



Bayer Fact Checks Netflix's *The Bleeding Edge*

Whippany, N.J., July 27, 2018 -- Bayer today released a Fact Check of *The Bleeding Edge*, which premieres on Netflix on July 27, devotes significant time to Essure, the only FDA-approved non-incisional form of permanent birth control, and is now the subject of media coverage by The New York Times, CBS News, and others. This Fact Check is based on Bayer's review of the film's premiere at the Tribeca Film Festival on April 21, 2018 and is intended to encourage a science-based conversation about Essure. Bayer also is reminding women with Essure that the safety profile of the device remains positive and unchanged.

As a leader in women's healthcare, Bayer believes strongly that women and their physicians should make reproductive health decisions based on sound science. In contrast, the portrayal of Essure in *The Bleeding Edge* lacks scientific support, despite the fact that Bayer provided the producers with extensive scientific information on Essure before the completion of the film. The film presents an inaccurate and misleading picture of Essure by relying almost entirely on anecdotes, cherry-picking information to fit a predetermined conclusion, ignoring the full body of scientific evidence that supports the Food and Drug Administration's (FDA) determination that Essure's benefits outweigh its risks and disregarding the appropriate warnings that accompany the device. The film also relies on many conflicted sources without disclosing their potential biases. This does a disservice to the thousands of women who rely on Essure for their reproductive health, as it may encourage them to pursue risky and unnecessary surgery to remove the device.

Notably, the film's only reference to scientific data regarding Essure is the [2018 Bouillon study](#) published in the *Journal of the American Medical Association* ("JAMA"), which its producers cite out of context and portray in its least favorable light. Taken as a whole, the study actually undermines the central premise of the film's representation of Essure. The independently funded research compared women with Essure to those who had tubal ligation surgery, the only other method of permanent birth control, and found that many of the concerns described in the film with regard to Essure -- pain (analgesic use) and hysterectomy -- were lower in Essure patients than in tubal ligation patients at both one and three years post procedure. The authors of the study concluded: "These findings do not support increased medical risks associated with hysteroscopic sterilization [e.g., Essure]." The decision by the filmmakers to exclude highly relevant conclusions from a study they cited, apparently because they conflict with their desired narrative, do raise serious concerns about the objectivity and accuracy of the movie.

The totality of scientific evidence, which was not discussed in the film, includes 40 published studies involving approximately 200,000 women over two decades, and demonstrates the safety

and efficacy of Essure, which has remained consistent over time. The FDA also has not changed its conclusion that Essure's benefits outweigh any potential risks.

Most of the movie's focus on Essure is told not through science, but rather through the stories of women who reported concerns about the device. Bayer takes any concerns regarding its medicines and devices seriously. Still, it is notable that not a single woman who is satisfied with Essure is included in the film. This omission is important because in the Phase II and Pivotal trials at follow up time points of three, six, 12, 18, 24, 36, 48, and 60 months, at least 99% of women were reported to have rated comfort of wearing the Essure inserts as "good" or "excellent." In the Pivotal trial, at least 97% of women were reported to be "somewhat" to "very satisfied" at all visits through five years. This is summarized in [FDA's executive summary](#) prepared in advance of the 2015 Advisory Committee.

No discussion of the movie and Essure should ignore the issue of removal, which most women featured in the film discuss. The film provides no balance on this important topic. Providing women with inaccurate or misleading information about the safety of Essure, or encouraging removal via hysterectomy, is potentially a serious public health issue as it may lead women with Essure to unnecessarily seek removal, and can result in new or additional health problems. Moreover, the singular focus on hysterectomy is inconsistent with Essure's FDA-approved [Instructions for Use \(IFU\)](#), which state that "hysterectomy generally is not required to remove the Essure inserts" as there are other methods identified in the IFU. The IFU is based on scientific/clinical data and opinions from medical experts worldwide. Bayer strongly encourages women with Essure who have questions or concerns to consult with their physicians.

