

HOLOGIC®



The Science of Sure

IS YOUR HEAVY PERIOD AFFECTING YOUR LIFE?

work

intimacy

emotional wellbeing

family activities

The one-time, five-minute procedure
for heavy menstrual bleeding

NovaSure®

We Hate Heavy Periods.™

3 million+

Over 3 million women have been treated with the NovaSure® endometrial ablation procedure.¹

NovaSure endometrial ablation (EA) is the simple, one-time, five-minute procedure that has been used to treat over 3 million women—without hormones or hysterectomy.

The NovaSure procedure is for premenopausal women with heavy periods due to benign causes who are finished childbearing. Pregnancy following the NovaSure procedure can be dangerous.

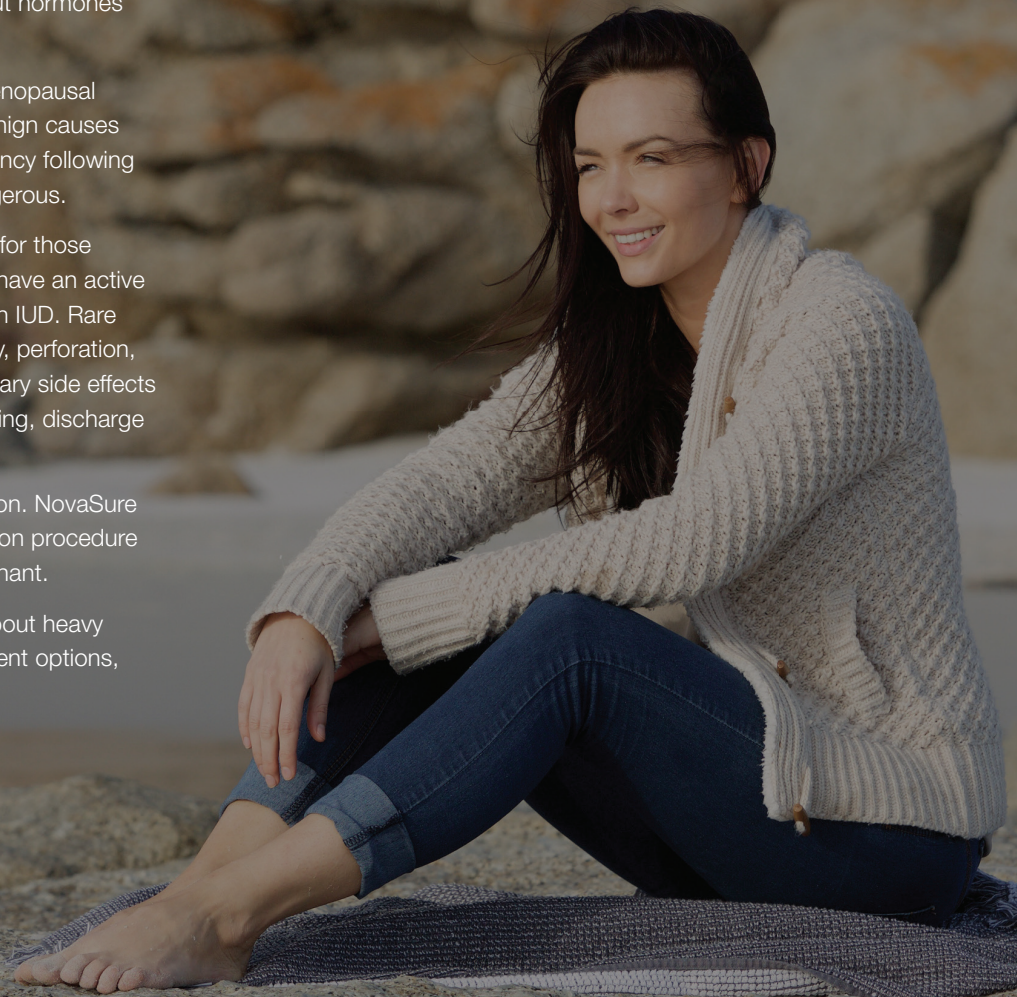
NovaSure endometrial ablation is not for those who have or suspect uterine cancer; have an active genital, urinary or pelvic infection or an IUD. Rare but serious risks include thermal injury, perforation, infection and other problems. Temporary side effects may include cramping, nausea, vomiting, discharge and spotting.

