minerva®

The Uterine Health Company

Minerva ES® System

Pointless Heavy Periods?

Minerva Endometrial Ablation for Abnormal Uterine Bleeding (AUB)

Table of Contents

Glossary

Abnormal Uterine Bleeding (AUB)—a gynecological condition characterized by prolonged bleeding, bleeding between monthly periods, and an extremely heavy flow.

Amenorrhea—No menstrual bleeding, not even one drop.

Anesthesia—Medical treatment with drugs to reduce and/or stop pain.

Cervix—Part of the uterus that contains the cervical canal and connects the uterus to the vagina.

Clinical Study—A carefully planned test in people to find out if a new medical product or treatment is safe and if it works.

Diagnostic—A test or procedure to identify a disease or problem.

Dilation and Curettage (also called a D & C)—A surgical procedure your doctor uses to go through your vagina to gently scrape and remove the lining of the uterus (endometrium).

Dysfunction—The change of a body or organ function from normal to not normal. Another word for dysfunction is abnormal.

Endometrial Ablation—A surgical treatment to eliminate the endometrium, the tissue lining of the uterus, and the source of excessive menstrual bleeding.

Effectiveness—The measure of how well a medical treatment works.

Endometrium—The tissue lining of the uterus and the source of excessive menstrual bleeding.

Estrogen—A chemical substance made by your body. Estrogen plays a very important role in your menstrual cycle, becoming pregnant, and many other body functions.

FDA—The United States Food and Drug Administration is the government agency whose mission is to protect and promote public health by protecting the safety of the food supply and giving the public access to safe and effective medical products.

Gynecologist—A doctor who specializes in treating the female reproductive system.

Glossary Continued

Hormone—A chemical made in your body. Your body makes hundreds of hormones and uses hormones to control a large number of body functions.

Hysterectomy—A surgical procedure to remove the uterus.

Hysteroscopy—Procedure completed using a hysteroscope, a thin, lighted tube with a camera that is inserted into the vagina to examine the cervix and inside of the uterus.

IUD—Intra-Uterine Device. A birth control device prescribed by your doctor to prevent pregnancy. Your doctor places the small device inside the uterus to prevent pregnancy.

Menopause—The natural biological process of gradually ending your monthly period (menstruation). Menopause also ends fertility. The average age of menopause is 51 years old in the United States. Women having menopause can have physical symptoms such as hot flashes, and emotional symptoms of menopause that may disrupt sleep, lower energy, or make them feel anxious or sad.

Minerva Controller—The computer and electronic part of the Minerva System that makes the device work.

Minerva Handpiece—The handheld part of the Minerva device that is used by physicians to treat the uterus.

Minimally Invasive Procedure—A procedure that can be done through the body's natural openings or through one or more small incisions to avoid large incisions (cuts).

Progestin—A hormone made by your body. Progestin has a very important role in your menstrual cycle, becoming pregnant, and many other body functions.

Success Rate—The percent (%) of patients who are expected to have their excessive bleeding reduced to a normal level or less than normal levels after endometrial ablation treatment.

Tubal Ligation—A surgical method of permanent birth control that closes a woman's Fallopian tubes.

Ultrasound—Images of internal organs, like the uterus, that are made by a machine using sound waves.

What is the Minerva Endometrial Ablation System?

Minerva and You

If heavy periods are making it difficult for you to live a normal life, Minerva may have the answer for you. The Minerva treatment is a one-time, safe, effective, quick, and complete procedure that can reduce heavy bleeding. The treatment can be done at the hospital or at the doctor's office or clinic without making incisions or using general anesthesia that puts you to sleep.

