

**RECOMMENDED PROTOCOL FOR THERMABLATE BALLOON ABLATION  
PERFORMED IN AN OUTPATIENT SETTING**

Dr. George Vilos, Obstetrics and Gynaecology; Western University, London, Ontario

**Patient Assessment and Selection**

- History of heavy menstrual bleeding (HMB, menorrhagia) > 3 months (cycles regular with no inter-menstrual bleeding). Since balloon ablation decreases, rather than eliminates menstrual bleeding, meno-metrorrhagia may result in “meno-metropotting” and patient dissatisfaction
- Pelvic examination
  - Normal size and shape uterus
- Pap smear and Endometrial biopsy as per clinical practice guidelines, but highly recommended prior to GEA
  - Endometrial biopsy determines:
    - Pain tolerance
    - Ease/difficulty of cervical cannulation
    - Uterine position (anteverted, mid-position, retroverted)
    - Uterine depth (cm markings on catheter)
    - Endometrial histopathology
- Office Hysteroscopy ± biopsy (The Gold Standard)
- Imaging
  - Saline/Gel Infusion Sonography (SIS/GIS) acceptable
    - SIS/GIS determines size and shape of uterine cavity and presence/absence of intra-cavity lesions
    - Transvaginal ultrasound (TVS) is acceptable if entirely normal

**Patient Eligibility**

- Normal Papanicolaou smear in accordance with clinical practice guidelines
- Normal endometrial biopsy (within past 6 months)
- Normal size and shape intrauterine cavity (8-12cm in length)
- Easy, non-painful cervical/uterine access during office biopsy/hysteroscopy
- Fertility is not required
- Contraception is not required. (Thermablate ablation does not confer contraception)

**Pre-Treatment**

- Oral contraceptives (taken daily for minimum 21 days until day of treatment)
- Misoprostol 400 mcg vaginal suppository inserted the evening before treatment with a moist tampon

- Ibuprofen 400-600 mg orally taken in the evening before, and one hour prior to treatment
- Percocet – one tablet prior to procedure (discretionary)
- Anxiolytics (discretionary)

### **Treatment Protocol**

In accordance with the current revision of Operators Manual LS2607

#### ***Caution:***

***Patients with either an acutely anteverted or retroverted uterus, or a fixed uterus (e.g. due to significant endometriosis or adhesions), or those that have had previous uterine surgery are at a higher risk for perforation. Particular attention should be paid to the angulation of the uterine sound, cervical dilator and Thermablate catheter during insertion.***

- Conduct pelvic examination to confirm position of uterus
- Insert speculum
- Inject a total of 15-20 mL of paracervical cocktail at 4, 8 and 12 o'clock of cervix
- Wait for 3 to 5 minutes for local anaesthetic effect
- Apply single tooth tenaculum
- Measure sounding length of uterus from external os to fundus using uterine sound. Confirm that measurement is between 8-12 cm
- Use dilator to gradually dilate cervix up to 7 mm. Dilators should pass easily through the cervix with minimal discomfort to the patient. Dilators should not be advanced deeper than the predetermined uterine depth
- Measure length of uterus a second time using the uterine sound. Confirm that sounding length of the uterus after dilation is the same as sounding length obtained prior to dilation. If there is a discrepancy of more than 0.5cm between the first and second measurements a false passage or perforation of the uterus may have been created during the dilation
- Perform hysteroscopy prior to balloon insertion to ensure that uterus has not been perforated or that a false passage has not been created during dilatation, sounding or curettage (if performed).

