The Genesys HTA™ System is designed to reduce menstrual flow in women who suffer excessive menstrual bleeding due to benign causes for whom childbearing is complete. Any user who considers ablation should understand that your physician can describe this as the right treatment for you. This procedure may result in some potential negative outcomes in women who are causing menstrual flow. A medical professional should always be present during each procedure.

Who is a candidate for the Genesys HTA™ System procedure? The Genesys HTA System is the use in primate-weeks experience with menorrhagia due to benign causes for whom childbearing is complete. Only your own physician can determine if this is the right treatment for you. Your physician may want to see some preliminary tests performed before they consider your treatment choices such as counseling or an ultrasound.

What is the indication for the treatment? This procedure should result in a reduction of menstrual flow and may be used to reduce the risk of symptomatic endometrial cancer. This treatment may also be used to reduce the risk of postmenopausal bleeding. Your physician may want to discuss these options with you before choosing the right treatment for you.

What is the risk of the treatment? The risk of this procedure in terms of treatment-induced endometrial cancer is very small. Your physician should discuss the potential risks of this treatment with you before choosing the right treatment for you.

What should I expect before the treatment? You should follow any instructions or heed any warnings given by your physician prior to the procedure. Your physician will perform a physical examination prior to the procedure to determine if you are a candidate for this treatment. Your physician may order a Pap smear, pelvic exam, and/or ultrasound before choosing the right treatment for you.

What should I expect after the treatment? You should expect some side effects following the procedure. Some women may experience nausea and vomiting. Your physician may want to discuss these options with you before choosing the right treatment for you.

Can I get pregnant after the Genesys HTA™ System procedure? Your physician will discuss the procedure in detail with you and should address any questions you may have. Please discuss your birth control options with your physician.

Glossary
Menorrhagia – Abnormally heavy menstrual bleeding.
Fallopian Tube – A duct through which blood and tissue is passed during menstruation and through which a baby is born during pregnancy.
Ovary – A gland that produces and releases monthly. These organs also produce estrogen and progesterone.
Endometrium – The membrane that lines the uterus.
Uterine Cavity – The cavity in which fetus develop during gestation. Sometime referred to as the womb.

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The Genesys HTA System is intended for use in primate-weeks experience with menorrhagia due to benign causes for whom childbearing is complete. Only your own physician can determine if this is the right treatment for you. Your physician may want to see some preliminary tests performed before they consider your treatment choices such as counseling or an ultrasound.

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What you need to know...

ABOUT THE GENESYS HTA™ SYSTEM TREATMENT

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

The most common of these are:

- Heavy or prolonged bleeding
- Blood clots in your menstrual period
- Nausea or other symptoms like fatigue or other anemia-like symptoms
- Menstrual flow that includes large blood clots
- Periods lasting longer than seven days
- Menstrual flow that is so intense you need to change your sanitary pads or tampons in an hour
- Menstrual flow that is so intense you need to change your sanitary pads or tampons every two hours
- Menstrual flow that is so heavy it interferes with your daily activities
- Fatigue or other symptoms like dizziness

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

What causes menorrhagia?

It is estimated that menorrhagia affects 1 in 5 women. It is a common but not inevitable condition. This condition is designed to help inform you about what menorrhagia is and some of your treatment options. Also, this article will make you realize some stigmas with your doctor.

What causes menorrhagia?

There are several different causes of menorrhagia.2

- Endometrial Hyperplasia – a condition of excess tissue and growth of the uterine lining - can lead to heavy periods.
- Uterine Fibroids & Polyps – these usually benign (non-cancerous) conditions can cause heavy periods in addition.
- Fibroids and polyps may combine to cause heavy periods.
- Infection – Infections of the uterus and cervix can cause heavy bleeding.
- Bladder Distress – Inflammation that impacts the bladder and cervix can result in excessive menstrual leakage.
- Uterine Cancer – A rare, but potential cause of menorrhagia. For this reason, your doctor will determine the cause of your symptoms 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 several different types of treatments that can be used to help you. Some of these are listed below.