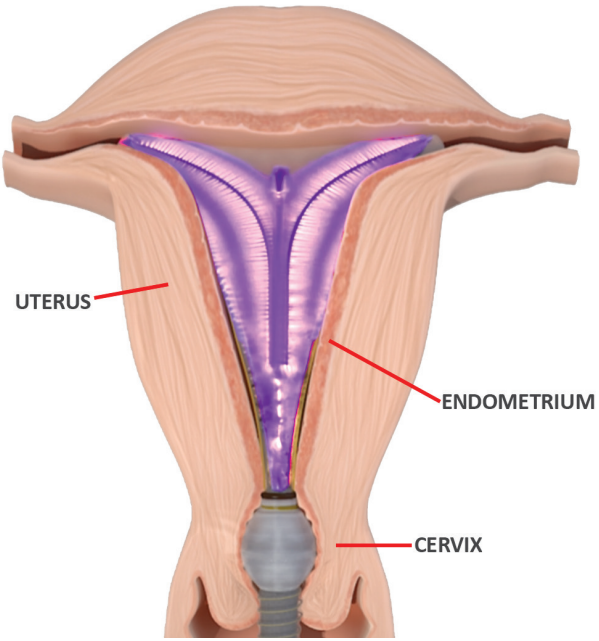
What is Heavy or Excessive Menstrual Bleeding?

A period with bleeding totaling over 1/3 cup (80ml) is considered heavy or excessive. If you have to change your sanitary protection (pads or tampons) frequently, (for example soaking through your usual pads or tampons each hour for two or more hours) you may be suffering from Abnormal Uterine Bleeding (AUB). You may also feel weak, tired, and have no energy. Many women also say that heavy periods make it difficult to work, exercise, and to be socially and sexually active.

This is a very common problem that affects about 1 in 5 women. The signs of heavy bleeding are most likely to start between the ages of 30 and 40.

How does the Minerva System Work?

The Minerva System works by destroying the endometrium (lining of the uterus) with heat. This tissue is the source of heavy bleeding in women who have not reached menopause. Minerva is only for women who do not want to have children in the future.



Minerva Handpiece Placement Inside the Uterus

Minerva System Description

The Minerva System has two main parts. The first is the Minerva Handpiece that your doctor inserts through your vagina into your uterus. The second part is the Minerva Controller that produces heat energy to treat the lining of your uterus. This energy is created by heating up argon gas that circulates inside of the Minerva Handpiece.

Minerva Endometrial Ablation System

The whole procedure time from insertion of the Minerva Handpiece to removal of the Minerva Handpiece is about 3 to 4 minutes.

Who Should Not Have This Treatment?

The Minerva System should not be used in patients who have, or had, the following conditions:

- Currently pregnant or wants to become pregnant in the future. PREGNANCY AFTER ABLATION CAN BE DANGEROUS FOR BOTH MOTHER AND UNBORN BABY.
- Known or suspected cancer of the uterus.
- Any weakness of the wall of the uterus. This may be due to past surgeries or long-term use of some medications. Talk to your doctor for more information.
- Had an endometrial ablation in the past. Repeat ablation can cause serious injury.
- Current infection, for example of the uterus, ovaries, bladder or other organs. This procedure should be not be used if you have an infection. Any infection must heal before the ablation procedure can be scheduled.

- Intrauterine device (IUD) in the uterus. Patient must agree to remove the IUD before the treatment.
- Patients with Essure. It is not known whether the Minerva procedure is safe and effective in patients with the Essure procedure.
- A patient with a very small uterus should not have the treatment because it may result in injury. Your doctor will measure your uterus to see if it is too short or too narrow for the Minerva procedure.

What are the Risks of the Minerva Treatment?

With any surgery, there are risks related to the treatment and to the anesthesia used during the treatment. Your doctor will talk to you about the risks of the Minerva treatment and will give you details about your individual situation. It is important for you to know the risks of the Minerva treatment.

The Minerva Endometrial Ablation System was tested in two clinical studies, the Minerva Single-Arm Study with 110 patients and the Minerva Randomized Study with 102 patients. Read *How Were The Clinical Studies Conducted* on page 18 for more information.

