

# **MEA**

## **A TREATMENT FOR**

### **Excessive Menstrual Bleeding PERIODS**

**Do you suffer from excessive menstrual bleeding?  
Are your menstrual periods restricting your  
lifestyle?**

**You don't have to suffer anymore!**

The average woman will have more than 300 periods in her lifetime. For some women, however, this natural but complex action can become a severe problem. Prolonged and sometimes painful bleeding prevents them from leading a normal lifestyle. On "heavy days" they may even become housebound. This problem can affect their overall well-being. This condition is known medically as **menorrhagia**.

- **MEA** is a clinically proven, minimally invasive treatment for menorrhagia.
- **MEA** is an alternative to hysterectomy or other major surgical procedures.
- **MEA** is an outpatient procedure requiring no hospital stay

Talk with your doctor and discuss **MEA** as an option to treating your excessive menstrual bleeding.

For more information:

### **How common are heavy periods?**

Heavy periods are a common condition. Each year about one in five women between the ages of 35 and 49 consult their gynecologist complaining of heavy menstrual bleeding.

### **What causes heavy periods?**

A period occurs when the lining of the uterus is shed every month. This lining, called the endometrium, always leaves behind a layer of cells from which a new lining will grow. For some women this process results in heavy periods. Approximately half of all cases of heavy bleeding have no obvious cause. In other cases, the possibility of uterine abnormalities or hormonal problems exists.

### **What should you do if your periods are heavy?**

A heavy period to one woman might be a moderate period to another. It is difficult to define what is a normal or abnormal period. However, if your periods are interfering with your lifestyle or have recently changed you should consult your doctor. Your gynecologist will need to find out how long your periods last, the length of time you bleed heavily and the number of days between your periods. A pelvic exam may be conducted as well as other tests, including blood tests. Your doctor will then suggest a course of treatment.

### **How is it treated?**

Heavy periods can be treated medically or surgically. The treatment will depend in part on whether or not you still want to have children. Medical options include hormonal or non-hormonal treatment to reduce the menstrual blood loss. Surgical options include dilation and curettage, hysterectomy or endometrial ablation. Your doctor has given you this pamphlet to further explain some of your treatment options.

- **Drug therapy**, such as low dose birth control pills and/or other types of hormones, are typically the first treatment option. This treatment is often chosen among women who wish to retain fertility. Repeated long term dosing is usually required and in some cases may provide only temporary or intermittent relief. Side effects are common and may include headache, breast tenderness and weight change. Major complications are rare.
- **Dilation and curettage (D&C)** is sometimes the first surgical step if drug therapy fails. The top layer of the uterine lining is scraped away reducing bleeding, but usually for only a few cycles. D&C is usually performed in an outpatient setting under general, regional, or local anesthesia (such as an epidural) anesthesia. Effectiveness is short term. This option allows you to maintain your fertility.
- **Hysterectomy** is the removal of whole or part of the uterus and therefore should only be used by women who do not want to still have children. It is the only definitive treatment for menorrhagia. It is a major surgical procedure, performed in the hospital under general or regional anesthesia, and is accompanied by surgical risks (such as infection and death), hospitalization, and depending on the type of hysterectomy performed, a recovery period of up to six weeks.

- **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. This method effectively reduces bleeding in approximately 85% of the patients. Some women find that their bleeding stops completely. It should be used only by women who are no longer interested in childbearing. Most women return to work within 3 days. Risks include uterine perforation, bleeding, infection, heart failure due to fluids required for the procedure, and death.
- **Endometrial ablation** may also be performed using a new generation of global endometrial ablation (GEA) devices that use different techniques to sometimes destroy the lining of the uterus and prevent it from coming back. There are approved devices that destroy the endometrium using heated fluid, extreme cold, or electrical energy. These methods offer a reduction of bleeding in approximately 67 – 87% of the patients treated. Some women find that their bleeding stops completely. Endometrial ablation allows for fast recovery, with return to normal activities generally within a few days. It should only be used in women who are no longer interested in childbearing. Risks include uterine perforation, bleeding, infection, cramping/pelvic pain, vaginal discharge, injury to nearby organs (such as bowel), or complications leading to death. One clinically proven form of endometrial ablation is **Microwave Endometrial Ablation (MEA)**.

#### **What is Microwave Endometrial Ablation (MEA)?**

**MEA** is a clinically proven treatment for heavy periods that can only be performed by a appropriately trained physician.. It is an outpatient procedure that destroys some or all of the endometrium with microwave energy.

#### **Am I a suitable candidate for MEA?**

If you a woman with heavy menstrual bleeding who does not want to have any more children, you may be a candidate for MEA. Your physician must first rule out other possible causes of heavy periods that cannot be cured by endometrial ablation. **MEA** is not a treatment for uterine cancer or endometriosis. **You cannot be treated by MEA if you have already undergone an endometrial ablation procedure, have an IUD in place, have had a classical cesarean section, or are using the Essure contraceptive micro-inserts to prevent pregnancy.** Your physician will need to perform several tests to determine if there are other medical reasons why you should not be treated with MEA. Common screening tests include, but are not limited to, a pap smear, an endometrial biopsy (sampling of tissue from the lining of the uterus to rule out cancer), and a vaginal ultrasound to measure the thickness of your uterine wall. If you have had a previous uterine surgery, such as a cesarean section, be sure to discuss this with your physician. He will ask you what type of scar you have on your uterus.

