

Treatment Options for Heavy Periods



Gynecare 
Thermachoice[®]

Uterine Balloon Therapy System



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Heavy Periods: Know Your Options

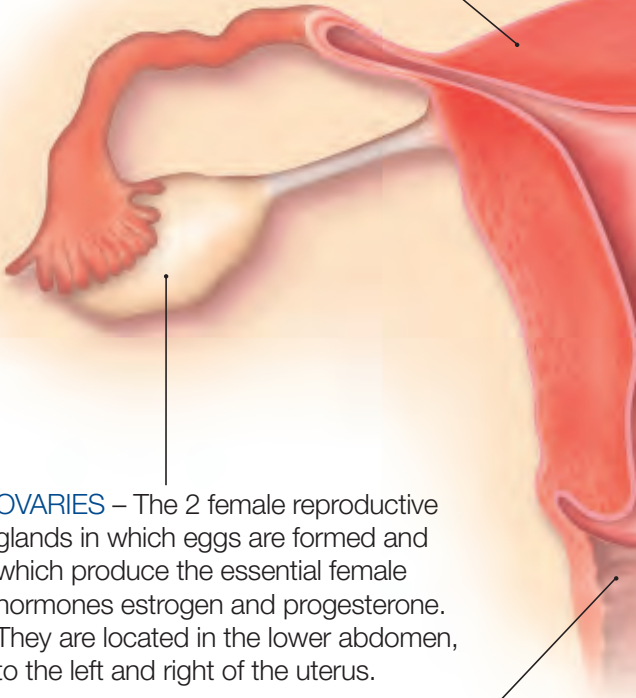
For most women, menstrual periods are a simple fact of life. But if you suffer from heavy periods, or menorrhagia (pronounced men-or-ah-jah), your periods can be a serious disruption to daily living. You may need to change pads or tampons constantly, or wear dark clothing to avoid embarrassing accidents.

More than 1 in 5 women suffer from heavy periods. If you find yourself scheduling your life around your period each month, you're not alone. The good news is that effective treatments are available, and you have choices. You don't have to live with heavy periods. This brochure will help you understand what causes heavy periods, and what you can do to get your life back.

A quick visual guide to the female reproductive system

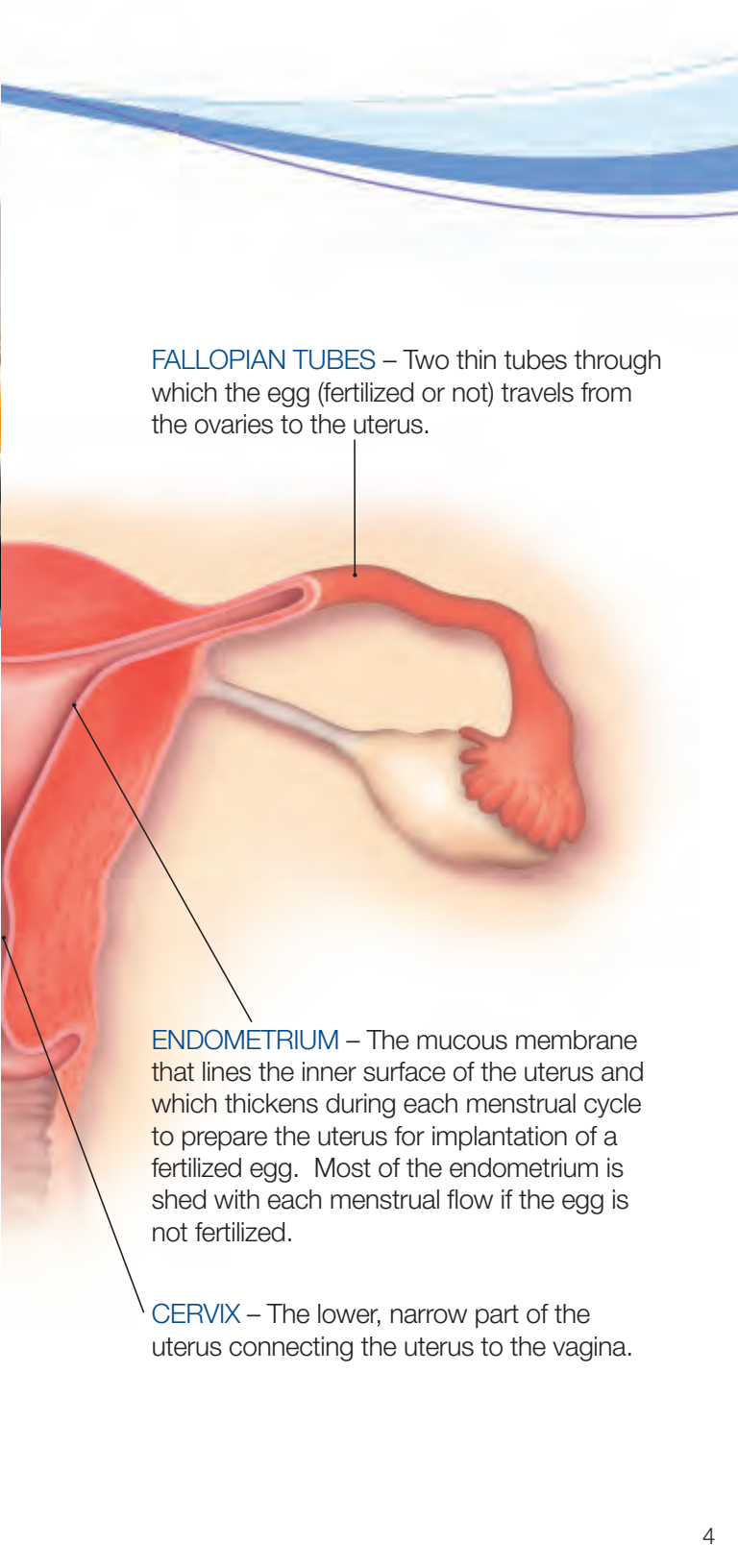
Knowing these terms will help you understand the information provided in this brochure.

