


Abnormal Uterine Bleeding:
Thermal Balloon Endometrial Ablation Treatment



Cavaterm™



The Efficacy
You Seek
The Efficacy
She Expects

VELDANA

Efficacy is her daily routine



ABNORMAL UTERINE BLEEDING, A BURDEN IN HER DAILY LIFE

- **A loss of energy**

Over 80 ml of blood loss/month, risk of anaemia :
Tiredness, Shortness of breath, Iron deficiency

- **A waste of time and a major discomfort**

Changing of sanitary protection ≥ 6 times/day
Changing protection during the night



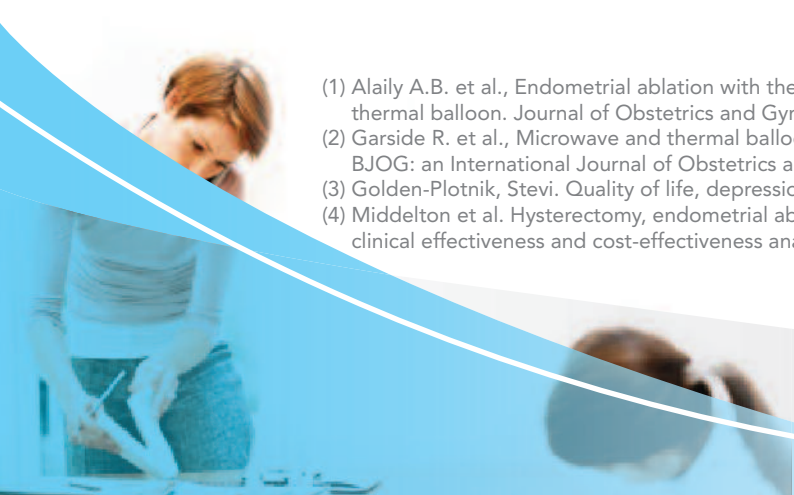
Overall, a real impairment in quality of life ⁽²⁾

Difficulties maintaining usual personal, social and professional activities

MANY WOMEN COPING WITH AUB EXPERIENCE EMOTIONAL DISTRESS:

- Depression
- Anxiety
- Lack of confidence ⁽³⁾

(1) Alaily A.B. et al., Endometrial ablation with the Cavaterm™ thermal balloon. Journal of Obstetrics and Gynaecology 2003; 23 (1): 51-54.
(2) Garside R. et al., Microwave and thermal balloon ablation for heavy menstrual bleeding: a systematic review. BJOG: an International Journal of Obstetrics and Gynaecology. 2005; 112: 12-23.
(3) Golden-Plotnik, Stevi. Quality of life, depression and anxiety in women with abnormal uterine bleeding. 2012
(4) Middelton et al. Hysterectomy, endometrial ablation and Mirena® for heavy menstrual bleeding: a systematic review of clinical effectiveness and cost-effectiveness analysis. Health Technol Assess. 2011; 15(19): 1-252



Decision making is her strength

ENDOMETRIAL ABLATION : when she wants it done, she means it

**20%
of women**

of reproductive age
complain at any one time
of heavy menstrual
bleeding ⁽³⁾



Key determinant

to referral and

subsequent treatment :

womens' own perception

of their own menstrual loss ⁽¹⁾

Each year, over **500,000** women in the world*
decide to proceed with endometrial ablation

* Based on US and major European markets

ENDOMETRIAL ABLATION TECHNIQUES

With similar efficacy as
1st Generation, **2nd Generation**



Your decision :
which 2nd Generation

treatment to meet
the overall challenge
for efficacy ?

- **Quicker** 15 mins shorter procedure) ⁽⁴⁾
- **Short learning curve**
- **Less operative complications** ⁽⁴⁾
- **Faster patient recovery** ⁽⁴⁾

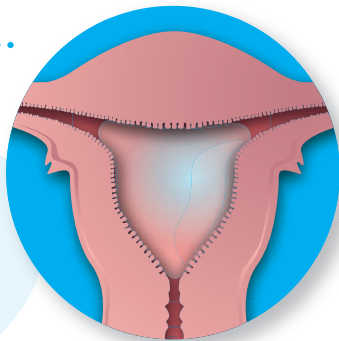


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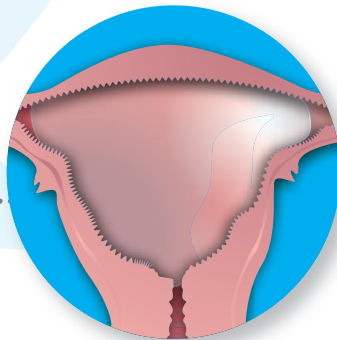
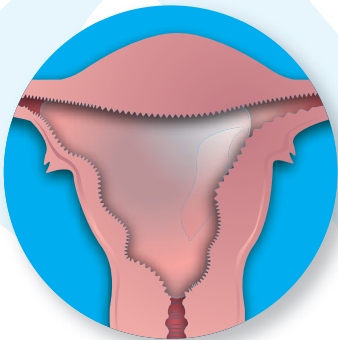
REPRODUCIBLE EFFICACY ACROSS DIFFERENT UTERINE CAVITIES

One device
to fit **most uterine
cavities**

Adapted to
most cavities ...