Talk to your doctor for more information. NovaSure endometrial ablation is not a sterilization procedure and not for women who may be pregnant.

This brochure contains information about heavy menstrual bleeding, as well as treatment options, including the NovaSure procedure.

Talk to your doctor.

Your doctor can explain the various treatment options for heavy periods and help you decide if NovaSure endometrial ablation is right for you.



Do heavy periods affect your life?

It's estimated that heavy menstrual bleeding affects 1 out of every 5 women—that's about 10 million women!¹

Many women begin to experience heavy and/or irregular bleeding in their 30s and 40s, as they begin to get closer to menopause. Heavy periods take a physical, social, and emotional toll as well.

Studies show heavy periods mean more than heavy bleeding. They can affect women in numerous ways:

Physical:

- Many feel tired and nauseated.
- Many experience bad cramps.
- Many have headaches.

Social:

- More than 60% have had to miss social or athletic events.³
- About 80% report avoiding sex.²
- 33% have been forced to miss work.³

Emotional:

- 77% have depression or moodiness.²
- 75% feel anxious.³
- 57% report a lack of confidence during their period.³

What is NovaSure endometrial ablation?

NovaSure endometrial ablation is a one-time, five-minute procedure that can lighten or end your heavy periods. No pills. No hormonal side effects. For 77.7% of women, menstrual bleeding is successfully reduced or stopped within one year.⁴ It's a simple procedure that can be done in your doctor's office.

The benefits of the NovaSure procedure:

- One-time procedure.⁴
- The procedure is quick—it usually takes less than five minutes.⁴
- It can be performed in a doctor's office with no general anesthesia.⁴
- For 77.7% of women, menstrual bleeding is successfully reduced or stopped within one year.⁴
- 36% reported that their periods stopped completely.⁴
- 97% of patients from the initial clinical trial experienced no post-procedural pelvic pain/cramping.⁴
- There are no incisions (cuts into your body).
- It can be performed at any time during your cycle, even if you're bleeding.⁴
- You don't need to prepare by taking any pre-treatment medicine.⁴

Choosing the right treatment for you.

There are several treatment options available. The chart below highlights the advantages and disadvantages of the most common options. Your doctor can help you decide which treatment may be right for you.

The following treatment options have not been studied head to head. This chart contains summary information from separate studies that each used different methods and criteria to measure efficacy or success. This is not intended to be medical advice and is not an exhaustive list of treatment options. Please consult your medical professional for specific advice regarding your health and treatment.

Treatment	Efficacy/Success Rate*	Description	Advantages	Disadvantages
Hysterectomy	100% ¹¹	Surgical procedure to remove the uterus	<ul style="list-style-type: none"> Eliminates problem bleeding One-time procedure Permanent 	<ul style="list-style-type: none"> Cost, major invasive surgery Risk associated w/ major surgery Requires general anesthesia 2-8 week recovery time Non-reversible, lose fertility May cause early onset of menopause¹⁵ Typically the last option for women not responsive to other treatments
Global Endometrial Ablation (Data represents the NovaSure procedure)	Successful reduction in bleeding (1 yr) 77.7% ⁴ Amenorrhea rate (1 yr): 36% ⁴	Procedure that removes the uterine lining while preserving the uterus to reduce or eliminate bleeding ⁴	<ul style="list-style-type: none"> One-time, five minute procedure⁴ Patient specific treatment⁴ Average treatment is 90 seconds⁴ Can be performed in-office under local anesthesia Immediate results, rapid recovery Not menstrual cycle dependent⁴ Minimally invasive 	<ul style="list-style-type: none"> Must have completed childbearing⁴ Non-reversible⁴ Contraception required, due to danger of pregnancy post procedure⁴ Potential for post-procedure cramping, pain, nausea, vomiting, vaginal discharge and vaginal spotting/bleeding⁴ May require anesthesia local/general⁴
Hormone Releasing Intrauterine Device Mirena [®] (levonorgestrel-releasing intrauterine system)	Decreased uterine bleeding (1 yr): 24% ⁵ Amenorrhea (1 yr): 20% ⁵	A hormone releasing system (device) placed in the uterus to prevent pregnancy for up to 5 years, which can also decrease heavy menstrual blood loss.	<ul style="list-style-type: none"> Reduces/eliminates problem bleeding combined with contraceptive⁵ Effective for 5 years⁵ Retain fertility (when IUD removed)⁵ 	<ul style="list-style-type: none"> Mirena may take up to 6 months to provide relief from heavy bleeding⁵ Replaced every 5 years⁵ 30% experience hormonal side effects⁵ 70% experience intermenstrual bleeding⁵
Tranexamic acid tablets Lysteda [™] (tranexamic acid, USP)	66% experienced a 1/3 reduction in menstrual blood loss ⁵	Anti-fibrinolytic, helps to normalize clot breakdown within the uterus ⁵	<ul style="list-style-type: none"> Non-invasive⁵ Self administered⁵ Retain fertility throughout⁵ 	<ul style="list-style-type: none"> Two tablets taken 3 times a day (high patient compliance required)⁵ Using Lysteda along with hormonal products may increase the chance of blood clots, stroke or heart attack⁵ Will not produce amenorrhea⁵
No Management (Do nothing and monitor)	No change until menopause	No treatment of any kind is given, patient is monitored and followed up with accordingly	<ul style="list-style-type: none"> No treatment given 	<ul style="list-style-type: none"> No change likely till menopause Average age of menopause is 51 years⁵

