

Safety Information 010/22

Issue date November 2022

Distributed to:

Chief Executives
Directors of Clinical
Governance

Director, Regulation and Compliance Unit

Action required by:

Chief Executives
Directors of Clinical
Governance

We recommend you also inform:

Directors, Managers and Staff of:

- Women's Health / Gynaecology Services
- Emergency Departments
- Medical Records
- Complaints / Patient Feedback

Content reviewed by:

Medical Director Patient Safety

Clinical Excellence Commission

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Internet Website:

https://www.health.nsw.gov. au/sabs/Pages/default.aspx

Intranet Website:

http://internal.health.nsw.gov.au/quality/sabs/

Review date November 2023

Essure contraceptive devices

Situation

- The Essure implant is an intrauterine device (IUD) that provides permanent contraception for women. It was used in Australia between 1999 and 2017.
- There has been no new clinical advice since the Essure contraceptive
 device was taken off the market in 2018 however, this is a reminder to
 clinicians that side effects from Essure may occur at any time following
 insertion, including years after insertion.

Background

 The risk of developing side effects or complications from the implantation of the Essure device is low.

Symptoms of side effects include:

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

Other symptoms that have been reported include:

- Severe bloating
- Fatigue
- Migraines
- Weight gain
- o Changed toilet habits
- Twinges in the implant location and aching joints
- Pain during sex that didn't exist previously
- Depression
- Autoimmune disease
- Hair loss
- Reduced libido
- Memory lapses, dizziness and fainting¹

Assessment

- Side effects from Essure may occur at any time following implantation.
- Some Essure side effects are mild and may only last a few days, while others may be more persistent. Symptoms may exacerbate due to the length of time women are exposed to the Essure device.

Clinical Recommendations

- Women who are not experiencing any symptoms do not require any follow up care.
- Women who believe they are experiencing complications should contact their GP to determine if the symptoms are associated with the Essure implant. In some instances, Gynaecological assessment may be required.





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Required actions for the Local Health Districts/Networks

- 1. Distribute this Safety Information to all clinicians and clinical departments where women may access emergency or gynaelogical care
- 2. Distribute this Safety Information to Medical Records Departments
- 1. Queensland Health, 2022, Essure permanent contraceptive device side effects

