Date: March 8, 2016

Dear Health Care Professional:

Urgent Field Safety Notice

Commercial name of the affected product: ESSURE®, ESS-305
Type of action: advice given by MANUFACTURER regarding the use of the device and/or the follow up of patients, users or others

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Attention:

Bayer Inc.
Pharmaceuticals Division
2920 Matheson Blvd. East
Mississauga, ON L4W 5R6

Tel. 905 282-5550
Fax 905 282-5721
www.bayer.com

Affected devices:

ESSURE® (contraceptive device for hysteroscopic placement)

1. Description:

Please be informed that women who undergo both an ESSURE® procedure and an endometrial ablation may be at increased risk for certain events known to be associated with each procedure. This notice provides you with advanced notification of an upcoming revision of the ESSURE® product Instructions for Use (IFU).

Endometrial ablation and the ESSURE® procedure should **not** be performed on the same day.

In women who have previously undergone an endometrial ablation, the ESSURE® procedure should only be performed if visualization and accurate localization 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 (eg, bowel); increased risk of infection; post-ablation tubal sterilization 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
- The ESSURE® procedure should only be performed in a woman who has undergone an endometrial ablation if visualization and accurate localization 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.
- 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 organization or to any organization where ESSURE® is used.

Please transfer this notice to other organizations 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 regarding this notice, please contact Bayer Inc. Medical Information at 1-800-265-7382 or email at canada.medinfo@bayer.com.

Sincerely,

Shurjeel Choudhri, MD FRCPC
Senior Vice President and Head
Medical and Scientific Affairs, Bayer Inc.

March 8/16
Date