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To: **ALL Medical Specialties**

Emphasis Specialties:
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Emergency Medicine Physicians Pain Management Specialists
Family Practice Physicians Primary Care Physicians
Psychologists/Psychiatrists Rheumatologists
Gastroenterologists

Subject: **Evaluation and Management of ESSURE Permanent Sterilization System; ESSURE United States Black Box Warning, European Member States ESSURE Recall, Ireland-Led License Suspension, and Patient Informed Consent**

8/24/17

Dear Colleagues in the United States, Canada, Central and South America and the European Union:

My name is Dr. Julio Cesar Novoa, M. D. I am a practicing OB/GYN and a medical consultant working pro-bono with a number of social media forums, including the UNITED STATES ESSURE PROBLEMS Facebook forum, as well as a number of international Facebook forums associated with medical complications of the ESSURE Permanent Birth Control device. The number of members in these social media forums now exceeds 40,000.

Over the past 4 years, I have volunteered my time and medical expertise to hundreds of women complaining about problems with the ESSURE. I have also personally managed over 50 patients with complications associated with the ESSURE and have assisted with the planning and management of over 300 patients being handled by other doctors across the United States.

In collaboration with a number of Board-certified OB/GYN surgeons who have shared their experiences having managed more than 350 ESSURE implant removals, we have made a number of recommendations which are more extensive as compared to those made by Bayer, the manufacturer of the ESSURE Permanent Birth Control (ESSURE).

For a more extensive research of these recommendations, It is recommended that our colleagues consider reading the recently published book, **"ESSUREAL Journey: Concepts, Concerns and Consideration for Hysteroscopic Sterilization."** *(Nova Science Publishers, 2017)***.**

Based on my extensive review and participation in the care and management of patients with complications related to ESSURE, as well as the 2015 United States FDA/Bayer Black Box Warning (BBW) and the recent European Union suspension of sale of the ESSURE, it is recommended, without hesitation, the immediate and world-wide ban and/or recall of all ESSURE devices. It appears that a total world wide recall or ban on the sale of the ESSURE will occur soon in light of the fact that Bayer has decided to stop the sale of the ESSURE device in every country except the United States.
Medical Xpress: *Bayer to end non-US sales of ESSURE, a contested sterilisation implant.*
(https://medicalxpress.com/news/2017-09-bayer-non-us-sales-essure-contested.html)

Further, all medical specialists managing or consulting on the care of patients with the ESSURE device, should be aware of the significant incidence of the following:

- **Improper ESSURE implant placement**
- **ESSURE implant failure leading to unwanted pregnancy, implant induced abortion, fetal death, spontaneous rupture of membranes, and premature delivery**
- **Implant migration or extrusion from the fallopian tubes**
- **Chronic pelvic pain, irregular bleeding, dyspareunia, and/or lower back pain (EVEN WHEN THE IMPLANT HAS BEEN CONFIRMED TO BE PROPERLY PLACED BY HYSTEROSALINGOGRAPHY (HSG), ULTRASOUND (US), XRAY, COMPUTERIZED TOMOGRAPHY (CT) SCAN, OR MAGNETIC RESONANCE IMAGING (MRI).**
- **Allergic reactions associated with both the nickel and Polyethylene terephthalate (PET) fibers of the ESSURE producing systemic and GI symptoms, as seen in the condition known as SYSTEMIC NICKEL ALLERGY SYNDROME**
- **Autoimmune symptoms resembling, triggering or worsening diseases, such as Chronic Fatigue Syndrome, Fibromyalgia, Lupus, Sjorgen's, Thyroid Dysfunction, or Diabetes**
- **Dental caries leading to the permanent loss of teeth**
- **Failure of gynecological treatment modalities, such as use of estrogen/progesterone medication, use of hormonal based intrauterine device (Mirena IUD), Dilation and Currettage (D&C), or Endometrial Ablation, which delays definitive surgical removal of the ESSURE device by salpingostomy, salpingectomy, cornual resection or hysterectomy**

As a practicing primary care physician/obstetrician/minimally invasive gynecological surgeon and cosmetic surgeon, I have over 18 years of clinical experience managing patients who have had complications with a variety of implants, including breast implants, intrauterine devices (IUDs), polyester vaginal meshes, urethral slings, as well as the ESSURE.

I have reviewed a significant number of studies regarding the ESSURE device, including the original clinical and pivotal trials that were used to obtain its Premarket Approval (PMA), as well as the video recorded US Food and Drug Administration (FDA) PMA expert panel discussions.

