

# Clinician information sheet

## Essure permanent contraception device

Essure is an implanted device that provides permanent contraception for women. A soft, flexible insert is placed into each of the patient's fallopian tubes and causes scar tissue to form around the Essure creating a barrier intended to prevent pregnancy. It takes approximately three months for this barrier to form and therefore for the device to be effective as a contraceptive.

The Essure device is a soft flexible metal coil insert that does not contain or release any hormones. The Essure inserts are made of materials that include polymers and the following metals: nickel, titanium, platinum, silver-tin and stainless steel.

### Reported symptoms and adverse events

Since the device was introduced into Australia in 1999, the Therapeutic Goods Administration have received reports of adverse reactions. These include:

- 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)

Other symptoms that have been reported 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.

Side effects from the Essure device may occur at any time following insertion. Some women may not experience any problems with the Essure device.

However, some patients have reported significant and chronic adverse events, especially when the Essure device has been in the body over several years.

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 women are advised to do if they think the Essure is affecting their health?

Women who are concerned about how the Essure is affecting their health are being advised to visit their GP or specialist.

Patients who think they may be pregnant after having an Essure implanted are advised to seek a medical review immediately because of the risk of ectopic pregnancy.

## Management options for GPs

Women presenting with complications following the implantation of an Essure device will require a physical examination of their abdomen, pelvis and vagina with detailed documentation of any reported symptoms. It is important to assess for any clinical indications of migration of the device.

Given the frequent reported incidence of pain in women having had the Essure implanted, it is suggested that a comprehensive pain assessment be undertaken.

Although patients who have less complex symptoms do not necessarily require surgical management, it is suggested that a gynaecologist opinion is considered to ascertain if surgical management is required. The type of surgery needed will depend on the positioning of the coils, woman's prior medical history and symptoms.

Hysterectomy is the preferred and safe surgical option (as indicated by the manufacturer); the coils need to remain intact so that fragmentation of the coils does not occur.

An ultrasound +/- CT scan to accurately locate the device are useful and appropriate investigations to perform prior to a gynaecology appointment.

If an immunology assessment is appropriate, consider contacting the immunology department at your nearest tertiary hospital to discuss the case and potential testing, treatment and referral options.

In order to triage patients appropriately please state clearly on the referral that a discussion about Essure is sought.

For more information

[www.health.qld.gov.au/essure](http://www.health.qld.gov.au/essure)

## Further resources

Therapeutic Goods Administration

[www.tga.gov.au/alert/essure-contraceptive-device](http://www.tga.gov.au/alert/essure-contraceptive-device)

