Hysteroscopic tubal occlusion: How new product labeling can be a resource for patient counseling

Hysteroscopically placed tubal implants are a nonsurgical permanent birth control option for some women, but you need to make sure you explain—and your patient understands—all the benefits, risks, and potential complications. A new discussion checklist can help you do that.

Q&A with Linda D. Bradley, MD

In November 2016, Bayer, the manufacturer of the permanent birth control tubal implant system (Essure), revised the Essure product labeling in accordance with a US Food and Drug Administration (FDA) guidance document.[1] The FDA developed its labeling guidance based on its examination of an increasing number of reported adverse events associated with the system's use (such as persistent pain, perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, abnormal or irregular bleeding, and allergy or hypersensitivity reactions) and its evaluation of a trade complaint regarding allegations initially made in a Citizen Petition.

Changes to the new FDA-approved labeling for Essure include:

- the addition of a boxed warning listing adverse events that have been reported either in clinical studies or through postmarket surveillance (see **BOX** on page 14)
- updated Instructions for Use document for clinicians and Patient Information Booklet, which contain additional information on safety (contraindications, warnings, and precautions), clinical data, and instructions[2,3]
- a Patient-Doctor Discussion Checklist (included within the Patient Information Booklet), designed to support appropriate patient counseling, facilitate the patient's understanding of birth control options, and explain the benefits and risks associated with the device and what to expect during and after the implantation procedure.[3]

How will these labeling changes impact clinicians and patients? OBG MANAGEMENT asked Linda Bradley, MD, Professor of Surgery and Vice Chair of Obstetrics and Gynecology at the Women's Health Institute, Cleveland Clinic, Cleveland, Ohio, to share her expertise with readers.

OBG MANAGEMENT: What does the new product labeling mean for clinicians who offer tubal implants as an option for permanent sterilization?

Linda D. Bradley, MD: The FDA-approved revised labeling for the Essure system means

Dr. Bradley is Professor of Surgery and Vice Chair of Obstetrics and Gynecology at the Women's Health Institute, and Director, Center for Menstrual Disorders, Fibroids, and Hysteroscopic Services, Cleveland Clinic, Cleveland, Ohio. Dr. Bradley serves on the OBG MANAGEMENT Board of Editors.

Dr. Bradley reports that she has received research or grant support from and is a consultant and speaker for Bayer, is a speaker for Smith & Nephew and Teva, serves on the scientific advisory board for Boston Scientific, is a consultant for Karl Storz, and has received royalties from UpToDate and Elsevier.

IN THIS ARTICLE

CONTINUED ON PAGE 14

CONTINUED FROM PAGE 13

Boxed warning is now included in Essure product labeling[1]

"WARNING: Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System for Permanent Birth Control during discussion of the benefits and risks of the device."

Reference

1. Essure permanent birth control (Bayer) Instructions for use. http://www.hcp.essure-us.com/assets/pdf/Link%20Essure%20IFU.pdf. Accessed January 5, 2017.

FAST TRACK

Clinicians can use the Doctor-Patient Discussion Checklist as a guide in reviewing the device's benefits and risks, outcomes of the procedure, and possible need for future surgical intervention

that physicians should have a very detailed, in-depth conversation with their patients who are contemplating hysteroscopic tubal insert placement for permanent sterilization. This counseling really should not differ from what doctors were doing before the label was revised. However, physicians can now use the new Patient-Doctor Discussion Checklist as a guide in reviewing the benefits of the device, its known risks and potential risks, outcomes of the insertion procedure, and the possible need for future surgical intervention if device placement–related issues arise.

For clinicians, this counseling adds just a few more minutes to the visit. The Patient-Doctor Discussion Checklist will become an inherent part of the informed consent process, aiding in the review of the device's benefits, potential risks, and more importantly its permanence.

In the past, there was some concern that perhaps patients did not receive enough guidance for informed consent, so one of the first things listed on the checklist is confirmation—in the form of a printed line where the patient can sign her initials—that she understands that Essure is a permanent form of birth control. The checklist covers additional important issues, including that the doctor has indeed shared with the patient other options for birth control or sterilization, such as laparoscopic sterilization, vasectomy for her male partner, an intrauterine device (IUD), and birth control pills. This is an opportunity to reinforce the fact that tubal implants are a permanent form of birth control, and if the patient is uncertain about ending her fertility, the clinician can inform her about reversible options. The checklist also includes for discussion the pregnancy risk with use of the device, what the patient can expect during the implant insertion procedure and for the days afterwards (such as cramping, mild to moderate pain, nausea and vomiting), and the need for a confirmation test 3 months after device placement.

Other discussion points covered include long-term risks and benefits of the device, the potential for complications, and the possibility (due to pelvic pain) that the hysteroscopically placed devices may need to be removed with a surgical procedure requiring general anesthesia.

