



Thermablade *EAS*[™]

Your Solution to Balloon Ablation



Fully Automated
2 Minute Treatment
Ideal for Outpatient Use

Simple. Safe. Effective.

IDOMAN
TEORANTA
Innovative Solutions for Women's Health

THERMABLATE Endometrial Ablation System Conforms to a Variety of Uterine Cavity Shapes & Sizes



*Because **NOT** Every Woman is the Same*

Proven long term results demonstrate high efficacy and patient satisfaction as well as low reintervention in the form of hysterectomy³

AT 2 YEARS:

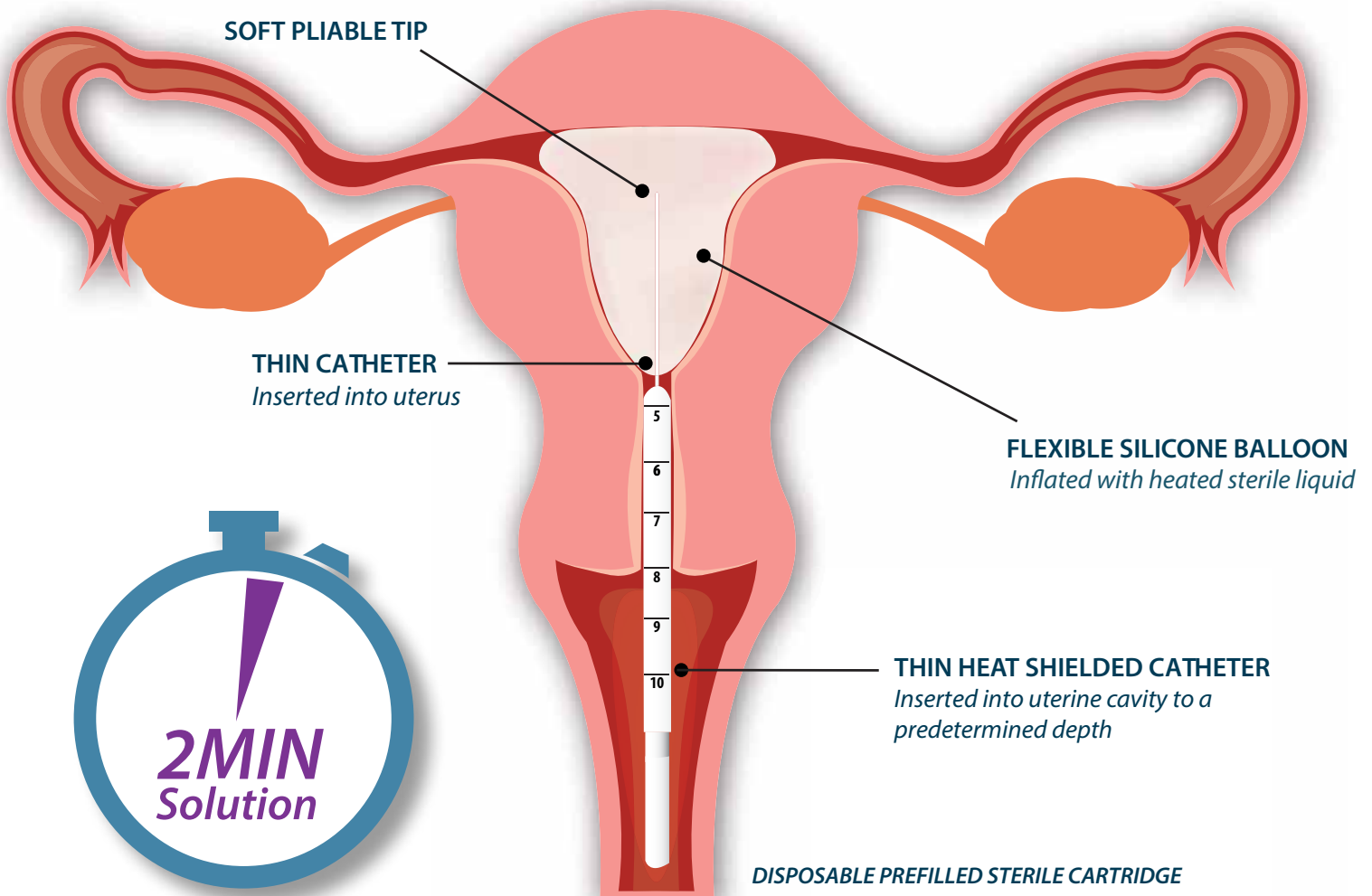
- Up to **98%** of patients reported return to normal menstrual bleeding, hypomenorrhea or amenorrhea¹
- **82%** of women were satisfied with their treatment²

