Full Title: POET: An open-label, non-randomized, prospective observational cohort study to assess post-procedural outcomes in two cohorts of women who chose to undergo either hysteroscopic sterilization (Essure®) or laparoscopic tubal sterilization.

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Study Objectives:
To evaluate the proportion of subjects who have undergone Essure placement compared to the proportion of subjects who had an attempt at laparoscopic tubal sterilization and experience:
- new onset or worsening chronic lower abdominal and/or pelvic pain
- new onset or worsening abnormal uterine bleeding
- gynecologic or related surgical intervention
- new onset or worsening allergic, hypersensitivity, or autoimmune-like reactions

To collect data on patient reported outcomes in subjects who have undergone hysteroscopic or laparoscopic tubal sterilization procedures.

Inclusion Criteria:
Patients are eligible to be included in the study if they meet all of the following criteria:
- Subject is 21 to 45 years of age
- Subjects who are scheduled to undergo an Essure insert placement procedure for permanent birth control or laparoscopic tubal sterilization. Decision for either treatment based upon clinical practice and physician/patient counseling;
- For the Essure group only
  - Subjects selecting Essure who are willing to use alternative contraception for at least 3 months post-Essure placement procedure, until a satisfactory Essure Confirmation Test is documented;
  - Subjects who are believed to have two viable fallopian tubes.
• For the laparoscopic tubal sterilization group only:
  o Subjects selecting laparoscopic sterilization who are not contraindicated for laparoscopic tubal sterilization according to common clinical practice standard of care;
• Subjects who are willing to accept the risk of pregnancy occurring while relying on the Essure device or laparoscopic tubal sterilization for prevention of pregnancy;

**Exclusion Criteria**

Patients are excluded if they meet any of the following criteria:

- Subjects post-partum or undergone pregnancy termination ≤6 weeks prior to scheduled procedure;
- Subjects with an active upper or lower genital tract infection;
- Subjects with gynecologic malignancy (suspected or known);
- For the Essure group only:
  o Subjects who can have only one insert placed (including contralateral proximal tubal occlusion or suspected unicornuate uterus);
  o Subjects who have a known abnormal uterine cavity that makes visualization of the tubal ostia impossible and/or abnormal tubal anatomy or previous tubal ligation (including failed ligation);
  o Subjects who have had total or partial salpingectomies;

**Affiliations & Sponsors**  Bayer HealthCare

**Status**  Open to enrollment

**Keywords**  Essure, hysteroscopic sterilization, tubal sterilization, laparoscopic sterilization, sterilization, birth control