# HEAVY MENSTRUAL BLEEDING

An Introduction to

NovaSure®

Endometrial Ablation

**The 90 second solution for menorrhagia**

# HEAVY MENSTRUAL BLEEDING: MENORRHAGIA

**FACT**

**1 in 4 women in the UK suffer with menorrhagia[1]**

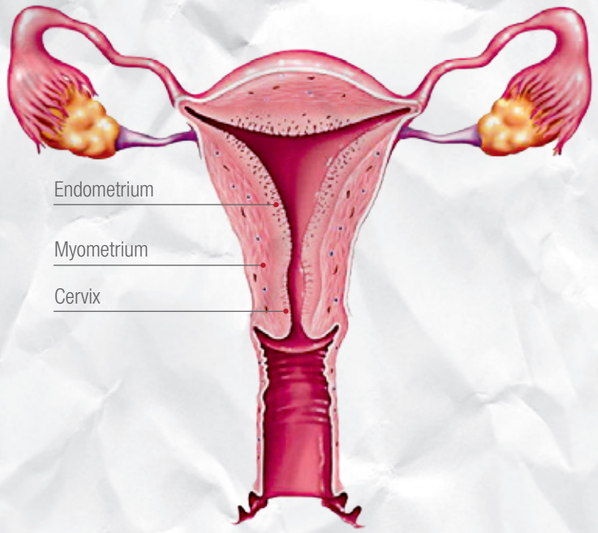
## 1 in 4 women in the UK suffer from menorrhagia[1]

Abnormally heavy and prolonged menstrual bleeding (menorrhagia) is a common gynaecologic condition, affecting around 25% (1 in 4) of women aged between 30 and 50 in the UK[1 2] and is estimated to be the fourth most common reason for referral to gynaecological services[1]. Each year, 30,000 women undergo surgical treatments for HMB in England and Wales.[1]

Efficient treatment options are available and there is no need for women to suffer in silence. This information booklet provides details on treatment options available to women who have menorrhagia, for you to discuss with your patients.

## Abnormal Uterine Bleeding is defined by:

- Length of cycle (days)
- Duration of menses (days)
- Amount of blood loss (ml)




1. The Royal College of Obstetricians & Gynaecologists (RCOG). National Heavy Menstrual Bleeding Audit, Second Annual Report, 2012 and Final Report, July 2014. 2. Shapley M.Jordan K, Croft PR. An epidemiological survey of symptoms of menstrual loss in the community. Br J Gen Pract, 2004:54:359-63. 3. National Institute for Health and Clinical Excellence (NICE). Heavy Menstrual Bleeding: Draft Scope for Consultation. London: NICE 2004. 4. National Women's Health Resource Center. National survey of 653 women, 35-49 with reported heavy periods and intact uterus; conducted Sept 29-Oct 12, 2005. 5. Cooper J, 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; 9:418-428

# IMPACT OF MENORRHAGIA[4]

## Heavy and/Or Long-Lasting Periods

- 7+ days per menstrual cycle
- Protection changes every 1-2 hours or double-protection

## Can Severely Impact Quality Of Life

- Very disruptive effects on family and social lives, sex lives, work lives, mood, energy levels and regular daily activities

## Symptoms:

- Severe pain
- Fatigue and/or anaemia
- Headaches
- Nausea
- Emotional turmoil, embarrassment
- Can lead to restricted activity

WEAR WHITE AGAIN

Direct your patients to our consumer information website on heavy periods at **www.wearwhiteagain.co.uk**

# MENORRHAGIA

## The facts:

**20%**

20% of the 1.2 million referrals to specialist gynaecologist services concern women with HMB[5]

**1 IN 4**

1 in 4 women aged 30-50 experiences heavy menstrual bleeding[1,2]

Equivalent to 30,000 women in England and Wales[3]

**4TH**

4th most common reason for specialist gynaecological referral[1]

**1/3**

A third of women had received no previous treatment in primary care before being referred to secondary care, despite 50% being in severe pain[1]

## MOST WOMEN DO NOT MENTION THEIR HEAVY BLEEDING

**70%**

70% of women suffering with HMB had symptoms for over a year before being referred to secondary care[1]

