ETHICON
Women's Health & Urology

INSTRUCTIONS FOR USE

GYNECARE THERMACHOICE* III
Uterine Balloon Therapy System

Thermal Balloon Ablation Silicone Catheter and Syringe (Single-Use)

Read all directions, precautions and warnings prior to use.

This instructions for use provides directions for using the GYNECARE THERMACHOICE* III Uterine Balloon Therapy (UBT) Catheter.

CAUTION
Federal law (USA) restricts this device to sale by or on the order of a physician with appropriate training.

DEVICE DESCRIPTION

The GYNECARE THERMACHOICE UBT System is a software-controlled device designed to ablate uterine tissue by thermal energy. The system is comprised of a single-use silicone balloon catheter, a reusable controller, umbilical cable, and power cord. The GYNECARE THERMACHOICE III Catheter is designed for use only with the GYNECARE THERMACHOICE UBT Controller.

The silicone balloon catheter is 1) connected to the controller, 2) inserted through the cervix into the uterus, 3) filled with sterile, injectable fluid (5% dextrose in water- D_5W) carefully stabilizing the pressure to 160-180 mmHg pressure, and 4) activated to thermally ablate endometrial tissue by maintaining a temperature of approximately 87°C (188°F) for 8 minutes.

INDICATIONS

The GYNECARE THERMACHOICE III 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 who is pregnant or who wants to become pregnant in the future. **Pregnancies following ablation can be dangerous for both mother and fetus.**
- 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 condition (e.g. history of previous classical cesarean sections or transmural myomectomy) or pathologic condition (e.g., chronic immunosuppressive therapy) that could lead to weakening of the myometrium.
- To clarify, patients with low transverse uterine scar from a previous Caesarian section remain candidates for uterine ablation with the GYNECARE THERMACHOICE III UBT System. If a patient has had multiple Caesarian sections with low transverse uterine incisions, it may be prudent to evaluate the thickness of the uterine scar with ultrasound prior to carrying out a uterine ablation procedure with the GYNECARE THERMACHOICE III UBT System.
- A patient with active genital or urinary tract infection at the time of procedure (e.g., cervicitis, vaginitis, endometritis, salpingitis, or cystitis) or with active pelvic inflammatory disease (PID).
- A patient with an intrauterine device (IUD) currently in place.

WARNINGS

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

GENERAL

- 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 III UBT System is not a sterilization procedure. The patient should be advised of appropriate birth control methods.
- 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 III 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 III 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.

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 up to 35ml of fluid (35ml of fluid in the THERMACHOICE III device is approximately equal to the 30ml used in the THERMACHOICE I clinical study) and there is no evidence of a balloon leak

    If the pressure drops precipitously at any point during the procedure
- If a perforation is suspected, THE PROCEDURE SHOULD BE TERMINATED IMMEDIATELY.
- 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.

TECHNICAL

- 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.
- Hold the catheter so it does not rest on the vaginal wall during treatment and cool down periods to prevent possible burns.
- Allow the catheter to complete the cool down cycle prior to removal of the fluid. Remove the fluid and then the catheter.
- After completing the procedure it is important not to touch the GYNECARE THERMACHOICE III 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 35 cc. **Titration to achieve a stable pressure (no fluctuations greater that ±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 up to 35 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.**
- **Never add additional fluid during a therapy cycle.**
- 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.
- The safety and effectiveness of the GYNECARE THERMACHOICE III UBT System has not been fully evaluated in patients:
    - with submucosal myomas greater than 3cm**
    - bicornuate or septate uteri or previous endometrial resection/ablation
    - with large uterine cavities (>35 ml in volume or uterine sound > 12 cm)
    - with small uterine cavities (<2 ml in volume or uterine sound <4 cm)
    - undergoing repeat endometrial ablation procedures
    - who are post-menopausal

Assuming a margin of equivalence delta of 25%.

- 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

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.

In a multi-center study of 250 women, performed with GYNECARE **THERMACHOICE III** (version 3.0), in which patients were randomized to receive either treatment with Thermachoice III with an additional post-procedure curettage (PPC Group) or treatment with Thermachoice III alone (NPPC Group), the following adverse events were reported during the first one year of follow-up: These events may or may not be related to the procedure.

Table 1a. Adverse Events- Day of Procedure†

Adverse Event	**NPPC Group** N=124	**PPC Group N=126**
Endometritis	3 (2.4%)	2 (1.6%)
Vaginal burn	0	2 (1.6%)
Other abdominal or pelvic pain/cramping	1 (0.8%)	1 (0.8%)
Uterine perforation	1 (0.8%)	0
Post –op Nausea	0	1 (0.8%)
Endometrial polyp removal	0	1 (0.8%)
Injury to tongue (bitten)	1 (0.8%)	0
Swollen hand	1 (0.8%)	0
Knot on wrist	1 (0.8%)	0
TOTAL	8 (6.5%)	7 (5.6%)

† One subject in the NPPC group experienced 3 adverse events.

Table 1b. Adverse Events- ≥1 Day -2 weeks†

Adverse Event	**NPPC Group N=124**	**PPC Group N=126**
Bleeding or abdominal or back or pelvic pain/cramping	3 (2.4%)	2 (1.6%)
Discharge and/ or vaginal infection	3 (2.4%)	2 (1.6%)
Endometritis	0	2 (1.6%)
UTI	0	1 (0.8%)
Fever	0	1 (0.8%)
Fainting	0	1 (0.8%)
Migraine headache	0	3 (2.4%)
Worsening carpel tunnel syndrome	0	2 (1.6%)
TOTAL	6 (4.8%)	14 (11.1%)

† Three subjects in the PPC group experienced multiple adverse events.

