

Good morning esteemed ladies and gentlemen of the committee.

My name is Dr. Julio Novoa. I am a practicing OB/GYN and Cosmetic Surgeon from El Paso, Texas. I have been in private practice since 1999. Over the past 15 years, I have managed over 15,000 patient cases. I have delivered over 5,000 babies, and have performed over 1,000 in-office AWAKE surgical procedures. I am the main doctor commentator for the ESSURE Problems forum on FaceBook representing over 22,000 women who have had problems following the placement of the ESSURE System.

I would like to state, as is customary, that I have no financial conflicts of interest to declare regarding my assistance to these women nor am I being paid by any person or organization for my assistance.

I and my fellow OB/GYN colleagues at this site have volunteered our time and efforts in an attempt to provide as much assistance as possible regarding problems with the ESSURE.

What is the ESSURE Permanent Birth Control?

The ESSURE System is marketed as a non-surgical permanent sterilization device and has been available in the US since it received Class III medical device approval by the Food and Drug Administration (FDA) on November 4, 2002.

The Bayer Corp acquired Conceptus, the original manufacturer of the ESSURE System, on June 5, 2013.

The ESSURE System is composed of 4cm long, flexible metallic coils and polyester fibers which are inserted into the fallopian tubes. The fallopian tubes carry the eggs from the ovaries to the uterus.

Once in place and over a period of about three months, the polyester fibers cause a contract and permanent foreign body inflammatory response which causes scar tissue to form around the inserts.

The build-up of tissue creates a barrier that keeps sperm from reaching the eggs, thus preventing conception.

Essure Permanent Birth Control

Essure is a permanent birth control method for women that creates a barrier against pregnancy. It involves placing soft, flexible inserts into the fallopian tubes, which carry the eggs from the ovaries to the uterus. Over a period of about three months, tissue forms around the inserts. The

build-up of tissue creates a barrier that keeps sperm from reaching the eggs, thus preventing conception.

Essure can be an effective means of female sterilization when health care providers and patients follow the appropriate instructions for use.

(FDA Website)

<http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/ucm371014.htm>

Although both the FDA and the Bayer Corporation have stated that the ESSURE is safe and effective, data collected from its own clinical trials, and over the past 12 years place in doubt the validity of their assurances.

In order to get a better understanding of the problems with the ESSURE, I would like to address the shortcomings of the Food and Drug Administration (FDA) regarding the following:

1. Its initial Class III approval of the ESSURE device
2. Inadequate FDA follow-up documentation policies
3. Inadequate policing of deceptive advertising of the ESSURE device by the FDA once it was made available to the US market.
4. Inadequate monitoring of the promotion of the device by Bayer in regards to the training in the placement and management of complications of the ESSURE device by the inserting GYN.
5. Inappropriate marketing; failure to obtain proper informed consent; conflict of interest and unethical practices on the part of the inserting GYN surgeon.
6. Inadequate follow-up and evaluation of significant and potentially life threatening complications associated with the ESSURE device even when optimal placement has been initially achieved.

Concerns Regarding FDA Approval

As stated on its official website, the FDA approved the ESSURE System based on clinical trials from 1999-2001.

Between November of 1998 and June of 2001, a total of 745 women underwent an Essure 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). Some women underwent more than one procedure if successful bilateral placement was not achieved in the initial procedure.

(Conceptus Physician Instruction Manual, p. 9, 12/18/02)

Essure Clinical Resource, Physicians Training Manual, p. 10.

http://www.essuremd.com/docs/resources/250-40-0001-14a_clinical-resource_digital-use_final.pdf

Since this date, the evaluation of the ESSURE by the FDA has relied primarily on voluntary reporting of adverse events by the manufacturer of the device, the patient, or the patient's physicians.

Specifically, the FDA has relied heavily on data submitted as part of the Manufacturer and User Facility Device Experience (MAUDE) database which included 943 reports of adverse events related to the ESSURE from November 4, 2002- October 25, 2013.

We reviewed Essure patient reports of problems (including web-based testimonials) and reports of problems submitted to the FDA from other sources, including doctors, patients, and the manufacturer of Essure, Conceptus Inc. (Bayer acquired Conceptus on June 5, 2013.)

The FDA conducted a search of the Manufacturer and User Facility Device Experience (MAUDE) database. From Nov. 4, 2002, Essure's approval date, through Oct. 25, 2013, the FDA received 943 reports of adverse events related to Essure. The most frequently reported adverse events were pain (606), hemorrhage (140), headache (130), menstrual irregularities (95), fatigue (88), and weight fluctuations (77). The most frequent device problems reported were the migration of the device or device component (116), patient device incompatibility (113) (e.g., possible nickel allergy), device operating differently than expected (73), malposition of the device (46), and device breakage (37).

