

EXCESSIVE MENSTRUAL BLEEDING

*One day you'll
enjoy EVERY DAY
of the month*

ONE DAY
*That's all it takes to end
heavy periods.*

What causes heavy periods?

Hormonal Imbalance – Estrogen and progesterone regulate the thickening of the endometrium – the lining 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.

Submucosal Fibroids – Usually benign (non-cancerous), fibrous growths in the uterus that can cause pressure and pain in addition to heavy periods.

Polyps – Usually benign, fleshy growths on the lining of the uterus.

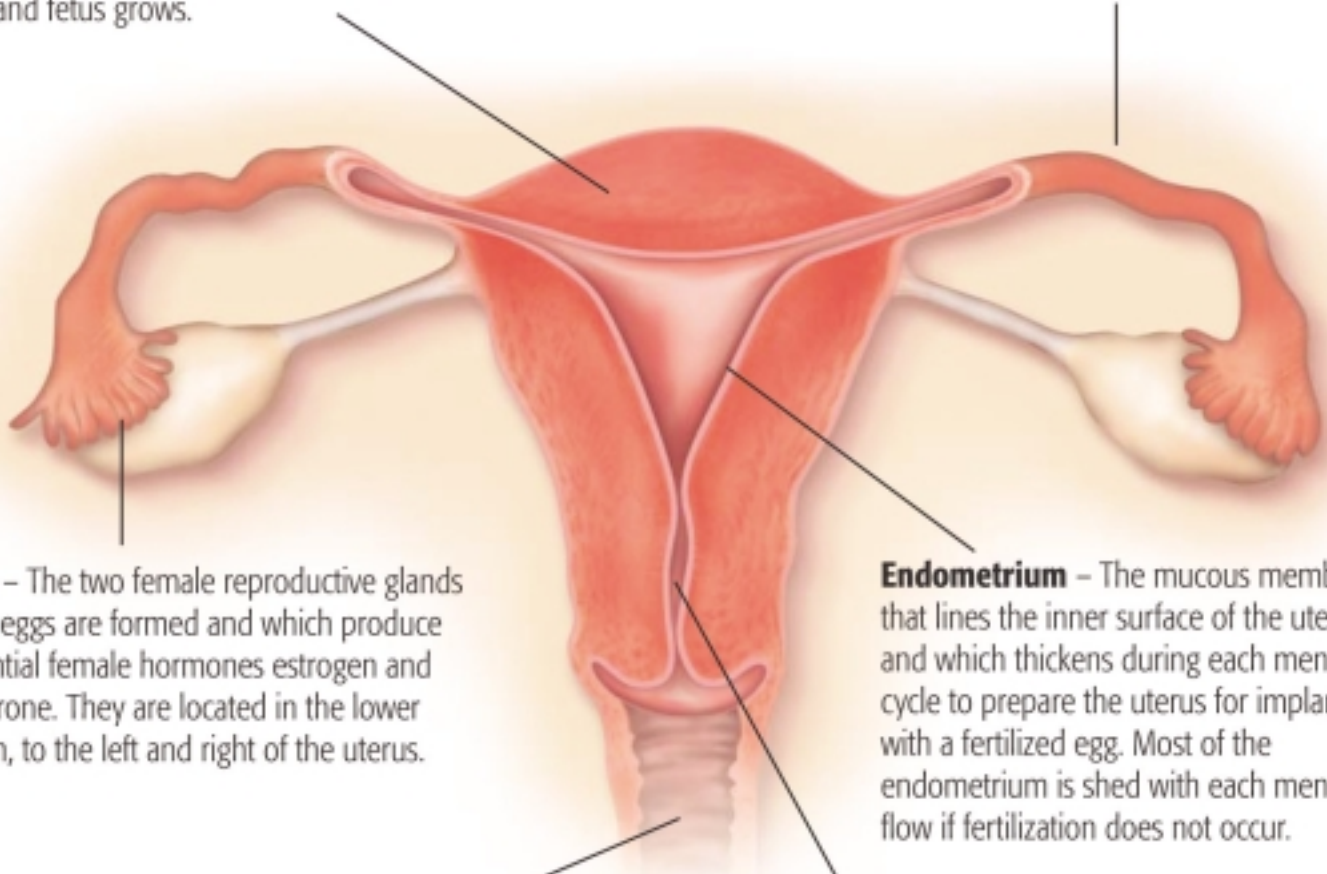
Your doctor can tell you about other causes of heavy periods, including;
Neoplasia, blood clotting disorders and endometriosis.