UTERUS – Also known as the womb. It is the muscular, pear-shaped female reproductive organ inside which a fertilized egg is implanted and a developing embryo and fetus grows.



OVARIES – The 2 female reproductive glands in which eggs are formed and which produce the essential female hormones estrogen and progesterone. They are located in the lower abdomen, to the left and right of the uterus.

VAGINA – The organ through which blood and tissues pass out of the body during menstrual periods and through which a baby passes during birth.

An anatomical illustration of the female reproductive system. The uterus is shown in a reddish-pink color, with two fallopian tubes extending from its upper corners. The endometrium is the inner lining of the uterus, shown as a lighter, textured surface. The cervix is the lower, narrow part of the uterus. Labels with lines point to the fallopian tubes, endometrium, and cervix.

FALLOPIAN TUBES – Two thin tubes through which the egg (fertilized or not) travels from the ovaries to the uterus.

ENDOMETRIUM – The mucous membrane that lines the inner surface of the uterus and which thickens during each menstrual cycle to prepare the uterus for implantation of a fertilized egg. Most of the endometrium is shed with each menstrual flow if the egg is not fertilized.

CERVIX – The lower, narrow part of the uterus connecting the uterus to the vagina.

Symptoms of Heavy Periods

An average period lasts 5-7 days. However, if you suffer from heavy periods, you may experience one or more of these difficult and disruptive symptoms:

- Menstrual flow that soaks through one or more tampons or pads every hour for several consecutive hours
- Fear and anxiety about embarrassing accidents
- Severe pain or cramping
- Periods that last longer than 7 days
- Heavy menstrual flow even while taking a birth control pill
- Menstrual flow that includes large blood clots
- Exhaustion and fatigue during your period

If you have heavy periods, talk with your doctor. You have options to help relieve your symptoms.

Common Causes of Heavy Periods

A number of medical conditions may cause heavy periods, including:

Hormonal Imbalance – An imbalance of the female hormones estrogen and progesterone. These hormones regulate the thickening of the endometrium – the tissue lining of the inside of the uterus that is shed each month during menstruation. An imbalance of these hormones can cause the endometrium to thicken more than usual, causing periods to be heavier than normal.



In other cases, heavy bleeding may be due to:

Fibroids – Benign (noncancerous), fibrous growths in the uterus that can cause heavy periods as well as pressure and pain.

Polyps – Fleishy growths on the lining of the uterus that are usually benign.

