A Personal Choice

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To whom it may concern

I am a board certified Obstetrician and Gynecologist with extensive experience in the field of Women's Reproductive Health. I previously served as the Medical Director for Planned Parenthood of Central North Carolina from 2001 to 2013 and I am currently a specialist in the surgical reversal of female sterilization.

I am writing to share my professional experience and dissatisfaction with the Essure micro-insert sterilization system. Unlike many physicians, I have experience with both Essure device insertion and Essure device removal. The safety of the Essure micro-insert system needs to be reevaluated because we are observing a higher than anticipated number of Essure failures and Essure related complications.

Essure insertion problems

As Medical Director of Planned Parenthood of Central North Carolina, I helped to introduce Essure sterilization and over a four (4) year period I performed over sixty (60) Essure sterilization procedures.

I personally observed two (2) defective devices in which the micro-inserts partially deployed inside a patient, one (1) case of a device perforating the uterus requiring referral for surgical removal and one (1) case of pain at twelve months after the procedure requiring referral and surgical intervention. Equally distressing were six (6) cases of inability to successfully complete the procedure due to an inability to insert the devices safely within the fallopian tubes. In comparison, over my fifteen year professional career I have performed countless numbers traditional sterilization procedures and I have never encountered a single sterilization procedure I could not complete.

After a series of Essure device related problems, I began to develop anxiety at the start of every procedure because I was never certain if the procedure was going to be successful.

At first I doubted my professional abilities but over time I began to realize these were problems inherent to the Essure sterilization procedure itself. Although it is easy for others to ask why physicians have not identified problems sooner, we should all understand the environment in which this evolved.

1. Physicians were informed financial reimbursement for the procedure would be sizeable and would be even more sizeable if the procedure was performed within a doctor's private office rather than a hospital setting. This created a financial incentive for physicians to prefer Essure over other sterilization procedures and to perform these procedures in an office setting rather than within a hospital setting. When procedures are not performed within hospital settings there is less peer oversight. Since academic physicians work mostly in hospital based settings then there is less exposure of these types of procedures to academic physicians and these are the physicians who are most likely to study and publish outcomes and long term risks.

2. Initially Conceptus arranged for physicians to obtain the surgical equipment for Essure insertion at no cost if two Essure kits were purchased each month. Under the terms of the agreement, the kits were sold to the physician even if they were not used. This created financial pressure among physicians to perform a continuous minimum number of Essure procedures.
3. There were extensive commercial advertisements suggesting 100% effectiveness and high patient satisfaction. There were numerous Conceptus sponsored physicians who touted their complete satisfaction with the Essure device and patient outcome. When others speak about how great things are it makes it less likely those who are having problems will be open about it.
4. Since many of these procedures were being performed in private doctor's offices, many academic physicians had little experience with the procedure, complications, and risk of device related complications and, as a result, this newer sterilization procedure has not been as extensively studied within the first 10 years as it likely should have been.

All of the above create financial incentives to continue with a product you may feel is suboptimal and also makes you doubt yourself because everyone else is reporting it to be such a great procedure. It takes time to push through these additional financial and psychological obstacles.

Over the last 5 (five) years there has been a slow but steadily increasing amount of medical literature documenting Essure related complications. In the August 2014 issue of the medical journal, Contraception, Dr. Gariepy *et al.* analyzed Essure device failure data submitted to the U.S. Food and Drug Administration and concluded,

> "Based on available data, the expected population risk of pregnancy is higher after hysteroscopic (Essure sterilization) than laparoscopic sterilization. Consistent with existing contraceptive classification, future characterization of hysteroscopic sterilization should distinguish "perfect" and "typical" use failure rates."

This translates into Essure sterilization failure rates seen after ***typical use*** in the community by a variety of physicians on a variety of patients are higher than the failure rates after ***prefect use*** in a well controlled, small study conducted by Conceptus and submitted to the U.S. Food and Drug Administration.

We are now seeing a much larger group of women who have Essure and are having device related failure because of typical usage device failure rates.

Sterilization procedures should be similar in function to fire extinguishers, guns, and calling 911. When you pull the trigger it needs to work without fail and when you call they need to respond reliably. Essure sterilization does not meet this degree of reliability. Moreover, Essure sterilization system is causing complications requiring additional surgical procedures in an increasingly growing number of women.

Essure removal because of device related complications

I specialize in female and male sterilization reversal. In 2009, I performed the first successful surgical sterilization reversal of Essure which resulted in pregnancy and was described within the medical literature. Soon after this case report, we began to be contacted by women who were having Essure related complications. Many of these women were not able to be helped by their local doctors because of their doctor's inexperience with device removal and many of these women had health insurance plans which did not recognize or readily reimburse for Essure related complications.

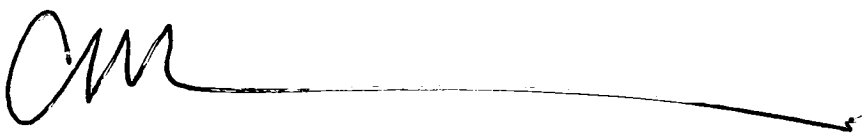
Since 2009, I have performed over forty (40) Essure removal surgeries for Essure related side-effects. Although forty (40) is a small number compared to the over 700,000 Essure insertions, one must understand health insurance does not pay for device removal at our facility and our patients are paying directly for these surgeries. Since 2009 some physicians have become increasingly more confident and skilled in device removal and health insurance companies are more readily reimbursing for these procedures. There is a much larger group of women who are having Essure related complications and these women are being treated by other providers or are suffering. Unfortunately many of these women are having hysterectomy as a result of Essure related side-effects.

In 2014 we surveyed our Essure removal patients two (2) years after their procedures and 92% of patients reported improvement in their symptoms after Essure removal surgery. The dramatic response to treatment would suggest Essure was the primary cause of their side-effects.

We should all acknowledge Essure sterilization does cause symptoms in some women up to a year or more after insertion. In the data submitted to the U.S. Food and Drug Administration by Conceptus for Essure sterilization approval, 9% of women reported back pain, 3.8% reported abdominal pain, and 2.5% of women reported severe pelvic pain at twelve (12) months after Essure micro insert device insertion. Essentially 1 out of 10 women can experience symptoms at twelve (12) months after the procedure. This is an unacceptably high percentage of women reporting side-effects after a surgical sterilization procedure.

In summary, the Essure micro-insert sterilization system needs to be reevaluated for patient safety and for the greater good of the public health. Essure sterilization seems to have a much higher failure rate then was initially reported and appears to have an unacceptably higher side-effect profile requiring many women to seek additional surgical intervention.

Sincerely,



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