

Patient information sheet

Essure permanent contraception device

About the Essure device

The Essure permanent contraceptive device (**'Essure device'**) is a medical device that provides permanent contraception for women.

The Essure device is a soft flexible metal coil insert that does not contain or release any hormones. It is placed into the woman's fallopian tubes and causes scar tissue to form around the Essure creating a barrier which is intended to prevent pregnancy. It takes approximately three months for the barrier to form and therefore for the device to be effective as a contraceptive.

The Essure device inserts are made of materials that include polyester PET fibres, nickel, titanium, platinum, silver-tin and stainless steel.

Following an increase in reports of side effects and complications in some women, the Essure device was recalled around the world, and in Australia in August 2017.



What are the concerns with the Essure device?

The Essure device has been used in Australia since 1999 and, for many women, the device is effective and has not resulted in any side effects or complications.

However, some women have reported experiencing side effects and complications including:

- the device moving to other locations in the abdomen or pelvis (migration)
- the device cutting into the wall of the uterus, fallopian tubes, bladder or bowel (perforation)
- the possibility of metal allergy or hypersensitivity to polyester fibres (itching, swelling, rash or hives)
- infection
- unintended pregnancy, including ectopic pregnancy (pregnancy that occurs outside the uterus)



What symptoms might I notice after insertion?

Some Essure symptoms are mild and may only last a few days, with others being more persistent and women experiencing longer term symptoms. Symptoms may be exacerbated due to the length of time women are exposed to the Essure device.

Symptoms may include:

- Abdominal or pelvic pain
- Abnormal periods
- Allergic symptoms such as itching, swelling, rash or hives.

Other symptoms that have been reported:

- Severe bloating
- Fatigue
- Migraines
- Weight gain
- Changed toilet habits
- Twinges in the implant location and aching joints
- Pain during sex, that had never existed before
- Depression
- Autoimmune disease
- Hair loss
- Reduced libido
- Memory lapses, dizziness and fainting.

What should I do if I think the Essure device is affecting my health?

Your general practitioner (GP) is the best health professional to assist you in the first instance. Your GP will assess you and may recommend you visit a gynaecologist or other health professional.

Can my Essure device be removed?

Yes, although the Essure device is recognised as a permanent contraceptive device and was not designed for removal. Your gynaecologist will be able to ascertain the best type of surgery for removal based on the positioning of the Essure device, prior medical history and symptoms.

However, hysterectomy is the preferred and a safe surgical option (as indicated by the manufacturer) as the Essure device needs to remain intact so that fragmentation of the device does not occur during removal.

If you are not experiencing any side effects or complications the Essure device is considered safe to remain in place.

For more information

www.qld.gov.au/essure

Further resources

Therapeutic Goods Administration
www.tga.gov.au/alert/essure-contraceptive-device

