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To: **ALL Medical Specialties Emphasis Specialties**

Emphasis Specialties:
Allergy and Immunology, Dentistry, Emergency Medicine, Family Practice, Gastroenterologists, General Surgeons, Internal Medicine, Obstetricians /Gynecologists, OroMaxillary, Pain Management, Primary Care, Psychologists/Psychiatrists, Rheumatologists

Subject: **Management of ESSURE Permanent Birth Control, Local and Systemic Foreign Body Reaction**

2/26/20

Dear Colleague,

My name is Dr. Julio Cesar Novoa, M.D. I am a practicing OB/GYN and have been managing the care of patients with complications associated the ESSURE Permanent Birth Control System manufactured and marketed by the Bayer Corporation.

Over the past 6 years, I have consulted in the care of over 600 women with the ESSURE device and am a medical consultant working with international organizations and social media forums concerning ESSURE. This include 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 60,000.

On December 31, 2019, Bayer terminated sales of the ESSURE Permanent Birth Control System throughout the world. This was done due to a significant number of reported complications associated with the device and decrease in sales following the placement of a mandatory FDA Black Box Warning (BBW) on the labeling of the ESSURE.

The BBW reads as follows:

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.

https://labeling.bayerhealthcare.com/html/products/pi/essure_pib_en.pdf

In managing patients with ESSURE, it is fundamentally important to understand that clinical studies and the FDA have documented evidence of chronic local and systemic foreign body reactions even when the device appears to be optimally placed as determined by ultrasound, x-ray, CT scan or MRI.

The most common GYN related issues associated with ESSURE are the following:

- **Chronic lower abdominal and/or pelvic pain**
- **Abnormal uterine bleeding (new onset or worsening)**
- **Dysmenorrhea (severe menstrual related pain)**
- **Dyspareunia (Pain with intercourse)**

Complications associated with ESSURE do not solely present as gynecological signs and symptoms; rather, complications caused by the ESSURE have been found to be localized and systemic, as well as, acute and chronic.

Systemic reactions to the ESSURE appear to be in response to a chronic, inflammatory, foreign body reaction and as been described as part of the Systemic Nickel Allergy Syndrome (SNAS) and Autoimmune/Inflammatory Syndrome Induced by Adjuvants (ASIA).

Complaints from patients associated with the female reproductive system **should not be dismissed as normal gynecological problems**, especially symptoms associated with abnormal bleeding, pelvic pain, lower back pain, sciatica, or dyspareunia.

Allergic and/or autoimmune symptoms such as cognitive changes, chronic headaches, excessive weight gain, localized or systemic rashes and symptoms with characteristics which resemble Systemic Lupus, Sjorgen's Syndrome, Fibromyalgia, Chronic Fatigue Syndrome and Chronic Pain Syndrome should be carefully evaluated.

Autoimmune diseases with relapse or worsening signs and symptoms, such as cardiac anomalies, hypothyroidism and diabetes should be evaluated as complications of a Type IV hypersensitivity foreign body reaction associated with the ESSURE.

For our colleagues specializing in dental and oromaxillary specialties, ESSURE has been associated with dental caries, dental fractures and loss of teeth.

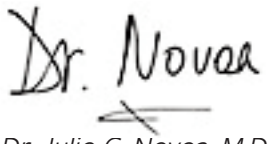
Due to the complexity of the ESSURE foreign body reaction and potential life-threatening risks of chronic autoimmune reactions, the management of ESSURE complications warrants a multidisciplinary approach to patient care.

Although ESSURE is no longer on the market, Bayer and the FDA are continuing to study its complications. As such, all physicians examining, managing or consulting on patients with the ESSURE device are ethically and professionally obligated to refer patients to the subspecialty of gynecology. And, in the case of signs and symptoms of foreign body reactions, referrals to the subspecialties specifically trained in the fields managing foreign body reactions, such as rheumatology, allergy and immunology.

We, as doctors with significant experience in managing patients with ESSURE would like you to be aware of the current medio-legal issues regarding the ESSURE. In compliance with the FDA mandated study and data collection, as well as, the professional and ethical management of patients with ESSURE, we respectfully request that you appropriately refer patient with complaints, signs and symptoms characteristic of conditions outside of your specialty, especially those associated with autoimmune or hypersensitivity reactions, to specialties managing foreign body reactions, such as immunology and rheumatology. Failure to do so could compromise patient care, delay proper and definitive diagnosis and management, and could present *medio-legal* issues regarding failure to provide informed consent and failure to treat.

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

Sincerely,



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