### Why?

- They are embarrassed
- They falsely believe their bleeding is 'normal'
- Women are unaware that excessive menstruation is a medical condition for which they can seek treatment

## START THE CONVERSATION

## HELP WOMEN RECOGNISE THEIR PROBLEM

- ☑ Are your periods heavy or do they last a long time?
- ☑ Do you wake up during the night to change protection?
- ☑ Are you bothered by the amount of bleeding/pain during your period?
- ☑ Does your period affect your quality of life?
- ☑ Would your quality of life improve if you could decrease or eliminate your heavy periods?
- ☑ Do your heavy periods affect your social, athletic or sexual activities or cause you to miss work?
- ☑ Do you change protection frequently or carry large quantities of feminine products and/or a change of clothes?
- ☑ Does your period make you feel depressed, tired or moody?

1. The Royal College of Obstetricians & Gynaecologists (RCOG). National Heavy Menstrual Bleeding Audit, Final Report, July 2014. 2. Shapley M.Jordan K, Croft PR. An epidemiological survey of symptoms of menstrual loss in the community. Br J Gen Pract, 2004:54:359-63. 3. National Institute for Health and Clinical Excellence (NICE). Heavy Menstrual Bleeding: Draft Scope for Consultation. London: NICE 2004. 5. Brit et al, 2003

# NOVASURE® ENDOMETRIAL ABLATION:

**for women who are looking for a permanent solution to their HMB and have completed childbearing**

The 2007 NICE guidelines for Heavy Menstrual Bleeding (HMB) lists endometrial ablation as a first line treatment option.

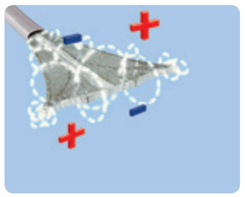
## NICE RECOMMENDS:

- Endometrial ablation may be offered as an initial treatment for HMB after full discussion with your patient of the risks and benefits and of other treatment options
- Endometrial ablation should be considered where bleeding is having a severe impact on a woman's quality of life, and she does not want to conceive in the future.
- Endometrial ablation should be considered in women who have a normal uterus and also those with small uterine fibroids (less than 3 cm in diameter).*
- All women considering endometrial ablation should have access to a second generation ablation technique.

**For more information on guideline 44 for Heavy Menstrual Bleeding visit the NICE website www.nice.org.uk/guidance/CG44**

## THE NOVASURE® ENDOMETRIAL ABLATION SYSTEM IS THE ONLY SYSTEM WITH:

- A proactive safety feature to assess uterine cavity integrity prior to the 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
  – Ensures 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 delivered
  – Customised ablation is independent of endometrial thickness



*NovaSure® Endometrial Ablation is approved only for fibroids 2cm or smaller.

## DO YOU WANT YOUR PATIENT TO RECEIVE THE BEST POSSIBLE TREATMENT FOR HEAVY MENSTRUAL BLEEDING?

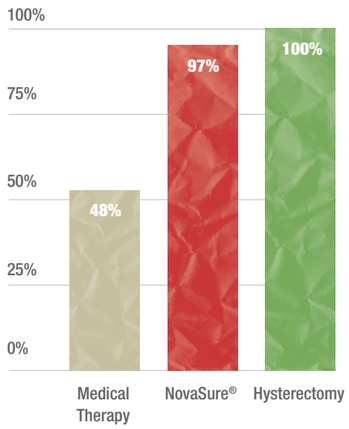
**FACT**

**Over 2 million women have been treated with NovaSure® worldwide**

- **3 out of 4 women with menorrhagia wished they had heard about NovaSure® upon their initial diagnosis[6]**
- **You could help by informing your patient of the available treatment options to permanently resolve her problem.**

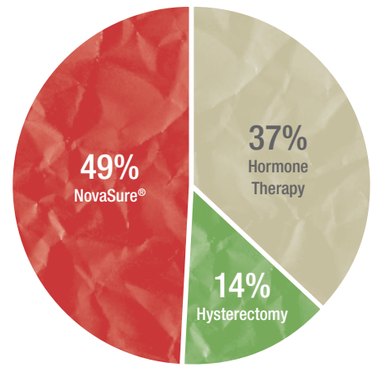
## THE NOVASURE® SYSTEM GIVES WOMEN THE SUCCESSFUL RESULTS THEY WANT.