- Drug Therapy
- Surgery
- Endometrial Ablation

Drug Therapy

Various medications are used which are referred to as non-hormonal therapy. They are delivered through a variety of methods, most commonly by oral pain or intravenous therapy. Additionally, some women may require additional evaluation, testing, and follow-up.10 Other than non-hormonal therapy, there are minor side effects with high blood pressure, headaches or migraines, depression and weight fluctuations.4

Surgery

Surgery may be performed as an outpatient procedure. Surgery is usually done as a last resort when other treatment options have failed. Surgery generally means a stay in the hospital and reinforcement of the surgical site. Surgery is accomplished using an incision to access the uterus, which is then excised. Depending upon the method of surgery, the uterus is either removed or removed.

Endometrial Ablation

Endometrial Ablation is a procedure that is intended to treat and remove the lining of the uterus. The uterine lining is an endometrium. Large, thickened, and usually irregular sized endometrium can cause heavy bleeding. Small amounts of blood are removed each month during the menstrual period. The uterine lining is removed through 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 (194ºF) and circulated throughout the procedure. The saline is employed by your physician to perform an endometrial ablation. The system allows saline heated to 90°C (194ºF) to be circulated in the uterus.

After a slight dilation of the cervix, a saline balloon 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. After the treatment cycle has been completed the uterus will be flushed with cold saline. The cold saline is drained and the procedure sheet is removed.

How does it work?

The Genesys System treatment uses a balloon that is deployed by your physician to perform an endometrial ablation. The system saline solution heated to 98.6°F (37°C) to be circulated in the uterus.

After a slight dilation of the cervix, a saline balloon sheath will be placed in your cervix. Your uterus will be filled with saline at room temperature. The saline will conform to your uterus and circulate throughout the procedure. After the treatment cycle has been completed the uterus will be flushed with cold saline. The cold saline is drained and the procedure sheet is removed.
What you need to know...

ABOUT THE GENESYS HTA™ SYSTEM TREATMENT

The Genesys HTA System is a treatment procedure that uses heated saline to treat the lining of your uterus, called the endometrium. The saline is heated to 90°C (194°F) and serves to destroy the endometrium.

The Genesys HTA System is indicated for the treatment of heavy menstrual bleeding, clinically known as menorrhagia, in women who are not pregnant.

What is Excessive Menstrual Bleeding, or menorrhagia?
Excessive Menstrual Bleeding, clinically known as menorrhagia, is pronounced men-ah-zha. It is a prolonged or abnormally heavy menstrual period. The following symptoms may be indicative of menorrhagia:
- Periods lasting longer than seven days
- Menstrual flow that is so severe your sanitary pads or tampons are in use for an hour or more
- Menstrual flow that is longer in duration than you actually have your menstrual period
- Menstrual flow that is heavier enough to interfere with your daily activities
- Fatigue or other adverse side effects

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

What causes menorrhagia?
It is estimated that menorrhagia affects 1 in 5 women. It is a common but treatable condition. This brochure is designed to help you understand about the possibility that you may have menorrhagia.

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

As with any menorrhagia treatment, this may or may not work for you. As with your doctor in deciding if the Genesys HTA System therapy is right for you.

What is the Genesys HTA System?

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Drugs Therapy
Drug therapy options include birth control pills, non-steroidal anti-inflammatory drugs (NSAIDs), hormones, and anti-depressants.

Menorrhagia is often treated with hormones. Hormones are delivered through a variety of methods, most commonly oral birth control pills. This is an oral medication that is frequently prescribed. It is not a cure, but instead it provides relief from excessive bleeding.

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Endometrial Ablation
Endometrial ablation is a procedure that is intended to treat and remove the lining of the uterus. The uterine lining is an endometrial tissue that is shed and replaces itself every cycle. Endometrial ablation has been performed as an acceptable alternative for women who are not candidates for hormonal therapy or other therapies. There are several different devices that are used for endometrial ablation. The choice of which device to use depends on the extent of disease and the severity of the symptoms. One such device is the Genesys HTA System.

Dilatation and Curettage
Dilatation and curettage (D&C) is a simple outpatient surgical procedure that is used to remove the lining of the uterus. It is a common procedure that can be performed in an office or hospital setting. The procedure is performed under sedation and is not considered a major surgery. It is used to diagnose and treat a variety of conditions, including menorrhagia.

Hysterectomy
Hysterectomy is a surgical procedure that removes the uterus. It is a common procedure that can be performed in an office or hospital setting. The procedure is performed under sedation and is not considered a major surgery. It is used to diagnose and treat a variety of conditions, including menorrhagia.

