

Update

Essure®: An Important Option for Family PACT Clients By Donna Bell Sanders, MPH

In the spring of 2008, Family PACT added the Essure® system of permanent contraception to the list of offerings for Family PACT clients. Essure is designed to provide a non-incisional alternative for women who want sterilization. All Family PACT clients considering permanent contraception should be counseled about this alternative to tubal ligations.

Using a hysteroscope, one Essure micro-insert is placed in the proximal portion of each fallopian tube lumen. Each micro-insert expands upon release and anchors itself in the fallopian tube. The micro-insert elicits a natural tissue response. The scarring it causes blocks the fallopian tubes to permanently prevent pregnancy.

Essure's advantages over laparoscopic or mini-laparotomy tubal occlusions include:

- No skin incisions,
- No entry into the abdominal cavity, and
- Rapid post-procedure resumption of normal activities.

Essure is especially helpful for women who want sterilization, but who:

- Are obese (with a BMI of more or equal to 45).
- Have an abdominal mesh that prevents laparoscopy.
- Have a permanent colostomy.
- Have had multiple abdominal or pelvic surgeries, especially those who may have adhesions.
- Use anticoagulation medications.
- Have medical problems that would contradict the use of general anesthesia.

In order to perform the Essure procedure, Family PACT providers **MUST**:

- 1) Be experienced hysteroscopists.
- 2) Be trained, proctored, and certified by Conceptus, the manufacturer of Essure.
- 3) Have an initial placement rate of 86%-90%.

For more information about the training program offered by Conceptus, go to their website at www.essuremd.com.

Providing Essure through Family PACT

Essure is an excellent option for women who have achieved their desired family size or are not interested in having children. To provide Essure through the Family PACT program, you must follow the same steps as you would with any sterilization procedure.

An Essure sterilization will be covered by Family PACT only if the following conditions are met:

- 1) The individual is at least 21 years old at the time you obtain her written consent.
- 2) The individual has not been declared mentally incompetent by a court.
- 3) The person is able to understand the content and nature of the informed consent process.
- 4) The individual is not in jail or confined to a mental institution.
- 5) The person has freely given her consent to have the procedure done.

In addition, you must follow the regulations regarding the waiting period between the time the consent form is signed and when the procedure will actually be performed. In most cases, the Essure procedure cannot be performed unless at least 30 days, but not more than 180 days, have passed between the date the consent form is signed and the date of the actual procedure.

As with all other sterilization procedures, a completed Sterilization Consent Form PM 330 must accompany all claims for Essure services. Claims for pre-surgical visits or services related to post-surgical complications or tests do not require consent documentation. Use the CPT code 58565 (with modifiers) when Essure is performed in a physician's office. Check the *Family PACT Benefits Grid* and the Policies, Procedures, and Billing Instructions (PPBI) Manual Benefits: Primary Contraceptive Services (ben prim) section for the various codes for each procedure.

Continued on page 2

THIS ISSUE

- **Essure®: An Important Option for Family PACT Clients**
- **Using the PM 330**
- **Upcoming Trainings**
- **Helpful Resources**

Essure®: An Important Option for Family PACT Clients continued...

Obtaining Informed Consent

Informed consent may not be obtained if the individual:

- 1) Has been drinking or using drugs.
- 2) Is in labor or gave birth within the last 24 hours.
- 3) Is seeking to obtain an abortion, is obtaining an abortion, or had an abortion within the last 24 hours.

It is important to follow all these steps when you obtain consent for an Essure sterilization from your client:

- 1) Offer to answer any questions your client may have.
- 2) Provide your client with a copy of the consent form (PM 330) and the booklet on sterilization provided by the California Department of Health Care Services. In addition to this booklet, you may also provide your client with a copy of the easy-to-read information sheet provided by Family PACT entitled, *All about Sterilization: Essure®*. This sheet is available online at www.familypact.org
- 3) You must tell the client that she is free to withhold or withdraw consent at any time before the procedure takes place. Assure your client that this will not affect her care in any way.
- 4) Make sure your client knows about all the available birth control methods.
- 5) Thoroughly explain how the Essure procedure will be performed.
- 6) Explain any discomforts or risks that may occur.
- 7) Talk about the procedure's benefits.
- 8) Make sure your client knows where the procedure will take place, how long it will take, and how long the recovery period lasts.
- 9) Make sure the client is aware of the waiting period before the procedure takes place.
- 10) Explain that she must continue to use another birth control method during that waiting period, as well as at least 3 months after the procedure.
- 11) Don't forget to explain the post-procedure X-ray that will need to take place 3 months later to assure that the tubes are fully occluded.

Post-Placement Follow-up

Three months after the Essure placement, a low pressure hysterosalpingogram (HSG) must be performed.

- The HSG must be performed by a radiologist trained in this technique. The protocol for the Essure Confirmation Test is available at www.essuremd.com.
- Decide who will be responsible for notifying the client (the referring or rendering provider.) Notification letters are available from the same website, which you can download and use with your clients.
- If occlusion is not demonstrated by the HSG at 3 months, you must repeat the HSG three months later. The client should continue to use another method of contraception during this time.

Remember These Basic Tips

Get trained in the Essure procedure or develop a referral list of trained providers.

Only hysteroscopists who have completed the Essure training with a certified specialist can administer Essure. If you are unable to provide Essure in your office, make sure you have an up-to-date referral list so clients know where they can get this service. Visit www.essuremd.com to request a training.

Identify clients interested in long-acting or permanent methods.

- **Ask all clients what their family planning goals are.** How long would they like to avoid pregnancy? Do they want to have children in the future? See if Essure or a long-acting method would meet their needs.
- **Let them know about the various sterilization options available to them.** Options include tubal ligation and vasectomy, as well as the Essure procedure. Explain the advantages and disadvantages of each type of sterilization. Determine which procedure best fits their needs.