Effectiveness in reducing bleeding to normal levels or lower



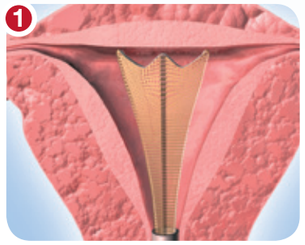

## PATIENTS PREFER NOVASURE® OVER HYSTERECTOMY AND HORMONE THERAPY

Treatment preference for heavy menstrual bleeding (n=550)[5]




6. Glazerman, L. Patient Satisfaction After Radiofrequency Ablation, Obstetrics Gynecology 2008; 111(4);796.

# THE NOVASURE® PROCESS

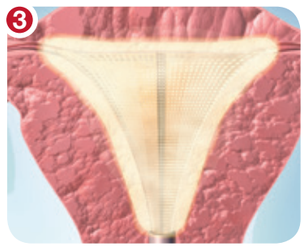



The NovaSure® electrode array expands to conform to the contours of each patient's uterine cavity


Cavity Integrity Assessment is performed using a small amount of $CO_2$

**FACT**

**Free her from heavy menstrual bleeding in just 90 seconds!**




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

## THE STATE OF THE ART NOVASURE® ENDOMETRIAL ABLATION SYSTEM IS:

### QUICK...

- Just 90 seconds average treatment time[7]
- Can be performed in an outpatient / primary care facility[7]
- Rapid recovery time - patients return to normal activity in 24 to 48 hours[7]

### SAFE...

- Tests for uterine perforation and terminates procedure at proper tissue impedance… automatically[7]
- Can be used with local anaesthetic, with or without IV sedation[7]

### SIMPLE...

- No pre-treatment needed[7]
- Easy to use
- Can be used anytime during the menstrual cycle[7]

### SUCCESSFUL...

- 91% of women have normal or reduced bleeding one year after the procedure[8]
- 93% patient satisfaction[7]
- 97% hysterectomy avoidance at five years[9]
- 97% would recommend the procedure to other women[8]
- 97% of patients experience no post-procedural pain[7]
- 98% successful reduction of bleeding at five years[9]

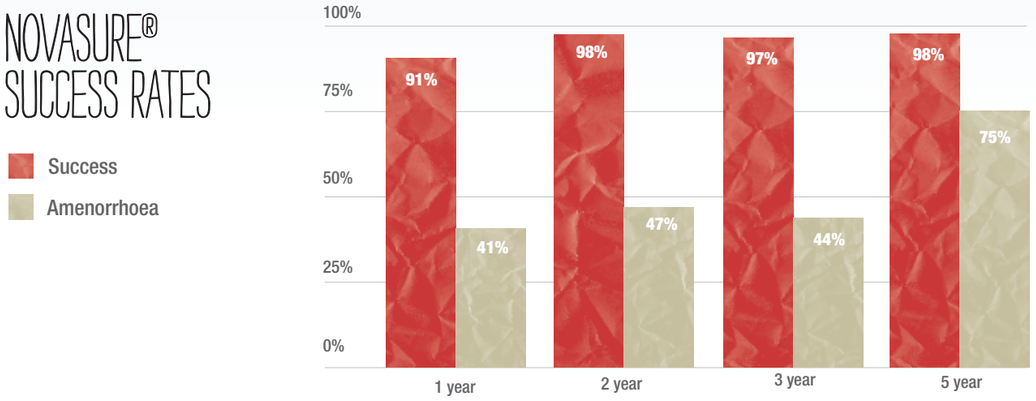
## WHY IS THE NOVASURE® ENDOMETRIAL ABLATION SYSTEM THE MARKET LEADER IN THE UK?

