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Essure®: Patient Education, Identification, and Counseling

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A note from the manufacturer of Essure®

Recent communication from the US Food and Drug Administration emphasizes the importance of patient counseling with the use of Essure®. The labeling of Essure® is proposed to be updated to include a boxed warning outlining the need to convey specific risk information to patients as well as to have both the patient and the physician sign a patient counseling checklist. It is important that all labeling be reviewed by providers prior to the use of Essure®. The decision to undergo treatment with Essure® is at the patient's discretion, following appropriate patient counseling and informed consent.

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Disclosures
Dr. Basinski reports acting as a consultant for Bayer, including on Essure®.
Dr. Bradley reports acting as a consultant for Bayer, including on Essure®.

Introduction

Female sterilization is the most widely used form of permanent birth control around the world, and for more than 3 decades, laparoscopic procedures have been the preferred intervention.[1,2] However, in 2002, hysteroscopic sterilization became possible with the introduction of the Essure procedure/insert (Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ, USA). Essure® is a soft flexible insert comprised of a stainless steel inner coil wrapped in polyethylene terephthalate (PET) fibers, surrounded by an elastic nitinol outer coil.[3] After insertion of the Essure device, the PET fibers cause benign fibrotic in-growth in the fallopian tubes. This leads to permanent tubal obstruction over 3 months, during which time women need to use additional methods of birth control; hysterosalpingography (HSG) or, most recently, transvaginal ultrasonograpy

(TVU) is then used to confirm permanent sterilization. Essure® is more cost-effective and is associated with enhanced patient satisfaction relative to laparoscopy.[2,4,5] Essure® can be inserted in an outpatient setting, without the need for general anesthesia.[5] The device may therefore be appropriate for use in women at high anesthetic or surgical risk.[2]

The overall choice of birth control for a particular individual requires thoughtful selection and proactive patient counseling. Significant considerations for any birth control method include potential failure rates with subsequent unintended pregnancy, risks of the underlying procedure, cost-effectiveness, and, most importantly, patient preference and satisfaction.[2] With relevant guidance from a health care professional, patients are encouraged to be actively involved in decision making about their own health care; this is particularly pertinent for permanent birth control.

Significant considerations for any birth control method include potential failure rates with subsequent unintended pregnancy, risks of the underlying procedure, cost-effectiveness, and, most importantly, patient preference and satisfaction.[2]

The establishment and content of effective patient-practitioner communication with women considering Essure® was discussed at a roundtable meeting of experts sponsored by Bayer and held in Vancouver, Canada, in conjunction with the annual meeting of the AAGL, formerly known as the American Association of Gynecologic Laparoscopists, in November 2014. Discussions focused on how to identify patients best suited for Essure use; the best avenues of physician-patient communication before, during, and after Essure placement; and the required content of patient-physician discussions around the use of Essure® for permanent contraception. This supplement summarizes the content of the roundtable deliberations and recommendations.

Education about Essure

Physician communication concerning risk-benefit considerations are especially important for patients planning to use any method of birth control. Patients should therefore be well educated about their possible birth control options. Well-informed patients are typically more accepting of outcomes (positive or negative) associated with a particular procedure. Further, if physicians provide sufficient information about procedural history and safety, and about materials used in any device, patients are more likely to feel at ease and confident in use of that device.

A potential source of patient education about the Essure product is office staff, such as nurses, administrators, medical assistants, and receptionists; education of clinic personnel should not be overlooked as a necessary process for a successful Essure® program. Physicians should work to educate their staff members about the Essure® procedure so they are well equipped to answer questions from patients. Ideally, to facilitate learning, staff should have the opportunity to observe device-placement procedures or watch videos or simulations of device insertion. Educating office staff can assist the health care professional in the process of informing patients.

A standardized team approach to patient counseling is advocated, with physicians and health care facility staff delivering clear, consistent messages. Information about device use can be reinforced by providing patients with educational brochures or "tear-off" leaflets containing device pictures. Patients may also feel more comfortable about a future procedure if an Essure® device is available for them to touch and handle. The opportunity for a family member or support person to sit in on the initial consultation and also receive educational information may be reassuring for the patient. Discussion of information obtained from the Internet, family, friends, or work colleagues should be addressed in an open, nondefensive manner. If a patient expresses serious concerns about the device, consideration should be given to other forms of birth control.