<http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/ucm371014.htm>

HOWEVER, a serious flaw exists with this method of data collection.

(1) The reporting is voluntary and only a fraction of patient or the patient's physicians are aware that the reporting database even exists.

Therefore, the survey pool of patients with adverse effects is only a fraction of the actual number of patients which have had complications with the ESSURE.

Through the efforts of patient advocate groups, such as Essure Problems and Essure Procedures. net, the number of adverse events reports has doubled in the past 7 months, from 943 in the previous 11 years to over 2000 today.

(2) The FDA approved the ESSURE System based on data from two clinical studies totaling only 745 patients and uses this study as the main source of specific reference in regards to the effectiveness of the device.

What is extremely worrisome regarding a review of this FDA data are the following:

1. The ESSURE System is a relatively difficult device to place even by Expert Level GYN hysteroscopic surgeons with an insertion failure rate of 14%.

ESSURE Clinical Resource, Physicians Training Manual, p.14.

http://www.essuremd.com/docs/resources/250-40-0001-14a_clinical-resource_digital-use_final.pdf

This means that the FDA was aware that even in the hands of an expert, the device can be improperly placed more than 1 out of 10 times.

Most Board-certified GYN doctors are only nominally proficient in the use of the hysteroscope, so you can imagine the actual rate of improper placement with the device.

2. The FDA clinical trials data shows that the ESSURE System had an incidence of adverse side effects of over 30% to include perforation, migration, severe abdominal and pelvic pain, severe and prolonged menstrual periods, and pain with intercourse.

ESSURE Clinical Resource, Physicians Training Manual, p.13.

http://www.essuremd.com/docs/resources/250-40-0001-14a_clinical-resource_digital-use_final.pdf

This means that the FDA was aware that the ESSURE was associated with greater than a 1 in 3 incidence of serious complications at the 1 year mark. Yet, they still approved it for use in the US.

3. The ESSURE System has an incidence of migration, expulsion or extrusion out of the fallopian tube or uterus of 4%.

(ESSURE Clinical Resource, Physicians Training Manual, p.11.)

http://www.essuremd.com/docs/resources/250-40-0001-14a_clinical-resource_digital-use_final.pdf

This means that the FDA was aware that, even if properly placed, 1 out of 25 women would end up having the device expelled from their body or expelled into the pelvis where it would continue to produce a chronic foreign body inflammatory response effecting the adjacent organs to the fallopian tubes to include the bowels and eventually cause scarring of the pelvic organs as it had been designed to do in the fallopian tube.

What is extremely concerning is that the FDA made no provisions nor did it require that any protocols be established to either warn women of this potential risk or require that the manufacturer establish a surgical management plan for doctors to follow when migration of the device had occurred.

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 12-24 months of implantation, with little data at 36 months. Therefore, beyond 24 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.

(Conceptus Physician Instruction Manual, p. 4, 12/18/02)

Patients have not been properly informed of the fact that the ESSURE produces a chronic and permanent inflammatory response and have not been properly informed to notify the manufacturer or the FDA about their complications to the ESSURE System to include hysterectomy.

In fact, to date, there have been no double blind, peer reviewed studies evaluating the complications or management of the ESSURE device once it has expelled into the pelvis.

4. The FDA continues to post on its website that the ESSURE System has an effective rate of 99.83%, even though no study outside of the pilot studies has been able to duplicate this percentage.

The FDA has also not required any additional information from the manufacturer beyond the 5 year mark in order to see if the ESSURE is truly a safe and effective form of PERMANENT BIRTH CONTROL, as advertised by Bayer.

There is also the fact that the FDA does not include the 14% insertion failure rate in its calculations of overall efficacy.

Benefits of Essure

- *Essure is the only sterilization choice that does not require a skin incision for women who want permanent birth control.*
- ***The Essure procedure is 99.83 percent effective when used according to the approved instructions for use based on five-year clinical study data.***
- *Patients do not require general anesthesia when Essure is placed in the fallopian tubes.*
- *Essure inserts do not contain or release hormones.*
- *Recovery is quicker than other types of sterilization. Most women can go home 45 minutes after the procedure, and return to normal activity within one to two days.*

(FDA Website)

<http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/ucm371014.htm>

The currently accepted rate of failure as documented in the literature regarding the ESSURE device ranges from 4-9%.