| EA Device | Ablation energy source | Average treatment time | Average procedure time | Drug Pretreatment utilised? | Cycle dependent? | Submucous myomas allowed? | Requires uterine distention |
|---|---|---|---|---|---|---|---|
| **NovaSure®[7]** | **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 balloon[10] | Saline heated to 87ºC within an intrauterine balloon | 8 minutes | 27.4 minutes | Yes | Yes | No | Yes |
| Circulated hot fluid[11] | Saline heated to 90ºC directly touching myometrium | 10 minutes | 26.4 minutes | Yes | Yes | No | Yes |

7. NovaSure(R) Instructions for Use, Bedford MA; Hologic, Inc, 2001. 8. Cooper et al. A randomized, multicenter trial of safety and efficacy of the NovaSure(R) system in the treatmentof menorrhagia. J Am Assoc Gynecol Laparosc 2002;9:418-28. 9. Gallinat A: An Impedance-controller system for endometrial ablation: five-year follow-up on 107 patients. J Reprod Med 2007;52(6):467-72. 10. Gynecare Thermachoice Instructions for Use. Somerville, NJ: Ethicon, Inc; 2003. 11. Hydro ThermAblator Instructions for Use. Natick, MA: Boston Scientific; 2006.

# FACTS & FIGURES:

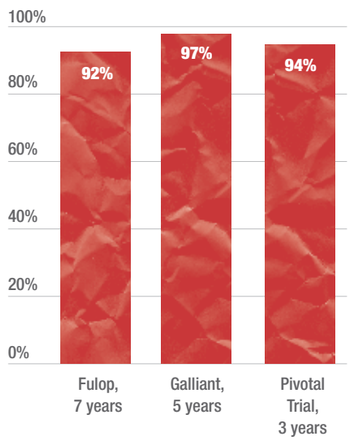
## NOVASURE® SUCCESS RATES




Fulop I. 2nd World Congress on Controversies in Obstetrics, Gynecology & Infertility. September 6-9, 200. Gallinat A: An Impedance-Controlled System for Endometrial Ablation: Five-Uear Follow-up on 107 Patients. J Reprod Med 2007;52(6):467-72.

## NOVASURE® AVOIDS ADDITIONAL INTERVENTION

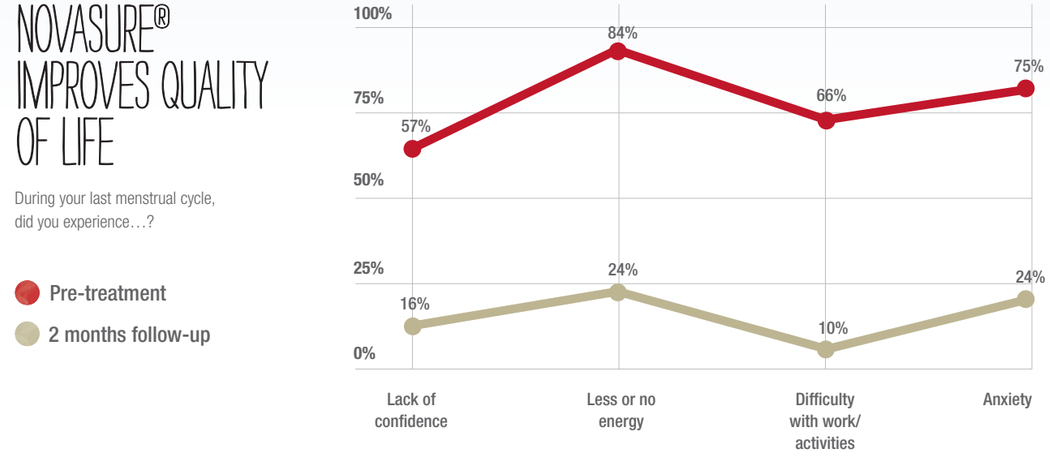
Long-term avoidance of hysterectomy




NovaSure® Instructions for Use. Gallinat A. J Reprod Med. 2007;52:467. Fulop T et al. J Minim Invasiv Gynecol. 2007;14:85

## NOVASURE® IMPROVES QUALITY OF LIFE

During your last menstrual cycle, did you experience…?




NovaSure® Instructions for Use, Bedford MA; Hologic, Inc, 2001.