Identifying candidates for Essure use

The first step in counseling patients about use of Essure® is to identify appropriate candidates for the device. Essure® is an appropriate means of birth control for a range of patients, but most importantly for patients who do not intend to have additional children and who desire a permanent birth control option.[6] Specific benefits of Essure® are that it does not require surgical incisions and is not placed within the peritoneal cavity.[7,8] It is also appropriate for women who desire or require nonhormonal birth control. Essure placement is a feasible birth control intervention in any woman without specific contraindications and in whom bilateral fallopian tubes can be visualized and are not previously occluded or removed.

Although in some countries age thresholds for sterilization may limit Essure use in younger women, in the United States there is no minimum age for use by an informed patient; however, if a patient is using Medicaid, a minimum age of 21 years is required. Importantly, it is essential to carefully counsel younger patients about the permanence of Essure® birth control, especially because the risk of regret after sterilization is higher in younger women.[9]

Contraindications, warnings, and precautions, according to the Essure® label Instructions for Use, should be carefully observed. Therefore, in the United States,* Essure use should be avoided in women who[3]:

- are unsure about ending fertility
- can have only one insert positioned (eg, because of contralateral proximal tubal occlusion or suspected unicornuate uterus)
- have previously undergone tubal ligation
- are pregnant or potentially pregnant
- have delivered, or terminated a pregnancy, less than 6 weeks before Essure® placement
- have an active or recent upper or lower pelvic infection
- have a known allergy to contrast media.

Certain patient categories may also be inappropriate for Essure use. Essure® is not suitable for women with congenital uterine anomalies or those who have undergone endometrial ablation and who have dense synechiae (adhesions) and scarring. Such postablation problems can interfere with interpretation of the Essure confirmation test.[3]

One retrospective cohort study found that patients who are experiencing ongoing pain of any kind (eg, chronic headache, chronic backache, chronic pelvic pain, or fibromyalgia) before the procedure, with or without a clear diagnosis, may be at increased risk for both acute and chronic pelvic pain after Essure placement.[10] Careful consideration of contraceptive options is needed in patients with a history of adenomyosis, endometriosis, or uterine fibroids with pelvic pain or heavy bleeding. Such patients may be using contraceptives to treat these conditions, as well as to prevent pregnancy, and may be better suited for ongoing hormonal contraceptive use. Although the Essure® device can be used safely in such patients, careful counseling is needed to educate them about the use of hormonal treatments for conditions causing pelvic pain and the potential exacerbation of prior symptoms with the discontinuation of their hormonal contraceptives.

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Patients receiving immunosuppressive drugs (eg, systemic corticosteroids or chemotherapy) are discouraged from undergoing the Essure procedure because it is theoretically possible that these drugs could reduce tissue in-growth in the fallopian tubes.[3]

Women who have had menstrual complications before the use of hormonal contraceptives, including a levonorgestrel-releasing intrauterine system (LNG IUS), may experience such complications after Essure placement. A history of sexually transmitted infection appears to increase the risk of failure to place the device within the tube, but it does not preclude the possibility of successful Essure place-

*In countries outside of the United States, Essure® is also contraindicated in women taking corticosteroids.

ment.[11] The presence of uterine fibroids or polyps can also obscure or block the ostial opening, making Essure placement difficult.[12]

Physicians should take a careful gynecologic history from patients considering Essure® and should investigate all functional gynecologic conditions, including menorrhagia, which may be associated with a need for other procedures (eg, ablation). Women should be informed that, as they age, normal fluctuations in hormone levels may lead to age-related changes to the volume and/or predictability of uterine bleeding unrelated to Essure®.

Communicating about Essure permanence

There is always a risk that women who undergo sterilization will subsequently regret their decision to be sterilized, and the risk of poststerilization regret is higher in younger women.[9] If there is any likelihood that a patient may wish to have children in the future, she should choose a reversible method of birth control.[13] Indeed, in line with Centers for Disease Control and Prevention (CDC) family planning recommendations, patients should be asked to clarify their decisions about reproductive life plans.[13] To establish how such plans "fit" with each patient's social, emotional, and environmental factors, health care providers should ask a range of questions covering issues such as planned family size, financial situation, domestic stress, and relationship stability. The permanence of the Essure procedure should be clearly emphasized.[14]