Anticoagulants
Anticoagulants are medications that are used to prevent blood clots. They are commonly used to treat and prevent the formation of blood clots. Anticoagulants are often prescribed to patients who have had a recent procedure, such as surgical procedures or childbirth.

Blood Clotting Problems
Blood clots can form in the blood vessels of the body. They can be caused by a variety of factors, including a genetic disorder, a medical condition, or an injury. Blood clots can be dangerous if they block the blood vessels and prevent the blood from flowing to the tissues. Blood clots can cause tissue damage and even death if they block the blood vessels supplying the heart or brain.

What is the Genesys HTA System?

The Genesys HTA System is an outpatient procedure that uses heated saline to treat the lining of your uterus, called the endometrium. The saline is heated to 90°C (194°F) and serves to destroy the endometrium.

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How does it work?
The Genesys HTA System treatment uses a sheath that is employed by your physician to perform an automated endometrial ablation. The procedure takes less than 90 minutes to be completed in the catheter.
ABOUT THE GENESYS HTA™ SYSTEM TREATMENT

Endometrial Ablation

Endometrial Ablation

The Genesys HTA System is a proven surgical alternative to hysterectomy for the treatment of menorrhagia. The Genesys HTA System uses a sheath that is inserted through the cervix and into the uterus. The sheath allows for a minimally invasive ablation procedure that can be performed in an outpatient or office setting.

The Genesys HTA System treatment is an outpatient procedure that uses heat to treat the lining of the uterus, endometrium. Once treated, most women no longer experience the symptoms of a heavy period. Many women stop having their period altogether.

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

What causes menorrhagia?

There are several different causes of menorrhagia. These usually benign (non-cancerous) conditions can appear anywhere within the uterus, Fallopian tubes and ovaries. Some of the common causes are:

Hormonal Imbalance – An imbalance of estrogen and progesterone can cause the uterus to continually thicken and shed in cycles causing your period. After this tissue is removed, some women experience light spotting. However, this is a major surgery done under general anesthesia. Recovery time is significantly longer than for other treatments.

Drug Therapy

Drugs 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 therapies, some women may experience an increase in blood loss and cramping, or side effects such as high blood pressure, headaches or depression, insomnia and weight fluctuations. Drug therapy is employed by your physician to perform an endometrial ablation procedure.

Dilatation and Curettage

Dilatation and Curettage (D&C) is a minimally invasive outpatient procedure that scrapes away the endometrium and may be performed in an outpatient or office setting. There are several ways in which endometrial ablation can be performed including heated saline, laser, microwave, and cryoablation. Drug therapy may be prescribed to bring about relief of heavy periods. This treatment may be an option for women who wish to have more children as it is reversible. 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, and you should discuss them with your physician. Some of these are elective. To determine the right course of action and to make sure that you thoroughly understand all the benefits and risks, talk to your physician.

What is the Genesys HTA System? How does it work?

Dr. Robert B. Luebke, Gynecologist & Obstetrician, has successfully treated heavy periods using the Genesys HTA System. The Genesys HTA System has been shown to significantly decrease the likelihood of pregnancy, it is not a sterilization procedure. You should seek advice from your physician about appropriate birth control options.

The Genesys HTA System is a proven surgical alternative to hysterectomy for the treatment of menorrhagia. The Genesys HTA System uses a sheath that is inserted through the cervix and into the uterus. The sheath allows for a minimally invasive ablation procedure that can be performed in an outpatient or office setting.

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

What is the Genesys HTA System treatment?

The Genesys HTA System treatment uses a sheath that is employed by your physician to perform an endometrial ablation. The system relies on heat to destroy the endometrium.

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ABOUT THE GENESYS HTA™ SYSTEM TREATMENT

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Am I a potential candidate for the Genesys HTA System procedure?

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What is the Genesys HTA System?

What do the numbers mean?

How does it work?

The Genesys HTA System treatment uses a sheath that is employed by your physician to perform an endometrial ablation. The system allows saline to be circulated in the uterus.

After a slight dilation of the cervix, a saline preload sheath will be placed in your uterus. The saline will be filled and room temperature saline will be circulated into your uterus and circulated through the procedure sheath. (Figure 1) Your procedure will then take place using your saline and a saline sheath in the uterus.

