



## **FSRH STATEMENT**

### **RESPONSE TO THE BMJ PAPER BY MAO ET AL - ESSURE 13 OCTOBER 2015**

A large observational study[1] from the United States found that the risk of unintended pregnancy after Essure sterilisation was similar to that after surgical sterilisation. However just over 2% of women who had Essure sterilisation required a further operation related to the sterilisation procedure within a year. This compares to 0.2% of women who had a surgical sterilisation. The indications for further surgery and details of the procedures carried out are not provided by the authors.

In this study, women were not randomly allocated to the two different methods of sterilisation. Those who underwent sterilisation with Essure were more likely to be older, to have other illnesses or a more complicated gynaecological or surgical history than those undergoing surgical sterilisation. These factors and others that relate to initial choice of sterilisation method may have an impact on the study findings and re-operation rates (although the results have been adjusted to try to allow for this).

The MHRA have confirmed that they currently have no information to suggest that Essure devices are unsafe to use. They conclude "We keep all such devices under review and will consider this latest evidence and offer updated advice where appropriate".

Hysteroscopic sterilisation with Essure increases contraceptive choice and offers an alternative to surgical sterilisation, particularly for women for whom surgery is not recommended. It is important that women are informed of the potential risks and benefits of all contraceptive options so that they are able to make informed decisions regarding their contraceptive choices. This study suggests that women may be more likely to require a further operation after Essure sterilisation compared to surgical sterilisation, but large, randomised trials are required to confirm these findings.

1. Mao J, Pfeifer S, Schlegel P, Sedrakyan A. Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study. *BMJ* 2015;351:h5162 doi:10.1136/bmj.h5162

Dr Sarah Hardman, Deputy Director, CEU, FSRH, 13/10/2015