

Text for Patient Brochure

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A new procedure proves to be reasonably safe and effective in treating excessive menstrual bleeding. The Her Option Uterine Cryoblation Therapy System is a cryosurgical device that uses extreme cold to destroy tissue and is intended to ablate the endometrial lining (inside lining of the uterus) in pre-menopausal women with menorrhagia (excessive menstrual bleeding) due to benign (non-cancerous) causes for whom childbearing is complete.

A COMMON PROBLEM A NEW SOLUTION

If abnormally heavy menstrual bleeding interferes with your life, you are not alone. Worldwide, an estimated 20 percent of women suffer from a menstrual abnormality known as menorrhagia.

The cause can be a hormonal imbalance, especially in women aged 35 to 45, prior to menopause, or non-cancerous growths such as fibroids or polyps. Certain infections and chronic illnesses can also result in menorrhagia.

Symptoms range from frequent and profuse bleeding, clotting, and gushing, to severe cramping, nausea, dizziness, weakness, fatigue and anemia. In short, menorrhagia can be emotionally and physically devastating.

But now there's a new procedure that offers hope.

INTRODUCING HER OPTION THERAPY

Designed to reduce menstrual bleeding, HER OPTION Uterine Cryoblation Therapy can be performed in your doctor's office under local anesthesia. The procedure may eliminate bleeding in some women. Using extreme cold (cryoablation) to ablate or destroy tissue, this cryosurgical procedure represents a clinically efficacious, more convenient, and cost-effective alternative to traditional treatments for menorrhagia.

Other advantages include keeping your uterus, avoiding a hospital stay and

experiencing a quick recovery.

YOU NEED THE FACTS

ARE YOU A CANDIDATE?

If you are not pregnant, and don't plan to have children in the future, you may be a candidate for this new procedure. It's important, too, that your Pap Smear and biopsy (small sample of uterine tissue to check for cancer) of the uterus are normal. HER OPTION Cryoblation Therapy is NOT a uterine cancer treatment.

Also, your menorrhagia cannot be caused by infection or chronic illness.

A QUICK OVERVIEW OF WHAT TO EXPECT

The following information describes the HER OPTION Cryoblation Therapy, and what you can expect.

PRE-Operative Process

Your doctor will provide thorough pre-operative instructions, which you should follow carefully. Your doctor may choose to give you a medication to thin your uterus. This option, including risks and benefits, should be discussed fully with your doctor prior to treatment.

Operative PROCEDURE

Prior to HER OPTION Cryoblation Therapy, your doctor may administer medication to minimize cramping during and after the procedure, as well as a mild sedative to help you relax. Your doctor may also use a local anesthetic to numb your cervix and uterus. Some patients want to be "put to sleep". This is an option to discuss with your doctor.

The actual treatment begins when a very thin probe (tube) is inserted into the uterine cavity through the vagina and cervix. This probe does not change in size, nor does it distend (stretch out) your uterus.

When the temperature at the tip of this probe is lowered, the uterus is progressively frozen. Your doctor will monitor the freezing of the tissue with ultrasound. After approximately twelve minutes, the treatment is completed and the probe removed.

Caption

HEROPTION Cryoblation showing freezing of the uterine tissue

POST-OPERATIVE EXPERIENCE

You may feel mild to moderate cramping like a menstrual period. Your doctor will give you a mild medication to keep you comfortable. After an hour or two in the recovery area, you should be able to go home. You may want to take it easy for the remainder of the day. Most patients can return to normal work or home activities the day after surgery. Sexual activity can be resumed after your first check-up, usually in 7-10 days. You may experience mild cramping and you may also have a pinkish watery discharge for approximately 2 weeks.

Possible Complications and Risks

Please call your physician if you develop a fever of 100.4° Fahrenheit or greater, worsening pelvic pain that is not relieved by pain medication given to you by your doctor or by ibuprofen (e.g., Advil), nausea, vomiting, bowel or bladder problems, and/or a greenish vaginal discharge or vaginal discharge that has a foul smell.

Risks include infection and/or uterine perforation (hole in your uterus), which can occur with any intrauterine procedure. Infection can be managed with antibiotics. The procedure may pose some rare but possible risks including blood loss, freezing of internal organs outside of your uterus, hemorrhage and collection of blood or tissue in the uterus or fallopian tubes during the months post-procedure. These conditions can be treated with an outpatient procedure, or may lead to hysterectomy.

