



The Thermablate®EAS system is a software-controlled thermal ablation device designed to ablate the endometrial lining of the uterus in women suffering from AUB, and in whom child bearing is complete.



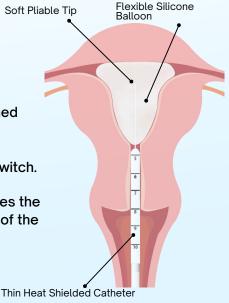
The system is comprised of a 1kg treatment control unit and a disposable balloon catheter cartridge.

Thermablate is indicated for women with sounding lengths between 8cm-12cm, inclusive.

How Does Thermablate Work?*

- The user slowly inserts catheter until balloon tip touches the fundus of the uterine cavity.
- Depth markings on catheter must match previously obtained sounding measurements.
- 3 Treatment cycle is activated with a simple finger trigger switch.
- The Thermablate system automatically inflates and deflates the balloon to ensure a uniform remodelling throughout most of the uterine lining.
- 5 Total treatment time: 2 minutes, 6 seconds

 $^*\text{Complete}$ operating instructions and treatment protocol can be found in the Thermablate IFU LS2607.



Benefits of a Thermablate Ablation

AT 2 YEARS

98%

of patients reported a return to normal menstrual bleeding, hypomenorrhea or amenorrhea¹ 82%

of patients were satisfied with their treatment² 92%

of patients avoided hysterectomy⁷

75.6%

of patients experienced a reduction in bleeding and required no additional therapy; 8% underwent hysterectomy. (Median of 19 months ranging from 6 to 60 months)⁷

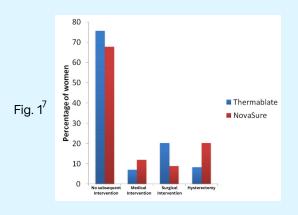


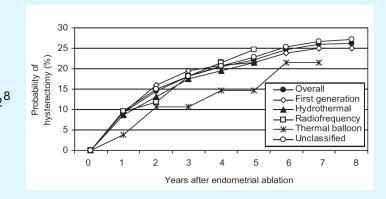


Lower Subsequent Hysterectomy Rate vs. RF

A retrospective review comparing outcomes of patients treated with Thermablate (N=168) and Novasure (N=123) over 5 years showed, "More women opted for hysterectomy in the Novasure group (20.3%) as compared to 8.3% in the Thermablate EA." See Fig 1.

These data are further supported by the findings in Fig 2. which show that of 3681 endometrial ablations performed from 1999-2004, a larger percentage of patients treated with radio frequency ablation underwent eventual hysterectomy when compared to thermal balloon patients.





Testimonial from Dr. Martin Powell, UK on Thermablate EAS:

"With hypomenorrhea judged as a satisfactory end point, our follow up showed high levels of patient satisfaction. These rates are equal to other ablation devices. The hysterectomy rate was significantly reduced and lower than with other ablation techniques. Because of the balloon technology employed by Thermablate, the cavities of most patients remain open, ie. any post menopausal bleeding will be revealed, not concealed."

Thermablate Under Local Anaesthesia

100%

of patients return to normal activity within 2 days⁶

of patients would have the procedure again^{5,6} 88%

of patients would recommend the procedure to a friend⁶ 30mins

the length of time the majority of patients spent in hospital post-ablation, until discharged³

"Global ablation technologies evaluated, including Thermablate, are equally efficacious, safe and well tolerated in an office setting under local anaesthesia."4

References

- 1.D'Afiero A et al. Efficacy of a Second Generation Thermal Balloon Device in the Treatment of Anemia Induced by Meno/Metrorrhagia. Int Jour of Gyne & Obstet 2012; S261-S530. 2. Karamanidis D et al. Twó Year Results of a New Two Minute Hot Liquid Balloon Endometrial Ablation System (Thermablate): A Pilot Study. Clinical Éxperimental Obstet & Gynecol 2009: 36(4):256-258
- 3. Oaiser A, Chen BF, Powell MC. A Long Term Follow Up of Results of Women Undergoing an Office Based Thermablate Endometrial Ablation for the Treatment of Menorrhagia. Obstet Gynecol Int Journal 2016; 4(5):00127.

 4. Leyland N. Office Based Global Endometrial Ablation: Feasibility and Outcome for 3 Modalities. Journal of Obstet and Gynecol Canada, 2004; 26:S22.
- 5. Hall M, Woodward Z. Outpatient Endometrial Ablation: Patient Reported Efficacy and Acceptability. Royal College of Obstet and Gynecol World Congress 2016; Poster Presentation.
 6. Prasad P, Powell M. Prospective Observational Study of Thermablate Endometrial Ablation System as an Outpatient Procedure. J Min Invas Gynecol 2008; 15:476-479
- 7. Chen BF M et al. An Observational Study on the Long Term Follow-up Following Thermablate and Novasure Endometrial Ablations. Obstet Gynecol Int J7:00252 2017.DOI:10.15406/ogij.2017.07.00252
- 8. Longinotti MK, Jacobson GF, Hung Y, Learman LA. Probability of Hysterectomy After Endometrial Ablation. Obstet Gynecol 2008; 112:1214-1220.