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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 the use in premenopausal women with menorrhagia due to benign causes for whom childbearing is complete. Only your physician can determine if this is the right treatment for you. You physician may want to do some preoperative tests to determine what is causing your menorrhagia such as a pap smear, endometrial biopsy, and hormone tests.

What will I experience during the procedure?

You and your physician will decide what anesthesia will be best for you. You can choose to have local anesthesia, general anesthesia, or IV sedation, depending on your preference. You can wake up and go home the same day of the procedure depending on how much the anesthesia will affect you. If you choose to have general anesthesia you will choose to remain in bed for a few days.

What should I expect after my treatment?

You should expect some light cramping the day of your treatment. Some patients report a fever the day after the procedure. Your physician may prescribe a pain reliever for you. You should continue to follow your physician's advice about sexual activity.

As your uterus 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 wear tampons seven days after your procedure to reduce your risk of infection. Your period may continue to be heavy for a few months after the procedure as part of the healing process. However, this is a good indicator of a new menstrual cycle.

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.

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

It is important to use effective contraception during the first year after your treatment. You should not use tampons for seven days after your treatment. If you choose to get pregnant, you will need to undergo tubal sterilization following endometrial ablation to prevent pregnancy.

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

The risks associated with your procedure may include:

- Pain, cramping, or nausea and vomiting. Most women are able to return to normal activities the next day. However, you should speak with your physician about resuming sexual activity.
- Fever or pain that increases beyond 24 hours after the procedure.
- Discharge or other symptoms similar to your menstrual period.
- Blood in your urine.
- Blood clots in your urine or vagina.
- Nausea and vomiting.
- Blood clots, which may be a sign of serious injury.

What are the risks of the Genesys HTA™ System procedure for menorrhagia treatment to you.

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

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You should undergo tubal sterilization 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 and sterilization should be used after the treatment to prevent pregnancy as it can still occur.

Please discuss your birth control options with your physician.

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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.

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

It is important to use effective contraception during the first year after your treatment. You should not use tampons for seven days after your treatment. If you choose to get pregnant, you will need to undergo tubal sterilization following endometrial ablation to prevent pregnancy.

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

The risks associated with your procedure may include:

- Pain, cramping, or nausea and vomiting. Most women are able to return to normal activities the next day. However, you should speak with your physician about resuming sexual activity.
- Fever or pain that increases beyond 24 hours after the procedure.
- Discharge or other symptoms similar to your menstrual period.
- Blood in your urine.
- Blood clots in your urine or vagina.
- Nausea and vomiting.
- Blood clots, which may be a sign of serious injury.

What are the risks of the Genesys HTA™ System procedure for menorrhagia treatment to you.

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

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

You should undergo tubal sterilization 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 and sterilization should be used after the treatment to prevent pregnancy as it can still occur.

Please discuss your birth control options with your physician.
**INDICATIONS:**
The Genesys HTA™ System is designed to reduce menstrual flow in women who suffer 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 ask you to do some preliminary tests to determine what is causing your menorrhagia such as a sonogram or an ultrasound.

**Who is a candidate for the Genesys HTA™ System procedure?**

- Procedure and is it the right treatment for me?
- As a candidate for the Genesys HTA™ System procedure, you should:
  - Have completed childbearing
  - Be free of endometrial pathology
  - Not be pregnant
  - Not 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.
  - Not 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.
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**What is the risk of the Genesys HTA™ System procedure?**

- Can I get pregnant after the Genesys HTA™ System procedure?
- System procedure?
- You should discuss the procedure with your doctor if you desire to get pregnant in the future. Although endometrial ablation significantly reduces the risk of pregnancy, it is not a guarantee that you will not get pregnant. A pregnancy after endometrial ablation would be high risk for both mother and baby. Consideration or sterilization should be a part of the treatment to prevent pregnancy if it is still an option. Please discuss your birth control options with your physician.

**Who is a candidate for the Genesys HTA™ System procedure?**

- Procedure and is it the right treatment for me?
- You may experience some discharge or other symptoms similar to your menstrual period. These symptoms may occur for several weeks after the procedure as part of the healing process. However, this should improve over a few months.