Communicating about Essure efficacy and safety

Efficacy and safety are key topics that should be included in patient counseling. Based on the clinical trials of Essure®, the observed effectiveness of the method was >99%; this includes 5-year follow-up of the pivotal trial. This effectiveness rate is consistent with retrospective analyses of commercial data.[3,15-19]

Patients need to understand that no method of birth control is 100% effective and, in the real-world, commercial setting, unintended pregnancies have been reported after the Essure procedure.[18,20] In an analysis of pregnancy rates after Essure® placement in France between 2006 and 2009, 143 pregnancies occurred in 39,169 women who had bilateral Essure® placement.[18] This represents a success rate of >99% and is comparable to the rate seen after tubal ligation.[18]

Most pregnancies that occur after Essure placement are related to patient noncompliance (ie, failure to use other birth control methods during the 3 months after Essure placement; failure to return for a confirmatory HSG test) or physician misinterpretation of the HSG test result.[17,20]

Physicians should discuss the possibility that one or both inserts will not be successfully placed, which occurs in approximately 4% of patients, and outline an alternative plan.[3] In addition, patients should be counseled on the risk of tubal perforation (which occurs at an incidence of between 0.9% and 2.6%),[7] device expulsion, and abdominal migration of the device. The most important aspect of this counseling is to be sure that patients are made aware of these potential outcomes and to discuss with the patient potential treatment options should they occur, which may include a continuation of hormonal contraceptives or laparoscopic removal of devices and tubes to achieve sterilization in these uncommon events.

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Nickel hypersensitivity

The Essure® micro-insert consists of a superelastic nitinol (nickel-titanium alloy) outer coil and a stainless steel inner coil wrapped in PET fibers.[3] These constituents are generally considered safe and, indeed, are frequently used in numerous devices in various medical specialties. Stainless steel and nickel-titanium alloys, for example, are widely used in orthopedic implants such as joint replacements; PET polymers have a ubiquitous role in vascular grafts and prostheses, shunts, sutures, and surgical mesh; and superelastic nitinol is a particularly prevalent device component, with an especially prominent role in self-expanding vascular/cardiac stents.[21,22]

In vitro testing has shown that nickel is released from the Essure® device, and a few patients may develop allergic reactions (eg, rash, pruritus, hives).[3] Overall, however, the potential for nickel sensitivity with Essure® is very low.[7,23-25] For example, in a large retrospective review of 4242 women who underwent hysteroscopic sterilization with Essure® device placement, 2 allergies to nickel occurred (0.05% of patients).[24] One woman with a history of allergy developed erythema and urticaria soon after the procedure, but symptoms resolved after device removal. The other woman presented 1 year after device placement with a history of chronic genital pruritus; she requested device removal and symptoms dissipated.

An analysis of the Manufacturer and User Facility Device Experience (MAUDE) database revealed a total of 63 reports of nickel hypersensitivity during postmarketing surveillance of Essure® from 2001 to 2010.[23] In 20 cases, skin patch testing was performed to corroborate nickel involvement: 13 tests were positive, and 7 were negative. In the 13 positive cases, 9 patients had the device removed; symptoms resolved in 5 patients, did not resolve in 2, and in the other 2, resolution was unclear because the patients were lost to follow-up. Importantly, only 2 of the 9 suspected hypersensitivity reactions were considered related to nickel. In the 4 patch test–positive cases in which the device was not removed, none of the hypersensitivity reactions was considered related to nickel.[23]

In another analysis of 5234 patients with Essure implants, 45 women had suspected nickel allergy prior to Essure placement, but none of these patients subsequently developed allergy symptoms or requested device removal.[25] Forty of the women with suspected nickel allergy in this study underwent patch testing, and 24 tested positive for nickel allergy; none of these women developed allergic symptoms after Essure placement.[25]

These findings underscore the very low incidence of suspected allergic reactions to Essure®; this is consistent with findings for other nickel-containing implantable devices and is encouraging.[7,23] Moreover, the reliability of self-reported nickel allergy is low, because many patients who report such allergy actually test negative on skin patch testing. Because of the lack of concordance between suspected symptoms and confirmed nickel allergy in women using the Essure® device, potential nickel allergy is not an absolute contraindication to hysteroscopic sterilization with nitinol-containing devices.[23]