You're NOT alone.
More than 1 in 5 women around the world suffer with menorrhagia.
(excessive menstrual bleeding)

Female Reproductive System

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.

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



Ovaries – The two 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.

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 with a fertilized egg. Most of the endometrium is shed with each menstrual flow if fertilization does not occur.

Vagina – The organ through which blood and tissue pass out of the body during menstrual periods, which receives the penis during intercourse, and through which a baby passes during birth.

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

What treatments are available for me?

Drug Therapy

- Medications – hormone therapy such as oral contraceptives, progestins, or progesterone-like medications.
- For many women, drug therapy is not effective in reducing heavy periods.
- May require long-term daily use or until menopause is reached.

Dilation and Curettage (D&C)

- Outpatient procedure in which the doctor dilates (opens) the cervix and scrapes away tissue from the lining of the uterus (curettage).
- Used to be the treatment of choice, but is not a long-term solution for heavy periods because endometrium grows back.

Endometrial Ablation

- A one-time outpatient procedure that removes the endometrium.
- For most women, cures heavy bleeding. Very little of the endometrium grows back and heavy bleeding is much less likely to continue.
- In most cases, women return to normal activities the next day.

Hysterectomy

- Surgical removal of the uterus.
- Can be performed abdominally, vaginally or laparoscopically.
- Will eliminate periods altogether.
- Longer recovery time than other options.

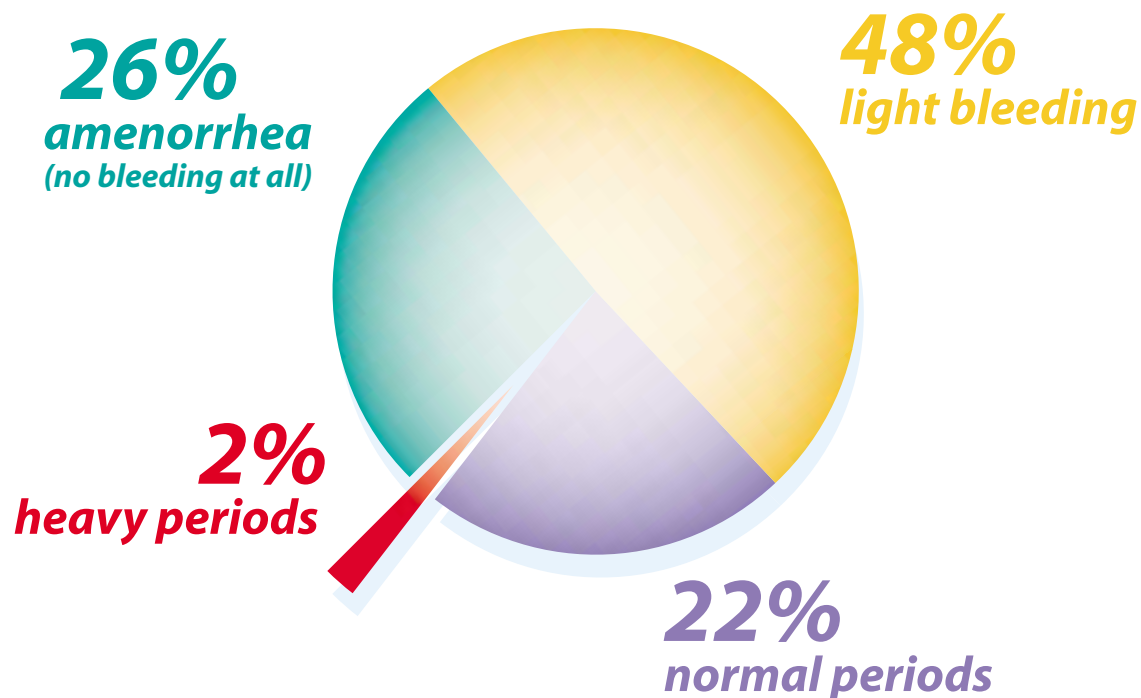
What is **Gynecare** 
Thermachoice* 
Uterine Balloon Therapy System