I also attended the September 24th, 2015 *FDA Obstetrics and Gynecology Device Panel Advisory Committee* (Ad Comm) meeting and was witness to the allegations of egregious or fraudulent data collection; discussion of alleged intentional failure to provide over 16,000 patient complaints to the FDA for documentation in the FDA, Manufacturer and User Facility Device Experience (MAUDE) database; and repeated complaints of debilitating complications associated with the ESSURE. The **MAUDE database** includes medical device reports submitted to the FDA by mandatory reporters, such as manufacturers, importers and device user facilities and voluntary reporters, such as hospitals, health care professionals, patients and consumers.

As a clinician, I am aware that medicine cannot be practiced without an acknowledgment of potential risk. However, the ESSURE device poses an unnecessary and potentially life-threatening risks to patients which cannot be justified by its continued marketing as a low-risk, minimally invasive, safe and effective permanent birth control option. Bluntly stated, it is none of these things. On the contrary, it is a high-risk, SURGICAL, potentially unsafe and ineffective, form of permanent birth control as compared to traditional tubal ligation.

Although the number of patients requiring surgical removal of ESSURE due to its complications or failures is unknown, **over 18,000+ adverse cases has been documented in the MAUDE database**, which includes a shocking **11,000+ reports indicating the surgical removal of the device** (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=4531887).

A recent Cornell (2015) study concluded that ESSURE is associated with more than 10-fold higher risk of undergoing reoperation compared with patients undergoing laparoscopic sterilization. (http://www.bmj.com/content/bmj/351/bmj.h5162.full.pdf)

In 2015-2016, legislation was introduced in the United States Congress to outright bar or significantly restrict the sale of the ESSURE due to their complications, including a significantly high number of reported fetal deaths associated with the device.

ESSURE induced abortions, stillborn births, premature deliveries, and fetal deaths have not been studied by Bayer, but are considered to be a serious concern, especially to patients and doctors with religions concerns on the subject. For example, fetal deaths, previously thought to be rare, have instead, been documented to be greater than 300+ in the MAUDE database.
(http://www.modernhealthcare.com/article/20160217/NEWS/160219918)
The Medical Device Safety Act H.R. 2164 (https://www.congress.gov/bill/115th-congress/house-bill/2164) **and the Ariel Grace Law H.R. 5403.** (https://www.congress.gov/bill/114th-congress/house-bill/5403/text).

Over the past 4 years, I have reviewed data collected by the ESSURE PROBLEMS Facebook forum, which includes over 32,000 members.

Despite the argument by Bayer that ESSURE does not require general anesthesia, patient surveys show that when done with local anesthetic, patients complain of excruciating pain during ESSURE insertion, which constitutes **medical battery and violates the ethical guidelines** associated with performing conscious medical procedures. The need for general anesthesia for the placement of the ESSURE in order to maintain patient comfort negates any benefit of ESSURE as compared to traditional tubal ligation.

Among the members of the ESSURE PROBLEMS social media group, over 100 medically necessary ESSURE surgical removals are performed **per month**, in order to remove the ESSURE devices due its complications. These surgeries include salpingectomies, salpingostomies, cornual resections, and hysterectomies with bilateral salpingectomies.

Further, over 1100 pregnancies have been recorded due to failed ESSURE sterilization. This data correlates to the Perkins and Morgan 2016 study analyzing a 27,724 group of women who had undergone ESSURE placement (https://www.ncbi.nlm.nih.gov/pubmed/27607866), as well as data provided by Bayer in it clinical manual. (http://www.hcp.ESSURE-us.com/about/efficacy/).

A comparison of ESSURE failure leading to pregnancy suggests a failure rate of between 2.4-5.5%, which is significantly higher than the 0.17% failure rate promoted by Bayer (http://www.hcp.ESSURE-us.com/about/efficacy/). **Nevertheless, recent comparative studies of laparoscopic sterilization vs. ESSURE permanent sterilizations, suggest a order of magnitude higher rate of ESSURE failure leading to unintended pregnancy as compared to the 0.17% rate promoted by Bayer and between 10-30x higher rate of failure as compared to traditional tubal ligation** *(Gariepsy, Yale, 2014)*. (https://www.ncbi.nlm.nih.gov/pubmed/24767963).

