

Patient Information

Minitouch Procedure for Heavy Menstrual Bleeding

Caution: US Federal Law restricts this device to sale by or on the order of a physician trained in the use of the Minitouch System.

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1. What is the Minitouch Procedure?

The Minitouch Procedure is for treating heavy periods. It is a one-time simple procedure that can be performed in your physician's office. It can be performed on any day of your cycle and without the need for prior thinning of your endometrium. Your cervix does not need to be dilated for this procedure. Based on your preference, it can be performed without intravenous sedation or general anesthesia. In most cases, the patients are able to leave shortly after the procedure.

What is Heavy Menstrual Bleeding (HMB)?

It is also called heavy periods, excessive menstrual bleeding, or menorrhagia. A period with bleeding totaling over 1/3 cup (80ml) is considered heavy. If you must change your sanitary protection (pads or tampons) frequently (for example, more than twice an hour), your bleeding may be heavy. You may also feel weak, tired, and have no energy. Many women say that heavy menstrual bleeding makes it difficult for them to work, exercise, and/or be socially and sexually active.

HMB is a common problem that affects about 1 in 5 women. The signs of heavy menstrual bleeding are most likely to start between the ages of 30 and 40, but some women experience heavy menstrual bleeding from an earlier age.

How Does the Minitouch Procedure Work?

The tissue lining the cavity of the uterus (endometrium) is the source of menstrual bleeding. The monthly shedding of the endometrium causes menstrual blood flow. The Minitouch Procedure uses a slim and flexible wand (Handpiece) to deliver microwave energy to heat the endometrium. The endometrium is then shed and should not regrow. Your menstrual bleeding may reduce, or even stop completely, as a result.



Figure 1. The Minitouch Handpiece

2. Who cannot have the Minitouch Procedure?

The Minitouch Procedure is intended for ablation of the endometrial lining of the uterus for the treatment of menorrhagia (heavy menstrual bleeding) due to benign causes in premenopausal women for whom childbearing is complete.

The Minitouch Procedure is not for the patient:

- who is pregnant or desires to retain fertility. **Pregnancy following the ablation can be dangerous for both mother and fetus.**
- who has known/suspected uterine cancer or pre-malignant conditions of the endometrium, such as unresolved adenomatous hyperplasia.
- with any anatomic condition (e.g., history of previous classical cesarean section or transmural myomectomy, including hysteroscopic and/or laparoscopic myomectomy performed immediately prior to the Minitouch procedure) or pathologic condition (e.g., requiring long-term medical therapy) that could lead to weakening of the myometrium.
- with a history of endometrial ablation and/or resection (including endometrial ablation/resection performed immediately prior to the Minitouch procedure), regardless of the modality by which it was performed. **Repeat ablation may result in serious patient injury.**
- who has active genital or urinary tract infection, or pelvic inflammatory disease.
- who has abnormal, obstructed, or perforated cavity. **Ablation in such cavities could result in serious injury.**
- who has intrauterine implant, such as intrauterine device (IUD).
- who has undiagnosed vaginal bleeding.
- who has uterine cavity length of less than 4 cm. The Handpiece may not deploy adequately and system may not initiate energy delivery.
- who has abnormal uterine/pelvic anatomy, such as frozen pelvis.

3. What are the risks of the Minitouch Procedure?

With any procedure, there are risks related to the treatment and to any medications used. Your doctor will discuss any risks that apply to your individual situation.

The following side effects are commonly reported for all endometrial ablation procedures, including the Minitouch Procedure.

- *uterine cramping (spasm)*
- *nausea*
- *vomiting*
- *fainting*
- *vaginal discharge*
- *bleeding*
- *spotting*

The following adverse events are rare but have been reported with other endometrial ablation procedures and may occur with the Minitouch Procedure.

