



Fully Automated **2 Minute** Treatment Ideal for Outpatient Use





# **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 hysterectomy <sup>3</sup>

#### AT 2 YEARS:

- Up to **98%** of patients reported return to normal menstrual bleeding, hypomenorrhea or amenorrhea<sup>1</sup>
- 82% of women were satisfied with their treatment<sup>2</sup>

#### AT A MEDIAN OF 5 YEARS

- 93.6% of women avoided hysterectomy<sup>3</sup>
- 80% of patients experienced reduction in menstrual bleeding and required no additional therapy. 6.4% underwent hysterectomy <sup>3</sup>



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."**<sup>7</sup>



5 Year Follow Up Data:7

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.<sup>8</sup>

### 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**

"Thermablate EAS is an extremely well tolerated device ideal for use in the outpatient or office setting" <sup>3</sup>

#### When treated under local anaesthesia:

- 100% of patients return to normal activity within 2 days <sup>6</sup>
- 93% of patients would have the procedure again <sup>5, 6</sup>
- 88% would recommend the procedure to a friend <sup>6</sup>
- Majority of patients treated are discharged within 30 minutes <sup>3</sup>

 Thermablate patients reported lower pain levels both intra and post operatively compared to those treated with Radio Frequency Ablation<sup>4</sup> (see Figure 3)



Figure 3<sup>4</sup>



# Thermablate EAS"

#### **REFERENCES:**

1. D'Afiero 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 (Thermablate): 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 Thermablate 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 Thermablate Endometrial Ablation System as an Outpatient Procedure. J Min Invas Gynecol 2008; 15:476-479.

7. Powell M et al. Subsequent Intervention Rates Following Thermablate 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

21 St. Clair Ave East, Suite 1100 Toronto ON, Canada Tel: 416-487-8397 • Toll Free: 1-800-768-1836



AA0020 Rev. A 2016-09-30