If you still want to have children, MEA like all ablation procedures is not an option.

### **What will happen if my doctor believes that MEA is the right procedure for me?**

If you are a candidate for MEA, your physician will perform an ultrasound on your uterus and most likely recommend that you take hormonal medicine to thin the lining of your uterus. This helps to improve the success of the procedure. After that, you may need a second vaginal ultrasound. It is possible that the hormonal medication may thin the uterine wall which could disqualify you as a candidate for MEA treatment.

Prior to the start of MEA treatment, your physician will discuss with you the appropriate type of anesthesia. After dilation (opening) of the cervix, your physician will examine the inside of the uterus with a hysteroscope (a lighted scope) to confirm that perforation (hole) of the uterus has not occurred prior to starting the MEA procedure.

The MEA Applicator (a slender tube) is then gently inserted into the uterus via the cervix. Microwave energy is then applied while the applicator is slowly withdrawn with a sweeping movement to ensure that as much of the endometrium is treated as possible. The microwave treatment takes about three minutes to complete.

### **How does MEA work?**

MEA uses high frequency microwave energy to cause rapid heating of the endometrium (the inner lining of the uterus), destroying it and preventing it from growing back. The strength of the microwaves has been specially selected so that only the uterine lining is affected.

US clinical trials have reported a successful outcome for 87% of the patients treated with MEA with menstrual bleeding being significantly reduced; 55% of patients treated with MEA stopped having periods entirely. About 62% of patients treated with MEA also find that period pain disappears completely or is far less intense than before treatment.

### **What will I feel after the procedure?**

You may feel mild cramping like a menstrual period, nausea, and vomiting. Your physician will give you appropriate pain medication if needed. After treatment you may have a pinkish and watery "healing" discharge that can last up to a few weeks.

You are normally allowed to go home the same day with two to four days of rest recommended. Normally, you can resume work and family commitments the next day. Following your endometrial ablation procedure, it is typically recommended that you refrain from sexual intercourse and the use of tampons for 7-10 days.

### **Are there any post-procedure complications?**

You should contact your physician if you develop fever higher than 100.4° F, pelvic or abdominal pain that becomes worse and unrelieved by ibuprofen (e.g., Advil), or other medication prescribed by your doctor, nausea, vomiting, bowel or bladder problems, and/or a greenish vaginal discharge.

### **What risks are associated with the MEA procedure?**

It is very important that you discuss with your doctor the possible risks associated with all treatment options. Possible risks associated with MEA include, perforation (hole) of the uterus, bleeding, infection, injury to organs within the abdomen (such as bowel), injury to the pelvis and death. Up to a year after the procedure, it is possible for blood or tissue to collect in the uterus and/or fallopian tubes which can cause pain and may require an outpatient procedure to correct the problem. If you have had your tubes tied (tubal ligation) you may develop a condition called post-ablation tubal sterilization syndrome. If you experience new pain with your menstrual cycles (periods), you should contact a physician. This syndrome can occur as late as 10 years after your ablation.

While the risk of death is very rare using the GEA devices, there have been 2 reports of death in more than 100,000 endometrial ablation procedures. Another rare, but important, risk of any endometrial ablation procedure is that it may decrease your doctor's ability to make an early diagnosis of cancer of the endometrium. The reason for this is that one of the warning signs of endometrial cancer is bleeding, and endometrial ablation procedures decrease or eliminate bleeding.

As part of the requirement for approval, women who are treated with MEA will need to carry a patient treatment card for 3-months after the procedure. This card will be given to you following your treatment and you will be asked to present it to any other physicians who treat you for any medical condition involving the pelvis within the next 3-months.

### **Can I get pregnant after treatment?**

Endometrial ablation does not prevent you from becoming pregnant. Pregnancies after an ablation are dangerous for both fetus and mother. Ablation treatments should not be used if you are interested in pregnancy. If there is a chance that you could still become pregnant, contraception or sterilization should be used after treatment as prevention. Please discuss these options with your doctor.

### **It's Your Body**

Don't be afraid to ask questions. Consider taking someone with you to your consultations to assist you in understanding the information presented and to help you consider your options. If you are unsure about your diagnosis or the treatment prescribed we encourage you to ask questions and get clarification

**Note:** If you experience any problem following your MEA treatment, please notify Microsulis Americas, Inc. at (800)-830-4904.

The Food and Drug Administration's (FDA) program for reporting serious reactions and problems with medical products is called "Medwatch". If you have experienced a problem associated with your MEA treatment, you may also report

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your problem by completing an Online Reporting Form via the internet, at <http://www.fda.gov/medwatch>.