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PET polymers and nitinol have a long history of safe and effective use in device implantation in humans.[21,22] For example, more than 1.5 million percutaneous coronary revascularization procedures are performed worldwide each year, and most of these involve intracoronary stent implantation. Common stainless steel stents contain about 12% nickel, and the overall risk of nickel allergy with these devices is very low: about 1 in 17,000 for endovascular and cardiac devices.[23]

The ubiquitous use of the materials contained in the Essure® insert throughout many medical specialties may help patients considering the Essure implants to put into perspective the long-term experience with PET and nitinol in the human body. Nevertheless, at the initial consultation, patients should be asked whether they are allergic to nickel. Although the risk is minimal, if any patient with a potential nickel allergy has concerns, careful counseling should be undertaken to educate the patient about available data and to confirm that the patient accepts this risk and does not prefer an alternative method of birth control.

Communicating during preprocedural preparation

Several key issues should be discussed with patients before Essure placement, and visual aids with diagrams may be particularly useful for facilitating relevant discussion. For example, visual charts depicting 100 women and the number who reported specific complications in clini-

cal studies may be pertinent. The timing of Essure placement, which is usually during the early proliferative phase of the cycle, should also be discussed, as should premedication.[23] During the early proliferative phase of the patient's cycle or with hormonal suppression, the visibility of the tubal ostia is optimized and may improve successful bilateral placement and reduce risk of a luteal phase pregnancy.

Among other preprocedural issues, patients should be informed about when to stop taking their current contraceptive and the effect this may have on their menstrual cycle. For instance, hormonal contraception may be suppressing known or unknown irregular or heavy cycles in some women. Once hormonal medications are stopped post–Essure placement and confirmation, a return to their natural, unsuppressed cycle will occur. Patients may erroneously believe that this return to their natural period is due to Essure®, rather than to the discontinuation of their previous hormonal contraceptive. Depo-Provera® (medroxyprogesterone acetate injection) may cause bleeding problems in some women and, if used in the 3 months between Essure placement and the confirmatory HSG, may lead to unwarranted dissatisfaction with the Essure procedure. Similarly, patients receiving hormonal therapies for pelvic pain (and/or birth control) should be instructed that stopping these treatments after a successful Essure procedure may lead to return or exacerbation of the original pain.

Patients should be clearly counseled that birth control options often suppress pelvic pain and menorrhagia or dysmenorrhea. Thus, before selecting a sterilization method, patients should be informed that underlying gynecologic problems controlled by hormonal therapies may be unveiled after sterilization (ie, when hormonal therapy is stopped). Physicians should encourage patients to return for further care should such poststerilization issues arise.

Communicating about periprocedural factors

The Essure placement procedure should be explained step by step to patients. Setting appropriate patient expectations for procedural and postprocedural discomfort are vital. Patient involvement in the actual placement procedure may improve acceptance of the entire sterilization process. For example, if the fallopian tubes cannot be accessed, patients can be asked to press down suprapubically from the right or left; this may facilitate device placement. An advantage of the office setting is that patients can visualize appropriate placement and gain further reassurance of a successful procedure.

The use of misoprostol or cervical dilators is not routinely recommended prior to Essure placement, but physicians may consider using these techniques at their own discretion, if cervical dilation is clinically indicated. Currently, there are limited data in the published literature to support the use of cervical dilatation techniques in women undergoing Essure placement. The addition of nonsteroidal anti-inflammatory drugs (NSAIDs) preprocedurally has been demonstrated to reduce both procedure and postprocedure discomfort and is recommended.[26]

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Generally, experienced physicians can leave an intrauterine device (IUD) in place while the Essure® device is positioned and until the postprocedural confirmation test at 3 months.[27-29] This applies if both tubal ostia are visible and can be easily accessed; however, if an IUD obstructs the view, or if access cannot be obtained, then the IUD should be removed before Essure® placement.[29,30] Other factors to consider are physician skill in performing the Essure procedure and the risk of disturbing the Essure® device during removal of the IUD; inexperienced physicians should remove an IUD before the Essure device is implanted. A new IUD or intrauterine system (IUS) placement should not be considered as the contraceptive method for use after Essure placement and prior to the 3-month confirmation test, because these are long-term methods of contraception.