Table 1c. Adverse Events >2 Weeks - 1 year[†‡]

Adverse Event	NPPC Group	PPC Group
Abdominal or back or pelvic pain/cramping	9 (7.3%)	8 (6.3%)
Discharge and/ or vaginal infection	9 (7.3%)	6 (4.8%)
Bleeding	6 (4.8%)	4 (3.2%)
UTI or Cystitis or Urinary incontinence	5 (4.0%)	3 (2.4%)
Uterine fibroid or cervical polyp or vulva warty lesion removal	2 (1.6%)	1 (0.8%)
Abnormal Pap (ASCUS)	2 (1.6%)	0
Endometritis	1 (0.8%)	1 (0.8%)
Sinus congestion or infection or polyp	2 (1.6%)	5 (4.0%)
Ear infection or tooth ache	0	2 (1.6%)
Asthma or bronchitis	1 (0.8%)	1 (0.8%)
Hot flush	0	1 (0.8%)
Hypothyroidism	0	1 (0.8%)
Depression	0	1 (0.8%)
Migraine headache	0	1 (0.8%)
Exacerbation of multiple sclerosis	0	1 (0.8%)
Cholecsytolithiasis	0	1 (0.8%)
Hernia	1 (0.8%)	0
Bloody stool	1 (0.8%)	0
Cracked distal fibula	1 (0.8%)	0
Plantar fasciitis	1 (0.8%)	0
TOTAL	41 (33.1%)	37 (29.4%)

[†]This table includes data from patients (5 NPPC, 3 PPC) who had their "12-month" visit at more than 1 year post-procedure. NOTE: There was one additional adverse event (pelvic pain) reported in the PPC Group, but the time interval was unknown.

[‡]Six subjects in NPPC group experienced multiple adverse events. Five subjects in PPC group experienced multiple adverse events.

OTHER ADVERSE EVENTS

As with all endometrial ablation procedures, serious injury or death can occur. The following adverse events could occur or have been reported in association with the use of the GYNECARE THERMACHOICE III 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. **Vesico-uterine** fistula formation
10. **Complications** leading to serious injury or **death**.

CLINICAL STUDIES

Two studies that have evaluated the safety and effectiveness of the GYNECARE THERMACHOICE UBT System in treating menorrhagia in premenopausal women are presented in this labeling. The first was conducted in support of the initial product approval, and was done using the first generation balloon catheter for GYNECARE THERMACHOICE I UBT. In 2006, a more recent study completed 12-month follow up on subjects treated with the third generation device, GYNCECARE THERMACHOICE III UBT. Results from both studies are summarized below.

GYNECARE THERMACHOICE I

The pivotal clinical trial conducted to support the original approval of GYNECARE THERMACHOICE I, Which was completed in 1997, is summarized below.

Conclusions: The GYNECARE THERMACHOICE I (version 1.2) [without the fluid circulation mechanism, inside the balloon], at twelve, twenty-four, and thirty-six months of follow-up, balloon ablation was demonstrated to be at least as safe (with fewer intra-operative complications and shorter procedure times) and as effective as hysteroscopic rollerball ablation in reducing menstrual bleeding to a clinically acceptable level in menorrhagic women who had completed their childbearing. Furthermore, statistically equivalent and significant reductions in patient-reported dysmenorrhea (mild, moderate, severe menstrual cramps), PMS symptoms (mild, moderate, severe common PMS symptoms), and overall impact of menses on lifestyle (scale of 1-10; 1=none, 10=severe) were experienced by both groups.

Purpose: The use of balloon thermal ablation for the treatment of menorrhagia for benign causes in an anatomically normal uterine cavity was compared with rollerball electrosurgical endometrial ablation with regard to safety and effectiveness. The primary effectiveness measure was a validated diary scoring system (adapted from Higham JM, O'Brien PMS, Shaw RW, Assessment of menstrual blood loss using a pictorial chart, Br J Obstet Gynaecol 1990;97:734-9). Success was defined as the reduction of excessive menstrual bleeding to normal flow or less. Secondary endpoints evaluated were overall percent decrease in diary scores and responses from a quality-of-life questionnaire. The endpoints for safety were based on the evaluation of adverse events associated with each procedure, including device-related complications, time of procedure, and type of anesthesia use.

Methods: This randomized, prospective multicenter clinical investigation using the previous generation non-circulating balloon catheter was conducted at 14 sites using investigators highly experienced with hysteroscopic rollerball endometrial ablation. All patients were ≥30 years old, premenopausal, and had completed childbearing. All had an anatomically normal uterine cavity ≥4cm and ≤10cm.

Three months of documented menorrhagia for benign causes was a requirement for inclusion and was confirmed with an average diary score of at least 150 points. Endometrial biopsy and pap smear were required to rule out premalignant or malignant cervical uterine disease. No endometrial thinning medications could be used for three months prior to treatment and all patients underwent a three-minute suction curettage just prior to suction treatment. Selection of anesthesia regimen was left to the individual investigators. Treatment success was defined as reduction menses to a diary score less than or equal to 75 reflecting eumenorrhea. In the original Higham study, a diary score of 100 had 86% sensitivity and 81% specificity for true menorrhagia for benign causes as determined by chemical analysis of the saturated pads.

Patient Population

- 260 patients in Intent to Treat (134 GYNECARE THERMACHOICE I; 126 RB)
    - 1 aborted RB for uterine perforation
    - 2 aborted (1 GYNECARE THERMACHOICE I; 1 RB) for submucous fibroid
    - 2 aborted GYNECARE THERMACHOICE I for inability to maintain device pressure

- 255 patients treated with test or control device (131 GYNECARE THERMACHOICE I; 124 RB)

Baseline demographic, physical exam and gynecological variables were statistically equivalent between the test and control groups with regard to age (GYNECARE THERMACHOICE I 40.2 years, RB 40.9 years), race, body mass index, mean baseline diary score (GYNECARE THERMACHOICE I 552.5, RB 570) and other criteria.

