The Medical Letter®

on Drugs and Therapeutics

Volume 60 May 21, 2018

ISSUE No. 1547

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The Medical Letter®
on Drugs and Therapeutics

Volume 60 (Issue 1547) May 21, 2018

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IN BRIEF

Restrictions on *Essure*

Essure (Bayer) is the only nonsurgical, permanent contraceptive available in the US. The coil-like devices are placed hysteroscopically in both fallopian tubes and, after several months, scar tissue causes tubal occlusion.[1] In 2016, the FDA required Bayer to revise the device's labeling to include a patient decision checklist and a boxed warning about the risks of uterine and fallopian tube perforation, migration of the device to the abdominal or pelvic cavity, persistent pain, and hypersensitivity reactions. Some women were apparently not being informed of these risks before implantation of the device, which can only be removed surgically. As a result, the FDA is now restricting the sale and distribution of *Essure* to healthcare providers who agree to review the "Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement" with their patients before implantation. The checklist includes information about the device, its safety, and its effectiveness. Patients and physicians must sign the checklist before the device is implanted.

From its approval in 2002 through 2017, the FDA received 26,773 medical device reports related to *Essure*. The most common adverse effects reported with its use were abdominal pain, heavier menses/menstrual irregularities, headache, fatigue, and weight fluctuations. Nickel allergy, migration of the device, dislodged or dislocated device, and device breakage have also been reported. During this time period, there were 1863 pregnancies (365 live births, 875 miscarriages, 623 unspecified) and 13 deaths (8 adults, 4 infants after live birth, 1 unspecified).[2]

Bayer states that more than 750,000 women have received *Essure* worldwide, but the device was taken off the market in the United Kingdom, the Netherlands, Finland, and Canada, and Bayer stopped sales of *Essure* outside the US altogether in September 2017.

Some women with contraindications or intolerance to hormonal contraceptives are also poor candidates for laparoscopic tubal ligation, leaving them few options for highly effective contraception. For these women, in the US, *Essure* remains an option. ■

1. Choice of contraceptives. Med Lett Drugs Ther 2015; 57:127.
2. FDA activities: Essure. Available at: www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm. Accessed May 10, 2018.

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 ISSN 1543-2859