Endometriosis – A disease in which tissue that normally makes up the lining of the uterus is found elsewhere, such as on the ovaries, on the outside of the uterus or elsewhere in the pelvis or lower abdomen.

Neoplasia – New tissue growth caused by anything from a simple thickening of uterine tissue to, in rare cases, a precancerous or cancerous condition.

Blood Clotting Disorders – Conditions such as von Willebrand's Disease that prevent the blood from clotting properly.

There are other potential causes of heavy bleeding, such as cancer, certain medications (including those that prevent blood from clotting), and other medical conditions. It is important to talk with your doctor if you experience heavy menstrual bleeding to determine whether this procedure is right for you.



Options to treat heavy periods

The best treatment option for you depends on what is causing your heavy periods, your overall health, the severity of your condition and the impact it has on your life. You will also need to consider your goals for treatment and your plans for the future, including pregnancy.

Treating heavy periods does not always involve the need for a hysterectomy. Medical experts often treat heavy periods with less invasive methods first, such as birth control pills or an endometrial ablation procedure. Hysterectomies may be done when other forms of treatment have failed or they are not an option. Your doctor can help you understand the best treatment for you.

Note: In cases where your periods are the result of a uterine abnormality or a medical problem like a clotting disorder or cancer, treatment will be individualized to manage those conditions first. Ask your doctor if these treatments are right for you.

Medical Treatment for Women with H

Procedure/Description	Benefits/Effectiveness
DRUG THERAPY	
<ul style="list-style-type: none">• Medications – hormone therapy such as oral contraceptives (birth control pills), progesterone, or progesterone-like medications• Often prescribed as a first step to bring heavy periods under control	<ul style="list-style-type: none">• Can help reduce heavy or prolonged menstrual bleeding• For some women, can be effective in decreasing bleeding without the need for surgery
DILATION & CURETTAGE (D&C)	
<ul style="list-style-type: none">• Surgical procedure in which doctor widens (dilates) the opening of cervix and scrapes away tissue from the lining of the uterus (curettage)	<ul style="list-style-type: none">• Minimally invasive treatment• Not a long-term solution for heavy periods because endometrium grows back• Can result in reduction of heavy flow for next few cycles• Outpatient procedure
ENDOMETRIAL ABLATION (heating, freezing, or electrosurgical)	
<ul style="list-style-type: none">• Treatment that permanently hinders the endometrium's ability to grow• Very little of the endometrium grows back and, as a result, heavy bleeding is significantly reduced <div data-bbox="70 1176 564 1332" style="background-color: #6a5acd; color: white; padding: 10px; border-radius: 15px; margin-top: 20px;"><p>GYNECARE THERMACHOICE® Uterine Balloon Therapy System falls within this category</p></div>	<ul style="list-style-type: none">• Minimally invasive treatment.• For most women, periods either return to normal, are much lighter or stop completely• Outpatient procedure• In most cases, women return to normal activities the next day
HYSTERECTOMY	
<ul style="list-style-type: none">• Surgical removal of all or part of the uterus• Hysterectomy can be performed:<ul style="list-style-type: none">Abdominally – through an incision in lower abdomenVaginally – through an incision on the top of the vagina near the cervixLaparoscopically – through tiny incisions using small laparoscopic instruments. The cervix may be left in place or removed	<ul style="list-style-type: none">• Because the uterus is removed, will cure heavy bleeding and eliminate periods. For women in which the cervix is left, some may experience light spotting

All treatment options have potential complications, some of which are more common than others. These risks should be discussed with your doctor.