Some patients may experience pain during the Essure® procedure. That is, pain may occur when the hysteroscope is introduced, when the uterine cavity is distended, and when the Essure® inserts are positioned.[31] Each individual's level of pain tolerance should be respected, and patient support is an important aspect of pain management. "Vocal local" pain management can be provided, and the environment should be calming and relaxing (eg, music can be played, and allowing the patient's partner in the procedure room may be considered to decrease anxiety). Additionally, avoiding use of cervical dilators and implementing hydrodilation with hysteroscopic fluid when possible can further reduce patient discomfort.[26] If a patient experiences discomfort during device placement in the office and requests the procedure to be stopped, it may be appropriate to reschedule this patient to the operating room or consider alternate methods of birth control.

If tissue perforation occurs, it is imperative to communicate to the patient that she cannot rely on Essure® for birth control, even if both fallopian tubes are effectively occluded. In cases of asymptomatic perforation, there is a lack of definitive evidence and consensus about whether the Essure® device should be removed. One approach is to discuss the situation with the patient and, if she desires device removal, attempt removal. Another option is to leave the device in place, after informing the patient about potential complications and after documenting (for medicolegal reasons) the patient's decision. In the original Essure® clinical trials, one patient elected to forgo removal of an abdominal device with no reports of complications short or long term. Additionally, in a study of 4306 patients undergoing the Essure procedure, 2 patients experienced abdominal migration of one Essure® device.[24] Both patients were asymptomatic and requested repeat procedures to replace the migrated devices, with no complications reported.

Communicating about postprocedural factors

At facilities conducting the Essure procedure, physicians should implement a protocol for continued follow-up of patients after a difficult placement or suspected perforation. The protocol should include opportunities for appropriate assessment of complications such as postprocedural pelvic pain or bleeding.

Potential for chronic pain

Pelvic pain is a common problem among reproductive-age women in the United States and may include dysmenorrhea, dyspareunia, or noncyclic pain.[32,33] The estimated 3-month prevalence of chronic pelvic pain in women in the United States aged 18 to 50 years is 15%.[34] A retrospective cohort study of 458 patients who underwent hysteroscopic sterilization with Essure® revealed that patients with previous chronic pain (eg, fibromyalgia, headache, lower back pain, pelvic pain) had an increased risk of postprocedural acute pain (odds ratio [OR], 6.81; 95% confidence interval [CI], 2.95–15.73) and chronic pain (OR, 6.15; 95% CI, 2.10–18.10).[10] The incidence of acute postprocedural pain in this study was 8.1%, and the incidence of persistent pain at 3 months was 4.2%.[10]

At facilities conducting the Essure procedure, physicians should implement a protocol for continued follow-up of patients after a difficult placement or suspected perforation.

For most women, pain after Essure placement generally resolves within a week of the procedure. In the phase II study of Essure, postprocedural pain resolved within 1 day (59% of patients), 3 days (88%), or 7 days (99%); the remaining 2 women reported pain resolution within 14 days of device placement.[35] A review of 4306 women who underwent hysteroscopic sterilization with Essure® reported successful device insertion in 4242 cases.[24] A total of 82.8% of women had nonexistent or only mild perioperative pain, which was treated with NSAIDs. In the remaining cases, perioperative pain was recorded as moderate (11.9%), severe (3.5%), or not documented (1.5%).[24]

Reported rates of chronic pain after Essure placement vary in the literature.[10,24,36] In the above-mentioned review of 4306 women undergoing the Essure procedure, 1 reported persistent

pain, despite NSAID therapy.[24] In another study of 4274 patients who underwent Essure placement at a single institution between January 2005 and December 2011, 7 patients (0.16%) had chronic pelvic pain necessitating device removal; in 6 cases, postprocedural analgesia was not required; and only 1 patient had vasovagal syndrome requiring intravenous analgesia and monitoring. In all cases, pain resolved after device removal.[36]

Pain that does not resolve within 1 to 2 weeks of Essure placement may be a sign of malpositioning or perforation. A systematic review of 107 articles identified 11 cases of chronic postprocedural pain, of which 5 were due to malpositioning of the Essure® device; in 3 of these cases, cornual perforation and subserosal device placement were evident.[7] In all 5 cases, pain resolved after device removal. Another 7 cases of persistent postprocedural pain, without perforation, were identified. Pain resolved completely in 4 patients after device removal. A fifth patient had improved daily pain but persistent irregular abdominal pain; a sixth was lost to follow-up; and the seventh patient, in whom the device was considered to be correctly positioned, had unresolved pain after laparoscopic salpingectomy with device removal and appendectomy.[7]