## NOVASURE® CONTRAINDICATIONS

- Pregnant or the desire to be pregnant in the future
- Known or suspected endometrial carcinoma or pre-malignancy
- Any anatomic condition that could lead to weakening of the myometrium:
  - Classical C-section
  - Transmural myomectomy
- Uterine cavity length <4cm
- Uterine cavity width <2.5cm as determined by the Disposable Device Width Dial
- Active Pelvic Inflammatory Disease (PID)
- Genital or urinary tract infection
- IUD currently in place

NovaSure® Instructions for Use, Bedford MA; Hologic, Inc, 2001.

# MENORRHAGIA TREATMENTS

**Discuss the best treatment options for menorrhagia with your patients:**

## HORMONE THERAPY

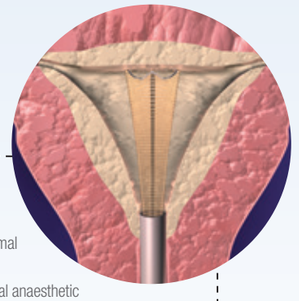
Oral contraceptive or medication that treats hormonal imbalances are not reliable treatments for menorrhagia.

- Oral contraceptives fail to control menorrhagia in 53% of women[12]
- About 50% of patients experience side effect[13 14]
- Additional surgical intervention is required in ~80% of women receiving medical therapy[15]
- Hormonal side effects can include depression,acne, headaches, weight gain, nausea[13 14]
- Requires patient compliance

**Caveats:**
Not an option for all patients, Known drug interactions,
Requires daily pill taking, follow-up and monitoring required.

12. Davis A, Godwin A. Lippman J, Olson W, Kafrissen M. Triphasic Norgestimate-ethinl estradiol for treating dysfunctional uterine bleeding. Obstet Gynecol. 2000;96(6):913-920. 13. Cooper KG, Parkin DE, Garatt AM, et al. A randomised comparison of medical and hysteroscopic management in women consulting a gynaecologist for treatment of heavy menstrual loss. Br J Gynaecol. 1997;104:1360-1366. 14. National Women's Health Resource Center. National survey of 653 women, 35-49 with reported heavy periods and intact uterus; conducted Sept 29-Oct 12, 2005. 15. Cooper KGH, Jack SA, Parkin DE, Grant AM. Five-year follow-up of women randomised to medical management or transcervical resection of the endometrium for heavy menstrual loss: clinical and quality of life outcomes. Br J Obstet Gynaecol. 2001;108(12):1222-28. 16. Hurskainen R, Teperi J, Rissanen P, et al. Clinical outcomes and costs with the levonorgestrel-releasing intrauterine system or hysterectomy for treatment of menorrhagia: randomized 5-year follow-up. JAMA 2004;291(12):1456-63. 17.Busfield RA, Farquhar CM, Sowter MC, et al. A Randomised Trial Comparing the Levonorgestrel Intra Uterine System and Thermal Balloon Ablation for Heavy Menstrual Bleeding. BJOG. 2006;113(3):257-263. 18. Mirena Prescribing Information. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; 2007.

## ENDOMETRIAL ABLATION



**NovaSure®** Endometrial ablation is a unique minimally invasive procedure that can performed in a secondary or primary care setting.

NovaSure® removes the lining of the uterus, to greatly reduce, or completely stop, heavy menstrual bleeding. This procedure is intended for women who have finished having children. NovaSure® is a quick, safe and simple 90-second procedure that is chosen by 75%* of women in the UK who have opted for an endometrial ablation. Because the treatment is associated with few side effects, women usually return to work or their daily activities the day after having the procedure.

*An approximation based on the UK marketshare (devices sold by product) and HES data.