A number of risks were seen during this testing of the Minerva System. These risks are listed in the following table and were reported within the first 3 years following the Minerva treatment. It is also important to know how often these risks may happen. In the table this information is shown using percent (%). The percent (%) shows how many patients had this event when 100 women were treated. For example, the 1% next to "fever" means that when 100 patients were treated, 1 patient experienced a fever. You can discuss these risks with your doctor for more information.

Additional Risk-Related Information

The Minerva treatment is a surgical procedure. As with all surgeries, serious injury or death can occur. The following are also possible risks during or after endometrial ablation treatment.

1. Injury (e.g., tear) of the uterus.
2. Injury to organs in the abdomen (e.g., bowel or bladder).
3. Potential complication (e.g., new pain during menstrual cycles) in women who have previously had a tubal ligation.
4. Serious pregnancy complications for both mother and unborn baby. The Minerva procedure does not protect women from future pregnancy. Patients will still need to use contraception or undergo a permanent sterilization procedure.
5. Life-threatening infection. Patients should contact their doctor if they develop any of the following:

   a. Fever higher than 100.4 °F

   b. Abdominal pain that becomes worse and does not get better by pain medication given by the doctor or by ibuprofen

   c. Nausea

   d. Vomiting

   e. Bowel or bladder problems

   f. Vaginal discharge that has a foul smell.
6. Other risks and complications leading to serious injury or death. Undergoing an endometrial ablation procedure may make it more difficult to diagnose endometrial cancer in the future.

Risks of the Minerva Treatment

The risks listed in the table below were reported within the first 3 years following the Minerva treatment in the 212 women evaluated in the two clinical studies.

Number and Percent of Patients with One or More Related* Adverse Events and Symptoms by Time of Occurrence

Adverse Event/Symptom	Minerva Single-Arm Study Minerva (n=110)	Minerva Randomized Study Minerva (n=102)	Rollerball (n=51)
Intra-operative Adverse Events and Symptoms			
Skin Rash and/or Itching or Burning Sensation	0 (0.0%)**	1 (1.0%)	0 (0.0%)
Post-operative Adverse Events and Symptoms (Recovery room to < 24 hours) * **			
Pelvic Cramping	64 (58.2%)	51 (50.0%)	23 (45.1%)
Vaginal Discharge and/or Unpleasant Vaginal Smell or Burning or Other Abnormal Sensation	15 (13.6%)	32 (31.4%)	16 (31.4%)
Bleeding or Spotting	8 (7.3%)	39 (38.2%)	15 (29.4%)
Nausea and/or Vomiting	17 (15.5%)	17 (16.7%)	8(15.7%)
Weakness, Fatigue, Sleepiness, Lack of Concentration, Dizziness	6 (5.5%)	5 (4.9%)	1 (2.0%)
Abdominal Pain and/or Bloating	10 (9.1%)	0 (0.0%)	0 (0.0%)
Circulatory Symptoms	4 (3.6%)	5 (4.9%)	3 (5.9%)
Headache	4 (3.6%)	0 (0.0%)	2 (3.9%)
Backache	3 (2.7%)	1 (1.0%)	0 (0.0%)
Fever	0 (0.0%)	1 (1.0%)	0 (0.0%)
Agitation	0 (0.0%)	1 (1.0%)	2 (3.9%)
Vulvar Pruritus	0 (0.0%)	1 (1.0%)	0 (0.0%)
Urinary Disturbance	0 (0.0%)	1 (1.0%)	1 (2.0%)
Post-operative Adverse Events and Symptoms (≥ 24 hours – 2 Weeks) * **			
Pelvic Cramping	12 (10.9%)	0 (0.0%)	0 (0.0%)
Abdominal Pain and/or Bloating	1 (0.9%)	3 (2.9%)	1 (2.0%)
Pelvic Pain	0 (0.0%)	1 (1.0%)	0 (0.0%)
Nausea and/or Vomiting	1 (0.9%)	0 (0.0%)	0 (0.0%)
Vaginal Discharge and/or Unpleasant Vaginal Smell or Burning or Other Abnormal Sensation	0 (0.0%)	1 (1.0%)	0 (0.0%)
Weakness, Fatigue, Sleepiness, Lack of Concentration, Dizziness	0 (0.0%)	1 (1.0%)	1 (2.0%)
Circulatory Symptoms	1 (0.9%)	0 (0.0%)	0 (0.0%)
Constipation	1 (0.9%)	0 (0.0%)	1 (2.0%)
Pelvic Inflammatory Disease	1 (0.9%)	0 (0.0%)	0 (0.0%)
Fever	1 (0.9%)	0 (0.0%)	0 (0.0%)
Endometritis or Endomyometritis	0 (0.0%)	1 (1.0%)	2 (3.9%)
Skin Rash and/or Itching or Burning Sensation	0 (0.0%)	1 (1.0%)	1 (2.0%)
Post-operative Adverse Events and Symptoms (>2 Weeks – 1 Year)			
Pelvic Inflammatory Disease	0 (0.0%)	1 (1.0%)	0 (0.0%)
Hematometra	0 (0.0%)	1 (1.0%)	0 (0.0%)
Dysmenorrhea	0 (0.0%)	0 (0.0%)	1 (2.0%)
Long-Term Follow-up Adverse Events and Symptoms	**(>1 Year – 3 Years) † (n = 101)**	**>1 Year**	
Pelvic Cramping	2 (2.0%)	-	