The Bleeding Edge also relies on a number of sources to explain and validate its story regarding Essure, but the movie does not disclose conflicts that are essential for viewers to fully evaluate the credibility of these individuals and the film. For instance, psychologist Diana Zuckerman appeared in the film and is well known in the Essure critics community. She spoke at the 2015 FDA Advisory Committee meeting arguing against Essure and participated in another meeting that same year with the FDA organized by an advocacy group that has been critical of Essure. She has also served as a paid expert in litigation for at least one Essure plaintiff, a fact confirmed by [The New York Times](#) on July 20, 2018, but not disclosed in the film.

Similarly, Madris Tomes is presented as an independent expert in the film, but she also has a long history working with an anti-Essure advocacy group and joined them in congressional meetings in February of this year. A May 9, 2016, press release by a plaintiff law firm involved in the Essure litigation, Unglesby + Williams, reported on Tomes' work on Essure and described her as someone who was "hired by Unglesby + Williams." Again, this litigation-related work against Essure is not disclosed in the film.

Dr. Julio Novoa was also interviewed in the film, but viewers were not told that he aggressively markets surgery to women to remove Essure and has a financial interest in recommending

removal of the product. Dr. Novoa is not a board-certified OB-GYN and has never been trained on the Essure procedure.

The film also omits any mention of the FDA-approved [Instructions For Use \(IFU\)](#), which provide doctors with important information about the product and include detailed references to the potential risks for Essure. For example, the IFU mentions the potential risk of perforation more than 20 times, contains multiple references to pain and allergic or hypersensitivity reactions – all based on Essure data.

Other content in the film is completely misrepresented in order to make Essure appear unsafe, ineffective or both. One example is the inclusion of a misleading and selectively edited portion of the Essure 2002 FDA Advisory Committee meeting, which recommended the approval of the device. The movie suggests that members of the committee joked about the possibility of serious adverse events. They did no such thing. The Advisory Committee was not even discussing adverse events or the safety of Essure in that portion of the meeting. The full body of scientific evidence, clinical trials and more than two decades of science and real world clinical experience continues to support the positive benefit/risk profile of Essure and [its strong efficacy of 99.3%](#) in patients who chose to rely on Essure for birth control.

Essure is an innovative Class III medical device that was approved under FDA's Premarket Approval (PMA) review, the agency's most rigorous pathway for medical devices. Since the initial application for Essure was approved in 2002, the agency has continued to review and approve Essure's safety and efficacy through 48 supplements to the original application.

On July 20, 2018, Bayer announced that it had made a business decision to voluntarily discontinue sales and distribution of the Essure System for Permanent Birth Control in the United States after December 31, 2018. This decision is based on a decline in U.S. sales of Essure in recent years and the conclusion that the Essure business is no longer sustainable. Several factors have contributed to declining interest in Essure among women in the U.S., including decreased use of permanent contraception overall, increased reliance on other birth control options, such as long-acting reversible contraceptives (LARCs), and inaccurate or misleading publicity about the device, such as *The Bleeding Edge*. Notably, the benefit-risk profile of Essure has not changed, and Bayer continues to stand behind the product's safety and efficacy.

About Essure

Essure is indicated for women who desire permanent birth control (female sterilization) by blocking the fallopian tubes.

Important Safety Information

WARNING: Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System of Permanent Birth Control during discussion of the benefits and risks of the device.

Essure is not right for you if you are uncertain about ending your fertility, suspect you are pregnant, can have only one insert placed, have had your tubes tied, have a known allergy to contrast dye, are unwilling to undergo the Essure Confirmation Test, have unexplained vaginal bleeding, or have suspected or known cancer of the female reproductive organs.

You should delay having the Essure procedure if you are or have been pregnant within the past 6 weeks, have an active gynecological infection, or are in the second half of your menstrual cycle.

