NovaSure Endometrial Ablation

Over one million patients treated!

Quick…

- Just 90 seconds average treatment time [4]
- Rapid recovery time - patients return to normal activity in 24 to 48 hours [4]

Simple…

- No pre-treatment needed [4]
- Easy to use
- Can be used anytime during the menstrual cycle [4]

Safe…

- Tests for uterine perforation and terminates procedure at proper tissue impedance….automatically
- Can be used with local anaesthetic, with or without IV sedation [4]

Successful…

- 91% of women have normal or less than normal bleeding one year after the procedure [1]
- 93% patient satisfaction [4]
- 97% hysterectomy avoidance at five years [12]
- 97% would recommend the procedure to other women [1]
- 97% of patients experience no post-procedural pain [4]
- 98% successful reduction of bleeding at five years [12]
- 75% of patients reported amenorrhea at five years [12]

For more information, please contact your local representative at:

HOLOGIC®
The Women's Health Company

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www.Hologic.com

REFERENCES: 1. Cooper et al. A randomized, multicenter trial of safety and efficacy of the NovaSure System in the treatment of menorrhagia. J Am Assoc Gynecol Laparosc 2002;9:418-28. 2. Cooper KG, Parkin DE, Garratt AM, et al. A randomised comparison of medical and hysteroscopic management in women consulting a gynaecologist for treatment of heavy menstrual loss. Br J Obstet Gynecol 1997;104:1360-66. 3. Data (rounded to the nearest whole number) on file. BioVid; January 2005. 4. NovaSure [Instructions for use]. Bedford, MA: Hologic, Inc.; 2011. 5. Millenium Research Group. European Markets for Gyneclogic Devices 2008. Medical Technology RPEU31GY07. Toronto, Ontario, Canada. 2007. 6. Gynecare Thermachoice [Instructions for use]. Somerville, NJ: Ethicon, Inc.; 2011. 7. Her Option [Instructions for Use]. Minnetonka, MN: American Medical Systems, Inc.; 2006. 8. Hydro ThermAblator [Instructions for use]. Natick, MA: Boston Scientific; 2006. 9. Thermablate (Instructions for use). Idoman Ltd, 2010. 10. Prasad P, Powell M, Prospective Observational Study of Thermablate Endometrial Ablation System as an Outpatient Procedure, Journal of Minimally Invasive Gynecology 2008;15:476-479. 11. Yackel D, Thermablate: A New Endometrial System, A Fully Automated Lightweight & Portable System for the Treatment of Menorrhagia. Gyn Surgery 2004;1(2): 129-32. 12. Gallinat A: An Impedance-Controlled System for Endometrial Ablation: Five-Uear Follow-up on 107 Patients. J Reprod Med 2007;52(6):467-72.

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NovaSure® Improving lives for over 10 YEARS

The patient preferred solution

to heavy menstrual bleeding

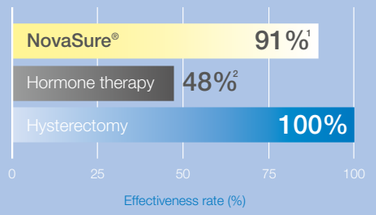
NovaSure® Impedance Controlled Endometrial Ablation:

- Requires no endometrial pretreatment
- Treatment time is approximately 90 seconds*
- Requires only local and/or IV sedation anaesthesia for most patients
- Unique Cavity Integrity Assessment safety test
- Total procedure control with impedance threshold

HOLOGIC®
The Women's Health Company

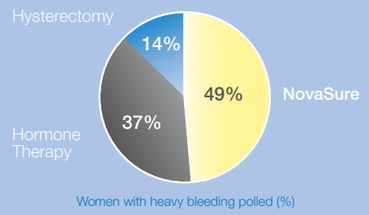
The NovaSure System gives women the successful results they want...

Effectiveness in reducing bleeding to normal levels or lower



...with the treatment option they prefer.

Treatment preference for heavy menstrual bleeding (n=550) [3]



NovaSure Endometrial Ablation:

The only customised endometrial ablation as unique as each patient

The only system with:

- A proactive safety feature to assess uterine cavity integrity prior to procedure
- Controller-predetermined power delivery specific to the patients uterine cavity size
- A patented Moisture Transport System that
  - Creates and maintains contact between the endometrium and the electrode array
  - Enhances the safe vaporisation and removal of endometrial tissue and debris
- Impedance control that automatically determines the depth of tissue ablation
  - As tissue is vaporised, resistance to radio frequency (RF) energy increases until tissue impedance reaches 50 ohms
  - At this point (~90 seconds) the controller self-terminates energy delivery
  - Customised ablation is independent of endometrial thickness

Only NovaSure Endometrial Ablation is **designed for full contouring with precise depth control**

The NovaSure Process:

The NovaSure electrode array expands to conform to the contours of each patient's uterine cavity

Cavity Integrity Assessment is performed using a small amount of CO_2

The NovaSure procedure delivers bipolar RF energy until the patient's ablation is complete; approximately 90 seconds*

The electrode array is retracted for easy removal, leaving the uterine lining dessicated down to the superficial myometrium.

NovaSure Technology Delivers Automated, Precisely Controlled Ablation

Advanced Technology, **Preferred Treatment.**

Why is NovaSure Endometrial Ablation the Market Leader[5]?

EA Device	Ablation energy source	Average treatment time	Average procedure time	Pretreatment utilised?	Cycle dependent?	Submucous myomas allowed?	Requires uterine distention
NovaSure[4]	Bipolar RF Energy desiccates and coagulates the endometrium and the underlying superficial myometrium	90 seconds	4.2 minutes	No	No	Yes, ≤ 2 cm	No
Intrauterine saline balloon[6]	Saline heated to 87°C within an intrauterine balloon	8 minutes	27.4 minutes	Yes	Yes	No	Yes
Cryoablation[7]	Probe cooled to between –100°C and –120°C by pressurised gas	10 to 12	20 minutes	Yes	Yes	No	No
Circulated hot fluid[8]	Saline heated to 90°C directly touching myometrium	10 minutes	26.4 minutes	Yes	Yes	No	Yes
Intrauterine glycerin balloon[9-11]	Glycerin heated to 173°C within an intrauterine balloon	2 minutes	10 minutes	Yes	No	No	Yes

Indications and contraindications for use of the NovaSure Endometrial Ablation System[4]

Indications

The NovaSure procedure is intended to ablate the endometrial lining of the uterus in pre-menopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete.

Contraindications

The NovaSure procedure is contraindicated for use in:

- A patient who is pregnant or who wants to become pregnant in the future. Pregnancies following ablation can be dangerous for both mother and fetus.
- A patient with known or suspected endometrial carcinoma (uterine cancer) or pre-malignant conditions of the endometrium, such as unresolved adenomatous hyperplasia.
- A patient with any anatomic condition (e.g., history of previous classical caesarean section or transmural myomectomy) or pathologic condition (e.g., long term medical therapy) that could lead to weakening of the myometrium.
- A patient with active genital or urinary tract infection at the time of the procedure (e.g., cervicitis, vaginitis, endometritis, salpingitis, or cystitis).
- A patient with an intrauterine device (IUD) currently in place.
- A patient with a uterine cavity length less than 4 cm. The minimum length of the electrode array is 4 cm. Treatment of a uterine cavity with a length less than 4 cm will result in thermal injury to the endocervical canal.
- A patient with a uterine cavity width less than 2.5 cm, as determined by the Width Dial of the Disposable Device following Device deployment.
- A patient with active pelvic inflammatory disease.