Information for informed consent for Novasure Endometrial Ablation

What is Novasure endometrial ablation?

Many things can cause abnormal bleeding or heavy periods. Endometrial ablation using Novasure can help women with heavy, painful, or frequent periods. The procedure destroys (ablates) the lining of the uterus, or endometrium, using electrical current. The endometrium heals by scarring, which usually reduces or prevents uterine bleeding. Endometrial ablation is used to control heavy, prolonged bleeding when:

- Bleeding has not responded other treatments.
- Childbearing is completed.
- You prefer not to have a hysterectomy to control bleeding.
- Other medical problems prevent a hysterectomy.
- Other medical treatments have failed.

Women with abnormal periods undergo an evaluation to make sure there is no evidence of cancer or other causes of abnormal bleeding like fibroids or polyps. Women whose abnormal bleeding has no obvious cause are said to have "dysfunctional" bleeding and can also benefit from a Novasure procedure. Endometrial ablation is not the same as having a hysterectomy. It is a less invasive option for women with problem periods who have tried other treatments without success.

What are my choices for treatment?

There are a number of choices that include:

1. Wait and see if the condition improves.
2. Try medications to lessen the bleeding.
3. Use surgery to correct the condition.

Surgery is not usually the first option because there are risks to any surgery. Hysterectomy (removal of the uterus) is the definitive surgical procedure but it involves the most risk and the longest recovery. Endometrial ablation is a less invasive, safer surgical approach in which only the lining of the uterus is destroyed. This usually takes care of the problem but it may not eliminate your period all together.

Novasure is one of several ways to destroy the lining of the uterus. Others include:

- HTA (hydrothermal ablation) which uses hot water.
• A thermal balloon which uses heated saline solution in a balloon that is inflated in the uterus.
• Cryo-ablation which freezes the lining of the uterus.
• Using microwaves to destroy the lining of the uterus.
• Surgically removing the lining of the uterus.

There are advantages, disadvantages, and potential risks for each option. Your doctor can help you choose which one may be best for you.

**What are the benefits of Novasure endometrial ablation?**

The benefits of the Novasure procedure include:

• Lighter periods. The majority of women are satisfied with the outcome of the procedure.
• About 40 percent of women will stop having periods.
• Quick procedure. The actual procedure takes only a few minutes.
• Less invasive and lower risk than hysterectomy.

**What are the risks of Novasure endometrial ablation?**

Like any procedure there are some risks associated with the Novasure procedure. They include:

Rarely:

• There could be an injury to the uterus (perforation) or injury to nearby organs like the bladder or bowel. The Novasure uses electrical current to destroy the lining of the uterus. There can be damage to the bowel or bladder that could require extensive surgery to repair and rarely could be life threatening.
• Your cervix, uterus or pelvis may become infected. Medication or another procedure could be needed to treat an infection.
• Bleeding could occur at the time of the procedure that is difficult to control and may require a transfusion or more invasive surgery to control.
• Allergic reactions to anesthesia and medications. In very rare cases, you can die from a serious reaction.
• Failure of the procedure. About 10% of women have no improvement in their bleeding and seek more definitive treatment.

**How do I prepare for a Novasure ablation?**

All patients should have certain tests performed prior to having a Novasure procedure, including:

• Endometrial biopsy- taking a sample of the lining of the uterus to make sure there is no pre-cancer or cancer causing the abnormal bleeding.
• Evaluation of the inside of the uterus to make sure it is normally shaped.

**Be sure to tell your doctor if you have...**

• A bleeding disorder
• An IUD
• Allergies to local anesthesia, latex, antibiotics, or iodine
• A vaginal infection
• An active herpes infection
• Pelvic inflammatory disease (PID)
• Possible pregnancy

**How can I manage pain during the procedure?**

Most procedures are done using a local anesthetic. Ask your doctor if it is OK to take Motrin or Advil an hour before the procedure, or a stronger medication like Vicodin. If you are nervous about the procedure, you can discuss whether to use a medicine like valium or an injected medication to help you relax before the HTA. In addition to oral medications, injectable medications may be used. If you are very concerned about pain control, talk to your doctor about all of your options.

**What happens during the Novasure endometrial ablation?**

The procedure typically takes about 15 minutes. Before the procedure, your doctor may want to slightly stretch open the cervix (the opening of the uterus) to make the procedure easier. This can be done by giving you medication or by temporarily placing a small sponge (“laminaria”) that will slowly expand and open your cervix.

At the start of the procedure, your doctor may gently inject a local anesthetic and a medication (epinephrine) to help control bleeding. Epinephrine can make your heart race. It may also cause a metallic taste in your mouth, ringing in your ears, or your legs to shake. These are normal side effects of the medication and this feeling typically passes quickly.

Once the Novasure device is placed into uterus the doctor will do a safety check to make sure it is OK to start the procedure. Once the procedure starts it only takes a few minutes to complete. It is normal to have cramping during this part of the procedure. Try to relax and stay still.

**What happens after the procedure is over?**

Most women have moderate cramping immediately after the procedure and it is common to have milder cramps in your lower belly for several days afterwards. (It is OK to use Tylenol, Motrin or Advil for pain relief.) Your doctor may also give you a prescription for a stronger pain medication.
It is normal to have bleeding similar to a menstrual period after the procedure. Do not use tampons as this may increase the risk of infection. Only use pads. It is also very common to have a lot of discharge for several weeks after the procedure as the lining of the uterus sheds. You may shower or take a bath any time after the procedure.

**Avoid the following:**

- Strenuous exercise for the next 2-3 days
- Tampons for the next 2-3 weeks
- Sexual intercourse or anything in the vagina for the next 2-3 weeks
- Douching for the next 2-3 weeks

**Follow up after the Novasure procedure**

- You do not need to have special follow up after the procedure.

**Call our advice center right away if you have any of these symptoms:**

- Vaginal bleeding greater than 1 pad per hour for more than 3 hours
- Vaginal bleeding for more than 3 weeks
- Pain that is not controlled with Tylenol, Advil, or the prescription pain medication that might have been given after the procedure.
- A temperature greater than 100.4 degrees Fahrenheit
- Pus (yellow or green discharge) coming from the vagina
- Severe nausea or vomiting

**Where can you learn more?**

- Visit your doctor's home page at kp.org/mydoctor. On click on “Prepare for your Procedure” (Emmi) to link to an interactive online program (Endometrial Ablation) that provides information for you and your family.

- Go online to kp.org and enter the code U581 in the search box to learn more about “Dysfunctional Uterine Bleeding.”