- **GYNECARE THERMACHOICE** is a 30-minute outpatient treatment with no incision that can make your periods light and less painful.
- One type of endometrial ablation.
- Unlike a hysterectomy, which removes the entire uterus, the procedure uses heat to treat the lining of the uterus.
- Studies show **GYNECARE THERMACHOICE** is a safe and effective treatment for most women.
- While there are ablation technologies, **GYNECARE THERMACHOICE** has a proven track record and 6 years of success and is the only one that has been used on over 300,000 women worldwide.
- Hormone free option - no more pills should be needed to control heavy periods.
- Chosen by doctors 3-to-1 over any other treatment of its kind.

For more information on **GYNECARE THERMACHOICE**
Visit womenshealthsolutions.co.uk or Call 0845 850 0305

What can I *expect* from GYNECARE THERMACHOICE?

97% success rate¹



- More than 3 out of 4 women treated 3 years ago are free from significant menstrual pain and cramping.¹
- Nearly 2 out of 3 women had either mild or no PMS symptoms years after being treated with GYNECARE THERMACHOICE.^{†2}
- 93% of women are satisfied with the result after 5 years.³

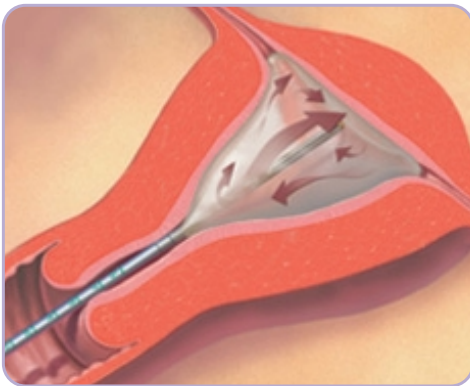
†Measured three years after treatment

What can I expect from GYNECARE THERMACHOICE?

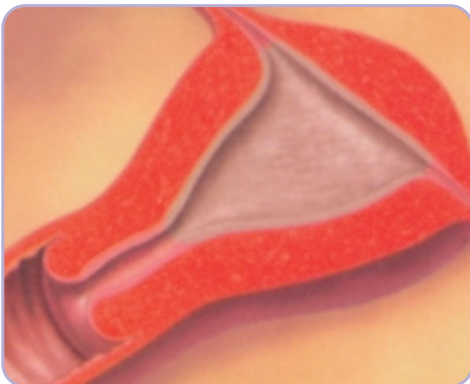
How does GYNECARE THERMACHOICE work?



1. Insertion and inflation



2. Treatment and monitoring



3. Deflation and removal

1. First a soft, flexible balloon attached to a thin catheter (tube) is inserted into the vagina, through the cervix, and placed gently into the uterus. No incision is required. Then, the balloon is inflated with a sterile fluid that expands the balloon to fit the size and shape of the uterus.
2. The fluid in the balloon is heated to 87° C, or 188° F, and the temperature is maintained for 8 minutes while the uterine lining is treated. During this time, the sterile liquid is circulated within the balloon, allowing for uniform heating.
3. When the treatment cycle is completed, all the fluid is withdrawn from the balloon and the catheter is removed. Nothing stays in the uterus. The uterine lining has been treated and will slough off like a period within the next 7-10 days.



Am I a candidate for GYNECARE THERMACHOICE?

Your doctor must rule out abnormal uterine conditions such as cancer and your Pap smear and biopsy must also be normal.

If you still want to become pregnant, GYNECARE THERMACHOICE is not an option for you, since the uterine lining is permanently altered during therapy.

Will I still need to use birth control?

Since there is still a small chance that pregnancy could occur, it is very important to use highly effective birth control correctly and consistently after being treated. If pregnancy does occur, it will be risky for you and your baby.

What are the risks associated with GYNECARE THERMACHOICE?

All surgical procedures present risks. Talk with your doctor to determine whether GYNECARE THERMACHOICE is right for you. For more information on risks, see the adverse events section of the product information on the next page.

