

NovaSure®
Endometrial Ablation

HOLOGIC®



Is your period
affecting your life?



Read how the **NovaSure**
procedure is quick,
simple and effective.

Visit gynsurgicalsolutions.com



1 in 3

Heavy menstrual bleeding is very common. In fact, **1 in 3** women seek treatment for it!

Many women begin to experience heavy and/or irregular menstrual bleeding in their 30's and 40's, as they begin to get closer to menopause. It can disrupt your life and may be a sign of a more serious health problem.

Heavy menstrual bleeding can affect women in numerous ways: physically, socially, and emotionally.

If you are worried that your menstrual bleeding is too heavy, tell your obstetrician–gynecologist (ob-gyn).

Patients Report

Physical Affects

80+%

of women with heavy menstrual bleeding find their period disruptive to their mental, emotional and physical well-being. Many feel tired and nauseated. Many experience bad cramps. Many have headaches.²

Social Affects

58+%

have had to miss social or athletic events.³

66%

report difficulty completing work and other activities³

81%

of patients report that their heavy period is disruptive to their sex life.²

Emotional Affects

75%

feel anxious.³

57%

report a lack of confidence.³

42%

of women feel depressed when their period is at its heaviest?

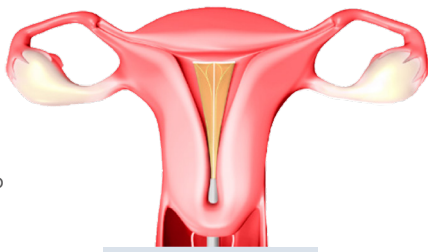


What is NovaSure Endometrial Ablation?

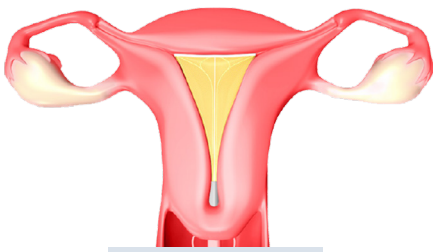
NovaSure endometrial ablation is a **one-time, five-minute** procedure that **can lighten or end your heavy periods**. No pills, or hormonal side effects. It's a simple procedure that can be done in your doctor's office.

How does the NovaSure procedure work?

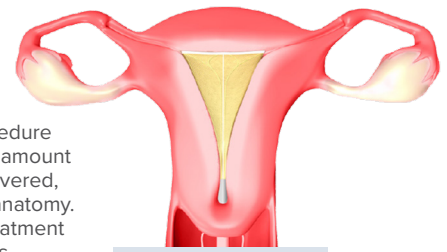
1 Your doctor slightly opens your cervix. Inserts a slender wand, and extends a triangular-shaped netted device into your uterus.



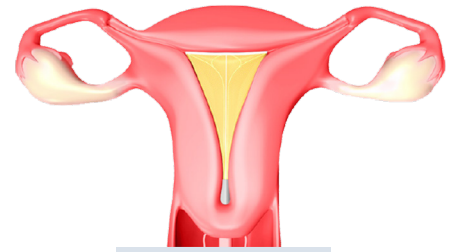
2 The netting expands, fitting to the size and shape of your uterus.



3 The NovaSure procedure uses radiofrequency to ablate the endometrium. During the procedure the appropriate amount of energy is delivered, based on your anatomy. The average treatment lasts 90 seconds.

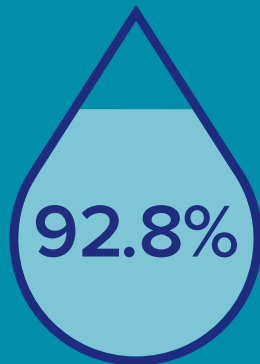


4 Once the procedure is complete, the array retracts and is safely removed from your uterus.



How satisfied are women with the NovaSure procedure?

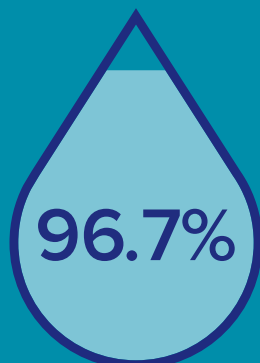
In a clinical study, 12 months after the NovaSure procedure



of patients were satisfied with the results³

Nearly
7 out of every 10

endometrial ablations performed are the NovaSure procedure.⁴



said they would recommend the procedure to a friend³



The benefits of the NovaSure procedure⁶

One-time procedure.

The procedure is quick—it usually takes less than five minutes.

It can be performed in a doctor's office with no general anesthesia.