A recent peer reviewed study from Yale published in the Journal of Contraception calculated a failure rate of the ESSURE of between 1:11 to 1:12 patients, which represents a 3x-18x higher rate of failure as compared to traditional laparoscopic tubal ligation.

Yet, the FDA has failed to require any warning to patients of this information.

The expected pregnancy rates per 1000 women at 1 year are 57, 7 and 3 for hysteroscopic sterilization, laparoscopic silicone rubber band application and laparoscopic bipolar coagulation, respectively. At 10 years, the cumulative pregnancy rates per 1000 women are 96, 24 and 30, respectively.*

**ESSURE SYSTEM*

Aileen M. Gariepy a,*, Mitchell D. Creinin b, Kenneth J. Smith c, Xiao Xu. **Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization.** Department of Obstetrics, Gynecology, and Reproductive Sciences, Yale School of Medicine, New Haven, CT 06510, USA Department of Obstetrics and Gynecology, University of California, Davis, Sacramento, CA 95817, USA. Department of Medicine, Division of General Internal Medicine, University of Pittsburgh School of Medicine, Pittsburgh, PA 15261, USA. 16 March 2014

The TWO MOST SERIOUS VIOLATIONS OF THE PUBLIC TRUST REGARDING THE FDA AND THE ESSURE ARE THE FOLLOWING:

1. The FDA has allowed the Bayer Corp to advertise the ESSURE System as a NON-SURGICAL procedure, the repercussions of which are immeasurable both in terms of the agency's credibility and the potential legal ramifications.

- **Non-surgical**—*Essure is a short 10-minute procedure that can be performed right in your doctor's office.* <http://www.essure.com/what-is-essure/what-is-essure>

The ESSURE System requires the use of an operative hysteroscope in order for it to be place.

The hysteroscope is a surgical device with a camera and instrument ports which is used by surgeons to perform a variety of surgical procedures inside of the uterus.

There is absolutely no way to place the ESSURE device without the use of the operative hysteroscope.

Medical State Board regulations, Hospital Surgical Privileges, Centers for Medicare and Medicaid (CMS) CPT and ICD-9-CM Billing and Coding, as well as, insurance companies list this operative hysteroscopic procedure as a SURGICAL procedure.

The FDA and Bayer have allowed the ESSURE device to be marketed as a NON-SURGICAL procedure in order to promote the device as an alternative to riskier surgical procedures, when it fact, the ESSURE procedure is itself a surgical procedure with higher risks of insertion compared to traditional laparoscopic surgery.

Bayer has even provided PowerPoint presentations to its representatives in order to teach doctors how to avoid using the term SURGERY and instead use the term PROCEDURE.

Speaking "Patient" Language

Instead Of.....

*Sterilization
Spring/coil
Non-incisional
Surgery
New procedure
HSG
Scar tissue*

Consider Using.....

*Permanent Birth Control
Essure insert
No cutting
Procedure
FDA approved since 2002
Essure Confirmation Test
Natural barrier*

<http://www.essuremd.com/portals/essuremd/pdfs/rPAE/cC-2343%2011MAR10F%20FPGP%20Referral%20Presentation.ppt>

Bayer also provides its **ESSURE Reimbursement Guide** which specifically describing the billing of the procedure as part of a “global/surgical package” with the appropriate CPT code.

Product Service- Essure Procedure

CPT Code- 58565

Code Description- Hysteroscopic surgical;with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants.

Essure Reimbursement Guide, p.3.

http://www.essuremd.com/docs/resources/250-40-0007-13d_reimbursement_brochure_for-e-use.pdf

This false, misleading and potentially deceptive advertising has been allowed to go on for years and has been one of the most important decision making factors for the consumer.

As such, not hundreds, not thousands, but literally hundreds of thousands of women have been given false information which at a minimum has violated their rights under Informed Consent requirements.

2. The failure of the ESSURE System is so high that mothers having their babies with the ESSURE System in place have come to call themselves, E-Moms and their babies, E-babies.

Literally hundreds of E-babies are being born every year.

Unfortunately, the FDA has failed to address or warn patients that when the ESSURE System fails, it can and does cause ESSURE INDUCED ABORTIONS (EIA).

According to the MAUDE data, as well as patient surveys done by the ESSURE Problems forum, when a pregnancy does occur, approximately 45% of the time, the pregnancy ends up as an ectopic pregnancy.