Table 2. Subject Withdrawals

Subjects:	**GYNECARE THERMACHOICE I**	**ROLLERBALL**
Entered into study (Intent to Treat Population)	**134**	**126**
Procedure aborted	3	2
Receiving complete treatment	131	124
For whom 12-month data not available: Hysterectomy Withdrew Lost to follow-up	6 2 1 3 • 1 diary score 14 • 1 amenorrhea @ 3 mo.	10 3 4 • 1 daughter's death • 1 menorrhagia • 1 depression • 1 amenorrhea @ 3 mo. 3 • 1 amenorrhea @ 3 mo. • 1 6-mo. diary score 32 • 1 6-mo. diary score 77
For whom 12-month data available	125	114
For whom 24-month data not available Hysterectomy Lost to follow-up	3 2 1 • 1 yr. hypomenorrhea	9 6 3
For whom 24-month data available	122	105
For whom 36-month data not available Repeat Ablation Hysterectomy Lost to follow-up Withdrew	8 1 4 2 • both hypomenorrhea @ 2 yr. 1	5
For whom 36-month data available	114	100

RESULTS

Effectiveness

Table 3. Effectiveness Bleeding Rates shows the success rates for the Intent to Treat Group (134 GYNECARE THERMACHOICE I; 126 RB) as based on diary scores at the 1-year follow-up of 75 or less. Success at 24 and 36 months, based on telephone questionnaires, is defined as elimination of bleeding or reduction to light or normal flow. The worst-case scenario is presented whereby each of the discontinued patients (described in Table 2 for Subject Withdrawals) is counted as a "failure" for calculating the values listed in the table. Only the amenorrhea rate at 1 year is statistically significantly different between treatment groups ($p \leq 0.05$).

Table 3. Effectiveness Bleeding Rates - Intention to Treat Group†

	GYNECARE THERMACHOICE I (n=134)			ROLLERBALL (n=126)		
Months Post Treatment	**12a**	**24b**	**36b**	**12a**	**24b**	**36b**
Number of Successful Patients	101	109	106	97	95	94
Study Success Rate	75.4%†	81.3%†	79.1%†	77.0%†	75.4%†	74.6%†
# of Patients with Amenorrhea (# of patients with diary scores = 0)	19	16	17	31	23	27
Amenorrhea Rate (% Patients with diary scores = 0)	14.2%§	11.9%†	12.7%†	24.6%†	18.2%†	21.4%†

[a] -based on diary scores
[b] -based on telephone questionnaires
† See Table 1a for Subject Withdrawals
‡Not Statistically Significant (P >0.05)
§Statistically Significant (P ≤0.05)

Table 4. Effectiveness Quality of Life presents the Quality of Life Questionnaire responses for patients who responded at 12, 24 and 36 months. Patients discontinued prior to the visit (described in Table 2) were not included in the calculations. There were no statistically significant differences between groups.

Table 4. Effectiveness Quality of Life†

	GYNECARE THERMACHOICE I			ROLLERBALL		
Months Post Ablation	**12**	**24**	**36**	**12**	**24**	**36**
# of Patients Who Responded to Quality of Life Questionnaire	**125**	**122**	**114**	**114**	**105**	**100**
% Patients with anemia pre-treatment (HCT)	29.9%	N/A	N/A	29.7%	N/A	N/A
% Patients with anemia post-treatment (HCT)	11.6%	N/A	N/A	10.6%	N/A	N/A
Satisfaction: very satisfied or satisfied	96.0%	95.9%	95.6%	98.2%	98.1%	97.0%
% Patients with reduction in dysmenorrhea	70.4%	72.1%	73.7%	75.4%	75.2%	78.0%
% Patients unable to work outside the home pre-treatment	39.7%	39.7%	39.7%	41.9%	41.9%	41.9%
% Patients unable to work outside the home post-treatment	4.0%	0.8%	2.7%	2.7%	2.9%	1.0%
% Patients reporting severe impact on life pre-treatment	70.3%	70.3%	70.3%	78.6%	78.6%	78.6%
% Patients reporting severe impact on life post-treatment	3.2%	4.9%	1.8%	1.8%	1.0%	2.0%

† See Table 2 for Subject Withdrawals

Safety
Table 5 Safety shows there were no intra-operative adverse events and 4 post-operative adverse events in the GYNECARE THERMACHOICE I Group (n=134). In the Rollerball Group (n=126) there were 4 intra-operative adverse events and 3 adverse events in the immediate post-operative period. These differences were not statistically significant. The mean procedure time for the GYNECARE THERMACHOICE I patients was statistically significantly less than for the RB patients.

Table 5. Safety

	GYNECARE THERMACHOICE I (n=134)	**ROLLERBALL (n=126)**
Intra-operative adverse events	None (0%)	2 fluid overload 1 cervical laceration 1 uterine perforation (3.2%)
Post-operative adverse events	1 post-coital bleeding 3 endometritis 1 UTI (3.7%)†	1 endometritis 1 hematometra 1 PATSS[1] (2.4%)†
Mean procedure time (minutes) Procedure time is duration between patient prep and catheter removal.	27.4‡	39.6‡

[1] PATSS = post-ablation tubal sterilization syndrome
† Not Statistically Significant (P >0.05)
‡Statistically Significant (P ≤0.05)

Anesthesia Regimen
Selection of anesthesia regimen was left to the individual investigators. Fewer cases were performed under general anesthesia in the GYNECARE THERMACHOICE I group as compared to the Rollerball group. For GYNECARE THERMACHOICE I only 53.7% had the procedure under general anesthesia (approximately 46% under local) versus 84.1% who had the Rollerball procedure performed using general anesthesia (approximately 16% under local).

Hysterectomy
There were a total of 22 patients (8 GYNECARE THERMACHOICE I; 14 RB) who had hysterectomies within 3 years following endometrial ablation.

Table 6. Hysterectomy

Reason for Hysterectomy	**Total**†	
	GYNECARE THERMACHOICE I **(n=134)**	**RB (n=126)**
Possible Carcinoma (found negative)	0	1
Menorrhagia/abnormal bleeding	3	5
Pelvic pain/severe dysmenorrhea	4	6
Endometriosis/ovarian cysts	1	2
Total	**8 (8.6%)**	**14 (11.1%)**

† 13 hysterectomies were in patients <40 years (4 GYNECARE THERMACHOICE I, 9 RB); 9 hysterectomies were in patients >40 years (4 GYNECARE THERMACHOICE I, 5 RB)

GYNECARE THERMACHOICE III

GYNECARE THERMACHOICE III Catheter (version 3.0) includes an active mechanism for circulation of the D_5W within the balloon. Laboratory testing showed that the active circulation of fluid within the balloon will

lead to a more even distribution of heat at the balloon surface and thereby, over the endometrial tissue. A clinical investigation was conducted to determine the incidence of post-procedure amenorrhea among women treated with GYNECARE THERMACHOICE **III.**

CONCLUSIONS:

In a study performed with GYNECARE THERMACHOICE III, the primary effectiveness analysis (ITT matched subjects comparison between historical GYNECARE THERMACHOICE I data and Thermachoice III (TCIII, NPPC group only) evaluated amenorrhea at 12 months after ablation. Results revealed that 32.6% of women experienced amenorrhea at 12 months after ablation with GYNECARE THERMACHOICE III as compared to 13.7% after ablation with GYNECARE THERMACHOICE I. The difference in amenorrhea rates between these groups was statistically significant (p=0.0025). The observed rate of return to normal bleeding levels was greater in NPPC subjects treated with GYNECARE THERMACHOICE III compared to GYNECARE THERMACHOICE I (82% vs. 77%). This difference was not statistically significant.

