Thank you for reaching out to Bayer for the segment you are developing.

At Bayer, we care about patients and take the safety of our products very seriously.  We are saddened to hear of any serious health condition affecting a patient using one of our products, regardless of the cause.  Essure was approved by the FDA in 2002, and has a well-documented benefit-risk profile, with over 400 peer-reviewed publications and abstracts supporting Essure’s safety, efficacy and cost-effectiveness.  Approximately 750,000 women worldwide rely upon the Essure procedure for permanent birth control.

The US Food & Drug Administration (FDA) reviewed, among other things, the results from a five-year Essure study. The FDA found that “[a]lthough there is evidence of complications, as there are with all medical devices, overall results from this study did not demonstrate any new safety problems or an increased incidence of problems already known.”

The full FDA report can be found at:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/ucm371014.htm>

In addition, a recent practice bulletin issued by the American College of Obstetricians and Gynecologists (ACOG) has recognized that hysteroscopic tubal occlusion for sterilization has high efficacy and low procedure-related risk, cost, and resource requirements.

No form of birth control is without risk or should be considered appropriate for every woman.  It is important that women discuss the risks and benefits of any birth control option with their physicians.

Thank you again for allowing us to provide our commentary.

Freundliche Grüße / Best regards,

Marcy Funk

Associate Director, Communications

