

PATIENT INFORMATION

ABOUT EXCESSIVE
MENSTRUAL BLEEDING



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The Genesys HTA™ System Treatment

What you need to know...

ABOUT THE GENESYS HTA™ SYSTEM TREATMENT

We understand how debilitating heavy periods can be. That is why we designed the Genesys HTA System to give you the potential opportunity to return to the things you love to do.

The Genesys HTA System therapy is an outpatient procedure that uses heated saline to treat the uterine lining, or endometrium. Once treated, most women no longer experience the symptoms or effects of a heavy period. Many women stop having their period altogether.¹

As with any menorrhagia treatment, this may or may not be appropriate for you, so consult with your doctor to find out if the Genesys HTA System therapy is right for you.

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What is Excessive Menstrual Bleeding, or menorrhagia?

Excessive Menstrual Bleeding, clinically known as menorrhagia, pronounced *men-or-ah-zha*, is a prolonged or abnormally heavy menstrual period. The following symptoms may be indicative of menorrhagia^{2,3}:

- Periods lasting longer than seven days
- Soaking through one or more sanitary pads or tampons in an hour
- Menstrual flow that includes large blood clots
- Menstrual flow that is heavy enough to interfere with your daily activities
- Fatigue or other anemia-like symptoms

If you are experiencing any of these symptoms consult with your doctor about the possibility that you may have menorrhagia.

How common is menorrhagia?

It is estimated that menorrhagia affects 1 in every 5 women. It is a common but treatable condition. This brochure is designed to help inform you about what menorrhagia is and some of your treatment options, but before you make any decisions talk with your doctor.⁴

What causes menorrhagia?

There are several different causes of menorrhagia.^{5,6} The most common of these are:

- **Hormonal Imbalance** – An imbalance of estrogen and progesterone—hormones that control the build up and monthly shedding of endometrium, the inner lining of the uterus—can lead to heavy periods.
- **Uterine Fibroids & Polyps** – These usually benign (non-cancerous) structures can occur almost anywhere in the uterus. Fibroids and polyps may contribute to heavy periods.
- **Infection** – Infections of the uterus and cervix may cause heavy bleeding.
- **Bleeding Disorders** – Disorders that impair the blood from coagulating and clotting can result in excessive menstrual bleeding.^{3,5}
- **Uterine Cancer** – A rare, but potential cause of menorrhagia. For this reason, your doctor will determine the cause of your menorrhagia before deciding on a treatment option.

Your physician will best be able to determine what is causing your excessive bleeding.

How can menorrhagia be treated?

There are a variety of treatment options available to you. Some of these are listed below. To determine the right course of action and to make sure that you thoroughly understand all the benefits and risks, talk with your physician.

Drug Therapy

Hormones, NSAIDs are both commonly used drug therapies. Hormones are delivered through a variety of methods, most commonly birth control pills or an intrauterine device. However, it is not always effective at controlling excessive bleeding. Additionally, as common to hormonal treatments, some women may experience an increased risk of blood clots and breast cancer, or side effects such as high blood pressure, headaches or migraines, depression and weight fluctuation.^{6,7,8} Talk to your physician about other drug therapy options. Drug therapy may be a treatment for women who wish to have more children as the treatments are reversible.

Dilatation and Curettage

An outpatient procedure that scrapes away the endometrium and may provide temporary relief of heavy periods. This is generally not a long term solution as relief usually lasts for only a few cycles. Risks include perforation of the uterus wall, injury to the bowel or other internal organs, bleeding and infection. This treatment may be an option for women who wish to have more children as it should not have an effect on fertility.

Hysterectomy

Hysterectomy, surgical removal of the uterus, will eliminate periods or stop heavy bleeding. For women in whom the cervix is left, some may experience light spotting. However, this is a major surgery done under general or regional anesthesia. A hospital stay is usually required and the recovery time is significantly longer than for other treatments.⁹ Your physician may determine that a hysterectomy is appropriate when other therapies have failed or are not an option. A woman cannot get pregnant after a hysterectomy.

Endometrial Ablation

Endometrial Ablation is a procedure that is intended to treat and remove the lining of the uterus. The uterine lining or endometrium is tissue that thickens and sheds in cycles causing your period. After this tissue is removed most women see a marked reduction in the heaviness of their menstrual flow, and some may never experience a period again. It may be performed in an outpatient or office setting. There are several ways in which endometrial ablation can be done; through heated fluid, a heated balloon, microwave energy, freezing, radiofrequency, or electrosurgery. Not all patients will experience a satisfactory reduction in bleeding so all treatment options should be discussed with your physician. Risks for endometrial ablation procedures include infection, bleeding, injury to organs including perforation and/or burns. Although endometrial ablation significantly decreased the likelihood of pregnancy, it is not a sterilization procedure.¹⁰ You should seek advice from your physician about appropriate birth control methods.