* Possibly, probably, or highly probably related to Device or Procedure
** Percent of patients who reported specific endometrial ablation-related adverse events and symptoms
*** 10 patients in the Single-Arm Study and 2 patients in the RCT reported the same AE at the <24 hr and 24 hr – 2 Wk
† Gynecologic Adverse Events during Long-Term Follow-up (2 and 3 years after the procedure)

Benefits of the Minerva Treatment

The Minerva Treatment can be done at any time during the menstrual cycle. It is a 3 to 4 minute treatment that can be done in a clinic, and you do not need general anesthesia. The most recent clinical study (Minerva Randomized Study) that tested the Minerva device found that at one year after the Minerva treatment the following benefits were seen:

- 93% of patients had their heavy bleeding reduced to a normal level or less.
- 72% of patients had no bleeding.*
- 47% of patients had less menstrual cramping.
- 54% of patients had a reduction of Pre-Menstrual Symptoms.
- 95% of patients would "Maybe or Definitely" recommend the procedure to a friend or relative.
- 92% of patients were satisfied with the results.

* No monthly bleeding was based on menstrual bleeding during the 30-day time period prior to the follow-up visit or phone call.

How to Decide if the Minerva Treatment is Right for You?

The first step is to talk to your doctor about your symptoms. Your doctor will do a series of tests to determine the cause of your symptoms. Excessive bleeding by itself is not a disease, but it is a symptom of a number of possible medical conditions, including AUB.

Using ultrasound and/or hysteroscopy (methods used by doctors to see your uterus), along with other tests, your doctor will find the cause of your heavy periods.

Your doctor will then help you select the right treatment. Depending on the cause of your heavy periods, your doctor may suggest that you first try medications. If medications do not work, or you are not allowed to take them for other medical reasons, your doctor may suggest endometrial ablation using the Minerva device.

It is very important for you to understand that ***treatment with the Minerva Endometrial Ablation Device should only be performed if you are absolutely sure that you do not want to have children in the future.*** This treatment cannot be undone or reversed. Becoming pregnant after this procedure is dangerous for both mother and unborn child. Your doctor will talk to you about ways to avoid pregnancy after surgery (birth control).

Treatments for AUB

The following table shows common treatments used for excessive bleeding and the advantages and disadvantages for each.