Physicians should alert patients with chronic pain before placement that they are at increased risk for pelvic pain after device placement. If pain does occur after Essure placement, the patient should be assessed for potential perforation or device malpositioning, particularly if pain has not resolved within 2 weeks of the procedure. A pelvic x-ray or ultrasound scan is the initial intervention, followed by HSG if the cause of pain remains unidentified.[7] Additionally, the physician may not need to wait until 3 months to obtain radiologic imaging to assess the patient for proper Essure location in the case of patients with persistent pain. However, these patients will still require another imaging test at 3 months to confirm Essure placement, and they should use an alternative contraception until this 3-month test has been conducted.

In the case of persistent pain prior to the 3-month imaging study, it is important to rule out a displaced insert sooner rather than later. Most patients will not experience persistent pain after Essure placement, but physicians need to pay careful attention to any reports of pain, regardless of the time elapsed since placement, and evaluate them thoroughly.[7,24,36] Even if a patient with persistent pain does not appear to have a perforation or malpositioning, it may still be appropriate to discuss removal of the Essure® device.

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Potential for bleeding

Abnormal uterine bleeding is common in the general population, with an estimated prevalence of 11% to 13%; this increases with age, up to an estimated 24% in women aged 36 to 40 years.[37] These statistics should be borne in mind when considering the potential for postprocedural bleeding or spotting after Essure placement. In the pivotal clinical trial of Essure®, bleeding or spotting on the day of placement was reported after 37 of 544 procedures (6.8%). When it occurred, bleeding or spotting continued for an average of 3 days after the procedure.[3] In one of the earliest clinical trials, in which patients kept diaries for up to 6 months after Essure placement, some women (10 of 114) reported greater pain during menstruation in the first month postplacement, but pain or bleeding was rare after 3 months. After the first 3 months, 3 of the 114 women (2.6%) in this study reported abnormal bleeding: 2 cases of occasional spotting and 1 case of a change in menstrual frequency.[38] Two of the 25 patients evaluated at 18 months reported irregularities in the timing of menstruation.[38] A review of the MAUDE database (2002–2012) revealed 44 cases of abnormal bleeding among a reported adverse event total of 457 events.[39]

These data indicate that the incidence of abnormal uterine bleeding after Essure placement is no higher than the incidence in the general population of women. Physicians need

TABLE 1 Key counseling points for discussion with patients[6]

- Essure® does not protect against HIV infections or other sexually transmitted infections
- Alternative contraception is needed for 3 months after the procedure, until tube occlusion is confirmed by the Essure confirmation test
- Risks associated with placement and wearing of the insert
- The procedure is permanent and irreversible
- Like all forms of birth control, there is a risk of pregnancy
- Management plan with the patient in the event that bilateral placement is not achieved
- Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Some patients may develop an allergy to nickel if this device is implanted

Abbreviation: HIV, human immunodeficiency virus.

to consider Essure-related issues as possible causes of menstrual irregularities, along with other likely etiologies in this age group, including the withdrawal of hormonal contraception, anovulation, underlying endometrial and uterine abnormalities such as polyps, fibroids, cancer, or adenomyosis.

Communicating about the Essure® confirmation test

The Essure confirmation test should be scheduled for 3 months after the Essure procedure. In the United States, the modified HSG or the recently approved TVU are methods for confirmation, while in Europe, pelvic x-ray, TVU, or HSG are approved options. The purpose of the test is to primarily assess device location and in the case of HSG, additionally confirm fallopian tube occlusion.[3]

Unfortunately, data suggest that compliance with the Essure confirmation test in clinical practice varies, and some studies report it is unacceptably low. One retrospective audit from a US hospital showed that only 12.7% of women returned for their confirmatory HSG after Essure placement.[40] This is a concern because poor compliance with the confirmation test is a leading cause of unwanted pregnancy after Essure placement.[20] A review of the MAUDE database (2001–2010) evaluated almost half a million Essure procedures worldwide to identify potential contributors to pregnancy.[19] A total of 508 of the 748 pregnancies identified were analyzed for potential contributing factors; most of these pregnancies were related to patient or physician noncompliance (n = 264; eg, the patient did not undergo the follow-up Essure confirmation test) or to misinterpreted confirmation tests (n = 212).[19] These data reinforce the importance of patients returning for the Essure confirmation test. Compliance of a patient returning for the Essure confirmation test relies on: patient motivation, effective counseling by providers, and institutional protocols that include thorough follow-up and reminders.[41,42]

The Essure confirmation test should be scheduled for 3 months after the Essure procedure.