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GYNECARE THERMACHOICE® III Uterine Balloon Therapy with Fluid Circulation Thermal Balloon Ablation Silicone Catheter and Syringe (Single-Use)

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.
- A patient with any anatomic or pathologic condition in which weakness of the myometrium could exist, such as history of previous classical cesarean sections or transmurial myomectomy.
- A patient with active genital or urinary tract infection at the time of procedure (e.g., cervicitis, vaginitis, endometritis, salpingitis, or cystitis).
- A patient with an intrauterine device (IUD) currently in place.
- A patient who is pregnant or who wants to become pregnant in the future.

WARNINGS

Failure to follow all instructions or to heed any warnings or precautions could result in serious patient injury.

- The device is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following this procedure. There have been reports of women becoming pregnant following this procedure. Pregnancies after ablation can be dangerous for both mother and fetus.
- Endometrial ablation using the GYNECARE THERMACHOICE UBT System is not a sterilization procedure.
- Patients who undergo endometrial ablation procedures who have previously undergone tubal ligation are at increased risk of developing post ablation tubal sterilization syndrome which can require hysterectomy. This can occur as late as 10 years post-procedure.
- 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 the GYNECARE THERMACHOICE UBT System.
- Endometrial ablation procedures do not eliminate the potential for endometrial hyperplasia, or adenocarcinoma of the endometrium and may mask the physician's ability to detect or make a diagnosis of such pathology.
- The GYNECARE THERMACHOICE III UBT Balloon Catheter is for single use only – do not reuse or resterilize.
- Do not treat patients for more than one therapy cycle in a given treatment session because of the potential for transmurial injury to the uterus or injury to adjacent viscera.

UTERINE PERFORATION

- Uterine perforation can occur during any procedure in which the uterus is instrumented. Use caution not to perforate the uterine wall when sounding the uterus, dilating the cervix or inserting the catheter.
- Any of the following indicates possible uterine perforation.
 1. If the catheter can be inserted to a greater depth than was determined by the uterine sound
 2. If the pressure cannot be stabilized at 160 – 180 mmHg with a maximum of 30ml of fluid
 3. If the pressure drops quickly at any point during the procedure
- If a perforation is suspected, **THE PROCEDURE SHOULD BE TERMINATED IMMEDIATELY.** The physician may elect to perform a diagnostic procedure to confirm perforation. If the physician cannot absolutely rule out perforation, the procedure should be abandoned.
 - For patients in whom the procedure was aborted due to a suspected uterine wall perforation, a work-up for perforation should be considered prior to discharge.

- If a perforation is present, and the procedure is not terminated, thermal injury to adjacent tissue may occur if the heater is activated.
- After completing the procedure it is important not to touch the GYNECARE THERMACHOICE Uterine Balloon for the following reasons:
 - The balloon is covered with blood and body fluids
 - There are mechanical and electrical parts that could puncture the balloon
- Proper care should be taken in disposing of the catheter.

PRECAUTIONS

- The GYNECARE THERMACHOICE III UBT catheter, controller, and umbilical cable are designed as a system. To ensure proper function, never use other components with the GYNECARE THERMACHOICE UBT System.
- A starting pressure of 160 – 180 mmHg is recommended and typically requires 6 – 15 cc of fluid and may require as much as 30 cc. **Titration to achieve a stable pressure (no fluctuations greater than ± 10 mmHg for at least 30 seconds) prior to activating the heating element is critical to proper functioning of the device. When inserting fluid, do not exceed a pressure of 200 mmHg.** Typically, pressure levels decline slowly during the course of the procedure as the uterus relaxes. If a pressure of 160 – 180 mmHg cannot be reached with 30 cc or less of fluid, or if there is a rapid drop in pressure, it is likely there is a uterine perforation.
- **Rapid loss of pressure during a therapy cycle may indicate a uterine wall defect. Adding additional fluid to the balloon may create (or exacerbate if already present) a uterine wall defect such as a perforation.**
- Those patients who have undergone endometrial ablation and are later placed on hormone replacement therapy should have progesterin included in their regimen in order to avoid the increased risk of endometrial adenocarcinoma associated with unopposed estrogen replacement therapy.
- **Never add additional fluid during a therapy cycle.**
- The safety and effectiveness of the GYNECARE THERMACHOICE UBT System has not been fully evaluated in patients:
 - with large uterine cavities (>30 cc in volume or uterine sound >10 cm)
 - with small uterine cavities (<2 cc in volume or uterine sound <6 cm)
 - with submucosal myomas, bicornuate or septate uteri or previous endometrial resection/ablation
 - undergoing repeat endometrial ablation procedures
 - who are post-menopausal
- It has been reported that patients with a severe anteverted retroflexed or laterally displaced uterus are at an increased risk of uterine wall perforation during any intrauterine manipulation. The clinician should use discretion in patient selection.
- A false passage can occur during any procedure in which the uterus is instrumented, especially in cases of severe anteverted retroflexed or a laterally displaced uterus. Use caution to insure that the device is properly positioned in the uterine cavity.