	Endometrial Ablation	Intrauterine (IUD) Hormone Releasing	Hormone Therapy	Dilation and Curettage (D&C)	Hysterectomy (removal of the Uterus)
Technology Description	Device inserted into uterus that destroys the uterine lining with heat or cold.	Drug covered device that the doctor inserts into the uterine cavity. The IUD gradually releases a steady amount of hormone which can help control bleeding.	Hormone pill that is taken daily.	Surgical procedure in which the doctor scrapes the inside of the uterus to remove the lining of the uterus.	Surgical removal of the uterus.
Advantages	For most women, menstrual bleeding is reduced to normal levels or less. For some women, menstrual bleeding completely stopped. Can usually be performed in a few minutes. Can be done in your doctor's office with minimal anesthesia. Rapid recovery.	Reduces bleeding problems in most women. Provides contraception for 5 years. Does not affect future childbearing potential.	Reduces bleeding in about half of patients. Provides contraception. Does not affect future child bearing potential.	Diagnostic tool that can provide tissue samples to test for cancer or pre-cancerous conditions of the lining of the uterus. Does not affect future childbearing potential.	Permanently eliminates bleeding. One-time procedure.
Disadvantages	Procedure only for women who have completed childbearing. Requires anesthesia Side effects include: • Pain/cramping • Vaginal discharge • Infection • Bleeding/spotting	Must be removed and replaced every 5 years. 70% of women experience bleeding/spotting between menstrual periods. 30% of women experience hormonal side effects that may include depression, acne, headache, nausea, weight gain, and hair loss. In a significant number of cases, the uterus will push the IUD out of the uterine cavity (expulsion) Other side effects include: • Uterine wall perforations following insertion • Abdominal pain • Infection • Difficulty inserting the device that requires cervical dilation	Results may vary depending on hormone used. Not suitable for smokers. Side effects may include: • Nausia • Headache • Weight gain	No longer considered a long-term solution for treatment of excessive bleeding. Requires anesthesia. Reduction in bleeding is temporary. Side effects include: • Uterine wall perforation • Abdominal pain • Infection	Irreversible and permanent loss of fertility. Possible complications include: • Intraoperative bleeding (which, if excessive, can require transfusion) • Wound infection • Injury to bladder or other organ • Hospitalization (1-3 days)

What Happens Before Treatment?

Before treatment, you will be taken to the treatment room. The nurse will take your blood pressure, temperature, and other important information. Nurses will likely tape a number of wires on your chest to keep track of how well your heart is working.

You will also be given some medication to help you with any pain and make you relax. An oxygen mask may also be placed on your face to help you breathe. Your doctor's assistant will prepare you for the procedure by cleaning your vagina with a special solution that kills germs.

What Happens During Treatment?

At the time of the procedure, the doctor will insert a speculum (a medical tool that opens your vagina) so that your doctor can see inside. The doctor may make your cervix numb so that you do not feel pain during the procedure. Based on this procedure, the doctor may determine that you are not a candidate for treatment with Minerva. In that case, the doctor will talk to you about other options to treat your heavy menstrual bleeding.

The doctor will turn on the Minerva Controller, and then gently dilate (open) your cervix to insert the soft tip of the Minerva device into your uterus. The Minerva Controller will then provide energy to heat the inside of your uterus for 2 minutes. At the end of the treatment, the doctor will remove the device from your uterus. The entire treatment, from the time the device is inserted until the device is removed, usually takes less than 4 minutes. No part of the Minerva device remains in the uterus after the treatment.

What Happens After Treatment?

After treatment, you will be taken to a recovery area where you will be watched for about 1 hour to make sure you are okay. You may experience some mild to moderate low abdominal cramping and pain. The recovery room nurse may give you some medication for this. You will then be released to go home. It is important that someone is with you to take you home. You cannot drive immediately after the procedure because of the drugs you were given.

Most patients experience some mild low abdominal pain for a day or so, which usually is treated with over the counter (non-prescription) pain medication that your doctor will recommend. Patients also reported vaginal discharge following the procedure. During the first few days, the discharge is likely to be bloody in color, but it will gradually turn clear. The total time of vaginal discharge may vary and may last approximately six weeks or more, so you may need to wear some sanitary protection (for example a panty liner) during this time.

When to Call Your Doctor?