In the Intent To Treat analysis for all treated subjects comparing subjects receiving no post procedure curettage (NPPC) to those receiving post procedure curettage (PPC), 37.1% (NPPC) and 33.3% (PPC), respectively, experienced amenorrhea at 12 months after ablation with GYNECARE THERMACHOICE III. There was no statistically significant difference in amenorrhea rates between NPPC group and PPC group (p=0.53). Similar rates of return to normal bleeding were observed in NPPC group compared to PPC group after GYNECARE THERMACHOICE III ablation. **Therefore, given these results and the added risks associated with post procedure curettage, this additional procedure is not recommended after ablation unless otherwise medically indicated.**

PURPOSE:

The purpose of the GYNECARE THERMACHOICE III study was to determine the incidence of amenorrhea 12-months post treatment among women treated with the GYNECARE THERMACHOICE III UBT System for the treatment of menorrhagia as compared to the incidence of amenorrhea observed in the original GYNECARE THERMACHOICE I UBT System clinical trial.

There were additional secondary study objectives:

- To confirm the post-procedure incidence of normal bleeding levels observed with GYNECARE THERMACHOICE III UBT System was comparable to the incidence of normal bleeding levels observed in the original GYNECARE THERMACHOICE I UBT System clinical trial
- To determine the effect of a post-procedure curettage on bleeding patterns and post-operative discharge and post-operative pain
- To evaluate changes in Quality of Life (QoL) following the procedure
- To evaluate system usability

STUDY ENDPOINTS:

For the primary objective, the incidence of amenorrhea among subjects randomized to no post-procedure curettage was compared to the incidence of amenorrhea among subjects who participated in the original GYNECARE THERMACHOICE UBT I System clinical trial. The primary effectiveness measure was a validated diary scoring system (adapted from Higham JM, O'Brien PMS, Shaw RW, Assessment of menstrual blood loss using a pictorial chart, Br J Obstet Gynaecol 1990; 97:734-9). Success (amenorrhea) was defined as a diary score of zero. Patient success was defined as a diary score of zero. Secondary endpoints evaluated were "return to normal bleeding" as indicated by a PBLAC score of 75 or less, responses from a quality-of-life questionnaire, and system usability. The endpoints for safety were based on the evaluation of adverse events associated with each procedure, including device-related complications and type of anesthesia used. Randomization was performed to accomplish a secondary objective of the study, the evaluation of the effect of post-procedure curettage on bleeding patterns, and the safety evaluation of post-operative discharge and pain parameters.

METHODS:

This was a randomized, historically controlled, multicenter, 2-arm evaluation conducted at 13 sites with 250 patients diagnosed with menorrhagia. Eligible subjects who had given consent were randomized to post-procedure curettage or to no post-procedure curettage. Menstrual diary scores were collected pre-treatment and at intervals out to 12

months post-procedure. All patients were to undergo a pre-procedure sharp or suction curettage immediately prior to the ablation to thin the endometrial lining.

Study subjects will be followed for a total of 36 months post-procedure.

Study subjects were required to meet the following patient selection criteria:

Inclusion criteria

The subject needed:

- to be a premenopausal female at least 30 yrs., in whom childbearing is complete
- excessive menstrual bleeding, documented by a diary score of at least 150,
- 3 months of documented failed, refused or contraindicated medical therapy,
- an anatomically normal uterine cavity sounding at least 4cm, but not greater than 12cm,
- a normal pap smear and no unexplained abnormal pap smears within 1 year of the procedure,
- to agree not to switch from hormonal to non-hormonal contraception or vice versa during or just prior to the study,
- to agree to use reliable contraception throughout the study,
- to agree to participate in the study including all study related procedures and evaluations, and document this agreement by signing the informed consent document.

Exclusion criteria

The subject could not have:

- an active pelvic inflammatory disease (PID) or recurrent chronic PID,
- active genital or urinary tract infection at the time of the procedure,
- history of malignancy of the reproductive system within 5 years of study entry
- history of malignancy of the endometrium, endometrial neoplasia, determined by endometrial biopsy taken within 6 months of study entry,
- cavity distorting myomas determined by preoperative hysterogram, hysteroscopy, or transvaginal sonography within 6 months of the procedure,
- previous endometrial ablation procedure,
- previous uterine surgeries (such as full thickness myomectomy, subserosal myomectomy, uterine reconstruction, or any surgery in which thinning of the uterine musculature could occur) except for low transverse caesarean section,
- been pregnant or desirous of future pregnancy,
- taken endometrial suppression therapy, except for oral contraceptives, within 3 months of procedure,
- concurrent open or laparoscopic surgery.

PATIENT POPULATION

Patients were between the ages of 28 and 55 with 37.2% under the age of 40 (inclusive), and 62.8% over the age of 40 years. Baseline demographic, physical exam and gynecological mean variables were not statistically different between the test and control groups with regard to age (NPPC 42 years, PPC 42.1 years), race, body mass index, and baseline diary score (NPPC 752.4, PPC 659). The table below (Table 7) describes the accountability of subjects throughout the study period:

Table 7. Subject Accountability

SUBJECTS	NPPC	PPC	TOTALS
Entered into study (Intent to Treat Population)	124	126	250
Unable to treat	1	3	4
Receiving complete treatment	123	123	246
Details for patients with 12-month data not available:			
Hysterectomy	2	4	6
Withdrew	4	3	7
Lost to follow-up	11	10	21
Unable to treat	1	3	4
Incomplete data	0	2	2
For whom 12-month data is available	**106**	**104**	**210**

RESULTS

Effectiveness – Bleeding

Comparison to Historical Control:
Subjects from the original GYNECARE THERMACHOICE I study were matched to subjects from the GYNECARE THERMACHOICE III (NPPC subjects) study using the Propensity score method. This included an identification of the covariates affecting treatment difference between GYNECARE THERMACHOICE III and GYNECARE THERMACHOICE I study; balancing the covariates using Propensity score method and then analysis of the results using matched and unmatched data. The matched data were used to test the (null) hypothesis that the amenorrhea rates in GYNECARE THERMACHOICE I and GYNECARE THERMACHOICE III treated subjects at 1-year are the same. Results showed that the amenorrhea rate for subjects treated with GYNECARE THERMACHOICE III was significantly higher than the amenorrhea rate for the matched cohort from the GYNECARE THERMACHOICE I study ($p=0.0025$). These results are found in Table 8.

