Bayer to end non-US sales of Essure, a contested sterilisation implant

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The pharmaceutical giant Bayer announced Monday that it would end non-US sales of Essure, a sterilisation implant that in news reports has been linked to major side effects.

"This decision is being taken for commercial reasons," the German group said.

The withdrawal extended a decision taken in May to halt sales of the device in most countries where it was being marketed, it said.

Essure, a non-hormonal coil implant used to sterilise women, has in some women caused chronic pain, perforation of the uterus and fallopian tubes and led to hysterectomies, news reports say.

In its statement in French, Bayer insisted "this decision is not linked to any problem of safety or quality of the product... the safety and effectiveness of Essure is supported by more than 10 years of scientific research and real-life clinical settings."

It added: "Bayer will continue to market the Essure medical device in the United States, where the FDA [Food and Drug Administration] recently assessed this device and concluded that the method had a favourable benefit-risk ratio."

The European Union had already suspended sales of Essure in the 28-nation bloc for three months from August in response to regulatory concern.

Bayer said that, under Monday's decision, it would halt sales and distribution of the product "in all countries except the United States."

In addition, it would not seek to renew its application for the "CE" marking—the letters that are a commercial licence enabling the device to be sold across the EU.

A tiny spring-shaped device, Essure is inserted under local anaesthetic into the fallopian tubes, blocking them in order to prevent fertilisation. It can be performed in the physician's office.

Approved in the United States in 2002, its perceived advantage is that it is a less invasive alternative to tubal litigation, in which a small hole is cut into the abdomen and the surgeon blocks or cuts the fallopian tube.