

**To: ALL Medical Specialties Emphasis Specialties**

**Emphasis Specialties:**

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

**Subject: Mandatory FDA Reporting and Management of ESSURE Patient Complaints, local and systemic; Referral of Patients for evaluation of Type IV Hypersensitivity reactions**

01/23/19

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 5 years, I have consulted in the care of over 500 women with the ESSURE device and am a medical consultant working with a number of international organizations and social media forums concerning ESSURE. These 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 **November 15, 2016**, the FDA approved a mandatory Black Box Warning (BBW) on the labeling for the Bayer ESSURE Permanent Birth Control System. 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](https://labeling.bayerhealthcare.com/html/products/pi/essure_pib_en.pdf)

On **April 9, 2018**, the FDA further restricted the use of ESSURE and “**issued an order to restrict the sale and distribution of the ESSURE device to ensure that all women considering use of the permanent contraceptiion device are provided with adequate risk information so that they can make informed decisions.**” <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm604098.htm>

This restriction specifically required doctors to **acknowledge and review the Black Box Warning and Patient Checklist** when discussing the potential risks, side-effects and complications associated with the device. The FDA also required Bayer’s new labeling to include the following statements:

- “The sale and distribution of this device are restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Bayer.”
- Bayer’s Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement, which is part of the patient information booklet, and has key items about the device, its use, and safety and effectiveness outcomes, which the patient should be aware of as they consider permanent birth control options.”

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452251.htm>

On **December 31, 2018**, Bayer corporation terminated sale of the ESSURE device in the United States thus ending sales of ESSURE in all markets throughout the world.

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/default.htm>

Despite the termination of sale and use of the ESSURE device, the FDA has mandated that Bayer continue the collection of post-insertion data including information collected in the MAUDE database (Manufacturer and User Facility Device Experience) and complete a post-marketing study to assess the long-term efficacy and side-effects of the Essure device over the next 5-10 years.

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm>

Data collection regarding potential side-effects include the following:

#### **Main Safety Endpoints:**

- Chronic lower abdominal and/or pelvic pain
- Abnormal uterine bleeding (new onset or worsening)
- Hypersensitivity and allergic reactions, and autoimmune disorders (new onset) or autoimmune-like reactions
- Invasive gynecologic surgery including Essure insert removal

#### **Secondary Safety Endpoints:**

- Other adverse events
- In the event of a device removal or event of interest, additional data collection may include bloodwork, pathology, histology, and metallurgic testing, as appropriate

#### **Effectiveness:**

- Pregnancy

[https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t\\_id=356&c\\_id=3854](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=356&c_id=3854)

The issues and complications of 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.

The rapid and proper dissemination of the information listed in the Black Box Warning and Patient Checklist should be provided as INFORMED CONSENT to all patients with a history of or those who currently have the ESSURE device. Complications 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 and chronic fatigue syndrome should be carefully evaluated. Autoimmune diseases with relapse or worsening signs and symptoms, such as hypothyroidism and diabetes should be evaluated as complications of a Type IV hypersensitivity foreign body reaction associated with the ESSURE.

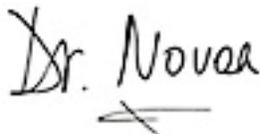
**Due to the complexity of the ESSURE foreign body reaction and potential life-threatening risks of chronic autoimmune reactions, the management of ESSURE complications warrants a multidisciplinary approach to patient care.**

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 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,

A handwritten signature in black ink that reads "Dr. Novoa". The signature is written in a cursive style with a horizontal line underneath the name.

*Dr. Julio C. Novoa, M.D.  
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ESSURE PROBLEMS Facebook forum  
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