#### ***Caution:***

***A perforation of the uterus or creation of a false passage, if undetected, can lead to thermal injuries of adjacent organs or tissue***

***Hysteroscopy should reveal both tubal ostia clearly before proceeding with the treatment. If distension of uterus during hysteroscopy cannot be maintained, it is possible that the uterus has been perforated and treatment should not proceed. Should the hysteroscopy reveal an excessively thick endometrial lining, a gentle curettage of the uterus may be performed. A second hysteroscopy should be performed immediately following curettage to ensure that the curettage has not created a perforation of the uterus***

- Alternatively, use ultrasonic surveillance during the treatment to check for correct balloon position inside the uterine cavity
- Slowly insert the Thermablate balloon until balloon tip touches the fundus. Tap the tip of catheter gently against the fundus to confirm placement of the catheter within the uterus
- Ensure that the depth marking on the balloon catheter matches the previously obtained sounding measurements. Should there be a discrepancy of more than 0.5 cm between the sounding measurements obtained and depth marking on the catheter, a repeat hysteroscopy should be performed
- Activate the treatment cycle by holding the trigger on device for 5 seconds. After hearing five (5) short and one (1) long beeping sounds, the treatment will automatically begin. Finger can be removed from the trigger switch at this point.
- As the balloon deploys, it may push the catheter slightly backwards (up to 0.5 cm is normal). Do not push the catheter forward during treatment.

***Caution:***

***At no time during the treatment should the catheter advance beyond the pre-determined sounding length. Should this occur, abort the procedure by turning the power switch off and then on again. Wait for the message: “Finished Withdraw Balloon” to appear on the LCD screen and slowly remove the Thermablate catheter from the uterus. Perform a hysteroscopy to ensure that the uterus has not been perforated.***

- Provide “Local Vocal”. The nurse and surgeon should engage the patient with trivial conversation throughout the treatment cycle
- Surgeon should keep a continuous feedback conversation with patient regarding the remaining duration of the treatment
- Patient should be asked to rate her discomfort on a scale from 0 to 10
- Observe the LCD screen on the Treatment Control Unit (TCU) as it automatically performs system checks and completes the treatment cycle
- Blood pressure, heart rate and oxygenation should be monitored continuously in the procedure room
- At end of the treatment cycle, the LCD screen will read **“FINISHED Withdraw Balloon”**
- Remove the catheter from the uterus and place the TCU in stand
- Post treatment hysteroscopy is recommended
- Turn off the TCU Power Switch
- Allow the cartridge to cool and discard

## Post Treatment

- Oral analgesics (Opioids if required)
- Observe for 1-2 hours and discharge
- Ibuprofen 400-600 mg 4 hours after treatment
- Provide printed instructions prior to discharge
- Follow up at 3-6, 12 months or as required

---

## Paracervical Cocktail

- 10 mL - Lidocaine with 1:200,000 epinephrine
- 10 mL - Bupivacaine 0.2% (long acting)
- 50 mL - Sodium Bicarbonate (1 ampoule)
- 3 mL - Atropine 1.5mg (3 ampoules)

**Total Solution: 73 mL** → **Inject 15-20 mL around cervix**  
→ **Monitor Blood Pressure**  
→ **Monitor Heart Rate**  
→ **Monitor Oxygen Saturation with Pulse Oximetry**

## REPEAT BALLOON ABLATION IS CONTRAINDICATED

Since the endometrial cavity, following any kind of endometrial ablation, is most likely distorted, repeat ablation should not be attempted with Thermablate. Patients requiring further treatment after thermal balloon ablation should be treated medically, by hysteroscopic endometrial ablation / resection or hysterectomy. Repeat hysteroscopic ablation / resection should be attempted only by experienced hysteroscopists since the complications can be severe.

---

## References:

Grow DC, Iromloo K. Oral contraceptives maintain a very thin endometrium before operative hysteroscopy. *Fertil Steril* 2006; 85:204-7.

Marsh F, Thewlis J, Duffy S. ThermaChoice endometrial ablation in the outpatient setting, without local anaesthesia or intravenous sedation: a prospective cohort study. *Fertil Steril* 2005; 83: 715:20.

Yackel DB, Vilos GA. Thermablate EAS: a new endometrial ablation system. *Gynecol Surg* 2004; 1: 129-32.

Vilos GA, Abu-Rafea B. New developments in ambulatory hysteroscopic surgery. *Best Practice and Research, Clin Obstet Gynecol* 2005; 19(5): 727-42.

Vilos, GA, Edris, F. Second Generation Endometrial Ablation Techniques: The Hot Liquid Balloons. *Best Practice and Research, Clin Obstet Gynecol* 2007:21(6); 947-67