FDA to add bold warning to Essure contraceptive device

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Federal health regulators plan to add new warnings to Essure, a much-debated contraceptive implant that has been subject to thousands of complaints from women reporting chronic pain, bleeding and other problems.

The Food and Drug Administration says it will also require manufacturer Bayer to study the risks of the metallic device for various groups of women.

Essure has been sold for more than a decade and is frequently pitched to women as the only non-surgical option for permanent birth control. Bayer estimates 750,000 women have received the device since 2002.

But since 2013, the Food and Drug Administration has received thousands of reports of problems with the device. Many women have said problems including pelvic pain and bleeding were so severe they required surgery to remove the device.