Al-Safi, ZA, Shavell VI, Hobson DTG, Berman JM, Diamond MP. *Analysis of Adverse Events With the ESSURE Hysteroscopic Sterilization Reported to the Manufacturer and User Facility Experience Database. J Minim Invasive Gynecol, 2013, 20, 825-829.*

HOWEVER, the incidence of either intrauterine or ectopic pregnancy has not categorized, let alone mentioned, by the FDA on its website, even though this adverse event is one of the most common adverse complaints listed in the MAUDE database.

The FDA conducted a search of the Manufacturer and User Facility Device Experience (MAUDE) database. From Nov. 4, 2002, Essure's approval date, through Oct. 25, 2013, the FDA received 943 reports of adverse events related to Essure. The most frequently reported adverse events were pain (606), hemorrhage (140), headache (130), menstrual irregularities (95), fatigue (88), and weight fluctuations (77). The most frequent device problems reported were the migration of the device or device component (116), patient device incompatibility (113) (e.g., possible nickel allergy), device operating differently than expected (73), malposition of the device (46), and device breakage (37).

<http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/ucm371014.htm>

I would challenge anyone to give us a reliable explanation as to why the number of device failures leading to pregnancy and abortions is not being acknowledged by the FDA even though it accounts for over 10% of the adverse events complaints listed in the MAUDE database.

Many question whether or not this data is intentionally being omitted from discussion.

In the case of ectopic pregnancies, the management is often emergency surgical removal of the pregnancy and the affected tube.

In the case where the pregnancy is able to enter the uterus, the ESSURE device has been associated with abortions or premature deliveries even past gestational ages where abortions are banned by State laws.

Unfortunately, we as OB/GYN doctors are unable to prevent ESSURE INDUCED ABORTIONS since it is not possible to remove the ESSURE device without risking the loss of the pregnancy or the death of the patient.

Regardless of your position on abortion, the fact that the FDA is neither acknowledging ESSURE INDUCED ABORTIONS (EIA) as a significant problem in direct contradiction to its own reference data and not posting a **FDA Alert** of this problem is a travesty for either side of

the Pro-Life vs. Pro-Choice position because it has fundamentally taken away the right of the patient to be properly informed.

Lack of Documentation Notification and Conflict of Interest Bias in reporting to the MAUDE Database

The lack of adequate public and consumer education regarding the process of reporting into the MAUDE database is fundamentally biased and self-serving on the part of the FDA, the Physician and the manufacturer of a medical product.

In regards to the FDA, the fewer adverse event reports that require review, the less scrutiny as to the validity of its Class III approval process.

In regards to the Inserting GYN Surgeon, the voluntary reporting of an adverse event associated with one of their patient increasing the risk and fear that they will later be involved in a malpractice lawsuit. For this reason alone, doctors are not inclined to participate in reporting into the MAUDE database.

In regards to the manufacturer, adverse event reports is associated with negative publicity and adversely affect the use and profitability of their product.

This is why, at a minimum, the FDA should make it mandatory for all doctors and their patients to fill out product evaluation reports in order to provide an appropriate census of the safety and efficacy of new and/or experimental medical products. This would also help to hasten the discovery of flaws with medical products approved for use by the FDA.

Recommended Inclusion of Independent Data into the MAUDE Database

It is also recommended that the FDA incorporate the data from the pathology reports associated with post-Essure surgical procedures, to include bilateral salpingectomy (tubal removal) and hysterectomy (the removal of the uterus).

A review of the pathology reports from women in the ESSURE Problems forum following hysterectomy have relieved an incidence of adenomyosis (endometrial tissue in the uterine muscle) and endometriosis (endometrial tissue in the pelvis) at rates 3x-8x higher than those found in the general population which are associated with chronic pelvic pain, abnormal uterine bleeding, excessive pelvic scarring, and pain with intercourse.

This information strongly supports a possible "Cause and Effect" relationship between the ESSURE System and these conditions which has not been included in the MAUDE data

because patients have simply been unaware that they could report these independent, medically-confirmed findings.

Concerns Regarding Inappropriate Marketing, Conflict of Interest and Unethical Behavior of the Gynecologist

Based on the initial clinical trial data, the FDA approved the ESSURE for insertion without the use of General Anesthesia.

Aside from the fact that the manufacturer promoted the placement of the ESSURE as a non-surgical procedure, it has used the fact that the procedure can be done in an office setting under local anesthesia as a selling point to doctors.

The product reps are also emphasizing the fact that, when done in the office, the compensation to the doctor for the procedure is between 3-5x higher than traditional sterilization procedures that are done in the hospital when factoring in time and convenience to the doctor.

This is being promoted as a monetary incentive for the surgeon to do the procedure in the office rather than in the hospital.

Unfortunately, each of these incentives has compromised surgeons' objectivity.

