

**Is your  
heavy  
period  
affecting  
your  
life?**

**NovaSure®**

Endometrial Ablation

The one time, five minute procedure for heavy  
menstrual bleeding

# 3 million+

**Over 3 million women have been treated with the NovaSure® endometrial ablation procedure.<sup>1</sup>**

NovaSure® endometrial ablation (EA) is a 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 may include thermal injury, perforation and infection, amongst 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 sterilisation 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.<sup>2</sup>

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.<sup>3</sup>
- About 80% report avoiding sex.<sup>3</sup>
- 33% have been forced to miss work.<sup>3</sup>

### Emotional:

- 63% feel impact on mental and emotional wellbeing.<sup>4</sup>
- 75% feel anxious.<sup>3</sup>
- 57% report a lack of confidence during their period.<sup>3</sup>

## 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 91% of women, menstrual bleeding is dramatically reduced or stopped.<sup>3</sup>

## The benefits of the NovaSure procedure:

- One-time procedure.<sup>5</sup>
- The procedure is quick—it usually takes less than five minutes.<sup>5</sup>
- It can be performed with no general anesthesia.<sup>5</sup>
- 91% of women returned to normal or light periods, or had no periods at all.<sup>3</sup>
- 41% reported that their periods stopped completely.<sup>3</sup>
- 97% of patients from the initial clinical trial experienced no post-procedural pain.<sup>3</sup>
- There are no incisions (cuts into your body).<sup>5</sup>
- It can be performed at any time during your cycle, even if you're bleeding.<sup>5</sup>
- You don't need to prepare by taking any pre-treatment medicine.<sup>5</sup>

# Choosing the right treatment for you.

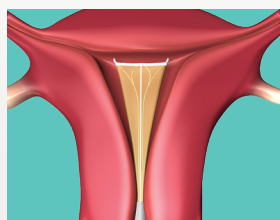
There are several treatment options available. The chart below highlights the advantages and disadvantages of the most common options. Your doctor can help you decide which treatment may be right for you.

Treatment	Efficacy/Success Rate	Description	Advantages	Disadvantages
<b>Hysterectomy</b>	100% <sup>6</sup>	Surgical procedure to remove the uterus	<ul style="list-style-type: none"> <li>• Eliminates problem bleeding</li> <li>• One-time procedure</li> <li>• Permanent</li> </ul>	<ul style="list-style-type: none"> <li>• Cost, major invasive surgery</li> <li>• Risk associated w/ major surgery</li> <li>• Requires general anesthesia</li> <li>• 2-8 week recovery time</li> <li>• Non-reversible, lose fertility</li> <li>• May cause early onset of menopause<sup>7</sup></li> <li>• Typically the last option for women not responsive to other treatments</li> </ul>
<b>Global Endometrial Ablation</b> (Data represents the NovaSure procedure)	Successful reduction in bleeding (1 yr) 98% <sup>8</sup> Reintervention rate (5 yrs) 2.8-8.2% <sup>8,9</sup> Amenorrhea rates range from 30-75% <sup>8,9</sup>	Procedure that removes the uterine lining while preserving the uterus to reduce or eliminate bleeding <sup>8</sup>	<ul style="list-style-type: none"> <li>• One-time, five minute procedure<sup>5</sup></li> <li>• Patient specific treatment<sup>5</sup></li> <li>• Average treatment is 90 seconds<sup>5</sup></li> <li>• Can be performed under local anesthesia</li> <li>• Immediate results, rapid recovery<sup>5</sup></li> <li>• Not menstrual cycle dependent<sup>5</sup></li> <li>• Minimally invasive</li> </ul>	<ul style="list-style-type: none"> <li>• Must have completed childbearing<sup>5</sup></li> <li>• Non-reversible<sup>5</sup></li> <li>• Contraception required, due to danger of pregnancy post procedure<sup>5</sup></li> <li>• Potential for post-procedure cramping, pain, nausea, vomiting, vaginal discharge and vaginal spotting/bleeding<sup>5</sup></li> <li>• May require anesthesia local/general<sup>5</sup></li> </ul>
<b>Hormone Releasing Intrauterine Device</b> (Data represents Mirena)	Reduction to normal bleeding (1 yr): 67% <sup>10</sup> Hysterectomy rate after (5 yrs): 42% <sup>10</sup> Amenorrhea (1 yr): 20% <sup>12</sup>	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. <sup>12</sup>	<ul style="list-style-type: none"> <li>• Reduces/eliminates problem bleeding combined with contraceptive<sup>12</sup></li> <li>• Effective for 5 years<sup>12</sup></li> <li>• Retain fertility (when IUD removed)<sup>12</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Mirena may take up to 6 months to provide relief from heavy bleeding<sup>12</sup></li> <li>• Replaced every 5 years<sup>12</sup></li> <li>• 30% experience hormonal side effects<sup>12</sup></li> <li>• 70% experience intermenstrual bleeding<sup>12</sup></li> </ul>
<b>Tranexamic acid</b> (Data represents Lysteda)	66% experienced a 1/3 reduction in menstrual blood loss <sup>13</sup>	Anti-fibrinolytic, helps to normalize clot breakdown within the uterus <sup>13</sup>	<ul style="list-style-type: none"> <li>• Non-invasive<sup>13</sup></li> <li>• Self administered<sup>13</sup></li> <li>• Retain fertility throughout<sup>13</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Two tablets taken 3 times a day (high patient compliance required)<sup>13</sup></li> <li>• Using Lysteda along with hormonal products may increase the chance of blood clots, stroke or heart attack<sup>13</sup></li> <li>• Will not produce amenorrhea<sup>13</sup></li> </ul>
<b>Hormone Therapy</b> (Data based on Progestogens)	Reduces problem bleeding in approximately 50% of patients <sup>3</sup>	Estrogen/progestin used for select low-risk patients	<ul style="list-style-type: none"> <li>• Self administered</li> <li>• Contraceptive</li> <li>• Non-invasive</li> <li>• Regain fertility once therapy is stopped</li> </ul>	<ul style="list-style-type: none"> <li>• Risk for hormonal side effects</li> <li>• Results may vary depending on hormone<sup>14</sup></li> </ul>
<b>No Management</b> (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"> <li>• No treatment given</li> </ul>	<ul style="list-style-type: none"> <li>• No change likely until menopause</li> <li>• Average age of menopause is 51 years<sup>15</sup></li> </ul>