Table 8. Effectiveness – Amenorrhea GYNECARE THERMACHOICE III NPPC VS. GYNECARE THERMACHOICE I (Matched Subjects) at One Year

ANALYSIS POPULATION		STUDY GROUP		SUCCESS RATE P-VALUE FOR GYNECARE THERMACHOICE I vs. GYNECARE THERMACHOICE III
		GYNECARE THERMACHOICE I	GYNECARE THERMACHOICE **III**	
ITT Matched Subjects	% (#Successes/N)	13.7% (13/95)	32.6% (31/95)	0.0025
	95% C.I. for Success Rate	(7.5% - 22.3%)	(23.4% - 43.0%)	

The effectiveness of GYNECARE THERMACHOICE III compared to GYNECARE THERMACHOICE I [matched subjects from GYNECARE THERMACHOICE III (NPPC) to GYNECARE THERMACHOICE I] was also evaluated in terms of achieving normal bleeding at one year post-procedure. This was defined as a PBLAC score of 75 or less. This information is provided in Table 9, as an intent to treat analysis where missing data are considered failures.

Table 9. Effectiveness- Return to Normal Bleeding: GYNECARE THERMACHOICE III NPPC VS. GYNECARE THERMACHOICE I at one Year

Effectiveness – Return to Normal Bleeding **ITT Matched subjects**	GYNECARE THERMACHOICE **III NPPC**	GYNECARE THERMACHOICE I	**p-value**
% Return to Normal (#Successes/N)	82.1% (78/95)	76.8% (73/95)	0.37

Randomized Cohorts:

An analysis was also conducted comparing amenorrhea rates for subjects receiving no post procedure curettage (NPPC) to those receiving post procedure curettage (PPC) at 12 months after ablation with GYNECARE THERMACHOICE III. Table 10 shows the success rates for the Intent to Treat Group (124 NPPC; 126 PPC) as based on a reduction in diary score from ≥150 to zero at the 1-year follow-up visit. Each of the discontinued subjects (described in Table 1a for Subject Accountability) is counted as a "failure" for calculating the values listed in the table. There was no statistical difference between the amenorrhea rates of the NPPC and PPC groups.

Additionally, a separate analysis of amenorrhea rates for all GYNECARE THERMACHOICE III treated subjects was performed in order to compare the NPPC group to PPC group for both Intent-to-Treat (ITT) and Per-Protocol (PP) groups. The PP group included all treated subjects with a 12-month diary score and no major protocol deviations.

For both the ITT and PP groups, the success rates within the two treatment groups were comparable and the difference in amenorrhea rates between the two treatment groups was not statistically significant (p=0.59). table 10 presents the amenorrhea rates within the two treatment groups.

Table 10. Effectiveness- Amenorrhea: GYNECARE THERMACHOICE III (NPPC VS. PPC) at One Year

ANALYSIS POPULATION		**TREATMENT GROUP** GYNECARE THERMACHOICE **III**		P-VALUE NPPC vs. PPC
		NPPC	**PPC**	
ITT Subjects, Matched And Unmatched	Study Success Rate	37.1% (46/124)	33.3% (42/126)	0.53
	95% C.I. for Success Rate	(28.6%-46.2%)	(25.2%- 42.3%)	
PP Subjects, Matched And Unmatched	Study Success Rate	44.7% (42/94)	40.8% (40/98)	0.59
	95% C.I. for Success Rate	(34.4%-55.3%)	(31.0%- 51.2%)	

The effectiveness of GYNECARE THERMACHOICE III in the NPPC and PPC groups was also evaluated in terms of achieving "normal bleeding" at one year post-procedure, which was defined as a PBLAC score of 75 or

Table 11: Effectiveness- Return to Normal Bleeding: TCIII (NPPC vs. PPC) at One Year

Effectiveness – Return to Normal Bleeding ITT Analysis	GYNECARE THERMACHOICE **III NPPC**	GYNECARE THERMACHOICE **III PPC**	**p-value**
% Return to Normal (#Successes/N)	80.6% (100/124)	76.2% (96/126)	0.39

Effectiveness – Quality of Life

Quality of Life (QoL) data was obtained using the same QoL questionnaire as was used in the TCI study. Patient satisfaction and improvement in some quality of life parameters at 12-months post-procedure are included in the Table 12. Results are provided based on the number of responders. There were no statistically significant differences between NPPC and PPC groups.

Table 12. Effectiveness Quality of Life

	NPPC	PPC
Satisfaction: Patients who were satisfied	96.1% (99/103)	95.9% (94/98)
Percent of Patients with Reduction in Dysmenorrhea†	88.7% (94/106)	90.4% (94/104)
Patients Who Missed at Least 1 Day per Month from Work – PRE-TREATMENT	54.4% (49/90)	53.4% (47/88)
Patients Who Missed at Least 1 Day per Month from Work – 12 Months POST-TREATMENT	1.3% (1/80)	2.7% (2/75)
Patients Reporting Severe Impact on Life Score (8 to10)- PRE-TREATMENT	74.0% (91/123)	75.2% (91/121)
Patients Reporting Severe Impact on Life Score (8 to10) 12 Months POST-TREATMENT †	3.9% (4/103)	9.1% (9/99)

† 12-month follow-up

CLINICAL OBSERVATIONS

Pretreatment Preparation for the Clinical Study

All study subjects were supposed to undergo a ***pre-treatment*** suction or sharp curettage to thin the endometrium prior to ablation. However, due to investigator practice not all subjects required curettage to thin the endometrium. An intent to treat analysis showed no significant impact of pre-treatment curettage on treatment outcome.

