An open letter to your doctor from Dr. Julio Novoa

Good morning Dr. My name is Dr. Julio Novoa. I am the main doctor commentary for the Post Tubal Ligation Syndrome (PTLS) and Essure Problems forum representing 8000 + women whom have had the Essure device placed and have had problems following the placement of the device.

I have spent at least two hours per day for the past 2 months on these websites answering questions regarding problems with the Essure device.

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

When I first started commenting regarding the Essure, I felt the same way as you, however, it took me only three days to change my mind.

Your premise regarding a comparison of the similarities between other metallic devices and Essure is not valid because other metallic device, such as the one you described regarding heart surgery, are not specifically designed to cause a chronic inflammatory response such as the Essure.

In the review of the Conceptus and Bayer Physicians Manual as well as the USA MSDS product declaration, the Essure device is composed of metallic material as well as PET fibers which are specifically designed to produce this chronic effect thus producing the desired scarring and closure if the tubes.

HOWEVER, this chronic effect has a known complication rate, as specifically stated by the manufacturer of a 4% migration or expulsion rate which pushes the device outside of the tubes over time even with a confirmation of proper placement with a HSG.

This means that you, as well as, the manufacturer are aware that this device has, at a minimum, a 1 in 25, complication rate.

Other metallic devices are neither expected to produce an inflammatory response nor are they expected to migrate from their position at a rate of 1 in 25. ESPECIALLY, not around the heart.

Further, the Bayer manufacturer specifically states in the Physicians Manual that if migration does occur, that the device should be removed by a total hysterectomy, not by either a bilateral salpingectomy or cornual resection.

FURTHER, the Bayer corporation has no establish or recommended protocols to handle confirmed complications with the Essure.

As a patient advocate could you explain why you feel comfortable with this position?

Next, the PET fibers are made of the same materials as the PVT material composed of vaginal meshes and as you should be aware, vaginal meshes have an extrusion rate of over 15%. Vaginal meshes have also been found to have complication rates as high as 30% in the USA.

Next, per MSDS and Bayer documents, it is known that a significant portion the Essure device are composed of materials considered to be toxic as individual products.

In discussing nickel as an individual material, the Bayer corporation states for the record that patients with a nickel allergy should be cautious regarding the placement of the device since some patients Can and Do develop a nickel allergy over time as the nickel bleeds out of the device.

What is exceptionally significant is that based on the documents sent to the FDA within the past year, which are the Adverse Effects reports regarding the Essure, at least 50% of women undergoing complications with the Essure requiring hysterectomy have confirmed adenomyosis on their pathology reports. And at least 30% of women have confirmed endometriosis on their pathology reports. These represent incidence of occurrence 8x and 3x the documented averages in the literature, respectively.

As a professional and doctor, I am sure that you practice based on a philosophy of Evidence Based Medicine (EBM).

Unfortunately, there are no EBM PEER REVIEWED double blind studies addressing the safety or the incidence of complications regarding the Essure as compared to the general population regarding chronic pelvic pain, abnormal vaginal bleeding, dysmenorrhea, menorrhagia, or dyspareunia. NONE, despite the product being on the market for over 10 years.

We, as doctors, have accepted the manufacturer word for the safety of the device without anything to confirm your points that it poses no higher incidences of complications higher than in the general population.

After extensive review of the original data and video footage of the FDA committee meetings for the approval of the device, after reviewing each of the MSDS reports on each of the individual materials included in the device, after reviewing the pathology reports sent to me regarding hysterectomy and after discussing complications with literally hundreds of women with the Essure device, I have come to the following conclusions:

The Essure device is designed to produce a chronic and PERMANENT inflammatory response. This response leads to a minimum extrusion rate of 4%. There is data to support the point that this chronic inflammatory response also becomes systemic in a significant number of women producing chronic symptoms similar to RA and Lupus. ESSURE is associate with greater than a 90% INCIDENCE AND PREVALENCE of Adenomyosis and/or Endometriosis for those women who become symptomatic.

Most doctors who have placed the Essure believe it to be safe. However, based on my calculations, a doctor would have to place at least 25 to see a migration complication and at least 100 to see a pattern. This pattern would be obvious if there were independent double blind studies to review, but there are none.

As a patient advocate, how would you propose we help the 1 in 25, which the Bayer Corp acknowledges has a complication but no established protocols on how to fix a complication?

In Texas, as well as, the majority of the US, the ESSURE can be placed in a hospital setting. Although more expensive to do so in a hospital, the savings are compensated by reducing the payment to the doctor.

HOWEVER, it is a known fact that when the device is placed by the doctor in their office, they are often paid significantly more for placing the device than they are paid for a hysterectomy in a hospital.

For those placing the Essure, there is no way to avoid the belief that there a financial bias present that can compromise a doctor's objectivity on placing the device.

I welcome your written rebuttal and as always, feel free to call me at 915 731 1776 for a one on one discussion on the subject of the Essure.

Sincerely,

DR. JULIO NOVOA