

GYNECARE THERMACHOICE* III

Uterine Balloon Therapy With Fluid Circulation

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 transmural 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 postprocedure.
- 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 transmural 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 progestin 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.**

For complete information, please consult the GYNECARE THERMACHOICE Uterine Balloon Therapy User's Manual.

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