I am sorry to say, that the very integrity of my specialty has been compromised.

Doctors with very little experience using the hysteroscope are undergoing a one-day training course by the manufacturer and being trained by product representatives who do not have medical degrees.

Doctors are telling patients the ESSURE is a non-surgical procedure that can safely and painlessly done in the office with almost 100% reliability without any serious complications.

Based on this point, there are countless of horror stories of what happens behind closed doors in the Doctor's office.

Women are telling stories of their doctors taking 30-45 minutes to insert the ESSURE device without giving them adequate anesthesia.

Some doctors, aware of the level of pain associated with the placement of the ESSURE are sedating patients without proper permits, without the required safety equipment (such as an emergency crash cart) and without having the required number of medical staff who are trained in either Basic Life Support (BLS) or Advanced Cardiac Life Support (ACLS) as required by law.

<http://www.csen.com/office.pdf>

https://www.tmb.state.tx.us/search/public/advanced/key/office+based+anesthesia/type_of_search/whole_words/pages/on/faqs/on/documents/on/page/2

Women have described the procedure as “pure agony”, “excruciating pain”, and even “torture”, as their doctors were attempting to insert their “E-hell” devices.

In a recent patient survey on the ESSURE Problems forum, 96% of the women surveyed that underwent the procedure while AWAKE stated that their level of pain was so severe and that they would have never undergone the procedure in the first place had they known that it would cause that level of pain.

The same percentage of women would never recommend that the procedure be done while awake to a friend or family member.

These complaints are in stark contrast to the surveys associated with the original trials and place in question the validity of the original clinical data.

A similar number of women complained that the hysterosalpinography or HSG which is required to confirm the occlusion of the tubes three months later involved enduring the same level of pain.

In all these cases, women have become victims of unprofessional and unethical behavior on the part of their GYN doctors because it violates the fundamental principles of performing AWAKE surgical procedures in an office setting.

Patients, having total trust in their doctors, have stated that they have allowed themselves to be subjected to unnecessary levels of pain, which under normal circumstances would not have occurred had the ESSURE device been placed while under General Anesthesia in a hospital.

Patients complain that the only reason that it was done in the doctor’s office is due to the significantly higher compensation that the doctor receives for doing the procedure in their office under local or IV sedation rather than in the hospital under General Anesthesia.

Patients have also complained that they were never told that the HSG was absolutely necessary and there are doctors placing the devices rather than perform a traditional laparoscopic sterilization, even though they know that the patient will lose her insurance before the HSG can confirm that the ESSURE device has closed her tubes.

Despite all these complaints, the FDA has again failed to address these serious allegations.

Management of Post Essure Complications

The FDA has also failed to address the significant increase in the incidence of post-ESSURE surgeries that are being done in order to remove the ESSURE device due to its complications.

Literally hundreds of laparoscopic tubal removals, cornual resections, and hysterectomies are being done each month as definitive treatment due to the complications of the ESSURE device.

Unfortunately, despite there having been hundreds of thousands of ESSURE devices placed over the past 12 years, there are no established protocols on how to manage the removal of the ESSURE.

Doctors are using "Best Guess" medicine.

Some attempt to remove the ESSURE hysteroscopically, despite it being specifically contraindicated by the manufacturer.

Others attempt to cut the coils out of the tube or uterus which fragments the devices and exposes the polyester fibers to the pelvis making the situation worse.

Most doctors simply refuse to remove the coils which leaves the patient suffering for years, in what ladies have described as E-hell.

What is most impressive is that, based on the ESSURE Problem survey data, 90% of women who have suffered for years with coil perforation, chronic pelvic pain, abnormal bleeding, pain with intercourse or a variety of autoimmune foreign body reactions to the ESSURE have almost immediate resolution of their symptoms once the ESSURE is removed.

At a minimum, I hope my commentary today will force the FDA to immediately act to make the Bayer corporation pull its ads stating that the ESSURE System is a NON-SURGICAL procedure, which is clearly false and misleading.

I hope that the FDA will immediately address the issues regarding the high rate of abortions caused by the ESSURE, especially in light of the fact that the company is heavily promoting the fact the ESSURE is expected to be cost free to the consumer under the Affordable Care Act.

Essure Reimbursement Guide . p. 5. http://www.essuremd.com/docs/resources/250-40-0007-13d_reimbursement_brochure_for-e-use.pdf

And I hope that the FDA will force the manufacturer to provide recommendations for the proper management of complications associated with the ESSURE device.

Thank you for allowing me to speak today.

Sincerely,

Dr. Julio Novoa