... including more difficult-to-treat ones :



CAVATERM™
Adjustable balloon

**Optimal use
for 2nd generation
procedures in your
practice**



Time saving

- Single training
- Optimal flow of procedures



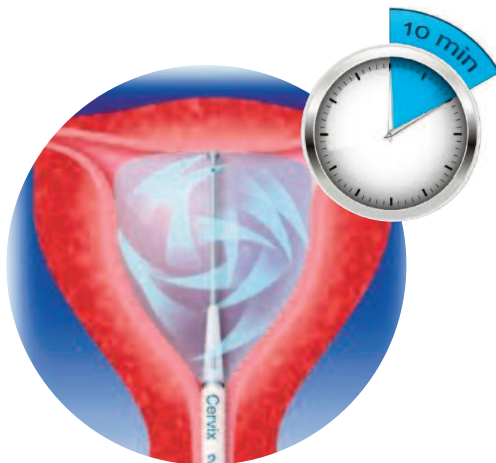
Cost saving

- One reliable device to meet your practice needs

The Effective way to be effective

REPRODUCIBLE QUALITY ACROSS PROCEDURES

A well-defined **time-to-efficacy** to reach out
for **the whole** uterine **cavity lining**



The **right time** with
the **right parameters**
for the **right quality**
of ablation

➔ **No-rush yet fast** onset of action

➔ **Up-to-date and validated** technology

- Delivers constant and homogeneous temperature at the balloon surface
- Maintains effective temperature and pressure throughout the procedure

➔ **Precise and clear** monitoring
of procedure status

- Designed to provide explicit read-out of procedure completion



Done!





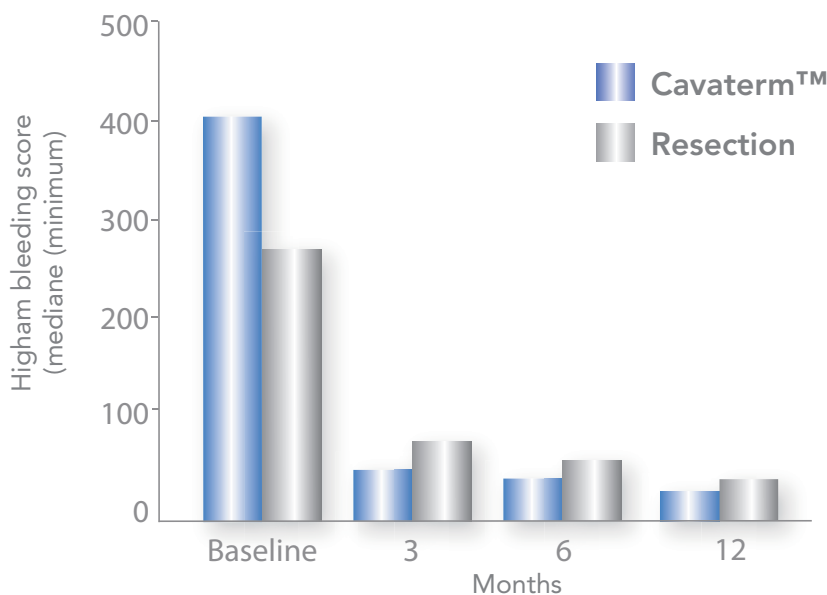
Cavaterm™

Done!



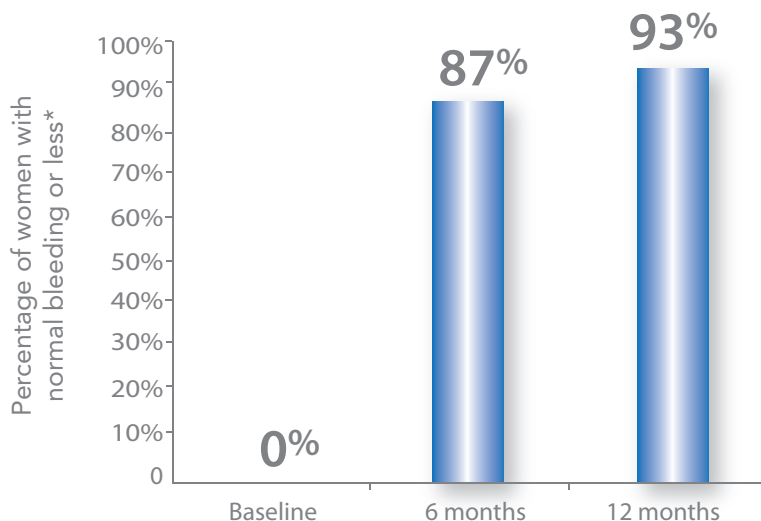
RELIABLE OUTCOME

Similar bleeding scores *versus* resection at 3, 6 and 12 months ⁽¹⁾



Higham bleeding score at baseline, 3, 6 and 12 months. Median (range) values at baseline were 400 (110-1300) and 266 (104-555) in Cavaterm™ and resection groups, respectively. Corresponding values at 12 months were 18 (0-222) and 12 (0-324), respectively.