Pregnancy is also a risk following any endometrial ablation procedure. You should not undergo this procedure if you ever want to have children. Pregnancy following ablation can be dangerous for both the mother and fetus. Since there is a chance that pregnancy could occur, contraception or sterilization should be used after treatment. Please discuss these options with your physician.

An additional risk of any endometrial ablation procedure is the possibility of "masking" or missed diagnosis of cancer within the uterus due to the changes in the uterine lining caused by the procedure. This can be permanent. Your physician will prescreen you for cancer prior to performing this procedure. We, however, recommend that you continue to be followed by your physician to reduce this risk.

You Can Be Free

Within the first three months following the procedure, you should experience a reduction in bleeding. Some women may experience spotting or no bleeding at all. Clinical data to date for Cryoblation suggests that less than 8% of patients undergo a hysterectomy or repeat endometrial ablation during the first year following the procedure. This does not include 10 patients in the multi-center study lost to follow-up during the first year following treatment with HerOption.

Other Available Treatments

A variety of therapeutic treatments are effective in alleviating menorrhagia. Some do this by altering hormone balances. Others remove the lining of the uterus (the endometrium) that produces excessive menstrual bleeding. The most effective option, but also the most invasive, is hysterectomy (surgical removal of the uterus).

Be sure to discuss all your treatment options with your physician to make an informed decision about which is best for you.

Drugs, Hormones

You may be treated by your doctor prescribing drug therapy such as low-dose birth control pills or other hormones. These options are especially good for those women who wish to remain fertile. Drug therapies usually require long term treatment and are successful for some patients. But for many others, they are unsuccessful or produce undesirable side effects including breast tenderness, mood swings and weight change.

Dilation and Curettage (D&C)

A D & C is typically the first surgical step if drug therapy does not work to reduce or eliminate excessive bleeding. Usually performed in an out patient setting, the top layer of the uterine lining is scraped away. This may reduce bleeding for a few cycles. If a polyp (small growth) is present and removed, the bleeding may stop.

You Have a Choice

Endometrial Ablation

If you do not plan to have any more children, your doctor may suggest more aggressive surgical treatment options.

Hysteroscopic Endometrial Ablation removes the lining of the uterus with an electrosurgical tool or laser. A hysteroscope (instrument to view the inside of the uterus) is used to visualize the area of treatment. Most women return to work

within 3 days. This method effectively reduces or eliminates bleeding in approximately 85% of the patients. Risks include perforation, bleeding, infection or even heart failure due to fluids used to open up or distend the uterus.

Thermal balloon ablation removes the lining of the uterus using a balloon filled with water heated to 87° C (188° F). Less anesthesia is usually required with this procedure as compared to hysteroscopic endometrial ablation. Most women return to work the day following the procedure. This method is reported to reduce bleeding in approximately 85% of patients.

Hysterectomy

Hysterectomy or surgical removal of the uterus is the only definitive treatment for menorrhagia. Hysterectomy is a major procedure, performed in the hospital under general anesthesia, and is accompanied by surgical risks, hospitalization and a recovery period up to six weeks.

It is very important that you understand and discuss all your treatment options with your personal physician. Only you and your doctor can decide what's best for you. Please be sure to ask questions and share your concerns with him or her, so you are as well informed as possible when making this important health care decision.

HER OPTION:

A quick summary

A new, minimally invasive choice for you and your doctor to consider in the treatment of excessive menstrual bleeding or menorrhagia. HER OPTION therapy has the potential to deliver:

Reduced bleeding with an opportunity for elimination of bleeding. In clinical follow-up of 174 patients at one year, use of the Her Option System resulted in 1 in 5 patients (22%) reporting no bleeding at 12 month follow-up.

A safe alternative to hysterectomy, hysteroscopy and hot water endometrial ablation methods

An outpatient or physician office procedure, no hospital stay required

In the multi center clinical study, Only 46% of the cryoablation patients treated were administered general anesthesia.

A fast recovery, usually only a day

Of 156 patients who completed Quality of Life questionnaires 12 months following the procedure (this does not include 8 patients who underwent repeat endometrial ablation or hysterectomy), 86.5% are "very" to "extremely" satisfied with their outcome and 98% would recommend cryoblation to a friend. An intent-to-treat analysis including all 193 patients randomized to the cryoblation group demonstrates 76% as "very" to "extremely" satisfied with the procedure and 78% would recommend the procedure to a friend.

To learn more about HEROPTION therapy, talk with your doctor.

Remember, it's important to discuss all appropriate options for treating your menorrhagia, and to choose the procedure you believe is best for you.