What is the Genesis HTA™ System?

How does it work?

The Genesis HTA System treatment uses a sheath that is employed by your physician to perform an endometrial ablation. The system allows saline heated to 90°C (194°F) to be circulated in the uterus.

After a slight dilation of the cervix, a slim procedure sheath will be placed in your cervix. Your uterus will be filled with room temperature saline. The saline will conform to your uterus and circulate throughout the procedure. (Figure 1) Your physician will then look inside your uterus with a hysteroscope, or a small camera, that fits inside of the procedure sheath.

The saline circulating in your uterus will then be heated to 90°C (194°F) by the Genesis HTA System Console. As the heated saline comes in contact with the uterine walls, the saline will begin to heat the endometrium. (Figure 2) This heat is intended to destroy the endometrium. This treatment cycle takes about 10 minutes.

After the treatment cycle has been completed the uterus will be flushed with cool saline (Figure 3). The cool saline is drained and the procedure sheath is removed.



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Figure 1:
Uterus being
filled with
saline.

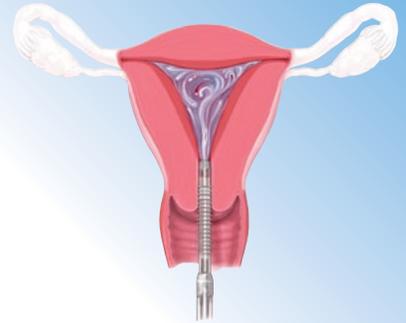


Figure 2:
Uterus with
circulating
heated
saline and
subsequent
blanching of
uterine
lining.



Figure 3:
Post-
procedure,
uterus being
cooled
with room
temperature
saline.



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Who is a candidate for the Genesys HTA™ System Procedure and is it the right treatment for me?

The Genesys HTA System is for use in premenopausal women with menorrhagia due to benign causes for whom childbearing is complete. Only you and your physician can decide if this is the right treatment for you. Your physician may want to do some preliminary tests to determine what is causing your menorrhagia such as a pap smear or an ultrasound.

What will I experience during the procedure?

You and your physician will decide what anesthesia will be best for you. Your options for anesthesia are to be fully asleep so that you do not feel anything during the procedure, to be partially sedated so that you feel drowsy during the procedure, or to receive only local anesthesia and be fully awake during the procedure. If you choose to be awake, you may feel some discomfort, such as mild cramping, during the procedure but it should not be painful. Your physician may give you pain medication before the procedure to help reduce cramping during or after the procedure.

What should I expect after my treatment?

You can expect some light cramping the day of your treatment. Some other common side effects you may experience include nausea and vomiting. Most women are able to return to normal activities by the next day. However, you should speak with your physician about resuming sexual activity.

As your endometrium begins to slough off after the treatment, you may experience some discharge or other symptoms similar to your menstrual period. These symptoms may occur for several weeks after your treatment. You should not use tampons for seven days after your procedure to reduce your risk of infection. Your periods may continue to be heavy for a few months after the procedure as part of the healing process. However, this should improve after a few months.

If you experience two days of heavy bleeding, abdominal or pelvic pain, a fever, or pain that increases over time beyond 24 hours after the procedure, call your physician.

What can I expect from my Genesys HTA™ System Treatment?

The majority of women see a dramatic decrease in the length and heaviness of their period. In clinical trials, after three years the majority of women reported a reduction of bleeding to normal levels or less.¹ In patients that completed the study 98% of women were satisfied with their periods.¹²



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Can I get pregnant after the Genesys HTA™ System procedure?

You should not have this procedure if you desire to get pregnant in the future. Although endometrial ablation significantly reduces the chances for pregnancy, it does not prevent you from getting pregnant. A pregnancy after endometrial ablation would be high risk for both mother and child. Contraception or sterilization should be used after this treatment to prevent pregnancy as it can still occur. Please discuss your birth control options with your physician.



What are the risks of the Genesys HTA™ System procedure?

Your physician should explain all the potential risks of your menorrhagia treatment to you.