Your doctor's office will likely call you to check on you after your treatment. However, ***if after the procedure you are experiencing increasing pain, increased bleeding, change to greenish vaginal discharge, or have a fever greater than 100.4°F, immediately call your doctor's office.*** In rare cases, endometrial ablation can cause a serious injury that, if not treated promptly, can lead to death. If you call your doctor at night or on a weekend, your doctor's office will likely have an answering service that will put you in touch with your doctor or the doctor on-call. If you are not able to talk to your doctor, call 911 or go to the nearest Emergency Room.

How Were the Clinical Studies Conducted?

The Minerva Endometrial Ablation System was tested in two clinical studies, the Minerva Single-Arm Study and the Minerva Randomized Study. Doctors who did these clinical studies were gynecologists and treated women with heavy bleeding. The women treated with the Minerva System were from 25 to 50 years old, had heavy monthly bleeding, and did not want to have more children. All of the women were examined to see if there was a cause of their excessive menstrual bleeding and to make sure they were healthy with no infection.

The Minerva Single-Arm study was conducted by seven doctors at different hospitals and clinics. There were 110 women included in this study. The women kept a record of their bleeding using special diary charts. They filled out the diaries for their periods before the Minerva treatment and then completed one diary for each monthly period after the Minerva treatment. Each diary was collected and the amount of bleeding each patient had before and after the Minerva treatment was determined. In order to be in the clinical study, the patient's bleeding level had to be more than a certain amount. The Minerva treatment was considered successful if a patient had a bleeding level that was normal or below normal at 12 months following the Minerva treatment.

The women had follow-up visits with their doctor at 3 months, 6 months, and 1 year following the Minerva procedure. During these visits, the doctor examined the patients and collected their diaries to check their monthly bleeding level.

After the first year, a phone follow-up was done at year 2 and 3 to ask each patient about their bleeding level and any gynecological problems. The doctor also made sure all women were using birth control.

The second clinical study, the Minerva Randomized Study, enrolled 153 patients at 13 hospitals and clinics in three countries, including the United States. In this study, the Minerva Endometrial Ablation System was compared to another treatment for abnormal uterine bleeding called Rollerball ablation. A randomized study is a study where a computer randomly assigns the patients to one of two treatment groups, the Minerva Endometrial Ablation Device or Rollerball ablation. A total of 153 patients were enrolled in this study, 102 of them were treated with the Minerva Endometrial Ablation System and 51 were treated with the Rollerball ablation. Unlike the Minerva Single-Arm study where women used diaries to measure bleeding levels, this study measured the patient's bleeding before and after the treatment by collecting and testing the patient's used sanitary products (tampons and pads). The used sanitary products were sent to a laboratory to measure the amount of blood. Women participating in this study had in-person visits at 3 months, 6 months, and 1 year following the Minerva procedure, as well as telephone follow-up visits at 2 and 3 years post-procedure. The reported patient risks through the 30-day period following treatment are shown in the Risks table on pages 10-11.

What Were the Results of the Clinical Studies?

Single-Arm Study Results:

The success results in terms of the percent of women reporting normal or less bleeding at one, two and three years following the Minerva procedure are shown in the below table:

Success (Normal or Less Monthly Bleeding)		
One Year*	**Two Years****	**Three Years****
92%	**92%**	**93%**

* Based on PBLAC Diary Scores

** Based on Telephone Questionnaires

The percent of women who completely stopped their monthly bleeding during the 30-day time period prior to the follow-up visit or phone call is shown in the below table at 1 year and at greater than 3 years (average of 4.8 years following treatment):

No Monthly Bleeding+	
One Year*	**More Than Three Years****
66%	**57%**

* Based on PBLAC Diary Scores

** Based on Telephone Questionnaires

\+ Based on menstrual bleeding during the 30-day time period prior to the follow-up visit or phone call.