*Efficacy/Success Rates are defined:

For Hysterectomy: Elimination of menstrual bleeding following removal of uterus via abdominal, vaginal, laparoscopic or robot-assisted laparoscopic approach.

For Global Endometrial Ablation: Effectiveness was measured based on patient reported blood loss. This method records the number of tampons or sanitary towels (pads) used and the degree to which they are stained with blood.

For Hormone Releasing Intrauterine Device: Effectiveness was measured based on weight of patient-used sanitary products by collecting tampons or sanitary towels (pads) for laboratory analysis.

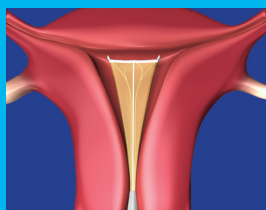
For Tranexamic Acid Tablets: Effectiveness was measured based on weight of patient-used sanitary products by collecting tampons or sanitary towels (pads) for laboratory analysis.

For No Management: N/A

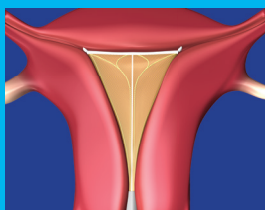
How does the NovaSure procedure work?

The NovaSure endometrial ablation (EA) procedure can reduce or stop menstrual bleeding. It works by permanently removing the endometrium, or the lining of the uterus (the part that causes the bleeding), with a quick delivery of radiofrequency energy.

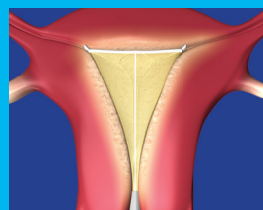
The NovaSure Procedure



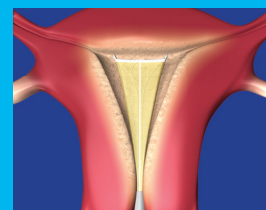
Your doctor opens your cervix (the opening to the uterus) slightly, inserts a slender wand and extends a triangular-shaped netted device into the uterus.



The netting expands, fitting to the size and shape of your uterus.



Precisely measured radiofrequency energy is delivered through the netting for about 90 seconds.



The netted device is pulled back into the wand, and both are removed from the uterus.

No part of the NovaSure device remains inside your body after the procedure.

Are women satisfied with the NovaSure procedure?

In a clinical study, 12 months after the NovaSure procedure:³

92.8%

of patients were satisfied with the results⁴

96.7%

said they would recommend the procedure to a friend⁴

Nearly 7 out of every 10 endometrial ablations performed are the NovaSure procedure.⁹

What can I expect?

