This was a comment Dr. Steve Parsons, Newfoundland, left on the Essure Awareness Newfoundland page. He joined the group, left this message on the wall and left the group.

Below you will see Dr. Julio Novoas reply to him.

Steve Parsons

I'd like to say thank you to Blossom McKay for allowing me access to this group.
As many women may or may not know, I am the main provider for Essure procedure in NL. In fact, I do have faith in this procedure because I am an advocate for women. I advocated for women by going to the administration of our hospital in 2010 and demanding the budget required for this device. Based on safety data and my tenacity, they agreed. Since that time I have performed hundreds of Essure insertions. The Essure system costs ~20x the amount required for classic tubal clips...this is why most hospitals try to prevent doctors from offering the service.
Essure is an inert small metal coil that is placed into a woman's Fallopian tube, causing it to seal from the inside within a few weeks. It is important to note that tubal ligation procedures done by other gynaecologists around the world also involve a metal device...the difference is that a clip is placed across the tube instead of inside it. What is further interesting is that metal clips are used to seal blood vessels after common operations like bowel surgery and gallbladder removal. Metal clips and coils are used to open blood vessels around the heart when patients have suffered a heart attack. Metal clips are even used at brain surgery to safely halt bleeding from potentially fatal aneurysms, when caught in time.
I'm not aware of any websites where patients are unhappy with their cardiac stents or neuroangio clips.
Regarding pelvic pain and symptoms that occur after Essure, there are two logical explanations:
1) the symptoms may actually be due to the device, whether it is just an odd placement, or even an "allergic reaction", as one poster suggested...I think allergy is unlikely, but not impossible.
2) more probable is that the described pain and symptoms are related to common conditions of PMS, perimenopause or other benign Gynecology conditions such as adenomyosis, endometriosis, pelvic congestion and other phenomena.
Whatever the cause of a patients symptoms, they can be dealt with in the same manner we look after all women - with dignity and respect.
I'm not really sure why we feel a need to attack the Essure product or it's manufacturer. This product has a unique mechanism of action; by inserting this device thru a woman's natural opening (vagina -> cervix -> uterus -> Fallopian tube) we avoid having to make an incision into her abdominal cavity and therefore avoid any potential harm associated with the same. For women with a history of pelvic infections, previous surgery or those who are significantly overweight, classic tubal ligation should be considered a MAJOR surgery and there should be a very serious discussion about the risks.
It is sad to me that this group, some of whom may have valid gynaecological problems (as listed above), are scaring a lot of women out of a safe procedure, thereby forcing them into a riskier option.
I don't really wish to debate this on a one by one basis...I appreciate being given the opportunity to address the group. However, we live in a democratic society where individuals are allowed the freedom to assemble and complain about a procedure and they can complain about me...but make no mistake, I am and will continue to be a vigorous advocate for better women's health. If that means that I will have to speak publically at some point to dispel myths being propagated by the leaders of this group, then I shall do so, "in defence of women".
You may think this statement is bold, but one example of "myths and untruths" include the

statements on this list pertaining to Dr. Caines...I have held personal conversations with her and other respected gynaecologists in this province and I reiterate, we believe in Essure because we believe in women.
As I believe that your group has a right to voice their opinions with freedom, I would now kindly request that I be removed from your list.
Best wishes to all women in resolving your concerns and/or symptoms.
Kindest regards.
Dr. Steven Parsons
Ob/Gyn

Good morning Dr. Parsons. My name is Dr. Julio Novoa. I am the main doctor commentary for the Post Tubal Ligation Syndrome (PTLS) and Essure Problems forum representing 7000 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?

Finally, I am not sure of how things work in Newfoundland, but 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.

Please BUMP

Sincerely,

DR. JULIO NOVOA

The admin of the Essure Awareness Newfoundland group posted this under the comment…

Blossom Hewlett McKay I will also tell you that this is the doctor I was initially referred to concerning my problems. He later refused to see me (and I'm not to be seen by anyone in his practice) because I had written on Facebook that I was on an extremely long waiting list to see him (wait list close to a year because I'm considered routine). He also told me that he could take legal action against me for slander but decided not to. I have found another doctor and I'm scheduled for a hysterectomy next week.