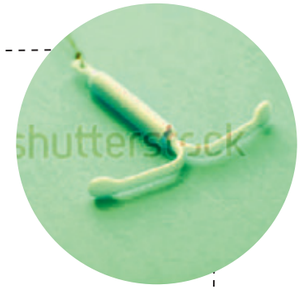
**Advantages:**

- More than 9 out of 10 women return to normal or lower than normal bleeding[7]
- Can be performed with either local or general anaesthetic
- Can be done at any time during the menstrual cycle without hormonal pretreatment
- Recovery in 1 to 2 days
- Removes uterine lining but leaves uterus intact
- 97% of women have avoided a hysterectomy 5 years after the procedure[8]
- 2007 NICE guidelines approved endometrial ablation as a first line treatment option
- Can be performed by a specialist GP or nurse
- Can be performed as an outpatient procedure

**Disadvantages:**

- Only appropriate for women who are finished having children
- Surgical risks associated with minimally invasive procedures
- The procedure cannot be reversed
- After an endometrial ablation some form of birth control is still required
- 3% of women may require further surgical treatment within 5 years[8]

## HORMONE-RELEASING IUD



Hormones are not designed for the treatment of menorrhagia. Levonorgestrel-releasing Intra Uterine System (LNG-IUS) fails to provide amenorrhoea or oligomenorrhoea in 61% of women with menorrhagia at five years[16]

### Clinical Results with the LNG-IUS

More than 40% of women treated with an IUD experienced a satisfactory improvement in bleeding, but still opted for a hysterectomy. Hormonal side effects include breast tenderness, mood swings and acne. Possible drawbacks include abdominal pain, infection, and a difficult placement of the LNG-IUS. A hormone releasing LNG-IUS should be regularly removed and replaced. It is not a permanent solution to heavy menstrual bleeding, but is an option for those women still wanting to have children.

### LNG-IUS effectiveness for menorrhagia

- Takes up to 6 months to achieve bleeding control[1]
- 39% efficacy after 5 years[2]
- 61% failure rate at controlling bleeding – patients experience irregular bleeding[17] yet ~30,000 women in the UK[1] are fitted for HMB ~20% amenorrhea rate by 1 year (contraceptive indication)[3]

**Advantages:**

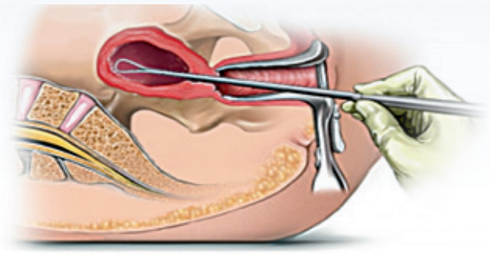
- Reduces bleeding for a short time
- 39% efficacy after 5 years[16]
- Can be inserted by a specialist GP or nurse
- Does not require taking pills
- Fewer side effects than hormones taken orally
- Reversible by removing IUD
- 2007 NICE guidelines approved for use as a 1st line treatment option

**Disadvantages:**

- May take up to 6 months to achieve bleeding control[17]
- Can cause bleeding between periods
- Possible hormonal side effects (eg. depression, acne, headache, weight gain)[18]
- Must be removed or replaced after 5 years
- 42% of women require surgery within 5 years[16]
- Actinomyces infection (chronic bacterial infection)

## DILATION AND CURETTAGE (D&C)

A minor surgical procedure that temporarily controls bleeding by scraping the inside of the uterus. Used mainly to help determine the cause of heavy bleeding.



**Advantages:**

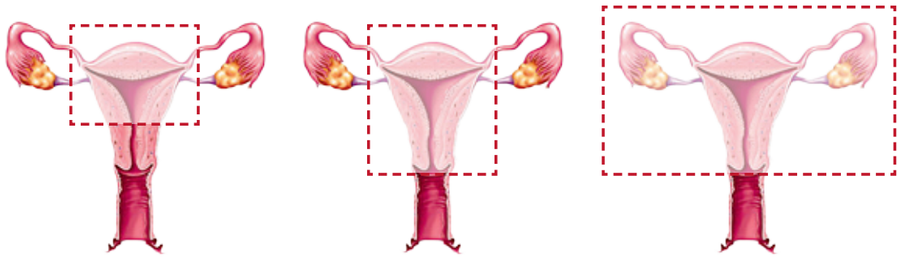
- Reduces bleeding for a short time
- Removes lining but leaves uterus intact
- Can be performed with either local or general anaesthetic

**Disadvantages:**

- Reduced bleeding is temporary
- Surgical risks associated with a minimally invasive procedure
- Not a permanent solution

## HYSTERECTOMY

Hysterectomy has a profound impact on patients. It is a permanent, more invasive, major surgical procedure performed when other medical treatments haven't worked.