Impact on Quality of Life ³		
Answered “Always,” “Frequently” or “Sometimes”	Before NovaSure	After NovaSure
Do you lack confidence due to your periods?	57%	16%
Do you have a problem working due to your periods?	66%	10%
Do your periods cause you to spend less time at work or other activities?	61%	9%
Do you feel anxious due to your periods?	75%	24%
Do your periods cause you to miss social activities?	63%	9%
Do your periods cause you to miss athletic activities?	66%	9%
Are you unable to work outside of your home due to your periods?	33%	6%
Do you have less energy or a total lack of energy?	84%	24%
Do you experience painful periods?	57%	21%
Do you have PMS symptoms?	65%	36%

Many women who've had the NovaSure procedure say they are now able to spend more time at work and daily activities, and miss out on fewer social and athletic outings because of heavy periods. They also report improved energy levels, better moods and a boost in self-confidence. And many also had a significant reduction in painful periods and PMS symptoms like irritability.³

Frequently asked questions

Is NovaSure endometrial ablation right for me?

Women with heavy or long-lasting periods who do not wish to have children in the future may be candidates for the NovaSure procedure.

Your doctor can help you decide if the NovaSure procedure is right for you. But if you're sure you don't want any children in the future, and your doctor rules out more serious causes of heavy bleeding, you may be a good candidate for the NovaSure procedure.

Can I still become pregnant after the NovaSure procedure?

Because NovaSure endometrial ablation treats the lining of the uterus, your chances of getting pregnant after the procedure will be reduced. However, it is still possible to get pregnant if you're sexually active. A pregnancy after an ablation is very dangerous for both the mother and the fetus, since the uterine lining would not be able to properly support fetal development. It's very important to talk to your doctor about what birth control you will use after the NovaSure procedure.

What can I expect after the NovaSure procedure?

Immediately after the NovaSure procedure, some women experience some cramping, mild pain, nausea and/or vomiting. Most women feel back to themselves and can resume normal activities within a day or so. Be sure to follow any instructions from your doctor, no matter how good you're feeling.

A watery and/or bloody discharge following the NovaSure procedure is normal. It could start anywhere from immediately after the procedure to a couple of weeks afterwards. The discharge may last only briefly, or for up to a month.⁴

It could even come and go, increasing after certain activities. This is quite normal and can be expected with any endometrial ablation procedure.

Are there any risks I should know about?

Your doctor will explain the risks of all treatment options. Some of the risks associated with the NovaSure endometrial ablation procedure are perforation of the uterus, bleeding, infection, abnormally slow heart beat, injury to organs within the abdomen or around the uterus or complications leading to serious injury or death.

Tell your doctor if you have a cardiac pacemaker or any other electrical device in your body.

Very few patients experience complications following the NovaSure procedure. But you should call your doctor right away if you develop:

- A fever higher than 100.4°F.
- Worsening pelvic pain that is not relieved by ibuprofen or other prescribed medicine.
- Nausea, vomiting, shortness of breath, dizziness.
- Bowel or bladder problems.
- A greenish vaginal discharge (reddish, yellowish or brownish is normal).

When will I know what my periods will be like after the NovaSure procedure?

Every woman is different. But plan to give your body about 3 months to fully heal on the inside and resume its normal cycle. Then, you and your doctor should be able to tell what your cycle and your periods will be like from that point on.

Talking to your doctor about heavy menstrual bleeding

Research has shown that many women who suffer from heavy periods do not bring the subject up with their doctors or seek treatment.¹⁰

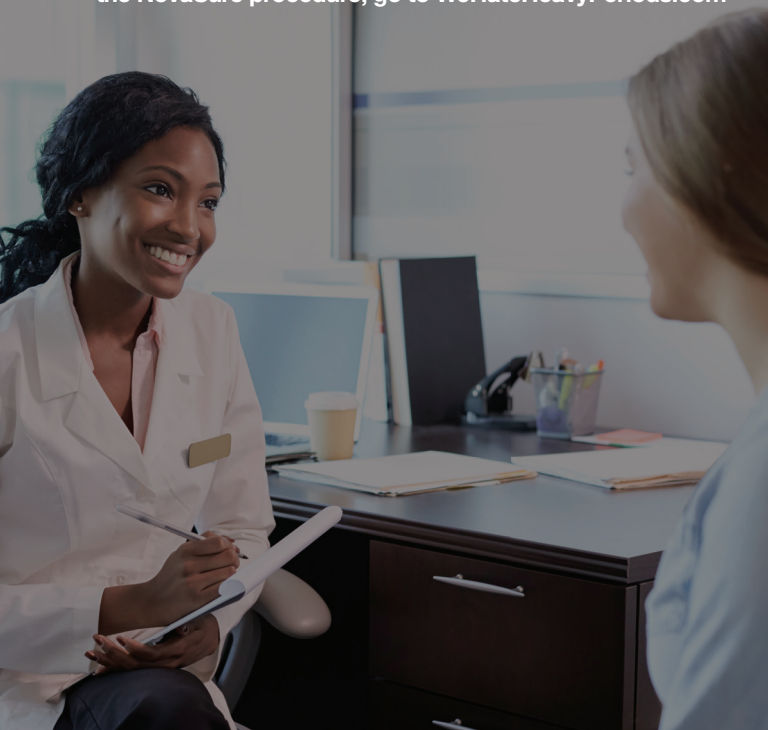
Heavy periods are a problem that affects 1 out of every 5 women.²

