Important Safety Information on ESSURE® (permanent birth control system) – Risk of Serious Complications

2016/05/30

Audience
Healthcare professionals who perform hysteroscopic sterilization using tubal implants with ESSURE®, hospitals and clinics that purchase ESSURE and the Society of Obstetricians and Gynecologists.

Key Messages

- **Complications have been reported with the use of ESSURE (permanent birth control system). These include changes in menstrual bleeding, unintended pregnancy, chronic pain, perforation and migration of device, allergy and sensitivity or immune-type reactions. Some complications may be considered serious.**
- **In some patients, these complications have led to the surgical removal of ESSURE, which may include hysterectomy.**
- **To help ensure that healthcare professionals and patients have a clear understanding of how ESSURE works and the risks involved with ESSURE, Bayer HealthCare LLC in collaboration with Health Canada is developing a Patient Information Sheet and Checklist intended to be reviewed and signed prior to the use of the device.**
- **The product labelling for ESSURE will be updated including a new Boxed Warning section to reflect this safety information.**
- **ESSURE users should be aware of the potential complications and seek medical advice if necessary.**

What is the issue?
Complications have been reported in some patients with the use of ESSURE (permanent birth control system) including changes in menstrual bleeding, unintended pregnancy, chronic pain, perforation and migration of device, allergy and various non-specific symptoms suggestive of sensitivity or immune-type reactions. Some complications may be considered serious. In some cases, the extent of the symptoms led to the removal of ESSURE. The removal of ESSURE requires surgery and may include hysterectomy.

Post-marketing information suggests that some patients may not always be fully informed of the various possible device and procedure-related complications before they choose whether to proceed with ESSURE.

Products affected
ESSURE (permanent birth control system) manufactured by Bayer Healthcare LLC.

Background information
Hysteroscopic sterilization using tubal implants is an alternative to other female sterilization techniques such as laparoscopic tubal occlusion using electrocautery, rings or clips. Currently, the only tubal implant system for hysteroscopic sterilization licensed for sale in Canada is ESSURE. ESSURE micro-insert is a spring-like implant that is inserted hysteroscopically into each fallopian tube and expands to conform to the inner walls of the tube. Components of the micro-insert elicit an intended localized benign tissue growth that occludes the tube and anchors the insert in place. The micro-insert is considered a permanent implant.

Unintended pregnancy (including ectopic pregnancy) has been reported in ESSURE users, sometimes due to noncompliance with the need for alternative contraception for at least three months after implantation.

Changes in menstrual bleeding patterns have been reported by women in the months to years after insertion (implantation) of ESSURE. These changes can include heavier or lighter than normal bleeding or irregular periods such as bleeding in the middle of a cycle.

Chronic pain (lasting longer than three months post-insertion) has been reported in some ESSURE users.

Cases of incorrect device location due to migration or perforation have also been reported.

Information for consumers
ESSURE is a permanent and irreversible form of birth control. Patients should discuss this with their physician when deciding if the device is right for them.

To help patients better understand the benefits and potential complications with ESSURE, a Patient Information Sheet and Checklist is being developed. This is intended to be reviewed and signed before the device is implanted.

Patients should also be aware that:

- Using ESSURE is a multi-step procedure. A healthcare professional inserts flexible coils through the vagina and cervix and into the fallopian tubes – the tubes that carry the eggs from the ovaries to the uterus. Over a period of about three months, tissue forms around the inserts. The build-up of tissue

creates a barrier that blocks the tubes and keeps sperm from reaching the eggs, thus preventing conception.

- ESSURE is **not** immediately effective in preventing pregnancy. Patients must use another form of birth control for about **3 months** following ESSURE insertion, until the **ESSURE Confirmation Test** has verified that the ESSURE inserts are placed correctly and are working as intended. Patients are required to return to their healthcare professional for the **ESSURE Confirmation Test.**

- Patients should be aware of potential complications reported with ESSURE including changes in menstrual bleeding, chronic pain, unintended pregnancy and various immune reactions (e.g., swelling, itching, rash, hives). Additional symptoms such as fatigue, nausea, weight gain, headaches and hair loss have also been reported. Some patients have chosen to have their ESSURE inserts removed due to complications. This requires surgery and may include a hysterectomy.

- ESSURE users should be aware of the potential complications and seek medical advice if necessary.

Information for health care professionals
Healthcare professionals should be aware of the following information:

- ESSURE is a permanent irreversible implant.

- Alternative contraception must be used for at least 3 months after the ESSURE device is implanted or until such time that the effectiveness of the ESSURE implants are confirmed with the ESSURE Confirmation Test.

- Serious adverse events have been reported in association with ESSURE, both around the time of insertion and in long-term device wearers.

The manufacturer is working with Health Canada to update the product labelling, including a new Boxed Warning section.

An ESSURE Patient Information Sheet and Checklist for patients is being developed by the manufacturer in collaboration with Health Canada and will describe the potential complications and procedure-related potential outcomes associated with the device. It is intended to be reviewed and signed prior to the procedure.

Action taken by Health Canada
Health Canada has completed a safety review of certain complications associated with the use of ESSURE. Health Canada is working with the manufacturer to update

the ESSURE product labelling and to develop a Patient Information Sheet and Checklist.

Health Canada will continue to monitor safety information associated with the use of ESSURE and will take action as appropriate if any new safety information is identified.

Report health or safety concerns

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any serious complications or unexpected side effects with the use of ESSURE (permanent birth control system) should be reported to Bayer Inc. or Health Canada.

Bayer Inc.
2920 Matheson Boulevard East
Mississauga, ON
L4W 5R6
Telephone: 1-800-265-7382
Email: canada.medinfo@bayer.com

To correct your mailing address or fax number, contact Bayer Inc.

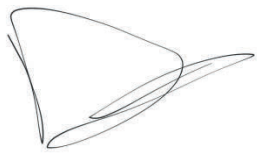
You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:

Marketed Health Products Directorate (MHPD)
E-mail: mhpd_dpsc@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Original signed by



Dario Mirski, MD
Senior Vice President and Head Medical Affairs Americas
Bayer HealthCare LLC