Although the results of hysterectomy are good and amenorrhoea is guaranteed, the procedure itself is invasive and can carry significant short-term morbidity.

**Overall, 1 woman in 30 suffers a major adverse event from having a hysterectomy**[19]

The need for General Anaesthesia, prolonged hospital stay and delayed recovery make hysterectomy a potentially expensive treatment for HMB. The Study[19] concluded that women who underwent hysterectomy for HMB were more likely to receive surgery for pelvic floor repair and stress urinary incontinence than those who were treated with an endometrial ablation.

**Advantages:**

- Definitive treatment

**Disadvantages:**

- Only appropriate for women who are finished having children
- Risks of major surgery
- Risks of general anaesthesia
- Recovery takes 2 to 8 weeks
- Cannot be reversed

19. K.Cooper, A.J.Lee, P.Chien, E.A.Raja, V.Timmaraju, S.Bhattacharya. Outcomes following Hysterectomy or Endometrial Ablation for Heavy Menstrual Bleeding. BJOG,March 2011

## STUDY:

# CLINICAL OUTCOMES AND COSTS:

### LNG-IUS or Hysterectomy

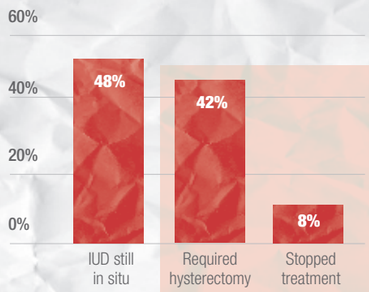
(Hurskainen et al., JAMA 2004)

**Compared outcomes, quality-of-life and costs of Levonorgestrel-Releasing Intrauterine System (LNG-IUS) vs. hysterectomy**

- 236 patients (mean age 43)
- Randomised controlled trial: LNG-IUS (n=119) and hysterectomy (n=117)
- Monitored for 5 years (n=232)

### LNG-IUS results at 5 years

**50%** discountinuation rate
**42%** surgery rate




**Reasons for discontinuing**

**32%** continued heavy bleeding (failure)
**70%** inter-menstrual bleeding
**30%** hormonal side effects

Hurskainen R, Teperi J, Rissanen P, et al. Clinical outcomes and costs with the levonorgestrel-releasing intrauterine system of hysterectomy for treatment of menorrhagia: randomized trial 5-year follow-up. JAMA 2004; 291:1456-1463

# 5 YEAR DATA SUMMARY

A survey of 1,500 women in the US found that 77% wished they had been given the option of a NovaSure® treatment for their HMB at their first doctor's visit.

### Oral contraceptives

77% require surgery
Only 10% still take medication

### Hormone-releasing LNG-IUS

50% discontinue use
42% require hysterectomy

### NovaSure® Endometrial Ablation

98% successful reduction of bleeding
75% amenorrhoea rate

### Hysterectomy

The only definitive menorrhagia treatment
Considered as the last resort

Reference: US Nationwide Data initiative from 2007-2009.

# NovaSure®

## 2 million women treated worldwide

Quick simple procedure

NO incisions NO hormones NO hysterectomy

# HELP YOUR PATIENTS MAKE AN INFORMED CHOICE OF THEIR TREATMENT OPTIONS FOR HEAVY MENSTRUAL BLEEDING.

## Order FREE today

| | | | | |
|---|---|---|---|---|
| NovaSure Information Brochure | NovaSure Patient Information Leaflets | Menstrual Diary | A3 Poster(s) for your GP surgery | Patient Information Postcard |

## Order on-line at: www.novasure.com/GP

email: ukreception@hologic.com

Direct your patients to our consumer information website on heavy periods at

www.wearwhiteagain.co.uk

STOP HER HEAVY PERIOD. PERIOD

PB-00340-GBR-EN, Rev. 001

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WEAR WHITE AGAIN