**Field Safety Notice**

**Commercial name of the affected product**: Essure ®
**FSCA-identifier**: V27207
**Type of action**: advice given by MANUFACTURER regarding the use of the device and/or the follow up of patients, users or others

**Attention:**

**Affected device:** Essure (contraceptive device for hysteroscopic placement)

**Please note: Bayer Ltd. understands that Essure has not been distributed in Ireland since January 2014. However, we would like to bring this important information to your attention.**

## 1. Description:

Please be informed that in the event of an endometrial ablation procedure, women who have an Essure insert in place may be at increased risk for certain events known to be associated with this procedure.

Endometrial ablation and the Essure procedure should **not** be performed on the same day. Endometrial ablation devices contraindicated with Essure should not be used.

In women who have previously undergone an endometrial ablation, the Essure procedure should only be performed if visualisation and accurate localisation of the tubal ostia is possible. Performing an Essure procedure after an endometrial ablation may be associated with the following: unsatisfactory micro-insert location and increased risk of perforation or creation of false passage.

Endometrial ablation should be performed only after a satisfactory Essure Confirmation Test to ensure the appropriate location of the Essure micro-inserts. Performing endometrial ablation after an Essure procedure may be associated with the following: compromised ability to conduct and interpret a modified hysterosalpingogram (HSG); injury to surrounding tissue (e.g. bowel); increased risk of infection; post-ablation tubal sterilisation syndrome; stretching or removal of the Essure micro-insert that could affect the patient's ability to rely on Essure for contraception.

The above risks are assessed as low but should be considered in any woman having undergone both an Essure procedure and an endometrial ablation.

## 2. Advice on Action to be taken by the user:

- Endometrial ablation and the Essure procedure should not be performed on the same day.

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December 12, 2018

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- The Essure procedure should only be performed in a woman who has undergone an endometrial ablation if visualisation and accurate localisation of the tubal ostia is possible.
- Endometrial ablation should only be performed after the correct location of the Essure micro-inserts is confirmed by a satisfactory Essure Confirmation Test, usually 3 months following the Essure procedure. Endometrial ablation devices contraindicated with Essure should not be used.
- Any intrauterine procedure, including endometrial ablation, may result in stretching or removal of the Essure micro-insert that could affect the patient's ability to rely on Essure for contraception.

**3. Transmission of this Field Safety Notice:**

This notice should be forwarded to all those who need to be aware of this information within your organisation or to any organisation where Essure is used. Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period of time to ensure effectiveness of the corrective action.

**4. Contact Person:**

If you have any questions, or if you require any further information, please contact our medical information team at Bayer Ltd, The Atrium, Blackthorn Road, Dublin 18; Tel: +353 1 216 3300; Fax: +353 1 2061539; E-mail: info.ireland@bayerhealthcare.com.

The undersigned confirms that this notice has been sent to the competent Regulatory Agency.

Yours sincerely,

**Dr. Tristan Cooper**
Medical Director
For and on behalf of Bayer Limited