ANESTHESIA

Anesthesia was delivered at the discretion of the investigator. The following table provides a summary of the types of anesthesia used in this study.

Table 13. Anesthesia Use

Anesthesia Type	NPPC N=124	PPC N=126	Total N=250
General†	76.6% (95/124)	74.6% (94/126)	75.6% (189/250)
Cervical Block	32.3% (40/124)	29.4% (37/126)	30.8% (77/250)
Epidural	0	2.4% (3/126)	1.2% (3/250)
Other‡	18.6% (23/124)	22.2% (28/126)	20.4% (51/250)

† General anesthesia typically involved endotracheal intubation

‡ "Other" included spinal, IV sedation, Laryngeal Mask Airway (LMA) and Monitored Anesthesia Care (MAC).

HYSTERECTOMY

Seven subjects (4 NPPC; 3 PPC) had hysterectomies within 12 months following endometrial ablation.

Table 14: Hysterectomy at or Before 12 Months

Reason for Hysterectomy	Total	
	NPPC (n=4)	PPC (n=3)
Hyperplasia		1
Menorrhagia/abnormal bleeding	3	1
Pelvic pain/severe dysmenorrhea	1	1
Total	**4**	**3**

System Usability Summary

System Usability was evaluated on all 250 subjects undergoing treatment during this GYNECARE THERMACHOICE III trial. The System Usability endpoint was any case requiring an intervention to overcome a system issue after connection of the catheter to the controller has begun, i.e. having to restart. There were 28 cases of procedure events meeting this definition out of the 250 cases, resulting in a final rate of 11.2%. This rate demonstrates an improvement over that observed in the original GYNECARE THERMACHOICE I trial (18.6%) and in the GYNECARE THERMACHOICE II Post-Market Study (31.7%).

PATIENT SELECTION

Menorrhagia can be caused by a variety of underlying problems including, but not limited to, endometrial cancer, myomas, polyps, anovulation, drugs and dysfunctional uterine bleeding. Patients should always be evaluated to determine the cause of their excessive uterine bleeding before any treatment option is initiated.

Consult medical literature relative to various endometrial ablation techniques, indications, contraindications, complications and hazards prior to the performance of any endometrial ablation procedures.

The patient selection criteria are:

- Documented diagnosis of menorrhagia for benign causes
- Completed childbearing
- Premenopausal
- Normal pap smear and endometrial biopsy
- Anatomically normal uterine cavity: standard sonography, saline infusion sonography, hysteroscopy, or hysterosalpingography within 6 months prior to performing GYNECARE THERMACHOICE UBT should be used to rule out submucous fibroids, large polyps and congenital abnormalities
- Uterine cavity depth of 4-12 cm
- Failed or contraindicated medical therapy

PATIENT COUNSELING

As with any procedure the physician needs to discuss risks, benefits and alternatives with the patient prior to performing endometrial ablation. In addition, the physician should discuss signs and symptoms of potential complications such as bleeding, infection or thermal 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. Post-procedure pregnancy may be dangerous for both mother and fetus. Patients of childbearing capacity should be counseled that endometrial ablation is not a sterilization procedure and should be provided an appropriate birth control method. Patients with childbearing capacity should be cautioned of the potential complications, which may ensue if they should become pregnant.

Vaginal discharge is typically experienced during the first few days following ablation and may last as long as a few weeks. Generally, the discharge is described as bloody during the first few days; serosanguinous by approximately one week; then profuse and watery thereafter.

SURGEON PREPARATION

1. Surgeon scrubs with antiseptic solution as per local practice.
2. Surgeon dons sterile gown and sterile gloves as per local practice.

SITE PREPARATION

Anesthesia Options Include:
- General
- IV Sedation and Local
- Local Only
- Regional (epidural, spinal)

Preparation Steps:
1. The patient is placed in the dorsal lithotomy position.
2. Surgeon thoroughly prepares perineum, vagina and cervix with antiseptic solution per local practice.
3. The patient is draped exposing perineum only.
4. A pelvic examination is performed to determine size, shape and position of cervix and uterus.
5. The uterus is sounded.
6. Adequate visualization of the cervix is accomplished with appropriate speculum.

PRETREATMENT PREPARATION OF PATIENT

The lining of the uterus should be thinned prior to GYNECARE THERMACHOICE III UBT. This can be accomplished by timing the menstrual cycle to the early proliferative phase, administering pretreatment drugs such as danocrine or GnRH agonists, or performing suction or sharp curettage immediately prior to performing the endometrial ablation. The optimum pretreatment regimes have not been determined at this time.

It is recommended that a non-steroidal anti-inflammatory drug (NSAID) be given at least one hour prior to treatment and continued post-operatively as necessary to reduce intra-operative and post-operative uterine cramping.

DIRECTIONS FOR USE

Please read all directions, precautions and warnings prior to use.

1.0 SET-UP

1.1 The following items are required for use of the GYNECARE THERMACHOICE UBT System.
GYNECARE THERMACHOICE III UBT System
1 sterile disposable GYNECARE THERMACHOICE III UBT silicone balloon catheter and syringe (30 cc)
1 umbilical cable
1 controller
1 power cord

Medical Supplies
50 cc sterile injectable 5% dextrose in water (D_5W)
tenaculum, (weighted) speculum
uterine sound, cervical dilator(s)
sterile drape for umbilical cord (optional)

Note: Use only plain D_5W to inflate balloon catheter. Never use any other liquid.

