



IDOMAN
TEORANTA
Innovative Solutions for Women's Health



SIMPLE
SAFE
EFFECTIVE

Your Solution to Outpatient Ablation



copyright 2008 Thermablade EAS

WWW.THERMABLATE-EAS.COM



SIMPLE

- Unique, fully automated design continually controls parameters of time, temperature and pressure to ensure consistent results.
- Minimal set up required. Fast treatment time of 2 minutes and 6 seconds.
- Easy to use trigger switch initiates treatment. Control unit provides simple step-by-step instructions throughout procedure.
- Thin, pliable, silicone balloon inflates three times to ensure optimal contact with endometrial tissue. Safely treats a variety of uterine shapes and sizes.

EXPERIENCE THE FREEDOM & FLEXIBILITY OF THERMABLATE EAS™



SAFE

The Thermablate EAS™ disposable cartridge is comprised of a slim 6.0mm catheter and a silicone balloon with a soft, pliable tip. Fluid is heated within the self-contained Treatment Control Unit prior to treatment

Adverse events have been reported in association with all global endometrial ablation technologies.

Unlike the majority of competitor products, the makers of Thermablate EAS instruct physicians to conduct hysteroscopy immediately prior to initiating treatment.⁹

In this way, the highest standard of safety is maintained and the physician is in compliance with the recommendations of international healthcare regulatory bodies.

The Medicines & Healthcare products Regulatory Agency—UK (MHRA) issued a *Guidance Document* in 2011 in response to the significant number of adverse events reported in association with endometrial ablation devices stating:

“IMMEDIATELY AFTER DILATION OF THE CERVIX AND PRIOR TO POSITIONING THE DEVICE FOR TREATMENT, ASSESS CAVITY FOR PERFORATION, FALSE PASSAGE OR EVEN TRAUMA TO THE UTERINE WALL USING HYSTEROSCOPY.”¹⁰

“Despite several safeguards devised by the manufacturer, the Novasure bipolar device can and will perforate the uterus and cause thermal injury leading to intestinal perforation.”⁸



	NOVASURE® –Impedance Controlled Endometrial Ablation System	THERMABLATE EAS™ Thermal Balloon Endometrial Ablation System
Method of ablation	Radio Frequency Energy	Thermal Energy
Procedure Time	90 seconds	2 minutes 6 seconds
Uterine Cavity Limitations	Cannot treat patients with cavity length less than 4 cm and/or patients with cavity width less than 2.5 cm. The safety and effectiveness of the NovaSure system has not been fully evaluated in patients with a uterine sound measurement greater than 10 cm ¹¹	Safely treats uterine cavities with sounding measurements of 8 – 12 cm, ⁹ regardless of length of cervical canal or width of cavity
IFU reflects recommendations of MHRA	NO ¹¹	YES ⁹
Occurrence of thermal bowel injury and/or transmural thermal injury when used according to manufacturers’ labeled instructions	YES – >90% of such events reported to the FDA occurred when physician followed manufacturers’ labeled instructions ¹²	NO such events have occurred when physician has been in compliance with manufacturers’ labeled instructions

EFFECTIVE

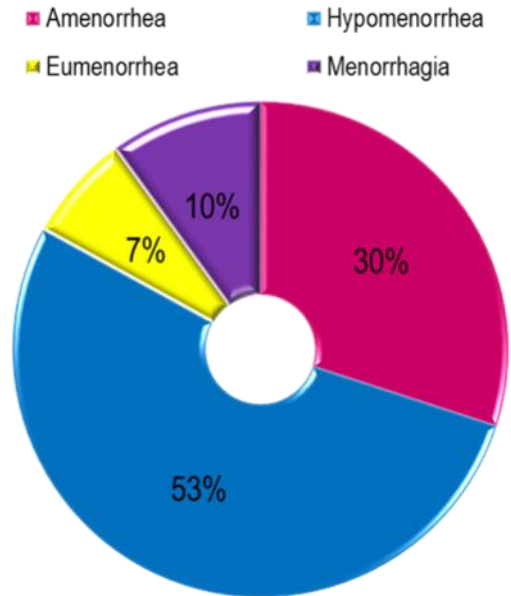
95% of patients treated with Thermablate EAS™ report menstrual blood loss improvement ¹ and 93% would have the treatment again ²

Thermablate EAS consistently delivers reliable results, with 30% of patients reporting Amenorrhea 9 and 12 months post procedure.⁵

Patient satisfaction rates after a treatment with Thermablate are similarly consistent, with >90% of patients stating they would recommend the procedure to a friend.²

A study comparing the definition of treatment success between female patients and their physicians found that the majority of women want less bleeding, and the minority want amenorrhea. ¹³

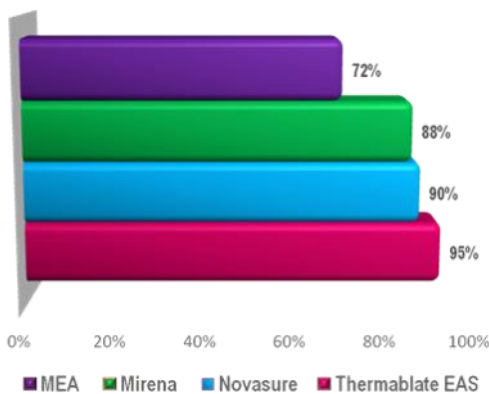
Bleeding Pattern 9 and 12 months Post Procedure⁵



According to a 2010 retrospective review comparing outcomes after treatment with 4 competitor products:

“MENSTRUAL LOSS IMPROVED IN 95% OF THE THERMABLATE GROUP, 90% OF THE NOVASURE GROUP, 72% OF THE MEA GROUP AND 88% MIRENA GROUP.”¹

IMPROVEMENT IN MENORRHAGIA 24 MONTH FOLLOW UP¹



Success measured as IMPROVED QUALITY OF LIFE

According to a clinical study comparing incidence of **new onset pelvic pain** within 2 years of either *radiofrequency or thermal balloon ablation*, patients reported greater pain after RF ablation at each time end point. **De novo pelvic pain occurred overall in 20% of RF and only 7% of TB patients.** ⁷

“AS MORE FOCUS IS BEING PLACED ON IMPROVED QUALITY OF LIFE MEASURES RATHER THAN JUST MENSTRUAL PATTERNS POSTABLATION,⁶ **DE NOVO PELVIC PAIN OCCURRENCE AND SEVERITY AFTER TWO COMMON GEA TECHNOLOGIES HAVE BEEN DOCUMENTED. THE INCIDENCE AS WELL AS ITS ASSOCIATED SEVERITY VARIES BY MODE OF THERAPY (RF>TB).**”⁷

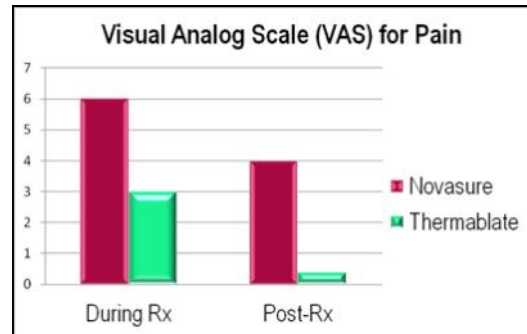
CONCLUSION: “THERMABLATE PATIENTS REPORTED THE GREATEST IMPROVEMENTS IN MENORRHAGIA (95%) AND DYSMENORRHEA (76%).”¹

WELL TOLERATED

Your Solution to Outpatient Ablation

Thermblate EAS™ offers physicians an innovative treatment option that is proven to be as effective, yet significantly less painful than competitor global ablation products, both during and after treatment. ¹

“PATIENT PAIN TOLERANCES WERE MEASURED USING VAS (VISUAL ANALOG PAIN SCALE MANAGEMENT) WHICH SHOWED LOWER PAIN LEVELS BOTH INTRA AND POST OPERATIVELY FOR THERMABLATE EAS™ WHEN COMPARED WITH THE NOVASURE SYSTEM.”⁴



“ENDOMETRIAL ABLATION WITH THERMABLATE EAS™ IS WELL TOLERATED BY PATIENTS UNDER LOCAL ANESTHESIA (VAS SCORE < 5 IN 63 %) AND CAN BE DONE QUICKLY IN AN OUTPATIENT SETTING.”³



IDOMAN TEORANTA
Killateeun Tourmakeady
Co. Mayo, Ireland
Tel: 353 94 9544726
Fax: 353 94 9544725
Toll Free: 0808 2343932



REFERENCES:

1. O'Kane C et al. A Retrospective Review of Patient Outcomes Comparing Novasure, Thermablade, MEA and the Mirena Intrauterine System. JMIG 2010; 17:S109-S127.
2. Prasad P, Powell M. Prospective Observational Study of Thermablade Endometrial Ablation System as an Outpatient Procedure. J Min Invas Gynecol 2008;15:476-479.
3. Chauhan P, Jannick Fredriksen J, Prætorius L. Thermablade—Third Generation Endometrial Ablation, Poster Presentation, Hillerød Hospital, Denmark
4. Leyland N. JOGC 2004;26:S22.
5. Vilos GA, Emanuel M, Fortin C, Leyland N, Abu-Rafea B. Multicentre Outpatient Thermal Balloon Endometrial Ablation (Thermablade EAS™) with & without Concomitant Hysteroscopic Fallopian Tube Microinserts (Essure™), ESGE 2010, AAGL 2010.
6. Abbott JA, Hawe J, Garry R. Quality of life should be considered the primary outcome for measuring success of endometrial ablation. J Am Assoc Gynecol Laparosc 2003;10:491.
7. Chapa H, Antonetti A, Sandate J, Bakker K, Silver L. Incidence of *de Novo* Pelvic Pain After Radiofrequency of Thermabl Balloon Global Endometrial Ablation Therapy. J Gynecol Surg 2010; 27.
8. Baggish Michael S, Bhati A. Case Reports—Intestinal Injuries Associated with the Novasure Bipolar Device. J Gynecol Surg 2009;25:73.
9. Thermablade EAS (Instructions for Use). Ireland: Idoman Teoranta; 2011.
10. Medicines and Healthcare products Regulatory Agency Royal College of Obstetricians and Gynaecologists British Society for Gynaecological Endoscopy 2011; Guidance on the responsibilities of manufacturers, the regulator and clinicians with respect to endometrial ablation
11. NovaSure (Instructions for Use). Bedford, MA: Hologic, Inc.; 2010.
12. Brown J, Blank K. Minimally Invasive Endometrial Ablation Device Complications and Use Outside of the Manufacturers' Instructions. J Obs & Gynecol 2012; 120:865-869.
13. Niles A. Women's Preferences for AUB Treatment and their Definition of a Successful Outcome Compared t Ob/Gyn Recommendations JMIG, 2005; 12:5.



copyright 2008 Thermablade EAS