Procedure success at 6 and 12 months with Cavaterm™ ⁽¹⁾



9/10
patients
satisfied after
2 years ^(2, 3)

* Higham blood loss score

Choosing Cavaterm™ : The Efficacy You Seek

Thousands of women have been successfully treated with Cavaterm™

SUSTAINABLE OUTCOME

Effectively improve outcomes at **4 years** ^(4, 5)

70 women followed up after Cavaterm™ procedure



93% of women

treated with Cavaterm™ **avoided hysterectomy** ⁽⁴⁾

116 women followed up after Cavaterm™ procedure



93% of women

had a **normal level** of menstrual bleeding or **lower** after 4 years ⁽⁵⁾

FAVORABLE SAFETY PROFILE

across clinical evaluations ⁽¹⁻⁵⁾

(1) Brun J.L. et al., Cavaterm thermal balloon endometrial ablation versus hysteroscopic endometrial resection to treat menorrhagia: the French, multicenter, randomized study. *Journal of Minimally Invasive Gynecology*. 2006; 13 : 424-430

(2) El-Toukhy T. et al., Outcome of the first 220 cases of endometrial balloon ablation using Cavaterm™ Plus. *Journal of Obstetrics and Gynaecology* 2004; 24 (6): 680-683.

(3) Alaily A.B. et al., Endometrial ablation with the Cavaterm™ thermal balloon. *Journal of Obstetrics and Gynaecology* 2003; 23 (1): 51-54.

(4) Mettler L. Long-term results in the treatment of menorrhagia and hypermenorrhea with a thermal balloon endometrial ablation technique. *JSLs* 2002; 6 : 305-309

(5) Friberg B., Ahlgren M., Thermal balloon endometrial destruction: the outcome of treatment of 117 women followed up for a maximum period of 4 years. *Gynaecological Endoscopy*. 2000; 9 (6): 389-395



Thermal Balloon Endometrial
Ablation Treatment



Cavaterm™

Done!



From training to follow-up services
A PARTNERSHIP YOU CAN COUNT ON



**FOR YOU
AND YOUR
TEAM**

**Customized
«Training upon delivery»
program**

- Full product and procedure training
- Support and assistance in the operating room by qualified product specialists
- Continuing product training and information on-demand
- Pain management peer sharing program



Choosing Cavaterm™ : The Efficacy You Seek

FOR YOUR PATIENTS



Patient awareness leaflet on dysfunctional uterine bleeding

Patient information guide on the procedure and post-procedure measures



Equipment quality & availability program

- Immediate handling of your requests (product supply, product information update)
- Loan of replacement Central Unit during servicing of your equipment
- Technical support and product servicing

Procedure quality assurance

A read-out tool records and displays the good progress of the procedure





Cavaterm™

Done!



➔ from the **TECHNOLOGY**
and the **MEDICAL DEVICE**

Thermal Balloon ablation

The most popular 2nd generation technique in many Western countries

Thousands of patients successfully treated with Cavaterm™

over years of continuous clinical evaluation and product excellence

➔ from the **MANUFACTURER**



VELDANA

Committed to You,
Your Team, Your Patients

➔ from the **short and long-term**
CLINICAL OUTCOME

Efficacy proven up to 4 years
after treatment

Choosing Cavaterm™ : The Efficacy You Seek



Indication

The Cavaterm™ system is indicated to ablate the endometrial lining of the uterus in premenopausal women with heavy menstrual bleeding due to benign causes for whom childbearing is complete.

Contraindications

Women presenting conditions listed below require examination, precautions and/or treatment before they can be treated with Cavaterm.

- Undiagnosed uterine bleeding
- Active infection of the internal and external genitalia
- Active urinary tract infection

A Cavaterm™ treatment is strictly contra-indicated for women presenting the following conditions

- Any premalignant or malignant condition by histology, e.g. adenomatous hyperplasia
- Any anatomical or pathological condition significantly deforming the uterine cavity and thus preventing the balloon from laying uniformly on the endometrium
- Any condition associated with a myometrio thickness less than 12 mm
- Any condition leading to uterine wall weakness regardless of myometrio thickness
- Any recent uterine damage or trauma
- Pregnancy or any desire to become pregnant in the future
- Uterine cavity length less than 4 cm or more than 10 cm (from the isthmus to the fundus)
- Cervical canal length more than 6 cm