Clinical Limitations of ESSURE Clinical Studies

Since its approval in 2002, a significant number of questions regarding the safety and efficacy of the ESSURE have been raised. An editorial in the New England Journal of Medicine (JAMA) pointed out that ESSURE Phase II and Pivotal studies were severely "limited" in their scope. The premarket approval of ESSURE in 2002 was based on two non-randomized, non-blinded, prospective studies that lacked a comparative group. A total of 926 women enrolled in the studies, which found that the ESSURE was "reliable" in 97% of women. However, hundreds of women (262) were excluded in the final results. (http://www.nejm.org/doi/full/10.1056/NEJMp1510514#t=article). Results from an international Phase III have failed to resolve questions of safety and reliability, patient selection-bias, or physician skill-bias.

(http://www.hcp.ESSURE-us.com/assets/pdf/PP-250-US-1583 ESSURE Clinical Resource Guide Phys Manual (Digital pdf).pdf)

US FDA/Bayer Black Box Warning

WARNING: Some patients implanted with the ESSURE System for Permanent Birth Control have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the ESSURE System of Permanent Birth Control during discussion of the benefits and risks of the device.
(http://labeling.bayerhealthcare.com/html/products/pi/ESSURE_pib_en.pdf)

"PHYSICIAN CONSIDERATION: IT IS CLEAR THAT CURRENT INTERNATIONAL DATA SHOWS THAT THE ESSURE IS ASSOCIATED WITH SIGNIFICANT NUMBER OF RISK FACTORS THAT MUST BE CONSIDERED, DISCUSSED AND MANAGED AND NOT DISMISSED AS NORMAL GYNECOLOGICAL PROBLEMS, ESPECIALLY SYMPTOMS ASSOCIATED WITH ABNORMAL BLEEDING, PELVIC PAIN OR ALLERGIC/AUTOIMMUNE SYMPTOMS. FAILURE TO DO SO COULD CONSTITUTE FAILURE TO OBTAIN INFORMED CONSENT, FAILURE TO DIAGNOSE, AND/OR FAILURE TO TREAT ON THE PART OF THE MANAGING PHYSICIAN." Dr. Julio C. Novoa, MD
(http://firstchoicemedicine.com/assets/pdfs/ESSURE-InformedConsent.pdf)

Recommendations for Clinical Management of ESSURE Patients

1. All patients with ESSURE should be evaluated by both physical examination and with the assistance of HSG, US, Xray, CT scan or MRI to determine location and number of implants placed in each fallopian tubes. This is recommended since improper placement of the ESSURE device is estimated to occur in up to 14% of patients, migration of the device out of the fallopian tubes can occur in up to 4% of patients and a significant number of patients have more than one ESSURE implant placed in each fallopian which is specifically contraindicated.
   (http://www.hcp.ESSURE-us.com/assets/pdf/PP-250-US 1583 ESSURE Clinical Resource Guide Phys Manual (Digital pdf).pdf)

   All patients should have preoperative confirmation of number and location of ESSURE coils before surgery is performed.

   IF AN ATTEMPT IS MADE TO OPEN THE FALLOPIAN TUBE, SEPARATE THE COIL FROM THE TUBE OR THE UTERUS, CUT THE COIL, MORCELLATE THE TUBE OR UTERUS OR LEAVE THE UTERUS INTACT, AN INTRAOPERATIVE FLUOROSCOPY SHOULD BE PLANNED OR POSTOPERATIVE XRAY PERFORMED TO CONFIRM THAT NO FRAGMENTS HAVE BEEN LEFT IN THE PATIENT.

   MORCELLATION OF THE TUBE OR UTERUS WITH A ESSURE DEVICE IS PLACE IS ALWAYS AND SPECIFICALLY CONTRAINDICATED.

2. US does not confirm the Grade location of the ESSURE or the lack of patency of the fallopian tube. HSG does diagnose Grade location, but does not confirm patency in up to 10% of patients. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4228547/)
3. In cases where an HSG, US, Xray, CT scan or MRI suggest the proper placement of the ESSURE, **THIS DOES NOT RULE OUT ESSURE AS THE CAUSE OF IRREGULAR BLEEDING, CHRONIC PELVIC PAIN, CHRONIC BACK OR LEG PAIN, OR DYSPAREUNIA. ESSURE CANNOT BE RULED AS A CAUSE OF THE AFOREMENTIONED DIAGNOSES. ON THE CONTRARY, SURGICAL POST-OP DIAGNOSES AND PATHOLOGY REPORTS VERY OFTEN CONFIRM THE ESSURE AS THE CAUSE OF THESE PROBLEMS.**