Incorporating the checklist into our clinical practice shows that we have listened to patients and complied with recommendations made by the FDA review panel, and we can use this document to have a more complete discussion with our patients.

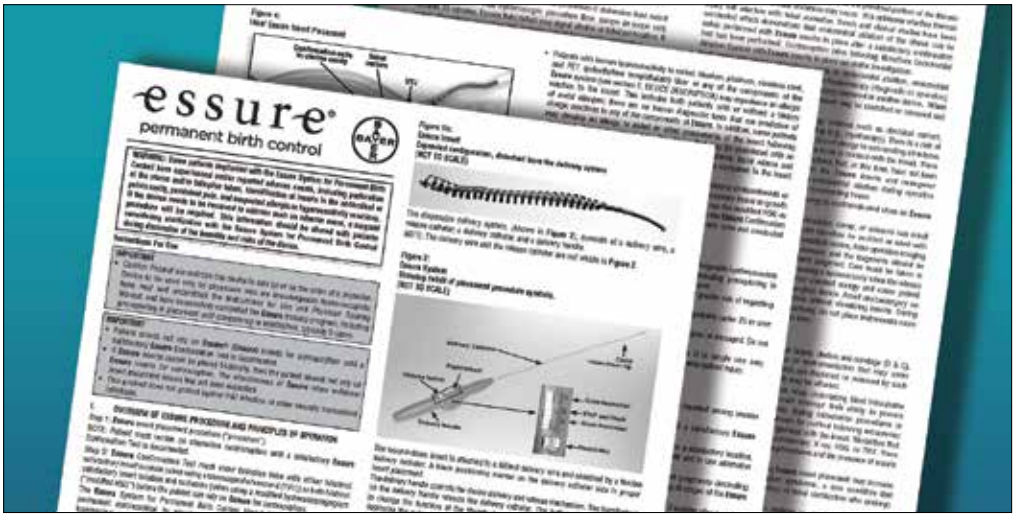
OBG MANAGEMENT: Do you agree with some clinicians who say that physicians who place the device also should have the skills required to remove it if necessary?

Dr. Bradley: Essure placement—which is a hysteroscopic procedure—is done very differently than a laparoscopic procedure. In the past, among women who needed to have the Essure system removed, most procedures would be done laparoscopically. Since we work collaboratively in teams, someone within the team or division would have the clinical expertise to remove the devices. An ObGyn who does laparoscopy with salpingectomy and/or cornual resection would best be able to remove the devices.

The clinician who does hysteroscopy is not always the same one who does laparoscopy. Someone within the division who is interested in removing the device will develop an expertise and algorithm that suits

CONTINUED ON PAGE 16

CONTINUED FROM PAGE 14



the practice, so that person in the practice becomes the expert. This is no different from many other things that physicians do. In our clinical practice, for example, we have a pelvic pain specialist, a sexual counselor, someone interested in menopause and management, and someone interested in alternatives to hysterectomies. Those who practice their craft and their art become proficient at it. So if you do not perform a particular procedure such as a tubal implant removal, know the expert to whom you can make a referral.

OBG MANAGEMENT: How do you now advise your colleagues to counsel patients on permanent sterilization?

Dr. Bradley: Hysteroscopic tubal implant sterilization, a minimally invasive procedure, is an excellent and viable option for women who meet the inclusion criteria and who do not have the exclusion criteria for placement. It is overall safe and extremely effective. If a patient has issues after undergoing implant placement—just like with any other surgery or procedure—for example, if she is not feeling better or is not doing as well as anticipated, we must not forget the patient. It is important for our patients to be listened to and to be heard. Postprocedure issues are generally transient and related to pain and discomfort or abnormal bleeding. If they are persistent, then further evaluation is needed.

Tell the patient to contact you if she has questions or issues, and have a tiered approach for working up any problems that she may present with. In addition, reiterate that the patient must use another form of birth control for 3 months until she undergoes the confirmation test and until the results verify that the implants can be relied on for contraception.

I am still placing the device. Before I perform the procedure, I speak with my patients—as I did before the checklist was developed—about all of the informed consent issues, the risk–benefit profile, and ruling out contraindications to use. I think this is good medical and surgical practice. The new labeling means we need to have a critical conversation with our patients, and we should be doing that for all procedures.

FAST TRACK

Tell the patient to contact you if she has any postprocedure issues, and have a tiered approach for working up problems

References

1. US Food and Drug Administration. Labeling for permanent hysteroscopically-placed tubal implants intended for sterilization: guidance for industry and Food and Drug Administration staff. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM488020.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery. Published October 31, 2016. Accessed January 5, 2017.
2. Essure permanent birth control (Bayer) Instructions for use. http://www.hcp.essure-us.com/assets/pdf/Link%20Essure%20IFU.pdf. Accessed January 5, 2017.
3. Essure patient information booklet. http://labeling.bayerhealthcare.com/html/products/pi/essure_pib_en.pdf. Accessed January 5, 2017.