Possible risks for all endometrial ablation procedures are: perforation (creation of a hole) of the uterus; bleeding; infection; injury to organs within the abdomen (e.g., bowel) and pelvis or to adjacent tissue (e.g., cervix and vagina); post-ablation tubal sterilization syndrome (a complication in women who have undergone tubal sterilization following endometrial ablation which can occur as long as 10 years after your ablation); and delayed diagnosis of cancer of the endometrium.

The risk of serious injury such as perforation (creation of a hole) of the uterus and injury to internal organs with the Genesys HTA System is low. However, there is a risk that heated fluid may leak out of your uterus during the procedure and result in a burn to your vagina or surrounding areas. These burns are usually treatable by your doctor with medicated cream. In very rare cases it may be necessary to seek specialized care from a burn center.

The Genesys HTA™ System is designed to reduce menstrual flow in women who suffer from menorrhagia and allow them the potential opportunity to return to the activities that they love.

Refer to Genesys HTA™ System Installation and Operator's Manual provided with product for complete instructions for use.

INDICATIONS: The Genesys HTA System is a hysteroscopic thermal ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete. **CONTRAINDICATIONS:** The Genesys HTA System is contraindicated for use in a patient: who is pregnant or wants to be pregnant in the future, as pregnancy after ablation can be dangerous to both mother and fetus; who has known or suspected endometrial carcinoma or premalignant change of the endometrium, such as adenomatous hyperplasia; who has active pelvic inflammatory disease or pyosalpinx; hydrosalpinx; in whom a tight cervical seal cannot be established and maintained around the procedure sheath; who has any anatomical or pathologic condition in which weakness of the myometrium could exist, such as, prior classic cesarean section or transmural myomectomy; who has an intrauterine device in place; or who has active genital or urinary tract infection, e.g., cervicitis, endometritis, vaginitis, cystitis, etc., at the time of treatment. **POTENTIAL ADVERSE EFFECTS** that may occur include: pain, cramping, nausea, vomiting, bleeding, infection, laceration, Endometritis, thermal injury to adjacent tissue including cervix, vagina, vulva, and/or perineum; heated saline escaping from the device system into the vascular spaces; hemorrhage; perforation of uterus; complications with pregnancy (Note: pregnancy following ablation is dangerous to both the mother and the fetus); risks associated with hysteroscopy, complications leading to serious injury and death, post-ablation tubal sterilization syndrome, and delayed diagnosis of cancer of the endometrium. **WARNINGS:** NOTE: Failure to follow any instructions or to heed any Warnings or Precautions could result in serious patient injury. **CAUTION: Federal Law restricts this device to sale by or on the order of a physician. The physician using the device must be trained in diagnostic hysteroscopy.**

Individuals depicted are models and included for illustrative purposes only.

¹ Evaluated population Goldrath MH. Evaluation of HydroThermAblator and rollerball endometrial ablation for menorrhagia 3 Years after treatment. J Am Assoc Gynecol Laparosc. 2003;10(4): 505-511.

² Warner, PE., Critchley, HOD, et al. Menorrhagia I: Measured blood loss, clinical features and outcome in women with heavy periods: A survey with follow-up data. American Journal of Obstetrics and Gynecology (2004) 190, 1216-23.

³ Mayo Clinic information on Menorrhagia: <http://www.mayoclinic.com/health/menorrhagia/DS00394>

⁴ Rosenbaum, SP, Fried, M., et al. Endometrial hydrothermablation: A comparison of short-term clinical effectiveness in patients with normal endometrial cavities and those with intracavitary pathology. Journal of Minimally Invasive Gynecology (2005) 12, 144-149.

⁵ Osei, J. Menorrhagia, mechanisms and targeted therapies. Current Opinion in Obstetrics and Gynecology. 2005, 17: 411-418.

⁶ Burkman, R., Schlesselman, JJ., et al. Safety concerns and health benefits associated with oral contraception. American Journal of Obstetrics and Gynecology (2004) 190: S5-22.

⁷ Kaunitz, AM. Beyond the pill: New data and options in hormonal and intrauterine contraception. American Journal of Obstetrics and Gynecology (2005) 192, 998-1004.

⁸ ACOG Education Pamphlet AP021 – Birth Control Pills. January 2006.

⁹ Carter JE. Alternatives to total abdominal hysterectomy. Journal of Society of Laparoscopic Surgeons. 1997;1:259-262.

¹⁰ ACOG Education Pamphlet AP134 – Endometrial Ablation. March 2009.

¹¹ Taber's Cyclopedic Medical Dictionary. F.A. Davis Company, Philadelphia, PA. 1997.

¹² Genesys HTA System User's Manual.

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