



# Essure contraceptive device FAQs

## What is the Essure contraceptive device?

Essure is a medical device that is intended to provide permanent birth control for women. The Essure procedure involves placing two small, spring-shaped inserts into the fallopian tubes (the tubes that carry the eggs from the ovaries to the uterus). The procedure does not require incisions or a general anaesthetic. Over a period of about 3 months, it is intended that a barrier forms around the inserts to prevent pregnancy. It was used for women who were certain that they did not want to have children or did not want to have any more children. Essure does not contain or release any hormones.<sup>1-3</sup>

## What are Essure inserts made of?

The Essure inserts contain metals and a polyester fibre.<sup>2</sup>

## Where was Essure used?

Essure was available in Australia from 1999 to 2017.<sup>1</sup> It was used in Western Australia, in both public and private facilities, and in other Australian states and territories.

## I'm not sure what contraceptive device I had implanted.

### How do I find out?

You will need to discuss this with your GP or specialist.

## What is the current status of Essure?

In August 2017, Essure was removed from the market in Australia and unused stock was recalled.<sup>1</sup> A Hazard Alert was also published

on the Therapeutic Goods Administration (TGA) website. Essure was cancelled from the Australian Register of Therapeutic Goods (ARTG) in February 2018.<sup>1</sup>

There have been reports of possible side effects and complications in relation to Essure in Australia and overseas.<sup>1-3</sup>

For further information visit the TGA website: <https://www.tga.gov.au/alert/essure-contraceptive-device>

## I've got the Essure implant. Do I need to have it removed immediately?

If you have any health concerns regarding the Essure device, please discuss these with your GP or specialist.

In the case of an emergency, please call 000 for an ambulance or attend the nearest hospital emergency department.

## What are the reported complaints following the Essure procedure?

Reported complaints following the Essure procedure include:<sup>1-3</sup>

- persistent (ongoing) pain
- changes in menstrual bleeding
- the device poking through the wall of the uterus or fallopian tubes ('perforation')
- the device moving to other locations in the abdomen or pelvis ('migration')
- allergy or hypersensitivity symptoms (including itching, rash, hives)
- unintended pregnancy including ectopic pregnancy (see below).



In some cases, symptoms have led patients to have the Essure device removed, which requires surgery.<sup>1,3</sup>

As with any birth control method, unintended pregnancy can occur. If pregnancy does occur, there may be an increased chance for the pregnancy occurring outside the uterus ('ectopic pregnancy').<sup>2,3</sup>

For further information on reported complaints please see the TGA website:  
<https://www.tga.gov.au/alert/essure-contraceptive-device>

## **I think I might be pregnant. What should I do?**

The Essure procedure is reported to be effective at preventing pregnancy in patients who have been told by their doctors that they could rely on Essure for birth control.<sup>2</sup>

If you think you may be pregnant after having Essure implanted you should be seen by a doctor immediately because of the risk of ectopic pregnancy (pregnancy occurring outside the uterus).

An ectopic pregnancy can be a medical emergency. In the case of an emergency, please call 000 for an ambulance or attend the nearest hospital emergency department.

## **What about other contraceptive devices?**

There are many different forms of contraception. You may wish to speak to your GP or specialist if you are concerned about your contraception.

### **Source**

1. TGA: <https://www.tga.gov.au/alert/essure-contraceptive-device>

### **2. FDA**

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/default.htm>

### **3. Health Canada**

<http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2016/58638a-eng.php>

## **Who do I speak to for advice?**

If you are concerned about the Essure device, or are experiencing symptoms, you may wish to:

- contact *healthdirect* on 1800 022 222 (24 hours a day, 7 days a week)
- visit your GP or specialist
- in the case of an emergency, call 000 for an ambulance or attend the nearest hospital emergency department.

**The information in this publication is provided to the reader in good faith. While every reasonable effort has been made to ensure the accuracy of the publication no guarantee can be given that its contents are (1) free from error or omissions, (2) current at the time you access it. Information in this publication is provided as a guide only.**

**The State of Western Australia, the Minister for Health, the Department of Health and the Office of Patient Safety and Clinical Quality and their employees and agents expressly disclaim liability for any act or omission occurring in reliance on the information in the publication and for any consequences of such act or omission.**

This document can be made available in alternative formats on request for a person with a disability.

Produced by the Communications Directorate © Department of Health 2018

Copyright to this material is vested in the State of Western Australia unless otherwise indicated. Apart from any fair dealing for the purposes of private study, research, criticism or review, as permitted under the provisions of the *Copyright Act 1968*, no part may be reproduced or re-used for any purposes whatsoever without written permission of the State of Western Australia.