- *pain*
- *hemorrhage*
- *endometritis*
- *infection*
- *fever*
- *sepsis*
- *cervical stenosis*
- *uterine necrosis*
- *adhesions*
- *hematometra*
- *pelvic inflammatory disease*
- *post-ablation tubal sterilization syndrome*
- *hydrosalpinx*
- *unintended thermal/mechanical injury to uterus and other organs*
- *cardiac complications*
- *death*

The Minitouch Procedure was evaluated in a clinical study, where a total of 114 US women were treated and then followed for 12 months to determine its safety and effectiveness. The table below lists non-serious anticipated adverse events (side effects) that were related to the device or the overall procedure:

Table 1. Non-serious anticipated adverse events

N = 114	Day 0	Day 1	Day 2 to Week 2	Week 2 to Month 12
Abdominal Distension	1		1	
Bacterial Vaginosis			1	1
Chills	2			
Dizziness	1			
Hot Flash	1			
Pollakiuria	1			
Presyncope	1			
Procedural Nausea	6			
Procedural Pain	2			1
Procedural Vomiting	5			
Somnolence	1			
Uterine Pain	2			
Uterine Spasm	44	2	3	1
Vaginal Discharge	2		1	
Vaginal Odor			1	
No. of Events	69	2	7	3
No. of Subjects	48	2	7	3
% of Subjects	43.0%	1.8%	6.1%	2.6%

4. How was the Minitouch clinical study performed?

The Minitouch clinical study was conducted at 5 Physician's Office locations across the US by 5 gynecologists. The women treated were between 30 and 50 years old, had heavy menstrual bleeding, and did not want to have more children.

The 114 women were treated and observed for 12 months to identify any complications. These women also recorded their monthly bleeding using a special diary designed for this purpose. The treatment was considered successful if the bleeding volume was below a pre-determined level at 12 months following the treatment.

5. What are the benefits of the Minitouch Procedure?

Reduction in Heavy Menstrual Bleeding

The Minitouch Procedure reduces or even eliminates heavy menstrual bleeding. The following results were observed at one year after the treatment in the clinical study:

- 89.5% (102 out of 114) women had their heavy menstrual bleeding reduced to a normal level or less.
- 51.8% (59 out of 114) women had no menstrual bleeding at all.

Reduction in Painful Periods

Painful periods (dysmenorrhea) decreased after the procedure in 98% (107 out of 109) of women who had dysmenorrhea. On a scale of 0-10, where 0 indicated no pain and 10 indicated worst pain possible, the average score decreased from 6.1 before the procedure to 0.8 at 12 months after the Minitouch Procedure. 67% (76 out of 114) of women reported having no dysmenorrhea (score 0) at all.

Patient Experience of Procedural Pain

In the clinical study, all women were asked to rank their level of procedural pain on a scale of 0-10, where 0 indicated no pain and 10 indicated worst pain possible. The average pain levels before the procedure, at discharge, and at 24 hours after the procedure are listed below.

Table 2. Patient Experience of Pain

	<i>Pain Score (0-10)</i>
Before the procedure	0.6
At discharge	2.6
24-hours after the procedure	1.2

Quality of Life

The women in the clinical trial reported a significant improvement in their quality of life:

- 95% of women reported having no limitation in work outside or inside the home because of their heavy periods at 12 months after the Minitouch Procedure. 8% said the same before the treatment.
- 93% of women reported having no limitation in physical activity because of their heavy periods at 12 months after the Minitouch Procedure. 2% said the same before the treatment.
- 95% of women reported having no limitation in social or leisure activities because of their heavy periods at 12 months after the Minitouch Procedure. 6% said the same before the treatment.

6. How is the Minitouch Procedure performed?

Before the procedure:

Before scheduling you for the treatment, your doctor may perform hysteroscopy (using a telescope to look into your uterus) and/or ultrasound examination to assess suitability of your uterine cavity for the treatment, and to confirm that your heavy menstrual bleeding is not caused by growth in the uterus such as a fibroid or polyp (for which different therapies may be more beneficial to you).

You may be given medications to help you with any discomfort and to make you relax. The doctor will then prepare you for the procedure by inserting a speculum and cleaning your vagina with a special solution that kills germs.