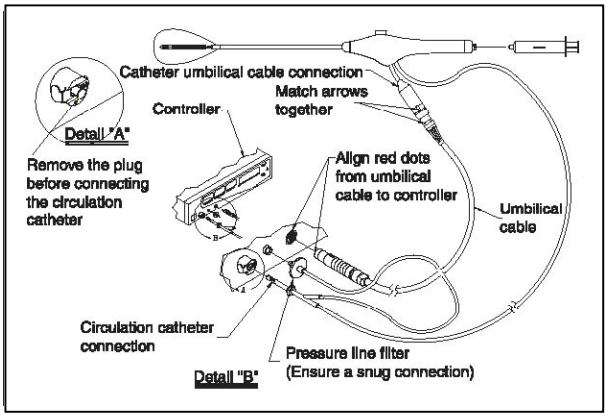
1.2 Open the sterile package containing the GYNECARE THERMACHOICE III UBT Catheter and Syringe. Disinfect umbilical cable as described in the GYNECARE THERMACHOICE UBT System Operating Manual. **Handle balloon portion of the catheter carefully to prevent damage.**

1.3 Make sure that the controller power is off before making the connection (Steps 1.4 – 1.6).

1.4 Plug the power cord into the back of the controller and into the wall outlet.

1.5 The umbilical cable includes a connector plug at each end to connect the balloon catheter to the controller. Visually inspect the cable and connector plug to ensure there are no defects or signs of wear. Drape umbilical cable with sterile drape, if necessary, and attach the cable to the connector on the catheter (match arrows together). Attach the opposite end of the cable to the connection port on the front panel of controller. (Align red dots from umbilical cable to controller). (**See Diagram 1**)
Note: When oriented correctly, the cable plugs will fit into the connectors easily and securely.

Diagram 1



1.6 Connect the pressure line (pre-attached to balloon catheter) to the connection port (luer lock) on the front panel of the controller. Do not overtighten, but ensure a snug connection or the device may not function properly. (**See Diagram 1**) **Ensure that the pressure line is fully connected prior to adding any fluid to the system. Avoid loops, kinks or bends in pressure line from controller to catheter to reduce the potential for motor fault issues.** Periodically clean the entrance of the controller's port, using a cotton swab with 70% isopropyl alcohol.

1.7 Remove the plug from the circulation catheter port. To remove the plug, press on the locking latch and pull the plug. Save the plug. It should be reinstalled when the controller is not in use. Connect the circulation catheter plug into the circulation port. It will lock in place with a slight click. Make sure it's locked in by slightly pulling on it.

1.8 TURN ON the controller POWER. The Message Display will read: Message Display:

Note: N.NN = software revision level

REVISION N.NN
INITIALIZING

Message Display:

CONNECT CATHETER

Once catheter is connected, the Message Display will read:

PRIME CATHETER

The pressure line MUST be connected to the controller BEFORE the balloon catheter is filled with fluid, or the device will not function properly.

2.0 CATHETER PRIMING
Note: When adding fluid during priming, ensure that the balloon fully opens so that none of its sides are touching.

2.1 **FILL** the 30 cc syringe with up to 20 cc (consistency w/2.4) of sterile injectable 5% dextrose in water (D_5W).
Use only sterile injectable 5% dextrose in water (D_5W). Use of other fluids may compromise the system.

2.2 **CONNECT** the syringe to the port in the proximal end of the balloon catheter. Do not overtighten syringe when connecting.

2.3 Point balloon catheter tip downward.

2.4 Press trumpet valve on top of balloon catheter handle and **SLOWLY** fill with up to 20 cc of D_5W. Ensure that the pressure does not go above 200mmHg indicated by the pressure display on the controller.

2.5 Press trumpet valve and evacuate fluid and air from balloon to a negative pressure of -150 to -200 mmHg (indicated by pressure display on controller).

Note: You may need to purge air from syringe several times to attain desired negative pressure. You must release the trumpet valve to maintain negative pressure. Air should be completely evacuated to optimize the function of the device. During priming, when catheter pressure is <-150 mmHg, the Message Display is: PRIME

PRIME CATHETER
<–150 mmHg

DO NOT EXCEED - 200 mmHg negative pressure during evacuation. Excessive negative pressure can lead to greater pressure fluctuation during therapy.

2.6 The negative pressure creates a low-profile balloon insertion (balloon is drawn tight against catheter tip). Do not go beyond –200 mmHg. Check that negative pressure is maintained for at least 10 seconds before proceeding. Once catheter pressure is >-150 mmHg, the Message Display is:

INSERT CATHETER
& FILL WITH D_5W

If negative pressure cannot be maintained for 10 seconds, remove the balloon catheter and replace.

3.0 PRESSURE TITRATION

3.1 **Fill syringe to 30 cc with D_5W**, purge air, and connect to balloon catheter (do not overtighten). **Up to 5 cc additional fluid may be used if needed, for a total of 35 cc.**

3.2 Measure depth of uterus.

3.3 Using appropriate sterile technique and cervical/vaginal preparation, dilate cervix to 5 mm if necessary. If a perforation is suspected at this point, perform appropriate diagnostic measures to evaluate for perforation before proceeding. If perforation can not be ruled out, abandon the procedure.

3.4 Wet the outside of balloon with D_5W.

3.5 After sounding the uterus, and wetting the balloon, **SLOWLY INSERT THE BALLOON CATHETER** into the uterus until the tip is touching the fundus. Ensure that the depth indicated by markings on catheter is consistent with previous sound measurement. Use a tenaculum to hold the cervix if necessary.

3.6 **Ensure that the cervix is dilated to 5mm and do not use excessive force during insertion, as such force can cause the balloon to tear or the catheter to perforate the uterine wall.** If a perforation is suspected at this point, perform appropriate diagnostic measures to evaluate for perforation before proceeding. If perforation cannot be ruled out, abandon the procedure.

3.7 Press trumpet valve on top of balloon catheter and fill balloon **SLOWLY** to pressure of 160-180 mmHg using 2-35 cc of D_5W (Release the trumpet valve to allow the pressure to stabilize). **Do not allow the pressure to exceed 200 mmHg during titration.** Incrementally add small volumes to achieve a stable pressure (no fluctuations greater than ±10 mmHg) of 160-180 mmHg for a minimum of 30 seconds. The pressure of the balloon against the uterine wall often precipitates uterine contraction, thereby temporarily increasing the pressure reading.

If pressure cannot be stabilized at 160-180 mmHg for 30-45 seconds with up to 35 cc of fluid, this may indicate uterine perforation. Remove the fluid and then remove the balloon catheter. If a balloon leak is present, replace the catheter and continue with the procedure. IF NO BALLOON LEAK IS FOUND, ABORT THE PROCEDURE.