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**Who is a candidate for the Genesys HTA™ System procedure?**

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**Who is a candidate for the Genesys HTA™ System procedure?**

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**Who is a candidate for the Genesys HTA™ System procedure?**

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**Who is a candidate for the Genesys HTA™ System procedure?**

- Procedure and is it the right treatment for me?
- You may experience some discharge or other symptoms similar to your menstrual period. These symptoms may occur for several weeks after the procedure as part of the healing process. However, this should improve over a few months.
The Genesys™ HTA System is designed to reduce menstrual flow in women who suffer from heavy periods. It is an office-based procedure performed for any women who has failed to respond to more conservative medical therapy and is effective and safe in properly selected women with heavy periods. This system is intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia due to benign causes for whom childbearing is intended. It may not be appropriate for all patients. The effectiveness of any ablation procedure cannot be assessed in a prospective manner.

Who is a candidate for the Genesys™ HTA System?

The Genesys™ HTA System is for use in premenopausal women with menorrhagia due to benign causes for whom childbearing is intended. It may not be appropriate for all patients. The effectiveness of any ablation procedure cannot be assessed in a prospective manner.

Who is a candidate for the Genesys™ HTA System?

- Women who are pregnant or want to be pregnant in the future
- Women who have undergone surgical sterilization

Who is a candidate for the Genesys™ HTA System?

- Who is a candidate for the Genesys™ HTA System?
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What are the risks of the Genesys™ HTA System?

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

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

- You can expect some light cramping the day of your treatment
- If you experience two days of heavy bleeding, abdominal or pelvic pain, a fever, or if pain increases over time beyond 24 hours after the procedure

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
- The majority of women see a dramatic decrease in the length and heaviness of their period

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

- The majority of women see a dramatic decrease in the length and heaviness of their period
- The majority of women see a dramatic decrease in the length and heaviness of their period

What should I expect after my treatment?

- You may give you pain medication before the procedure to help reduce
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What should I expect after my treatment?
NOTE: Failure to follow any instructions or to heed any Warnings or Precautions could result in hysteroscopy, complications leading to serious injury and death, post-ablation tubal occlusion (which is dangerous to both the mother and the fetus); risks associated with infection of the vulva, and/or perineum; heated saline escaping from the device system into the vascular system; burns of adjacent tissue (e.g., cervix and vagina); post-ablation tubal occlusion in women who have undergone laparoscopic sterilization; injury to organs within the abdomen (e.g., bowel) and pelvis or to adjacent tissue (e.g., cervix and vagina); post-ablation tubal occlusion in women who have undergone laparoscopic sterilization; injury to organs within the abdomen (e.g., bowel) and pelvis; perforation (creation of a hole) of the uterus; bleeding; infection; and even death. It is very important that you and your physician understand all of the potential risks associated with the Genesys HTA™ System procedure.

Who is a candidate for the Genesys HTA™ System procedure and is it the right treatment for me? The Genesys HTA™ System is for the treatment of women with menorrhagia due to benign causes for whom childbearing is complete. Only you and your physician can determine if this is the right treatment for you. Your physician may suggest you do some pre-menstrual tests to determine if you are causing a significant amount of menstrual blood.

What should I expect after my treatment? You can expect some light bleeding the day of your treatment. Some patients report that they experience minor nausea and vomiting during the procedure. If you experience any nausea or vomiting during the procedure, it should not be painful. Your physician may give you medication before the procedure to help reduce nausea during or after the procedure.

What are the risks of the Genesys HTA™ System procedure? Your physician should explain all the potential risks of your menorrhagia treatment to you. Please discuss your birth control options with your physician.

Can I get pregnant after the Genesys HTA™ System procedure? You should discuss this procedure with your doctor if you desire to get pregnant in the future. Although endometrial ablation significantly reduces the frequency of pregnancy, there is not a guarantee that you will not become pregnant after ablation. A pregnancy after endometrial ablation would have a high risk for mother and child. Consultation with your physician should be held well before the treatment to prevent pregnancy, if it can still occur.

