty off of Defendants' advertisement which was never approved or even evaluated by the FDA per Defendants' CPMA. (3) Plaintiff's warranty is not the same as the alleged FDA-approved source language as it omits significant qualifiers and conditions. As such, even if it was approved, the FDA requires no deviations under *Riegel.* (4) Defendants' CPMA expressly states: "CDRH does not evaluate information related to contract liability warranties…" (5) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[18]

[18] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

107	Defendants' CEO stated: "Essure allows you to push away the constant worry about an unplanned pregnancy that's our message and that's our theme.	This statement appears to come from a Q4 2007 Essure Earnings Call Transcript; patients were not the intended recipients.	(1) Notwithstanding Defendant's lack of an FDA-approved source for this warranty, the FDA stated that it does not evaluate information related to contractual warranties. (2) Defendants' CPMA expressly states: "CDRH does not evaluate information related to contract liability warranties…"
110(a)	Defendants warranted that Essure "allows for visual confirmation of each insert's proper placement both during the procedure and during the Essure Confirmation Test."	Defendants cannot respond since Plaintiffs have not identified the alleged source of this statement.	(1) Notwithstanding Defendant's lack of an FDA-approved source for this warranty, the FDA stated that it does not evaluate information related to contractual warranties. (2) Defendants' CPMA expressly states: "CDRH does not evaluate information related to contract liability warranties…"

111(a)	**"Worry free"**	"• You would like to **stop worrying about getting pregnant**." Page 4, 2014 Patient Information Booklet	(1) Plaintiff's warranty is not based on the 2014 PIB. (2) Moreover, Plaintiffs could not rely on a 2014 PIB because they were all implanted prior to the date. (3) Plaintiff's warranty claim is based on a warranty off of Defendants' brochure which was never approved or even evaluated by the FDA per Defendants' CPMA. (4) Plaintiff's warranty is not the same as the alleged FDA-approved source language as it omits significant qualifiers and conditions. As such, even if it was approved, the FDA requires no deviations under *Riegel*. (5) Eg. "…worrying about getting pregnant" is different than the device being "worry free" (6) Defendants' CPMA expressly states: "CDRH does not evaluate information related to contract liability warranties…" (7) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[19]

[19] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

111(b)	"The Essure inserts **stay secure**, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place."	Defendants cannot respond since Plaintiffs have not identified the alleged source of this statement .	(1) Plaintiffs have identified the source of the warranty (Defendants advertising brochure). (2) Notwithstanding Defendant's lack of an FDA-approved source for this warranty, the FDA stated that it does not evaluate information related to contractual warranties. (3) All of Plaintiffs' coils migrated.

111(c)	"The Essure inserts are made from the same **trusted**, silicone free material used in heart stents."	"The micro-inserts are made from polyester fibers and metals (nickel-titanium and stainless steel), materials that have been studied and **used in the heart and other parts of the human body for many years**." Page 4, **2002 Patient Information Booklet**	(1) Plaintiff's warranty is not based on the 2002 PIB. (2) Plaintiff's warranty claim is based on a warranty off of Defendants' advertising brochure which was never approved or even evaluated by the FDA per Defendants' CPMA. (3) Plaintiff's warranty is not the same as the alleged FDA-approved source language as it omits significant qualifiers and conditions. As such, even if it was approved, the FDA requires no deviations under *Riegel*. (4) Eg. "Essure inserts are made from the same trusted… material" is not the same as "the micro-inserts are made from …materials that have been studied and used in the heart..and human body for many years." (5) The inserts are not made from trusted material as Plaintiff's coils all migrated and/or broke. (6) Defendants' CPMA expressly states: "CDRH does not evaluate information related to contract liability warranties…" (7) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[20]

[20] *Rosci v. Acromed, Inc.*, 447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

111(f)	Step Two: "pregnancy **cannot** occur"; Step Three: The Confirmation	Defendants cannot respond since Plaintiffs have not identified the alleged source of this statement.	(1) Plaintiffs have identified the source of the warranty (Defendants advertising brochure). (2) Notwithstanding Defendant's lack of an FDA-approved source for this warranty, the FDA stated that it does not evaluate information related to contractual warranties.

111(g)	"Essure **eliminates the risks**, discomfort, and recovery time associated with surgical procedures."	"The Essure™ System provides permanent birth control without invasive surgery or general anesthesia, and their associated risks. The majority of women returned to normal activities within one day or less after the procedure. The vast majority of women rated their comfort with wearing the Micro- inserts at one -week as 'good' to 'excellent'. The vast majority of women rated their overall satisfaction with the Essure™ System as 'very satisfied'." Page 22, FDA's Summary of Safety and Effectiveness Data for Essure (FDA Document)[21]	(1) Plaintiff's warranty is not based on the FDA's Summary and Effectiveness Data. (2) In fact, the FDA's Summary and Effectiveness Data on page 24/24 specifically refers to the Approval order which states that it does not evaluate this type of information. Nowhere does it state that Defendants are allowed to use this representation /warranty in its advertising. (3) Plaintiff's warranty claim is based on a warranty off of Defendants' advertising brochure which was never approved or even evaluated by the FDA per Defendants' CPMA. (4) Plaintiff's warranty is not the same as the alleged FDA-approved source language as it omits significant qualifiers and conditions. As such, even if it was approved, the FDA requires no deviations under *Riegel.* (5) Defendants' CPMA expressly states: "CDRH does not evaluate information related to contract liability warranties…" (6) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[22]

[21] http://www.accessdata.fda.gov/cdrh_docs/pdf2/p020014b.pdf

[22] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

113(a)	"The inserts are made from ... safe, **trusted material.**"	"The micro-inserts are made from polyester fibers and metals (nickel-titanium and stainless steel), materials that have been studied and **used in the heart and other parts of the human body for many years.**" Page 4, 2002 Patient Information Booklet	(1) Plaintiff's warranty is not based on the 2002 PIB. (2) Plaintiff's warranty claim is based on a warranty off of Defendants' advertising brochure which was never approved or even evaluated by the FDA per Defendants' CPMA. (3) Plaintiff's warranty is not the same as the alleged FDA-approved source language as it omits significant qualifiers and conditions . As such, even if it was approved, the FDA requires no deviations under *Riegel*. (4) Eg. "Essure inserts are made from the safe, trusted, material" is not the same as "the micro-inserts are made from …materials that have been studied and used in the heart..and human body for many years." (5) The inserts are not made from trusted material as Plaintiff's coils all migrated and/or broke. (6) Defendants' CPMA expressly states: "CDRH does not evaluate information related to contract liability warranties…" (7) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[23]

[23] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hollis v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)

115(a)	"This viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus."	Verbatim statement: Page 9, 2007 Patient Information Booklet, part of PMA Supplement 13, Approved September 19, 2006	(1) Per Defendants' CPMA, the FDA expressly states that it "does not evaluate information related to contractual warranties…" (2) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[24]
115(b)	"there was no cutting, **no pain,** no scars ... "	Verbatim statement: Page 16, 2007 Patient Information Booklet, part of PMA Supplement 13, Approved September 19, 2006	(1) Per Defendants' CPMA, the FDA expressly states that it "does not evaluate information related to contractual warranties…" (2) Moreover, "even where the warranty terms have previously been submitted for approval by the FDA…the express warranty claim…is not preempted…the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA.[25]

[24] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)
[25] *Rosci v. Acromed, Inc.*,447 Pa. Super. 403 (1995);see also *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp. 2d 830 (S.D. Ind. 2009)