Note: Once the heater is activated, the pressure may initially rise 10-20 mmHg; the pressure may then drop slowly for the remainder of the procedure. The ending balloon pressure may be as low as approximately 100 mmHg, and is typically between 120-150 mmHg.

Note: It is recommended that for very small uteri, pressure titration should occur towards the lower end of the range (i.e. Use a minimum amount of fluid to reach 160 mmHg. This will reduce the potential for increase of pressure during the thermal treatment that might result in overpressure and system shutdown.)

Note: Positioning the device in a false passage may allow the balloon to reach operating pressure with a small amount of fluid. This may be misinterpreted as being a small uterine cavity. Care should be taken to insure the device is properly positioned in the uterine cavity.

Do not over pressurize balloon during titration.

Total fluid volume to achieve optimal balloon volume depends on the potential volume of the uterine cavity and is typically 6-20 cc at >160 mmHg (at start) and may be as great as 35 cc. If pressure level cannot be reached with up to 35 cc of fluid, remove balloon catheter and check for uterine perforation and/or balloon catheter leak. Replace balloon catheter if necessary.

4.0 TREATMENT

4.1 Message Display (alternating):

READY
PRESS START

and

STABILIZE START
PRESSURE >150 mmHg

When a steady pressure of 160–180 mmHg is maintained, press START (◇) button on controller to activate the heater.

Do not add fluid once heater is activated, as this could create (or exacerbate if already present) a uterine wall defect such as perforation. Hold the balloon catheter immobile and centered in the uterine cavity during procedure (with the valve oriented upwards). Failure to hold the balloon catheter immobile during procedure can result in catheter failure.

Caution: Ensure that the catheter is held such that it does not rest on the vaginal wall during treatment and cool down periods to prevent possible burns.

Note: Ensure that the balloon catheter is centered in the uterus to minimize potential overheat error codes during the treatment process. Prior to activating heater, ensure that fluid is on all sides of the catheter tip. It is no longer necessary to maintain contact with the fundus.

4.2 After the start button is pressed, the controller activates the heat to achieve treatment temperature of 87°C (188°F) within 4 minutes. (This preheat cycle may take up to 4 minutes for larger uteri, but is usually 15-45 seconds.)

PREHEATING
TO 87°C

Note: If the treatment temperature of 87°C is not reached within 4 minutes, the controller will terminate the procedure. Remove the fluid and then remove the catheter.

Note: During treatment and in case of emergency, the STOP (▽) button can be pressed to terminate the procedure. The stop button will power down the heater. The heater function can only be resumed by turning the unit off and restarting.

4.3 Message Display:

THERAPY CYCLE
CYCLE 87°C, 8 MIN

Once 87°C is reached, an audible tone will indicate the automatic activation of the 8 minute therapy cycle. The Time elapsed will be shown on the “THERAPY TIME” display. After the preheat cycle is completed the time resets to 0:00. The displayed time represents the exact therapy cycle time.

Note: Pressure may rise slightly with initial heating. It is common to then see the pressure fall gradually during procedure. If the pressure reaches 200 mmHg, an alarm will sound. If the pressure exceeds 210 mmHg for more than 2 seconds, the controller will terminate the procedure. The procedure may be restarted with a lower starting pressure to complete an 8 minute therapy.

Note: A rapid drop in pressure or a failure to maintain pressure may be the result of a catheter leak or uterine perforation. After sufficient cooling, remove the fluid and then remove the balloon catheter and abort the procedure. A work-up for perforation should be considered prior to discharge.

Note: Never add additional fluid during a therapy cycle as this could create (or excerbate if already present) a uterine wall defect such as a perforation.

4.4 When the treatment cycle is completed, the Message Display will alternate between the following messages:

THERAPY COMPLETE	and	COOLING DOWN PLEASE WAIT

4.5 The controller automatically terminates the heater at the end of the treatment (cycle) and an audible alarm will sound.

5.0 POST-TREATMENT

5.1 The cool down cycle takes 30 seconds. When the cycle is completed, the Message Display will read the following:

THERAPY & COOL DOWN COMPLETED	then	REMOVE FLUID REMOVE CATHETE

Remove fluid by drawing back on syringe while depressing trumpet valve.

Remove all fluid from balloon. Remove the balloon catheter. Check that the entire fluid volume is withdrawn.

5.2 Disconnect the catheter pressure line from the controller.
5.3 Disconnect the circulation catheter plug from the controller.
5.4 Disconnect the umbilical cable from the catheter umbilical cable by pulling back on the gray collar.
5.5 Disconnect the umbilical cable from the controller by holding the stainless steel ribbed shell and pulling back. Do not pull on the cable itself.
5.6 Discard the catheter. Retain the umbilical cable and disinfect for the next case.
5.7 The power must be turned off before beginning another procedure.

Note: When a controller is left on without use for 8 hours, the controller freezes and displays the following message:

MAX TIME EXPIRED TURN POWER OFF

ORDERING INFORMATION AND RELATED PARTS AND ACCESSORIES

REF	DESCRIPTION
#00826	GYNECARE THERMACHOICE UBT System Controller
#TC033	Sterile, single-use GYNECARE THERMACHOICE III Catheters (Version 3.0)
#TC043	Sterile, single-use GYNECARE THERMACHOICE III Catheters (Version 3.0) (5-Pack)
#01105	GYNECARE THERMACHOICE Umbilical Cable (reusable up to 20 applications)
#04994	GYNECARE THERMACHOICE Power Cord

Contact your distributor for ordering.

Assembled in Mexico of U.S. components.

Manufactured by:
GYNECARE
a Division of ETHICON, INC.
a Johnson & Johnson company
Somerville, N.J. 08876-0151 USA
Tel: 1-877-ETHICON

Authorized European Representative:
ETHICON, division of Johnson & Johnson Medical Limited
PO Box 1988
Simpson Parkway
Kirkton Campus
Livingston
EH54 0AB
Scotland

CE0086

SYMBOLS USED ON LABELING

STERILE EO — Method of Sterilization—Ethylene Oxide	LOT — Batch Number
2 — Do not reuse/resterilize	Use by—year and month
See instructions for use	CE 0086 — CE Mark and identification number of Notified Body. Product conforms to the essential requirements of the Medical Devices Directive 93/42/EEC.

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