4. ESSURE is associated with both local and systemic chronic inflammatory responses as part of a Type IV hypersensitivity, foreign body reaction. These reactions manifest themselves in the form of cognitive dysfunction, chronic headaches or migraines, body rashes, GI dysfunction, excessive weight gain or intestinal edema (E-belly) and mimic, trigger or worsen autoimmune diseases, such as chronic fatigue syndrome, diabetes, fibromyalgia, hypothyroidism, lupus, and Sjogen's syndrome.
5. Nickel is a known allergen in up to 17% of the world population. Symptoms manifesting as ESSURE associated contact dermatitis and/or GI dysfunction (Irritable Bowel Syndrome, Ulcerative Colitis, Crohn's Syndrome) are often associated with SYSTEMIC NICKEL ALLERGY SYNDROME. (http://www.medscape.com/viewarticle/753985)
6. ESSURE has a significantly high rate of failure leading to pregnancy as compared to traditional tubal ligation. A urine pregnancy test should be performed on any patient suspected of being pregnant with an ESSURE in place.
7. The use of oral contraceptive medication, hormonal IUD (MIRENA), Dilation and Curettage (D&C), or Endometrial Ablation are relatively contraindicated or delay definitive surgical management via removal of the ESSURE. The ESSURE induces an intentional local chronic inflammatory response in the endometrial lining, cornual junction and fallopian tubes which represents a mechanical insult. This mechanical insult cannot be corrected or mitigated by traditional techniques for irregular bleeding.

   On the contrary, the use of the IUD and D&C increase the risk of intrauterine coil damage and Endometrial Ablation increases the risk of **POST ABLATION TUBAL LIGATION SYNDROME (PATLS)**. Further, since ESSURE is associated with a high risk of improper placement, migration and extrusion, and neither US or HSG can confirm luminal location of the ESSURE, there is a significantly high risk of pelvic organ injury if the ESSURE is found to be in a subserosal or uterine/fallopian perforated location. **EXTENSIVE AND IN DEPTH INFORMED CONSENT SHOULD BE SIGNED IN CASES OF IUD, D&C OR ENDOMETRIAL ABLATION MANAGEMENT**. (http://www.hcp.ESSURE-us.com/assets/pdf/PP-250-US-1583 ESSURE Clinical Resource Guide Phys Manual (Digital pdf).pdf)
8. Due to the chronic inflammatory reaction of the ESSURE PET fibers, an increased risk of adenomyosis and endometriosis should be considered before surgery.
9. Hysteroscopic removal of the ESSURE is specifically contraindicated when scarred tissue has formed around the coils. Based on the high risk of coil fragmentation, hysteroscopic removal should not be attempted except during initial placement.
10. The removal of the ESSURE intact, including all nickel components, PET fibers and associated scar tissue is associated with a complete resolution of all symptoms, whether local or systemic in between 80-90% of patients. This appears to support a cause and effect relationship with ESSURE producing chronic foreign body responses which is resolved by its removal; yet it is not completely curative, which suggests that some symptoms are associated with a pre-existing or condition which is predisposed to have occurred even if the ESSURE had not been placed.
11. A significant number of patients have developed serious and debilitating dental problems following the placement of the ESSURE which is thought to be associated with a systemic reaction to the device or change in natural saliva production leading to dental caries or possibly a vitamin absorption deficiency. In many cases, patients note a fracturing of teeth or loss of teeth requiring extensive management by oral and cosmetic surgeons. Questions regarding dental hygiene and dental health should be routinely included in the patient history and physical and referrals made to dental specialists for baseline evaluation.
12. Due to its complex foreign body response, all ESSURE patients should be encouraged to seek a multidisciplinary approach to management, including the specialties of primary care, obstetrics/gynecology, gastroenterology, general surgery, nutrition, rheumatology, pain management and psychiatry.

In conclusion, there is overwhelming evidence to support the fact that the ESSURE device failed to meet the rigorous benchmarks required to deserve market approval. On the contrary, credible evidence supports the fact that the ESSURE was granted approval by the use of erroneous and incomplete data or fraudulent data, as alleged by participants in the original studies which has not been able to be discredited by the FDA.

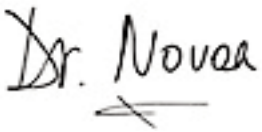
Every day, literally thousands of women are suffering from complications associated with the ESSURE device and hundreds are undergoing medically indicated major surgery under general anesthesia to remove the ESSURE devices which negates any benefit to having opted for this form of birth control in the first place.

The risks of immediate and long-term harm to the general public warrant the prompt removal of ESSURE PERMANENT BIRTH CONTROL from the US and international markets.

Due to the complexity of the foreign body reaction and potential life-threatening risks of removal, the management of ESSURE complications warrants a multidisciplinary approach to patient care.

Disclosure: No conflicts of interest to report regarding this written opinion

Sincerely,



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