AT A MEDIAN OF 5 YEARS

- **93.6%** of women avoided hysterectomy³
- **80%** of patients experienced reduction in menstrual bleeding and required no additional therapy. 6.4% underwent hysterectomy³

Thermablate *EAS*[™] *Balloon Ablation Simplified*

The **ONLY** Fully Automated Thermal Balloon Ablation System that Safely and Effectively Treats Patients in **JUST 2 MINUTES**



** How Does A Thermablate Treatment Work?*

- 1. User slowly inserts catheter until balloon tip touches the fundus of the uterine cavity*
- 2. Depth markings on catheter must match previously obtained sounding measurements*
- 3. Treatment cycle is activated with a simple finger trigger switch*
- 4. Thermablate system automatically inflates and deflates the balloon to ensure consistent delivery of energy and contact with the endometrium*
- 5. Total treatment time is 2 minutes and 6 seconds*

*NB: Complete operating instructions and treatment protocol can be found in the Thermablate IFU LS2101

The Benefits of the Balloon

Thermal Balloon Ablation is the ideal treatment option for avoiding Hysterectomy and De Novo Pelvic Pain post ablation

A retrospective review comparing outcomes of patients treated with Thermablate (N=175) and Novasure (N=133) over 5 years showed **“An eventual hysterectomy was carried out in 18.7% of the Novasure women vs 8% of the Thermablate group.”**⁷

5 Year Follow Up Data:⁷

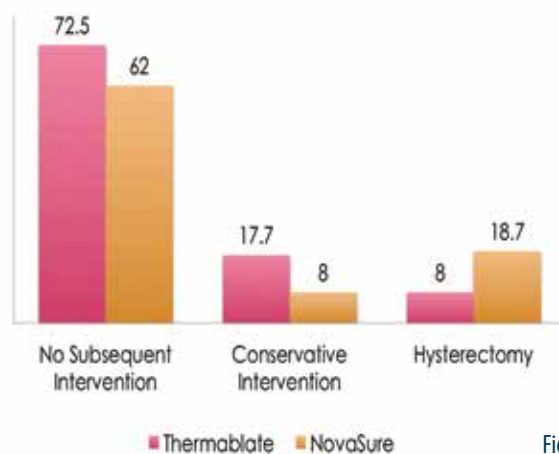


Figure 1⁷

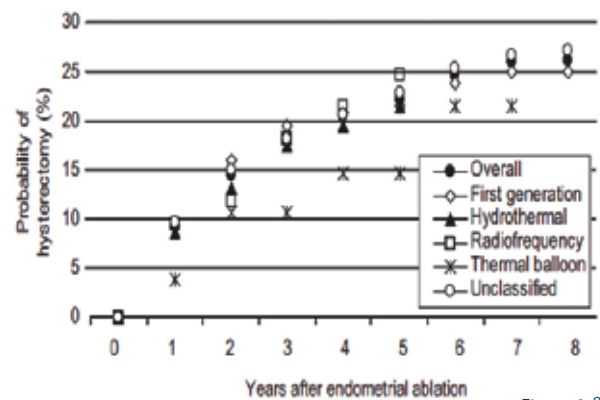


Figure 2⁸

These data are further supported by the findings in Figure 2 which shows 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.**⁸