Heavy Periods Due to Benign Causes

Impact on Fertility	Potential Side Effects/Drawbacks	Risks/Complications*
<ul style="list-style-type: none"> • No effect on fertility when discontinued 	<ul style="list-style-type: none"> • Headaches • Breast tenderness • Weight gain • Long-term daily or frequent dosing is required 	<ul style="list-style-type: none"> • Serious complications are rare • Risks of oral contraceptives increase as women age, especially if they smoke
<ul style="list-style-type: none"> • Normally, no effect on fertility 	<ul style="list-style-type: none"> • Mild cramping, spotting or light bleeding 	<ul style="list-style-type: none"> • Infection of the uterus • Injury to the cervix • Potential complications associated with surgery and general anesthesia, if used • Perforation of the wall of the uterus • Potential blood loss
<p>(methods)</p> <ul style="list-style-type: none"> • Not indicated for women who wish to become pregnant in the future because the safety of pregnancy after ablation has not been established • Most women are not able to become pregnant; however, pregnancy is still possible • Because pregnancy is still possible, requires consistent use of highly effective contraception until menopause 	<ul style="list-style-type: none"> • Cramping, pelvic pain, nausea, vaginal discharge and/or bleeding for a short time after the procedure 	<ul style="list-style-type: none"> • Any pregnancy may be risky for mother and baby • Infection of the uterus • Injury to the cervix • Potential complications associated with treatment and general anesthesia, if used • Perforation or rupture of the wall of the uterus • Potential blood loss
<ul style="list-style-type: none"> • Because the uterus is removed, you can no longer become pregnant 	<ul style="list-style-type: none"> • Major surgery – must be performed under either general or regional anesthesia • If ovaries are removed, onset of menopause is immediate, and drug therapy is often prescribed afterwards • If cervix is left in place, there is a small risk of cyclical bleeding • Hospital stay is required • Much longer recovery time (in some cases up to 6 weeks) than either endometrial ablation or D&C • In some cases, unsightly abdominal incision 	<ul style="list-style-type: none"> • Potential blood loss • Infection • Damage to other internal organs • Potential complications associated with surgery or general anesthesia, if used • Potential development of adhesions (scar tissue)

*Association of Professors of Obstetrics and Gynecology. Clinical Management of Abnormal Uterine Bleeding. APGO Educational Series on Women's Health Issues. 2002:25.

GYNECARE THERMACHOICE® Uterine Balloon Therapy System

One effective treatment for heavy periods is an endometrial ablation procedure using GYNECARE THERMACHOICE®. Endometrial ablation stops or reduces heavy bleeding by removing most, if not all of the lining of the uterus. GYNECARE THERMACHOICE® is used in an 8-minute outpatient treatment where heat is applied to treat the endometrium. It requires no incisions and may even be performed in your doctor's office under local anesthesia. GYNECARE THERMACHOICE® is hormone free and, unlike a hysterectomy, it allows you to retain your uterus. Endometrial ablation avoids the costs, recovery time and risks associated with hysterectomy, and patients are generally able to be back to their normal routines within a day or two.



Actual size of GYNECARE THERMACHOICE® balloon when inflated is approximately the size of a walnut. The balloon conforms to the unique contours of your uterus.

How does GYNECARE THERMACHOICE® Uterine Balloon Therapy System work?



INSERTION

A small soft, flexible balloon attached to a thin catheter (tube) is first inserted through the vagina and cervix, and then placed gently into the uterus. No incision is required. The balloon is made of silicone material, which eliminates the risk of allergy for latex-sensitive women. The balloon is then filled with fluid so that it inflates to the size and shape of the uterus.



TREATMENT & MONITORING

The fluid is heated and circulated in the uterus for 8 minutes while the lining of the uterus is treated.



DEFLATION & REMOVAL

When the treatment is completed, all the fluid is withdrawn from the balloon, and it is removed. Nothing remains in the uterus. The treated uterine lining will slough off, or shed, like a period.



Who can be treated with GYNECARE THERMACHOICE® Uterine Balloon Therapy System?

GYNECARE THERMACHOICE® is intended to treat premenopausal women with heavy bleeding (due to benign causes) who do not wish to become pregnant in the future.

It is not appropriate for:

- A patient who is pregnant or who wants to become pregnant in the future.
Pregnancies following ablation can be dangerous for both mother and fetus.
- Patients with known or suspected uterine cancer
- Patients with certain uterine conditions
- Patients with active infections
- Patients with an intrauterine device (IUD) currently in place

Your doctor will help you decide if treatment with GYNECARE THERMACHOICE® is right for you.

If your doctor has determined that your bleeding is a result of benign causes, GYNECARE THERMACHOICE® may be a good choice for you. It is an option if your Pap smear and biopsy (a tissue sample from inside the uterus) are also normal, and if you have not yet gone through menopause but do not wish to have children in the future. It is not a treatment for uterine cancer or precancerous conditions. If treatment with oral contraceptives fails to improve your condition or if you would prefer not to take hormone therapy, this might be a good time to ask your doctor about GYNECARE THERMACHOICE®.

