



## Frequently asked questions about sterilisation product Essure

### 1. Which sterilization product is involved?

It is the product Essure by the manufacturer Bayer. This product ensures permanent sterilization in women. During treatment, small metal coils are placed in the fallopian tubes, which gradually close up. Several months after implantation, fertilization can no longer take place.

### 2. How often is this sterilization method used and for how long has it been used?

Essure has been available on the European market since 2001. In 2002, Essure received FDA approval in the United States. Sales figures from the manufacturer show that Bayer sells more than 100,000 Essure products annually worldwide.

Since 2002, some 30,000 Essure treatments have been carried out in the Netherlands. The technique has been used hundreds of thousands of times worldwide.

### 3. What are the advantages of this sterilization method?

Women in the Netherlands can choose several sterilization treatments. The two most commonly performed treatments are sterilization with Essure and the traditional sterilization. In the case of traditional sterilization, during a laparoscopy (keyhole surgery), the fallopian tubes are closed by leaving a clip or a ring. These are advantages and disadvantages to both methods.

Advantages of the Essure sterilization method:

- Outpatient treatment (no hospitalization required).
- Less stressful than other sterilization methods.
- Minimally invasive sterilization method (no surgical procedure with associated risks).
- No local or general anaesthesia required.
- No hormone treatment needed.

### 4. What are the risks of the sterilization method?

During and shortly after treatment:

- Pain cramps and vaginal bleeding shortly after the placement procedure. These complaints are transient.
- There is a risk of perforation or tear of the fallopian tubes or the uterine nerve. This can cause bleeding or scarring.
- There is a risk that the product will break down.
- Some women become nauseous, have to vomit or may faint shortly after treatment.
- There is a risk that the coils will loosen from the fallopian tubes and dislodge. An additional X-ray examination may be needed to determine the location of the coils. The coils may need to be removed surgically. Displacement of the coils can cause (ectopic) pregnancy and/or pain, menstrual cycle disturbance and other side effects.

Risks of using Essure:

- Pain and cramps in the abdomen and pelvis. These complaints may occur more frequently during the menstrual period, during and after sexual contact or during other physical activities.
- Possible bleeding between menstrual periods and menstrual bleeding may be heavier than normal.
- In case of severe complications, there is the risk that surgery may be required. The Essure coils and/or fallopian tubes or uterus are then removed.

These are known risks that the manufacturer communicates in the operating instructions. The attending physician is responsible for informing the patient adequately. How this responsibility is regulated by law can be found in the [Medical Treatment Contract Acts](#) (WGBO).

#### **5. Is Essure safe?**

The product complies with European legal requirements for market acceptance. There is a group of women who experience serious health problems after Essure sterilization. The number, type and severity of these complaints is cause for concern and alertness for the Inspectorate. The starting point is the balance between the benefits and risks of this sterilization method. This balance must be monitored. The manufacturer is legally responsible for this.

The Dutch Society of Obstetrics and Gynaecology (NVOG) mentions in the information folder that there is a group of women who might have an increased risk of complaints, e.g. abdominal pain, fatigue and abnormal blood loss after Essure sterilization. Essure sterilization may be less suitable for this group of women.

Despite the fact that there is a group of women with serious complaints, there is a large group of women who benefit from this form of sterilization and have no complaints.

#### **6. I have been sterilised via the Essure method. What should I do?**

If you do not have any complaints, it is not necessary to have the coils removed or take other measures. If you are concerned, you can contact the gynaecologist who placed the Essure coils. This physician can advise you further.

#### **7. What kind of reports has the IGJ received about Essure in recent years?**

Since 2011, the Inspectorate has received several reports about Essure. Most of the reports come from the manufacturer. The Inspectorate also received reports from women. The reports include problems women encountered during or after placement of Essure.

The reports mainly indicate physical complaints such as back pain, abdominal pain, muscle and joint pain, bleeding and fatigue. There are also reports about broken coils or complaints about the treatment.

The Inspectorate has also received reports from women who indicate that they have a nickel allergy. Nickel allergy is mentioned in the NVOG guideline 'Sterilisation of the woman'. At the present time, nickel allergy is not a contraindication for Essure sterilization.

The Essure instructions for use include a warning about nickel allergy. The instructions for use inform about the risks of problems in women who have a proven nickel allergy or who are prone to allergic reactions. Gynaecologists advise and inform women about this when choosing the right sterilisation method.

#### **8. What was the purpose of the RIVM research?**

The purpose of the research was to get a better understanding of the type of complaints women encounter after sterilisation with Essure. The purpose of the research was not to establish whether there is a causal link between the complaints and Essure.

#### **9. What are the results of the RIVM research?**

Some 30,000 women in the Netherlands have been sterilised with Essure. The complaints that RIVM used for the research are derived from 1,5% of these women. The research shows that most women experience pain and fatigue complaints after Essure sterilisation. Complaints about bleeding, mood swings, memory loss and concentration problems have also been reported. Many women indicate that these complaints have an adverse effect on their daily lives. They feel the coils in their body or experience restrictions in movement. Furthermore, they are often hampered in their daily tasks and while caring for their children.

Several complaints may be attributed to the treatment itself, the placement of Essure, such as certain pain complaints. For other complaints, it is more difficult to establish a direct correlation since there are other matters that could play a role such as stopping the pill, which can exacerbate menstrual complaints. In addition, various complaints such as weight fluctuations and urinary tract problems also occur with some regularity in women who do not have Essure. RIVM research has shown that more extensive research is needed to determine whether and which complaints are caused by the product Essure itself.

The following is a link to the RIVM report '[Analysis of complaints in the Netherlands on Essure. Health problems following a non-surgical sterilization procedure for women](#)'. The report is in English but contains a Dutch synopsis.

**10. What did IGJ do with the outcome of the RIVM study?**

Together with RIVM, the Inspectorate discussed with the NVOG the complaints women experience after sterilisation with Essure. The NVOG has indicated that it takes the complaints seriously. It has indicated that it will devote extra attention to adequate information. The NVOG has organised training nights to train gynaecologists in removing Essure. The NVOG has also initiated research to determine whether the complaints women experience disappear or diminish after Essure has been removed.

More extensive research is needed to determine which complaints are caused by Essure. The Inspectorate will continue to monitor developments closely and maintain close contact with the NVOG and the manufacturer of this product.

**11. Has the IGJ also had contact with other countries about the complaints and use of Essure?**

The Inspectorate maintains contact on this topic with the supervisory authorities in other European member states. Information from the American Food and Drug Administration (FDA) is also used. In September 2015, the FDA organised a so-called 'Advisory Committee' meeting. Attendees of this meeting included: manufacturer Bayer, 'Essure patients', gynaecologists and scientific associations. The content of the discussions during this meeting was made [public by the FDA](#).

Following this meeting, on 29 February 2016, the FDA posted a [message on its website](#) about the actions of the FDA. The FDA instructed the manufacturer Bayer to investigate the benefits and risks of sterilisation with Essure. In addition, the manufacturer must better inform women who are considering sterilisation with Essure about the benefits and risks. Therefore, the manufacturer will add a warning and a checklist for users to Essure's packaging. This also applies to the packaging of Essure in the Netherlands.

**12. Where can I go for more information on Essure?**

For questions or concerns about their individual situation, patients are advised to consult their treating specialist.

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