Who is a candidate for the Genesys HTA™ System procedure and is it the right treatment for me? The Genesys HTA™ System is for the treatment of women with menorrhagia due to benign causes for whom childbearing is complete. Only you and your physician can determine if this is the right treatment for you. Your physician may suggest you do some pre-menstrual tests to determine what is causing your menorrhagia such as a pap test and tests for infections. Some patients report that they experience minor nausea and vomiting during the procedure. If you experience any nausea or vomiting during the procedure, it should not be painful. Your physician may give you medication before the procedure to help reduce nausea during or after the procedure.

What should I expect after my treatment? You can expect some light bleeding the day of your treatment. Some patients report that they experience minor nausea and vomiting during the procedure. If you experience any nausea or vomiting during the procedure, it should not be painful. Your physician may give you medication before the procedure to help reduce nausea during or after the procedure.

What are the risks of the Genesys HTA™ System procedure? Your physician should explain all the potential risks of your menorrhagia treatment to you. Please discuss your birth control options with your physician.

Can I get pregnant after the Genesys HTA™ System procedure? You should discuss this procedure with your doctor if you desire to get pregnant in the future. Although endometrial ablation significantly reduces the frequency of pregnancy, there is not a guarantee that you will not become pregnant after ablation. A pregnancy after endometrial ablation would have a high risk for mother and child. Consultation with your physician should be held well before the treatment to prevent pregnancy, if it can still occur. Please discuss your birth control options with your physician.
ADVERSE EFFECTS

The Genesys HTA System is contraindicated for use in:
- Any patient who is pregnant or wants to be pregnant in the future, as pregnancy after ablation can be dangerous to both mother and fetus;
- Any patient: who is pregnant or wants to be pregnant in the future, as pregnancy after ablation can be dangerous to both mother and fetus;
- Any patient who has any anatomical or pathologic condition in which weakness of the myometrium can occur, such as adenomatous hyperplasia or a diagnosis of cancer of the endometrium.

Possible risks for all endometrial ablation procedures are:
- Perforation (creation of a hole) of the uterus; bleeding; infection;
- The risk of serious injury such as perforation (creation of a hole) of the uterus; bleeding; infection; sterilization syndrome (a complication in women who have had an endometrial ablation).

Possible complications leading to serious injury and death, post-ablation tubal infection, laceration, endometritis, thermal injury to adjacent tissue including cervix, vagina, or surrounding areas can occur. These burns can usually be treated by your doctor with medicated cream. In very rare cases it may be necessary to seek specialized care from a burn center.

What should I expect after my treatment?

You may feel some light cramping the day of your treatment. Some women may experience nausea and vomiting. Most women are able to return to normal activities the next day. However, you should consult with your physician about resting normal activity.

As your uterus begins to slough off after the treatment, you may experience some discomfort or other symptoms such as your menstrual period. These symptoms may recur for several weeks after your treatment. You should not resume any exercises on your period.

Possible risks for all endometrial ablation procedures are:
- The majority of women see a dramatic decrease in the length and heaviness of their periods. In clinical trials, after the procedure, the majority of women expressed a reduction of bleeding in normal weeks or less. In patients that completed the study, 88% of women were satisfied with their periods.

The Genesys HTA System is for use in premenopausal women with normal uterine size for whom childbearing is intended. Only you and your physician can decide if this is the right treatment for you. Your physician may suggest to do the same prenatal tests to determine what is cause you many side effects such as amenorrhea or irregular menses.

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 medication before the procedure to help reduce discomfort during or after the procedure.

What are the risks of the Genesys HTA System procedures?

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

Possible risks for all endometrial ablation procedures are:
- Perforation (creation of a hole) of the uterus; bleeding; infection; sterilization syndrome (a complication in women who have undergone tubal sterilization following endometrial ablation). This can occur in long or short-term use; and delayed diagnosis of cancer of the endometrium.

The risk of serious injury such as perforation (creation of a hole) of the uterus; bleeding; infection; sterilization syndrome (a complication in women who have undergone tubal sterilization following endometrial ablation) can be dangerous to both mother and fetus.

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

You should consult with your physician if you desire to get pregnant in the future. Although endometrial ablation significantly reduces risk of pregnancy for 3 years after your procedure, getting pregnant 3 years after ablation would be high risk for mothers and infants. Consultation on contraception should be offered before the treatment to prevent pregnancy as it can still occur. Please discuss your birth control options with your physician.

Glossary

Gland – The glands in which eggs, or ovum, are produced. Sperm travels down these tubes and into the uterine cavity.

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