



Urgent – Medical Device Recall – Label Update

Type of action: Product label update only

Commercial name of the affected product: ESSURE[®], ESS-305

Attention:

Affected devices:

ESSURE Permanent Birth Control System (contraceptive device for hysteroscopic placement).

1. Description:

This notice does not include a stock recovery or any physical changes to product currently in use or on the market.

Bayer has been working with Health Canada to support the continued safe, effective and appropriate use of ESSURE for permanent birth control. Health Canada has approved the revised ESSURE Instructions for Use (IFU) and introduced a Patient Information Brochure (PIB) that includes a Patient-Doctor Discussion Checklist (Checklist).

A summary of changes to the labeling includes:

1. The addition of a **Boxed Warning** listing information on the ESSURE Confirmation test, adverse events that have been reported either in clinical studies or through post market surveillance and situations where device removal may be indicated.
2. The **IFU** has also been updated with additional information. This includes a new section on patient counseling in addition to revisions in the sections discussing safety, clinical studies, instructions for use and patient management.
3. The introduction of a **PIB** including a **Checklist**. The PIB, along with the Checklist, is intended to be reviewed by the physician and patient to facilitate the patient's understanding of birth control options, benefits and potential risks associated with the use of ESSURE, as well as what to expect during and after the ESSURE procedure.

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

The revised IFU and PIB, including the Checklist, available at <http://www.bayer.ca/essure>, should be reviewed by the physician prior to performing the ESSURE procedure.

The PIB, including the Checklist, is intended to be reviewed by the physician and patient and the Checklist signed prior to the use of the device.

3. 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,

Dr. Christoph Hofmann
Head of Medical Affairs TA & EMEA

Date

25.1.2017

25 January, 2017

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