ADVERSE EVENTS - CLINICAL STUDY

- In a study of 134 women, performed with a previous generation balloon catheter (version 1.2) [without the fluid circulation mechanism inside the balloon] the most frequent events reported during or after the procedure include:
- Cramping/pelvic pain – Post-treatment cramping was reported in 91.8% of the patients. The cramps/pain ranged from mild to severe as reported during the intra-operative and immediate post operative period. This cramping typically lasted a few hours and rarely continues beyond the first day following ablation. The use of non-steroidal anti-inflammatory drugs (NSAIDs) prior to and following GYNECARE THERMACHOICE UBT is usually sufficient to manage cramping and pelvic pain.
 - Nausea and Vomiting – Nausea and vomiting were reported in 23.9% of the patients in the immediate hours following the procedure. This may be attributed to general anesthesia, and was usually managed with medication.
 - Endometritis was reported in 2.1% of patients. All patients responded to a course of oral antibiotics.
 - Post-procedure symptoms such as pain, fever, nausea, vomiting and difficulty with defecation or micturition were reported. Failure of such symptoms to resolve over a reasonable period of time warrants evaluation by appropriate medical personnel.
 - Pregnancy was reported in one patient (0.8%) resulting in a 2-month premature live infant. Pregnancy following endometrial ablation may be dangerous to both mother and fetus.
 - Hematometra was reported in 0.6% of patients treated in clinical studies conducted outside of the United States. In all patients in this trial, the hematometra was resolved with insertion of a uterine sound, however, there have been reports of hysterectomy due to hematoma or hematosalpinx.
 - A single perforation of the uterus was reported in one controlled clinical study.

OTHER ADVERSE EFFECTS

As with all endometrial ablation procedures, serious injury or death can occur. The following adverse effects might be potentially expected or have been reported in association with the use of the GYNECARE THERMACHOICE UBT System:

1. Rupture of the Uterus
2. Thermal Injury to Adjacent Tissue
3. Heated Liquid Escaping Into the Vascular Spaces and/or Cervix, Vagina, Fallopian Tubes, and Abdominal Cavity
4. Electrical Burn
5. Hemorrhage
6. Infection or Sepsis
7. Perforation
8. Post-ablation-tubal sterilization syndrome – This is a complication following endometrial ablation in women who have also previously undergone tubal ligation. The pathophysiology of this condition is believed to be related to the regeneration of endometrium in the cornual areas of the uterus. Blood from these glands can flow back into the proximal fallopian tubes in cases where the lower uterine segment is extensively scarred. The proximal oviduct becomes filled with blood and fluid causing symptoms similar to those of an ectopic pregnancy.
9. Complications leading to serious injury or death.

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References: 1. Feitoza et al., Efficacy of thermal balloon ablation in patients with abnormal uterine bleeding. *Am J Obstet Gynecol* 2003; 189:453-457. 2. Loffer FD. Three-year comparison of thermal balloon and rollerball ablation in treatment of menorrhagia. *J Am Assoc Gynecol Laparosc.* 2001;8 (1):48-54. 3. Loffer and Grainger, Five-year follow-up of patients participating in a randomized trial of uterine balloon therapy versus rollerball ablation for treatment of menorrhagia. *J Am Assoc Gynecol Laparosc.* 2002;9 (4)429-435.