



IDOMAN  
TEORANTA  
*Innovative Solutions for Women's Health*



SIMPLE  
SAFE  
EFFECTIVE

Your Solution to Outpatient Ablation



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## 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.**<sup>9</sup>

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.”<sup>10</sup>

“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.”<sup>8</sup>



	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 <sup>11</sup>	Safely treats uterine cavities with sounding measurements of 8 – 12 cm, <sup>9</sup> regardless of length of cervical canal or width of cavity
IFU reflects recommendations of MHRA	NO <sup>11</sup>	YES <sup>9</sup>
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 <b>when physician followed manufacturers' labeled instructions</b> <sup>12</sup>	NO such events have occurred when physician has been in compliance with <b>manufacturers' labeled instructions</b>

# EFFECTIVE

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

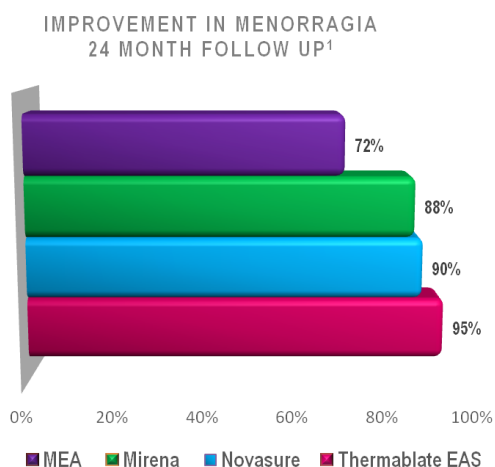
Thermablate EAS consistently delivers reliable results, with 30% of patients reporting Amenorrhea 9 and 12 months post procedure.<sup>5</sup>

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

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. <sup>13</sup>

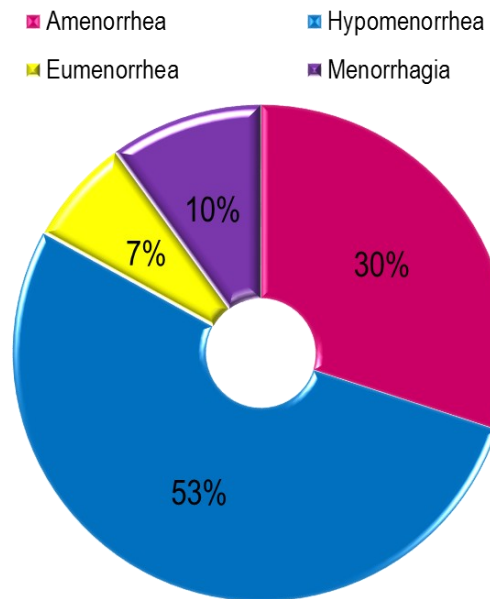
According to a 2010 retrospective review comparing outcomes after treatment with 4 competitor products:

"MENSTRUAL LOSS IMPROVED IN 95% OF THE THERMABLATE GROUP, 90% OF THE NOVASURE GROUP, 72% OF THE MEA GROUP AND 88% MIRENA GROUP."<sup>1</sup>



**CONCLUSION: "THERMABLATE PATIENTS REPORTED THE GREATEST IMPROVEMENTS IN MENORRHAGIA (95%) AND DYSMENORRHEA (76%)."**<sup>1</sup>

**Bleeding Pattern 9 and 12 months Post Procedure<sup>5</sup>**



## 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.** <sup>7</sup>

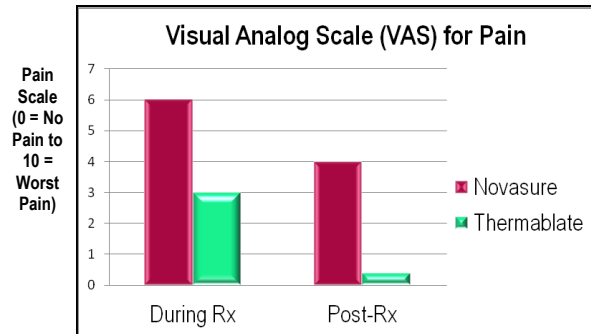
"AS MORE FOCUS IS BEING PLACED ON IMPROVED QUALITY OF LIFE MEASURES RATHER THAN JUST MENSTRUAL PATTERNS POSTABLATION,<sup>6</sup> *DE NOVO* PELVIC PAIN OCCURRENCE AND SEVERITY AFTER TWO COMMON GEA TECHNOLOGIES HAVE BEEN DOCUMENTED. THE INCIDENCE AS WELL AS ITS ASSOCIATED SEVERITY VARIES BY MODE OF THERAPY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

# WELL TOLERATED

## Your Solution to Outpatient Ablation

Thermablade 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. <sup>1</sup>

"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."<sup>4</sup>



"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."<sup>3</sup>





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**AA0006 Rev. B**