Tell your doctor if you are taking immunosuppressants, have, or think that you may have, a history of metal allergies, or an allergy to polyester fibers, nickel, titanium, platinum, silver-tin, or stainless steel or any other components of the Essure system, are currently using an IUD for contraception, or have had or are considering a procedure to reduce bleeding from the uterus such as endometrial ablation.

WARNING: Be sure you are done having children before you undergo the Essure procedure. Essure is a permanent method of birth control.

WARNING: You must continue to use another form of birth control until you have your **Essure Confirmation Test (3 months after the procedure)** and your doctor tells you that you can rely on Essure for birth control. For some women, it may take longer than 3 months for Essure to be effective, requiring a repeat confirmation test at 6 months. Talk to your doctor about which method of birth control you should use during this period. If you rely on Essure for birth control before receiving confirmation from your doctor, you are at risk of getting pregnant.

During the Procedure: In the premarketing study, some women experienced mild to moderate pain (9.3%). Your doctor may be unable to place one or both Essure inserts correctly. In rare cases, part of an Essure insert may break off during placement. If breakage occurs, your doctor will remove the piece, if appropriate. There is a risk of perforation of the uterus or fallopian tube by the hysteroscope, Essure system or other instruments used during the procedure. In the original premarket studies, perforation due to the Essure insert occurred in 1.8% of women. A perforation may lead to bleeding or injury to bowel or bladder, which may require surgery. Your doctor may recommend a local anesthesia. Ask your doctor about the risks associated with this type of anesthesia.

Immediately Following the Procedure: In the premarketing study, some women experienced mild to moderate pain (12.9%) and/or cramping (29.6%), vaginal bleeding (6.8%), and pelvic or back discomfort for a few days. Some women experience headaches, nausea and/or vomiting (10.8%), or dizziness and/or fainting. You should arrange to have someone take you home after the procedure. In rare instances, an Essure insert may be expelled from the body.

During the Essure Confirmation Test: As one of the Essure Confirmation Tests (a modified HSG) requires an x-ray, you may be exposed to very low levels of radiation, as with most x-rays, if this test is used. Some women may experience nausea and/or vomiting, dizziness and/or fainting, cramping, pain or discomfort. In rare instances, women may experience spotting and/or infection.

Long-term Risks: Pain (acute or persistent) of varying intensity and length of time may occur and continue following Essure placement. This is also more likely to occur in women with a history of pain. There are reports of an Essure insert being located in the lower abdomen and pelvis. If this occurs, you cannot rely on Essure for birth control. Patients with known hypersensitivity to any of the components of the Essure system may experience an allergic

reaction to the insert. In addition, some patients may develop an allergy to nickel or other components of the insert following placement. Symptoms reported in women using Essure that may be associated with an allergic reaction include hives, rash, swelling and itching. There is no reliable test to predict who may develop a reaction to the inserts. No birth control method is 100% effective. Ectopic pregnancies (pregnancy outside the uterus) may occur with Essure. This can be life-threatening. If insert removal is indicated, surgery will be necessary.

The safety and effectiveness of Essure has not been established in women under 21 or over 45 years old.

Essure does not protect against HIV or other sexually transmitted diseases.

Prescription Only

IMPORTANT

- **Caution:** Federal law restricts this device to sale by or on the order of a physician. Device to be used only by physicians who are knowledgeable hysteroscopists; have read and understood the Instructions for Use and Physician Training Manual; and have successfully completed the Essure training program, including preceptoring in placement until competency is established, typically 5 cases.
- The sale and distribution of this device are restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Bayer.

Talk to your doctor about Essure and whether it is right for you. Review the Patient-Doctor Discussion Checklist in the Patient Information Booklet with your doctor before deciding to have the Essure procedure.

About Bayer

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social

and ethical responsibilities as a corporate citizen. In fiscal 2017, the Group employed around 99,800 people and had sales of EUR 35.0 billion. Capital expenditures amounted to EUR 2.4 billion, R&D expenses to EUR 4.5 billion. For more information, go to www.bayer.us.

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