NovoaMedicalServices, PA

Central Office
5140 Montana Ave.
El Paso, TX 79903
tel 915.772.2757
tel 915.772.2713
fax 855.370.9257

East Office
10781 Pebble Hills
El Paso, TX 79935
tel 915.595.9944
tel 915.595.9919
fax 855.370.9257

10/26/15

Dear Department of Emergency Medicine,

The Food and Drug Administration (FDA) held a public meeting of the Obstetrics and Gynecology Devices Panel Advisory Committee on September 24, 2015, to discuss the risks and benefits of the ESSURE permanent birth control device owned by Bayer HealthCare.

The ESSURE system is composed of 2 metallic coils that are placed in the fallopian tubes during a surgical procedure. Polyester fibers located inside of the coils are designed to intentionally cause scar tissue formation in and around the coils which permanently block the lumen (opening) of the fallopian tubes. After three months, complete occlusion or blockage of the fallopian tubes is expected to be completed, thus preventing conception.

Since being approved in 2002, the FDA has received over 8000 adverse medical device reports associated with the ESSURE, which can be found in the Manufacturer and User Facility Device Experience (MAUDE) data. This does not include an additional 16,000 adverse reports collected by Bayer which has not be added to the MAUDE data.

The incidence and prevalence of ESSURE related complications are staggering. These include reports of pelvic pain and abdominal pain (8%), dysmenorrhea or cramping (30%), abnormal bleeding (7%), dyspareunia (5%); as well as, device migration (4%), breakage, and malposition (14%).

The ESSURE has also been associated with exceptional high rates of failure leading to pregnancy (12%), ESSURE Induced Abortion (EIA); as well as, ectopic pregnancy and premature delivery of ESSURE babies (E-babies). There have been 4 reported adult deaths following ESSURE insertion and 5 reported fetal deaths that occurred in patients who became pregnant following ESSURE placement. Based on the recommendations of the advisory committee, patients with a known hypersensitivity to metal, autoimmune disease, history of pelvic inflammatory disease, and those with a history of abnormal uterine bleeding may not be candidates for the ESSURE. The advisory committee also discussed additional physician training to mitigate risks. A consensus was reached by the committee that additional data on the ESSURE system is needed, including additional information regarding reactions to the metallic and polyester components of the ESSURE device, as well as, sensitivity and hypersensitivity to the device.

Further, evidence presented to the FDA and its advisory committee alleges improper or fraudulent data collection during the original trials which was used to obtain Class III preemption status from the FDA.

Due to the overwhelming amount of information regarding complications with the ESSURE device, members of Congress have sponsored legislation in order to have the ESSURE device taken off the U.S. market. Mandatory confirmation of proper placement of the ESSURE device is the Hysterosalpingography (HSG) or Pelvic Ultrasound (US). CT scan is limited in determining correct lumen positioning of the coils inside of the fallopian tubes. MOST IMPORTANTLY, THE VAST MAJORITY OF PATIENTS PRESENTING WITH PROBLEMS WITH THE ESSURE DEVICE TO THE EMERGENCY DEPARTMENT (ED/ER) HAVE APPARENT NORMAL PLACMENT OF THE ESSURE DEVICES AS SEEN BY PELVIC ULTRASOUND, CT, X-RAY OR MRI.

Due to the significant number of problems associated with the ESSURE device, the management of ESSURE related complications is dependent on a multi-disciplinary medical approach to treatment to include the fields of Obstetrics/Gynecology, General Surgery, Allergy and Immunology, Hematology, Rheumatology, Urology, and Pain Management.

Although the evaluation, management and treatment of ESSURE related complications can, and often does, require a significant number of medical tests and appointments with each of the aforementioned specialists, it is the department of Emergency Medicine that is most often the gatekeeper of initial and repeated care regarding the ESSURE device.

Therefore, it is exceedingly important for the entire ER medical staff to appreciate the significant range of complications associated with the ESSURE device. Your compassion and empathy in this regard must be a priority in managing these problems rather than dismissing or ignoring these ESSURE related complications.

Sincerely,

Julio Cesar Novoa, M.D.
OB/GYN
Medical Consultant for the ESSURE PROBLEMS Facebook Forum