Benefits of treatment with GYNECARE THERMACHOICE® Uterine Balloon Therapy System

This nonhormonal treatment reduces heavy bleeding in the vast majority of women. The minimally invasive treatment requires no incisions and can be performed in your doctor's office under local anesthesia. Unlike oral contraceptives, GYNECARE THERMACHOICE® has no impact on your natural hormonal composition and does not require taking pills daily.

A clinical study showed that following treatment, most women can expect lighter and less painful periods, or possibly no periods at all. Nearly 9 out of 10 women treated had a reduction in menstrual pain and cramping 1 year after treatment. In addition, 2 out of 3 women treated experienced mild or no PMS symptoms 1 year after treatment. One year after treatment, 96% of women treated were satisfied with their results, and 99% would recommend the treatment to others.

Eighty-one percent of women experience either lighter bleeding or no bleeding at all 1 year after treatment with GYNECARE THERMACHOICE®. Forty-three percent of women had lighter periods and 37% had no periods at all.

Risks

All of the choices to treat heavy periods present risks. Talk with your doctor to determine whether GYNECARE THERMACHOICE® is right for you.

Possible risks for all endometrial ablation procedures are: perforation (hole) of the uterus; bleeding; infection; injury to organs within the abdomen (eg, bowel) and pelvis or to adjacent tissue (eg, cervix and vagina); complications leading to serious injury or death;

and post-ablation tubal sterilization syndrome. This is a complication following endometrial ablation in women who have undergone tubal sterilization. This syndrome can occur as late as 10 years after your ablation.

If you experience new pain with your menstrual cycles (periods), you should contact your physician. Another rare but important risk of any endometrial ablation is that it may decrease your physician's ability to make an early diagnosis of cancer of the endometrium. Bleeding is one of the warning signs of endometrial cancer, and endometrial ablation procedures decrease or eliminate bleeding.





What to expect before the procedure

You should have a discussion with your physician regarding the type of anesthesia that will be used during your procedure (eg, local, IV sedation, general). Before treatment with GYNECARE THERMACHOICE[®], your doctor may give you medicine to reduce cramping during and after the procedure. You may also be given a mild sedative to help you relax. In addition, you may have a procedure in which the endometrium is thinned immediately before treatment with this device.

What to expect during the procedure

Depending on the anesthesia used during your treatment, you may feel some menstrual-like cramping. If your doctor doesn't give you medicine prior to the procedure, you should ask for an anti-inflammatory pain reliever such as ibuprofen (eg, Motrin[®] IB* or other medications).

What to expect after treatment with GYNECARE THERMACHOICE® Uterine Balloon Therapy System

You may feel some cramping, as with a period. Your doctor may suggest an anti-inflammatory pain reliever such as ibuprofen (eg, Motrin® IB or other medications) or a prescription pain reliever, to make you feel more comfortable. Most women can go back to work and family commitments the day after their procedure. Sexual activity can usually be resumed after your first check-up (usually in 7-14 days). You will probably have a pinkish, watery vaginal discharge. Your doctor will tell you what to expect after the procedure. **If you experience severe pain, high fever or abdominal bloating, contact your doctor immediately.**

Will I still need to use contraception after treatment?

Yes. Since there is still a small chance pregnancy could occur, it is very important to use a birth control method appropriate for you after any endometrial ablation procedure. As with all endometrial ablation procedures, this procedure should not be used if you think you might want to become pregnant in the future. Pregnancy after ablation is unlikely, but if it does occur, it may be risky for you and your baby because the endometrial lining of the uterus has been removed. There are several options available for birth control. You should discuss these options with your doctor.

If your doctor confirms that you have excessive menstrual bleeding, here are several questions you may want to ask before deciding on a treatment:

- What are my least invasive treatment options?
- Is there a treatment that can provide a permanent solution?
- Will a particular therapy require multiple treatments?
- How will treatment affect my ability to have children?
- How much time off from work will I need?
- What are the overall risks/benefits of each treatment option?
- What options for anesthesia do I have?
- How many of these procedures have you performed in the last year?
- Can this procedure be performed in the doctor's office?

Remember, the more you know, the more you can be confident that you're making the choice that's right for you.

For more information or to find a doctor in your area who has treated heavy periods with GYNECARE THERMACHOICE® Uterine Balloon Therapy System, visit www.PelvicHealthSolutions.com or call 1-888-GYNECARE to speak to a nurse.