Make sure clients know these key points:

- **Essure does not involve any surgery.** They will not be cut when the provider puts it in.
- **Essure is a very effective method.** Less than 1 out of 100 women who use it in a year may get pregnant.
- **Most women don't have any side effects.** Some women may feel pain or discomfort while Essure is put in.
- **After Essure is put in, it takes at least 3 months for the tubes to be blocked.** They must use another form of birth control for the first 3 months.
- **They'll need to come back in 3 months for an X-ray** of their fallopian tubes to make sure they can't get pregnant.

Screen interested clients for contraindications.

Essure is safe and effective. However, it may not be right for some women. Ask your clients about:

- Current or recent pelvic infections.
- Sensitivity or allergy to nickel.
- Past tubal ligations.

If your clients have any of these, you may need to talk to them about other forms of sterilization.

Provide sterilization counseling and obtain informed consent.

Use the correct forms and cover all the required points. Please see the following page for more information on using the PM 330.

Using the PM 330 Form

Many sterilization claims are denied because the Sterilization Consent Form PM 330 is filled out improperly. Family PACT has designed a comprehensive online module that provides step-by-step instructions on how to correctly complete the PM 330 form. Go to the Provider Training Online Module section of www.familypact.org to find this module entitled *Sterilization Consent: A Tutorial on Completing the PM 330*.

You can avoid common mistakes by following these suggestions:

- Use only the PM 330 form. Claims will be denied if any other forms are used. The PM 284 form is no longer valid.
- Avoid any writing in the margins of the PM 330 form.
- Ensure that the client's name is consistent throughout.
- Ensure that the client's name and date of birth is consistent on both the PM 330 and the claim form. The name and the date of birth must match the information found on the Health Access Programs (HAP) card.
- The client's signature on the PM 330 form must also match the name on the client's HAP card and the claim form.
- Make sure that the handwriting is consistent in any given section of the form. For example, the client's handwriting should be consistent and the provider's handwriting should be consistent.
- Keep all signatures within the line provided. Again, there should be no writing in the margins.
- A clear, readable copy of the signed PM 330 form must be attached to the claim form.
- A copy of the signed and completed PM 330 form must be given to the client.

Ordering Sterilization Consent Forms

You must order the **Sterilization Consent Form PM 330** (English on one side, Spanish on the other) from the Department of Health Care Services, Sacramento Warehouse by using the DHCS 2031 order form (see instructions and address in the right column.)

When you order, provide the following information:

- ◆ Date;
- ◆ Name of document (Sterilization Consent Form, PM 330);
- ◆ Quantity of forms requested;
- ◆ Name of county;
- ◆ Name of provider/facility;
- ◆ Complete shipping address (street, city, state, ZIP code) P.O. Box not accepted;
- ◆ Contact person; and
- ◆ Phone number.

Obtaining Booklets on Sterilization

Booklets on sterilization may be ordered from the Sacramento Warehouse using the DHCS 2031 Order Form.

- Fax a copy of your request for the DHCS 2031 Order Form on your office or clinic letterhead to 916-928-1326.
- They will fax you a copy of the order form.
- Complete the order form and request the versions of the booklets you need:
 - ◆ Permanent Birth Control for Women English PUB 353
 - ◆ Permanent Birth Control for Women Spanish PUB 354
 - ◆ Permanent Birth Control for Men English PUB 355
 - ◆ Permanent Birth Control For Men Spanish PUB 356
- Fax the completed DHCS 2031 Order Form to 916-928-1326.

Use this contact information as needed:

Department of Health Care Services,
Sacramento Warehouse
1037 North Market Boulevard, Suite 9
Sacramento, CA 95834
Phone: 916-928-9203
Fax: 916-928-1326

Upcoming Family PACT Trainings

February 11, 2010

Ask the Experts: Primary (Contraceptive) Benefits
Webcast

February 18, 2010

Provider Orientation
Palm Springs

March 3, 2010

Ask the Experts: Secondary (Sexually Transmitted Infections) Benefits
Webcast

March 4, 2010

Provider Orientation
Modesto

March 16, 2010

Counseling Your Teen Clients about LARCs
Webcast.

Go to www.familypact.org/Providers.aspx and click on **Calendar of Events** for more trainings.

HELPFUL RESOURCES FOR PROVIDING ESSURE AND OTHER LONG-ACTING METHODS

MORE INFORMATION ON ESSURE: Go to www.essuremd.com

TRAINING FOR ESSURE PROCEDURE: Go to Conceptus at www.essuremd.com

CLIENT EDUCATION MATERIALS ON ESSURE, IMPLANTS, AND IUC:

Go to www.familypact.org and click on Client Education Materials, Birth Control Methods. Information Sheets in 6 languages are available for Essure, Implants, and IUC. Consent forms in 6 languages are available for Implant removal, IUC insertion, and IUC removal.

INFORMATION ON STERILIZATION FROM THE POLICIES, PROCEDURES, AND BILLING INSTRUCTIONS (PPBI) MANUAL:

The Benefits: Primary Contraceptive Services (ben prim) section of the PPBI describes the procedure codes used for sterilization services.

ONLINE TRAINING ON USING THE PM 330:

Go to www.familypact.org and click on Provider Training.

Go to Online Modules and click on Sterilization: A Tutorial for Completing the PM 330.

PREVIOUSLY RECORDED WEBCASTS ON USING LONG-ACTING CONTRACEPTIVE METHODS:

- Making Long-Acting Reversible Contraceptives Available in Your Practice
- Clinician Coding for Family PACT Services
- Reversible and Irreversible Long-Acting Contraception in Family PACT

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