Your Solution to Outpatient Ablation

SIMPLE
SAFE
EFFECTIVE

Copyright 2008 Thermablate 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™
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. 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.”

<table>
<thead>
<tr>
<th>NOVASURE® –Impedance Controlled Endometrial Ablation System</th>
<th>THERMABLADE EAS™ Thermal Balloon Endometrial Ablation System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Method of ablation</strong></td>
<td>Radio Frequency Energy</td>
</tr>
<tr>
<td></td>
<td>Thermal Energy</td>
</tr>
<tr>
<td><strong>Procedure Time</strong></td>
<td>90 seconds</td>
</tr>
<tr>
<td></td>
<td>2 minutes 6 seconds</td>
</tr>
<tr>
<td><strong>Uterine Cavity Limitations</strong></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Safely treats uterine cavities with sounding measurements of 8 – 12 cm, regardless of length of cervical canal or width of cavity</td>
</tr>
<tr>
<td><strong>IFU reflects recommendations of MHRA</strong></td>
<td>NO 11</td>
</tr>
<tr>
<td></td>
<td>YES 9</td>
</tr>
<tr>
<td><strong>Occurrence of thermal bowel injury and/or transmural thermal injury</strong></td>
<td>YES – &gt;90% of such events reported to the FDA occurred when physician followed manufacturers’ labeled instructions 12</td>
</tr>
<tr>
<td></td>
<td>NO such events have occurred when physician has been in compliance with manufacturers’ labeled instructions</td>
</tr>
</tbody>
</table>
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.\(^13\)

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.”\(^1\)

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 MENORRAGHIA (95%) AND DYSMENORRHEA (76%).”\(^1\)
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
REFERENCES:

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.
13. Niles A. Women’s Preferences for AUB Treatment and their Definition of a Successful Outcome Compared to Ob/Gyn Recommendations JMI, 2009; 12:5.