In a clinical study, 77.7% of women reported that menstrual bleeding was successfully reduced within one year.

In a clinical study, 36% of women reported that their periods stopped completely.

97% of patients from the initial clinical trial experienced no post-procedural pelvic pain/cramping.

There are no incisions (no cuts into your body).

It can be performed at any time during your cycle, even if you're bleeding.

You don't need to prepare by taking any pre-treatment medicine.

Non-hormonal

Many women return to normal activities the next day.



Watch the video to learn more

Visit gynsurgicalsolutions.com

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% ⁷	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 menopause⁸ 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% ³ Amenorrhea rate (1 yr): 36% ³	Procedure that removes the uterine lining while preserving the uterus to reduce or eliminate bleeding ⁶	<ul style="list-style-type: none"> One-time, five minute procedure⁶ Patient specific treatment⁶ Average treatment is 90 seconds⁶ Can be performed in-office under local anesthesia Immediate results, rapid recovery Not menstrual cycle dependent⁶ Minimally invasive 	<ul style="list-style-type: none"> Must have completed childbearing⁶ Non-reversible⁶ Contraception required, due to danger of pregnancy post procedure⁶ Potential for post-procedure cramping, pain, nausea, vomiting, vaginal discharge and vaginal spotting/bleeding⁶ May require anesthesia local/general⁶
Hormone Releasing Intrauterine Device Mirena [®] (levonorgestrel-releasing intrauterine system)	Decreased uterine bleeding (1 yr): 24% ⁹ Amenorrhea (1 yr): 20% ⁹	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 contraceptive⁹ Effective for 5 years⁹ Retain fertility (when IUD removed)⁹ 	<ul style="list-style-type: none"> Mirena may take up to 6 months to provide relief from heavy bleeding⁹ Replaced every 5 years⁹ 30% experience hormonal side effects⁹ 70% experience intermenstrual bleeding⁹
Tranexamic acid tablets Lysteda™ (tranexamic acid, USP)	66% experienced a 1/3 reduction in menstrual blood loss ¹⁰	Anti-fibrinolytic, helps to normalize clot breakdown within the uterus ¹⁰	<ul style="list-style-type: none"> Non-invasive¹⁰ Self administered¹⁰ Retain fertility throughout¹⁰ 	<ul style="list-style-type: none"> Two tablets taken 3 times a day (high patient compliance required)¹⁰ Using Lysteda along with hormonal products may increase the chance of blood clots, stroke or heart attack¹⁰ Will not produce amenorrhea¹⁰
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 years¹¹

*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

Frequently asked questions

**Based on the NovaSure IFU and physician experience*

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. 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.

Can the NovaSure procedure be combined with other procedures?

Yes. Ask your doctor.



To find out more about the
NovaSure procedure visit
our website

<https://gynsurgicalsolutions.com/patients/novasure/>

Important Safety Information

NovaSure endometrial ablation is for premenopausal women with heavy periods due to benign causes who are finished childbearing. During a NovaSure procedure, a trained gynecologist inserts the NovaSure device through your vagina and then treats the uterine lining—the endometrium. Because pregnancy following the NovaSure procedure is still possible and dangerous, it is important to talk to your doctor about birth control or permanent sterilization following the procedure. The NovaSure procedure is not for those who have or suspect uterine cancer; have an active genital, urinary or pelvic infection; or an IUD. As with any surgical procedure, there are potential risks including but not limited to internal injury, infection, and complications related to anesthesia. Temporary side effects may include cramping, nausea, vomiting, discharge and spotting. This information is not medical advice. Please discuss the risks and benefits with your doctor to find out if the NovaSure procedure may be right for you.

References

1. NIH National Library of Medicine, <https://www.ncbi.nlm.nih.gov/books/NBK532913> Accessed Sept. 20, 2022.
2. Hologic, Inc. Data on File; AUB Patient Journey Research, conducted January 2017. Survey of 1,003 women who self-identified as currently or recently experiencing heavy bleeding with need to change feminine hygiene product every hour or more.
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. Hologic, Inc., Data on file; Based on publicly reported sales data of NovaSure endometrial ablation system and competitive devices.
5. Hologic, Inc., Data on file, 2018. Based on units shipped from 2004-2018.
6. NovaSure Instructions for Use.
7. 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]
8. 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. 3
9. Mirena [package insert]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; 2007.
10. Lysteda Prescribing Information.
11. The American College of Obstetricians and Gynecologists. Frequently Asked Questions, Gynecologic Problems. ACOG. 2011; FAQ162.

NovaSure[®]
Endometrial Ablation