During the procedure:

The doctor will first take measurements inside your uterus. Then, after gently inserting the slim flexible Minitouch Handpiece into your uterine cavity and performing a few quick pre-procedure checks, the treatment will be given for about 3 minutes. Your doctor will pause/resume or change the speed of energy delivery to minimize any discomfort. Once the treatment is complete, the Handpiece is removed, and you can get off the treatment table and usually leave after a short recovery time. The entire treatment, from Handpiece insertion to removal, will take about 7 minutes on average.

After the procedure:

Before you leave, you will be given instructions and medications to take home with you. Depending on the medications used during your procedure, you may need to arrange for another adult to drive you home.

Your doctor's office will likely call to check on you after your Minitouch Procedure. However, if after the procedure you are experiencing unexpected symptoms, such as increasing pain or fever, immediately call your doctor's office, as it may indicate injury to the pelvic anatomy and risk of a serious adverse condition. If you are unable to reach your doctor for any reason, call 911 or go to the nearest emergency room.

You will experience vaginal discharge that may last up to six weeks. This discharge is a normal occurrence with endometrial ablation and is part of the healing process.

7. How do I know if the Minitouch Procedure is right for me?

Your doctor will do a series of tests to find the cause of your heavy menstrual bleeding and then discuss available options to help you select the right treatment.

The following table shows common treatments used for heavy menstrual bleeding, and the advantages and disadvantages for each.

Table 3. Advantages and Disadvantages of Treatments for Heavy Menstrual Bleeding

Treatment	Description	Advantages	Disadvantages
Minitouch Procedure	A slim, flexible device inserted into uterus to gently and precisely warm and destroy the endometrium. A type of endometrial ablation.	<ul style="list-style-type: none">• Does not use hormones• Less invasive than hysterectomy• Cervical dilation is not required.• For most women, menstrual bleeding is reduced to normal levels or completely stopped.• Can be performed in your doctor's office, usually in a few minutes.• Can be performed without intravenous sedation, or general anesthesia.• Pretreatment, or procedure timing are not required.• Can treat uterine cavities longer than 6.5cm.• Rapid recovery.	<p>Procedure only for women who have completed childbearing.</p> <p>Side effects include:</p> <ul style="list-style-type: none">• Pain/cramping• Vaginal discharge• Infection• Bleeding/spotting
Procedures using Other	Device inserted into uterus to destroy the endometrium with heat	<ul style="list-style-type: none">• Does not use hormones• Less invasive than hysterectomy	<p>Procedure only for women who have completed childbearing. Requires anesthesia.</p>