For complete product information, consult product package insert. Rx only.



**GYNECARE THERMACHOICE®
UTERINE BALLOON THERAPY SYSTEM**

INDICATIONS

The GYNECARE THERMACHOICE® UBT System is a thermal balloon 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 device is contraindicated for use in a patient: with known or suspected endometrial carcinoma (uterine cancer) or premalignant change of the endometrium, such as unresolved adenomatous hyperplasia; with any anatomic or pathologic condition in which weakness of the myometrium could exist, such as history of previous classical cesarean sections or transmural myomectomy; with active genital or urinary tract infection at the time of procedure (eg, cervicitis, vaginitis, endometritis, salpingitis, or cystitis); with an intrauterine device (IUD) currently in place; or who is pregnant or who wants to become pregnant in the future.

POTENTIAL ADVERSE EFFECTS

that may occur include: rupture of the uterus; thermal injury to adjacent tissue; heated liquid escaping into the vascular spaces and/or cervix, vagina, fallopian tubes, and abdominal cavity; electrical burn; hemorrhage; infection or sepsis; perforation; post-ablation tubal sterilization syndrome; complications leading to serious injury or death; complications with pregnancy (Note: pregnancy following ablation is dangerous to both the mother and the fetus); and risks associated with hysteroscopy.

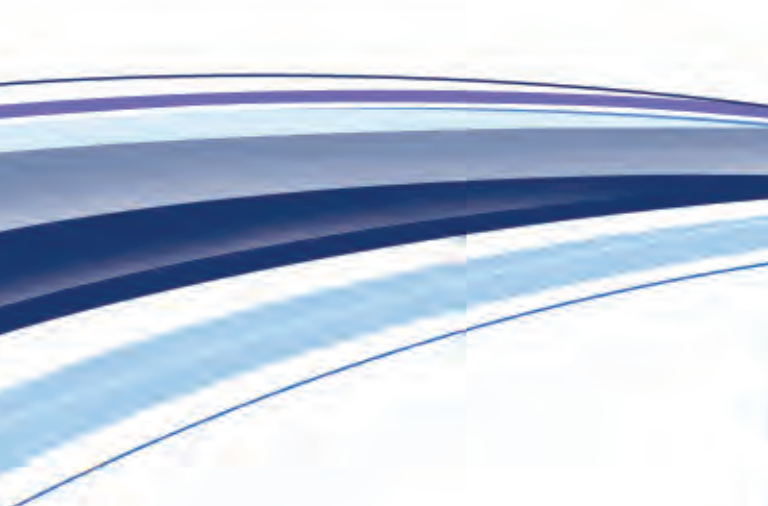
WARNINGS

Failure to follow all instructions or to heed any warnings or precautions could result in serious patient injury. If a perforation is present, and the procedure is not terminated, thermal injury to adjacent tissue may occur if the heater is activated.

CAUTION

Endometrial ablation procedures using the GYNECARE THERMACHOICE® UBT System should be performed only by medical professionals who have experience in performing procedures within the uterine cavity, such as IUD insertion or dilation and curettage (D&C), and who have adequate training and familiarity with GYNECARE THERMACHOICE® UBT System.

For complete product information, consult product package insert. Rx Only.



Ethicon Women's Health & Urology, a Johnson & Johnson company, is dedicated to transforming women's health by providing innovative solutions for common women's health conditions. Our goal is to provide you access to advanced technology and valuable, easy-to-understand information so that you can weigh your options, and along with your physician, make informed decisions.

Ethicon Women's Health & Urology is the leader in minimally invasive gynecological health solutions. Our clinically proven technologies have touched the lives of 1.5 million women. Ethicon Women's Health & Urology offers minimally invasive diagnosis and treatment options for heavy periods, uterine disorders, stress urinary incontinence and pelvic organ prolapse. GYNECARE THERMACHOICE® Uterine Balloon Therapy System is an effective treatment for heavy periods that can be performed in your doctor's office and allows most women to return to their normal activities the next day.

To find a doctor in your area who has treated heavy periods with GYNECARE THERMACHOICE®, or for more information, visit **www.PelvicHealthSolutions.com** or call **1-888-GYNECARE** to speak to a nurse.