Success Measured as Improved Quality of Life

“De novo pelvic pain occurred overall in 20% of RF and 7% of TB patients”⁹

A Study Comparing the Incidence of De Novo Pelvic Pain within 2 years of either Radiofrequency or Balloon Ablation found that:

- More focus is being placed on improved **QUALITY OF LIFE** rather than solely menstrual patterns post ablation
- The possibility of **De Novo Pelvic Pain** post ablation should be reviewed with the patient pre-procedure
- The incidence as well as its associated severity varies by mode of therapy (RF>TB)⁹

Outpatient Ablation Made Easy

“Thermablade EAS is an extremely well tolerated device ideal for use in the outpatient or office setting”³

When treated under local anaesthesia:

- 100% of patients return to normal activity within 2 days⁶
- 93% of patients would have the procedure again^{5,6}
- 88% would recommend the procedure to a friend⁶
- Majority of patients treated are discharged within 30 minutes³

- Thermablade patients reported lower pain levels both intra and post operatively compared to those treated with Radio Frequency Ablation⁴ (see Figure 3)

Pain scale
(0= No pain,
10= worst
pain)

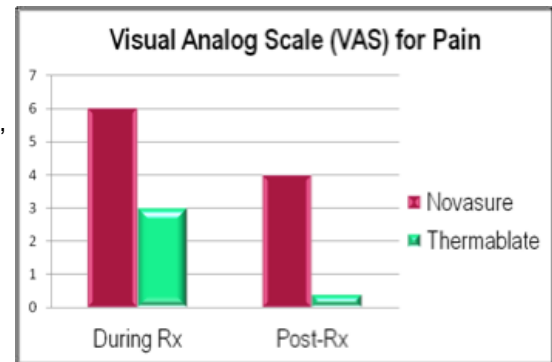


Figure 3⁴





REFERENCES:

1. D'Aferio A et al. Efficacy of a Second Generation Thermal Balloon Device in the Treatment of Anemia Induced by Meno/ Metrorrhagia. *International Journal of Gynecology & Obstetrics* 2012; S261-S530.
2. Karamanidis D et al. Two Year Results of a New Two Minute Hot Liquid Balloon Endometrial Ablation System (Thermablade): A Pilot Study. *Clinical and Experimental Obstetrics & Gynecology* 2009; 36(4): 256-258.
3. Qaiser A, Chen BF, Powell MC. A Long Term Follow up of Results of Women undergoing an Office Based Thermablade Endometrial Ablation for the Treatment of Menorrhagia. *Obstet Gynecol Int J* 2016, 4(5): 00127.
4. Leyland N. Office Based Global Endometrial Ablation: Feasibility and Outcome for 3 Modalities. *Journal of Obstetrics and Gynaecology Canada* 2004; 26:S22.
5. Hall M, Woodward Z. Outpatient Endometrial Ablation: Patient Reported Efficacy and Acceptability. *Royal College of Obstetricians and Gynaecologists World Congress 2016; Poster Presentation.*
6. Prasad P, Powell M. Prospective Observational Study of Thermablade Endometrial Ablation System as an Outpatient Procedure. *J Min Invas Gynecol* 2008; 15:476-479.
7. Powell M et al. Subsequent Intervention Rates Following Thermablade and Novasure Endometrial Ablations. *J Min Invas Gynecol* 2014; 21:S136-S190.
8. Longinotti MK, Jacobson GF, Hung Y, Learman LA. Probability of Hysterectomy After Endometrial Ablation. *Obstet Gynecol* 2008; 112:1214-1220.
9. Chapa H, Antonetti A, Sandate J, Bakker K, Silver L. Incidence of de Novo Pelvic Pain After Radiofrequency or Thermal Balloon Global Endometrial Ablation Therapy. *J Gynecol Surg* 2011; 27(4): 203-207.

www.idoman-med.com

+ 353 094 9544726 • info@idoman-med.com

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