In addition, of those subjects who answered the survey, 81% of patients reported a decrease in symptoms like moodiness, irritability, vaginal dryness and hot flashes at 1 year, 65% at 2 years, and 72% at 3 years. At 1 year, over half of the patients (55%) indicated that their monthly cramping decreased after the Minerva treatment. At 2 years; this figure was 49% and at 3 years 56%.

In this study, of those women who answered the survey, the overall patient satisfaction with the procedure was 98% at 1 year, 97% at 2 years, and 99% at 3 years. Nearly 99% of the patients indicated that they would recommend the Minerva procedure to a friend or a relative at 1 year, and 100% at 2 and 3 years.

Minerva Randomized Study Results:

At one year after the Minerva treatment, 93% of patients had bleeding that was reduced to a normal level or less (versus 80% in the Rollerball treated patients), and 72% of patients treated completely stopped their monthly periods during the 30-day period prior to the 1 year visit (versus 49% in the Rollerball patients). In the Minerva treated patients 54 % of patients reported a decrease in symptoms like moodiness, irritability, vaginal dryness and hot flashes, and 43% in the Rollerball patients. In addition, 47% indicated that their monthly cramping decreased after the Minerva treatment, and 46% after treatment with Rollerball.

At one year, of those subjects who answered the survey, the overall patient satisfaction with the procedure was 92% in the Minerva treated patients (versus 80% in Rollerball patients). Nearly 95% of the patients indicated that they would recommend the Minerva procedure to a friend or a relative (versus 89% of the Rollerball patients).

Where Can You Find Out More About Your Condition?

To find out more about your condition and the Minerva System, please see the Minerva Surgical Website at:
www.minervasurgical.com.

Other excellent sources of information are the following:

1. American College of Obstetricians and Gynecologists – provides many useful publications on Women's Health.
2. American Association of Gynecologic Laparoscopists - Excellent source of information.
3. The National Women's Health Information Center - The National Women's Health Information Center (NWHIC) is the most reliable and current information resource on women's health today. NWHIC offers FREE women's health information on more than 800 topics.
4. Mayo Clinic - Information on Diseases and Conditions, Symptoms, Drugs and Supplements, Tests and procedures, Healthy Lifestyle, First Aid, and other.

References

1. Minerva Endometrial Ablation System [Operators Manual]. Santa Clara, CA: Minerva Surgical Inc.; L0120
2. Department of Health and Human Services. The Food and Drug Administration. Summary of Safety and Effectiveness Data. Minerva Endometrial Ablation System. **http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140013b.pdf.** Published August 27, 2015. Accessed August 31, 2015.

Notes

Minerva ES® Endometrial Ablation

The Minerva ES® Endometrial Ablation System is intended to ablate the endometrial lining of the uterus in pre-menopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete.

CONTRAINDICATIONS:
The Minerva ES Endometrial Ablation System is contraindicated for use in a patient: who is pregnant or wants to be pregnant in the future; who has known or suspected endometrial carcinoma or premalignant change of the endometrium; with any anatomic condition or pathologic condition that could lead to weakening of the myometrium; with active genital or urinary tract infection at the time of the procedure; with an intrauterine device (IUD) currently in place and which is not removed prior to the Minerva ES procedure; with a uterine cavity length less than 4 cm; with a narrow uterine cavity; where the Array Opening Indicator is in the Red Zone following deployment of the Minerva ES Disposable Handpiece, or with undiagnosed vaginal bleeding.

POTENTIAL ADVERSE EVENTS: The most common side effects of endometrial ablation occur during or immediately following the procedure and include uterine cramping, vaginal discharge, bleeding or spotting, nausea and/or vomiting, fatigue, abdominal pain. As with all endometrial ablation procedures, serious injury or death can occur.

WARNINGS: Failure to follow any instructions or to heed any Warnings or Precautions could result in serious patient injury.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. The physician using the system must be trained in hysteroscopy. www.minervasurgical.com/safety

Visit MinervaSurgical.com for additional educational resources.

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The Uterine Health Company

Minerva Surgical
4255 Burton Dr
Santa Clara, CA 95054

www.minervasurgical.com

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