

Risks and adverse events

As with all procedures, there are risks associated with the Essure procedure and micro-insert. There may be more risks that have not yet been identified. Fortunately many of these risks are rare:

- Unsatisfactory or no placement of the micro-inserts. In the clinical trials approximately 10% of women were not able to have the micro-inserts placed in both fallopian tubes. At their routine 3 month follow-up, an additional 4% were found to be incorrectly placed. These women could not rely on the micro-inserts for birth control. The types of improper placement include:
 - perforation (e.g. a small hole in the wall of the fallopian tubes or uterus)
 - movement of the micro-insert after placement, (including expulsion of the micro-insert from the body due to improper placement).
- Breakage of the micro-insert.
- Vasovagal response (e.g. nausea, sweating, slowness of the heartbeat and rapid fall in blood pressure).
- Leg paraesthesia (a numbness in the legs).
- Fluid absorption (absorption by the body of the saline used in the procedure in excessive quantities).
- Pain, cramping, vaginal bleeding.
- Nausea/vomiting or fainting.
- Regret
- Menses (periods) that are heavier or longer than normal, as well as bleeding between periods.
- Infection.

The following are 'other risks not experience by women in the clinical studies but are still possible'.

- Pregnancy and ectopic pregnancy.
- Perforation (a small hole) in internal bodily structures, other than the uterus and fallopian tube.
- Risks associated with the hysterosalpingogram or X-rays.
- The effect of future medical procedures that involve the uterus or fallopian tubes on the ability of the Essure micro-insert to provide protection against pregnancy.
- The risks and success of in vitro fertilization (IVF) with the Essure micro-inserts in place.

Finally

If you have any questions, then please discuss these with the doctor or nurse.

For further information see the website www.essure.co.uk where you can download a more detailed patient information pamphlet.

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The Essure™ Procedure

Information for patients

Your choice above permanent birth control

The information in this leaflet is for women considering choices about permanent birth control. Permanent birth control is intended to prevent pregnancy for the rest of your life.

This leaflet will provide you with information, including the benefits and risks, about a new method of permanent birth control called the Essure procedure. Because it is intended to permanently prevent pregnancy, it is similar to other permanent birth control procedures such as tubal ligation (having your tubes tied) or vasectomy. However, Essure is a lower impact approach that is gentler on your body because it can be performed without general anaesthesia, does not involve cutting through the skin and recovery is quick.

What is the Essure procedure?

The Essure procedure involves placing a small flexible device called a micro-insert into each of your two fallopian tubes (the tubes where your egg travels from your ovaries to the uterus). The micro-inserts are made from materials that have been well studied and used successfully in heart and other surgeries for many years. The devices do contain nickel, so if you have any sensitivity to this do inform your doctor. Once the micro-inserts are in place, your body tissue grows into the micro-inserts, blocking the fallopian tubes. Blocking the tubes is intended to prevent sperm from fertilizing the egg, thereby preventing pregnancy.

Benefits of Essure over standard general anaesthetic female sterilization

- [No general anaesthesia](#)

General anaesthesia (being asleep while surgery takes place) is not required. You will not need to fast. In fact, we encourage you to have a good breakfast or lunch. Although local anaesthesia may be used, the majority of patients will not require this either.

- [Fast recovery](#)

You may feel cramp-type pains and wet through the procedure. If the pains persist after the procedure, you will be given painkillers. You may feel wet because we use fluid to look inside your womb which will leak out. On average, patients are able to go home between 45 minutes – 2 hours after the procedure.

- [Quick](#)

Your procedure time should be no longer than 30 minutes. The average time to complete the actual procedure is 12 minutes.

- [No scars](#)

You will not have any scars because it does not involve cutting into the skin.

- [Rapid return to work](#)

Over 90% of women miss one day or less off work following the procedure (not including the day of the procedure).

Is Essure right for you?

The Essure procedure is only appropriate if you are sure you do not want any more children, would like to have permanent birth control and believe you will not change your mind. This procedure cannot be reversed. You should be aware that there are other methods of birth control, both long term and reversible, e.g. contraceptive coil such as the Mirena coil as well as alternative birth control and permanent sterilization procedures e.g. tubal ligation using clips or rings.

Important points to note

- [The procedure is not reversible](#)

There is no data (information) on the safety or effectiveness of surgery to reverse the Essure procedure. It is only meant to be used by women who are certain they no longer want to have children. There is also only limited information on the safety or effectiveness of in vitro fertilization (IVF) after the Essure procedure.

- [Like all methods of birth control, the Essure procedure should not be considered 100% effective](#)

No method of birth control is 100% effective and there is a small chance you could become pregnant. As with other forms of permanent birth control e.g. tubal ligation 1 in every 200 patients may become pregnant.

- [There is a waiting period after the procedure](#)

After the procedure it takes 3 months (occasionally longer) before the Essure micro-insert can be relied on for permanent birth control. Before the procedure, it is important to discuss alternative contraceptive options to cover this time. A pelvic ultrasound scan or x-ray test (hysterosalpingogram 'HSG') will be done at 3 months to check if the micro-inserts are in the right place. If so, your doctor will give you the all clear.

- [The Essure procedure is newer than other procedures](#)

Essure is one of the newest methods of permanent birth control so it has not been studied in as many women or for as long as most other birth control methods. However, a clinical trial of the effectiveness of the Essure procedure has been conducted in the United States, Australia and Europe involving over 500 women. This trial as well as a substantial amount of recent published data (including our own data from the Birmingham Women's Hospital) has shown the Essure procedure to be:

- Quick
- Effective
- Highly rated by women

However, it should be noted that Essure lacks long term failure rate data and comparison with standard laparoscopic sterilization failure rates.