If getting the conversation started seems hard once you're at your doctor's office, try one of these openers:

- "I'd like to ask you a few questions about my menstrual cycle..."
- "I've noticed that my periods are different than they used to be..."
- "I've heard that a lot of women are getting treated for heavy periods—is this something I should consider?"

If you suffer from heavy menstrual bleeding and do not wish to have any children in the future, be sure to ask your doctor if NovaSure endometrial ablation may be right for you.

To find a physician in your area who performs the NovaSure procedure, go to WeHateHeavyPeriods.com



Heavy menstrual bleeding checklist

Do any of the following statements apply to you?

- My period affects my quality of life.
- I am bothered by the amount of bleeding or level of pain I have during my periods.
- My period makes me feel depressed, tired or moody.
- I am afraid of having an embarrassing accident.
- I have PMS symptoms, such as headaches, during my period.
- I bleed more than once a month.
- My period lasts too long.
- My period affects my social, athletic or sexual activities or causes me to miss work.
- My life would improve if I could decrease or completely eliminate my period.
- I would like to learn about a simple procedure that can help me get back to living.

Use the space below to write down any additional questions or concerns:

Bring this checklist with you to your next doctor's appointment.

NovaSure[®]
We Hate Heavy Periods.[™]

To find out more about the NovaSure procedure:

- Talk to your doctor
- Visit WeHateHeavyPeriods.com
- Visit ChangeTheCycle.com

Important Safety Information

NovaSure endometrial ablation is for premenopausal women with heavy periods due to benign causes who are finished childbearing. Pregnancy following the NovaSure procedure can be dangerous. The NovaSure procedure is not for those who have or suspect uterine cancer; have an active genital, urinary or pelvic infection; or an IUD. NovaSure endometrial ablation is not a sterilization procedure. Rare but serious risks include, but are not limited to, thermal injury, perforation and infection. Temporary side effects may include cramping, nausea, vomiting, discharge and spotting. If you or someone you know, have possibly experienced a side effect when using our product, please contact your physician.

References

1. Hologic Inc., Data on file, 2018. Based on units shipped from 2004-2018. **2.** Centers for Disease Control and Prevention. Heavy menstrual bleeding. <https://www.cdc.gov/ncbddd/blooddisorders/women/menorrhagia.html>. Accessed April 07, 2017. **3.** 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. **4.** NovaSure Instructions for Use. **5.** Mirena [package insert]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; 2007. **6.** Siddle N, et al. The effect of hysterectomy on the age at ovarian failure: identification of a subgroup of women with premature loss of ovarian function and literature review. *Fertil Steril.* 1987; 47:94-100. **7.** Lysteda Prescribing Information. **8.** The American College of Obstetricians and Gynecologists. Frequently Asked Questions, Gynecologic Problems. ACOG. 2011; FAQ162. **9.** Hologic, Inc. Data on file. "GSS Share, ATU and Message Update". March 28, 2017. **10.** Hologic, Inc. Data on file; 2017. "Surgical Patient Journey Quantitative Findings. Understanding the AUB Patient Experience." **11.** Dickersin K, Munro MG, Clark M, Langenberg P, Scherer R, Frick K, et al. Surgical Treatments Outcomes Project for Dysfunctional Uterine Bleeding (STOP-DUB) Research Group. Hysterectomy compared with endometrial ablation for dysfunctional uterine bleeding: a randomized controlled trial. *Obstet Gynecol.* 2007;110(6):1279-89. [PubMed]

WeHateHeavyPeriods.com

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