Treatment	Description	Advantages	Disadvantages
Endometrial Ablation Devices	or cold. A type of endometrial ablation.	<ul style="list-style-type: none"> • 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. 	<p>Side effects include:</p> <ul style="list-style-type: none"> • Pain/cramping • Vaginal discharge • Infection • Bleeding/spotting <p>Cervical dilation is required.</p> <p>Some devices are limited to treating uterine cavities that are 6.5cm or shorter.</p> <p>Some devices require pretreatment for thinning the endometrium prior to the procedure, or timing the procedure just after your menstrual period has ended.</p>
Progestin IUD¹	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.	Reduces bleeding problems in most women. Provides contraception for 5 years. Does not affect future childbearing potential.	<p>Must be removed and replaced every 5 years. 70% of women experience bleeding/spotting between menstrual periods.</p> <p>30% of women experience hormonal side effects that may include depression, acne, headache, nausea, weight gain, and hair loss. In 3-5% of women, the uterus will push the IUD out of the uterine cavity (expulsion).</p> <p>Other side effects include:</p> <ul style="list-style-type: none"> • Uterine wall perforations following insertion • Abdominal Pain • Infection • Difficulty inserting the device that requires cervical dilation.
Hormonal Therapy	Hormone that can be provided in a patch or injection that works for a given amount of time, or a pill that is taken daily.	Reduces bleeding in about half of the patients. Provides contraception. Does not affect future childbearing potential.	<p>Results may vary depending on hormone used. Not suitable for smokers or others with certain medical conditions.</p> <p>Side effects may include:</p> <ul style="list-style-type: none"> • Nausea • Headache • Weight gain
D&C	Surgical procedure in which the doctor scrapes the inside of the uterus to remove the lining of the uterus.	Diagnostic tool that can provide tissue samples to test for cancer or pre-cancerous conditions of the lining of the uterus.	<p>No longer considered a long-term solution for treatment of excessive bleeding.</p> <p>Requires sedation or general anesthesia to perform because the cervix is dilated and the uterine contents are mechanically removed or suctioned away. Reduction in bleeding is temporary. Fertility may be impacted by the formation of scarring in the uterus, if performed frequently.</p> <p>Side effects include:</p> <ul style="list-style-type: none"> • Uterine wall perforation • Abdominal pain • Infection
Hysterectomy	Surgical removal of the uterus.	Permanently eliminates bleeding. One-time procedure.	<p>Major surgical procedure, requires general anesthesia.</p> <ul style="list-style-type: none"> - 2–8-week recovery time. - associated with risks and complications of a major surgery. - irreversible and permanent loss of fertility. <p>Side effects may include:</p> <ul style="list-style-type: none"> • Bleeding (which, if excessive, can require transfusion) • Wound infection • Injury to bladder or another organ • Hospitalization (1-3 days)

¹ Mirena Prescribing Information, NDA 21225 Mirena; FDA. Approved 21 Dec 2016

8. Places to find out more about your condition

To learn more about heavy menstrual bleeding and the Minitouch Procedure, please visit the Minitouch website at: www.XXXXXXXXXX.YYY

Other sources of information:

1. American College of Obstetricians and Gynecologists. Heavy Menstrual Bleeding. <https://www.acog.org/Patients/FAQs/Heavy-Menstrual-Bleeding>
2. Mayo Clinic. Heavy Menstrual Bleeding. <https://www.mayoclinic.org/diseases-conditions/menorrhagia/symptoms-causes/syc-20352829>
3. <https://www.cdc.gov/ncbddd/blooddisorders/women/menorrhagia.html>
4. Clue. Heavy Periods: How to tell if your heavy periods are normal. <https://helloclue.com/articles/cycle-a-z/heavy-periods-how-to-tell-if-your-heavy-periods-are-normal>
5. FDA PATIENT INFORMATION WEBSITE ON ENDOMETRIAL ABLATION (“Endometrial Ablation for Heavy Menstrual Bleeding”) <https://www.fda.gov/medical-devices/surgery-devices/endometrial-ablation-heavy-menstrual-bleeding>

9. Glossary

Anesthesia: Medical treatment with drugs to reduce and/or stop pain, usually used to prevent pain during surgery.

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 (“D & C”): A surgical procedure your doctor uses to go through your vagina and cervical canal to gently remove the lining of the uterus (endometrium).

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.

FDA: The United States Food and Drug Administration is the government agency whose mission is to protect and promote public health by giving the public access to safe and effective medical products.

Fibroids: Noncancerous tumors of the uterine muscle that can alter the shape of the uterine cavity and be the cause of excessive menstrual bleeding.

General Anesthesia: Under general anesthesia, you are completely unconscious and unable to feel pain

during medical procedures. General anesthesia usually uses a combination of intravenous drugs and inhaled gasses.

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

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: A procedure completed using a hysteroscope, a thin, lighted telescope that is inserted into the vagina to examine the cervix and inside of the uterus.

Intrauterine Device (“IUD”): 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.

Progesterone or progestin: A hormone made by your body. Progesterone has a very important role in your menstrual cycle, becoming pregnant, and many other body functions. A progestin is the form of progesterone found in medical treatments.

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

Uterus: Also known as the womb, the uterus is the part of the female reproductive system that is responsible for the development of a fetus during pregnancy.