The importance of the Essure confirmation test needs to be clearly emphasized to patients, as should the need for an alternative means of birth control during the interim phase between device insertion and acceptable results from the confirmation test.[6] Patients should be informed that if alternative contraception is not used, pregnancy or ectopic pregnancy may result. If a physician is not confident the patient will be compliant with both the confirmation test and an alternative means of birth control during the interim phase, a different form of contraception should be selected. Only when the confirmation test has established satisfactory location of the Essure® inserts (and when HSG is utilized bilateral tubal occlusion), can women rely on the Essure® device for birth control. If one or both tubes are still pat-

TABLE 2 Suggested topics to consider when developing a patient tear-away sheet

Checklist for inclusions on patient information sheet on Essure®
• Patient has reviewed Patient Information Booklet
• History of the device, including the materials used to produce the device (use in other medical devices)
• Age-related hormonal/functional changes
• Common functional reproduction problems
• How the Essure procedure is performed - Include a picture of the device - Step-by-step illustration
• Premedication
• Risks of procedure (placement rate related to parity, risk of perforation, pregnancy rate)
• Changes to period after cessation of hormonal treatment
• Need for confirmation test according to country protocol
• Confirmation test and use of contraception before confirmation - Relate to the waiting period with vasectomy - Can be misplaced or tubes can remain patent (risk of pregnancy)

ent at the 3-month HSG confirmation test, alternative birth control should be continued, and the test should be repeated at 6 months.

In regions outside the United States, only a relatively small percentage of patients require confirmatory HSG, because the algorithm for the confirmation test differs, and most patients primarily undergo TVU and/or plain-film x-ray for Essure confirmation testing, resulting in higher compliance rates. If the TVU is unsatisfactory or equivocal, an HSG is then performed. In the United States, important strategies to improve patient compliance with the Essure confirmation test include sending patients text message reminders, pop-up direct messaging, or electronic medical record (EMR) reminders.[42]

Conclusions

Physician-patient communication about the Essure® device should start with identification of suitable candidates for the procedure, establishment of an active patient-practitioner counseling opportunity, and confirmation that patients are unlikely to regret any decision to use permanent birth control. Discussion of the efficacy and safety of the Essure procedure may focus on the 5-year efficacy rate of >99% and include the limited potential for nickel sensitivity. Patients should be informed that some problems after Essure® placement (eg, bleeding, pelvic pain) may be related to pre- or postprocedural hormonal therapy cessation (eg, oral hormonal contraceptives, LNG IUS, or Depo-Provera®) and not necessarily to the Essure® device. At the same time, the risks of Essure® should not be minimized. Well-informed patients are typically more accepting of outcomes (positive or negative) associated with a particular procedure.

Physician-patient communication about the Essure® device should start with identification of suitable candidates for the procedure, establishment of an active patient-practitioner counseling opportunity, and confirmation that patients are unlikely to regret any decision to use permanent birth control.

Step-by-step explanation of the Essure procedure is necessary for all patients, and procedural expectations should be clearly expressed. Vigilance is essential for possible perforation during

device placement and for potential postprocedural complications, such as bleeding or chronic pelvic pain. Other essential factors are scheduling of the Essure confirmation test for 3 months after device placement, and emphasizing to patients that alternative methods of birth control should be used during this interim 3-month phase.[17] **TABLE 1** (page S9) includes key counseling points to include during discussions with the patient. A checklist of suggested topics for a patient tear-away sheet is provided in **TABLE 2** (page S10). It is important to establish effective communication with the patient throughout the decision-making process and to maintain communication after Essure placement to ensure that patients who choose this form of sterilization achieve the best possible short- and long-term outcomes.

Overall, if these processes of education, patient identification, and communication are rigorously followed, and if powerful patient-practitioner partnerships are established, then the already high rates of Essure efficacy, safety, patient acceptability, and satisfaction will continue to gain broader recognition in the real-world clinical setting.

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