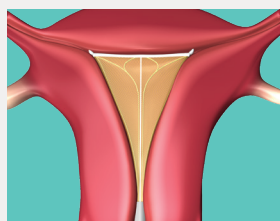
# How does the NovaSure® procedure work?

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.

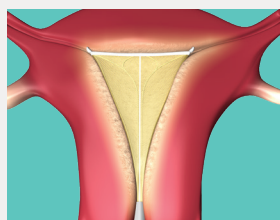
## The NovaSure® Procedure



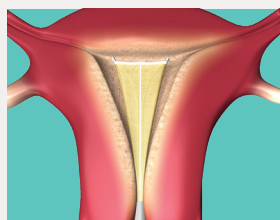
A doctor opens the cervix (the opening to the uterus) slightly, inserts a slender wand and extends a triangular-shaped netted device into the uterus.



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

## Are women satisfied with the NovaSure® procedure?

In a clinical study, 12 months after the NovaSure® procedure:<sup>3</sup>



**93%**  
of patients were  
satisfied with the  
results<sup>3</sup>



**97%**  
said they would  
recommend the  
procedure to a friend<sup>3</sup>

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

# What can I expect?

Most women who have had the NovaSure procedure have lighter periods or no periods afterwards.

In a clinical study, 9 out of 10 women returned to normal or light periods and 4 out of 10 stopped bleeding altogether.<sup>3</sup>

Impact on Quality of Life <sup>3</sup>			
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%

## ...and more

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.<sup>3</sup>

# 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.<sup>5</sup> Most women feel back to themselves and can resume normal activities within a day or so.<sup>3</sup> Be sure to follow any instructions from your doctor, no matter how 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.<sup>5</sup>

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. These problems are very rare and reported at a rate of less than 0.01%.<sup>8</sup>

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 38°C / 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. 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

Heavy periods are a problem that affects 1 out of every 5 women.<sup>2</sup>

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.

**Visit: [www.hologic.ca/novasure](http://www.hologic.ca/novasure) for materials to help you prepare for your doctors appointment.**



## 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:**

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

**NovaSure**<sup>®</sup>  
Endometrial Ablation



## To find out more about the NovaSure<sup>®</sup> procedure:

- Talk to your doctor
- Visit [hologic.ca/novasure](https://hologic.ca/novasure)

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**NovaSure**<sup>®</sup>  
Endometrial Ablation

### 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., units shipped from 2004-2018. 2. NHS Choices: Periods (2016) Available at: <https://www.nhs.uk/conditions/periods/fertility-in-the-menstrual-cycle/> Accessed: Jan 2019 3. Cooper J, Gimpelson R, Laberge P 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 Ltd. Data on file: MISC-05659-GBR-EN Rev 001 5. NovaSure Instructions for Use AW-09898-001 6. Lethaby A, Sheppard S, Cooke I, Farquhar C. Endometrial resection and ablation versus hysterectomy for heavy menstrual bleeding. *Cochrane Database System Review*, 2000;(2) 7. Farquhar CM, Sadler L, Harvey SA, Stewart AW. The association of hysterectomy and menopause: a prospective cohort study. *BJOG.* 2005 Jul;112(7):956-62. doi: 10.1111/j.1471-0528.2005.00696.x. PMID: 15957999. 8. Gimpelson RJ. Ten-year literature review of global endometrial ablation with the NovaSure device. *Int J Womens Health.* 2014;6:269-280. 9. Gallinat A. An impedance-controlled system for endometrial ablation: five-year follow-up on 107 patients *J Reprod Med.* 2007;52(6):467-472. 10. Istre O, Trolle B. Treatment of menorrhagia with levonorgestrel intrauterine system versus endometrial resection. *Fertil Steril.* 2001;76:304-309. 11. 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 trial 5-year follow-up. *JAMA.* 2004; 291:1456-1463 12. Mirena [package insert]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; 2007. [https://www.bayer.com/sites/default/files/MIRENA\\_EN\\_PI.pdf](https://www.bayer.com/sites/default/files/MIRENA_EN_PI.pdf) accessed on 02-15-22 13. Tranexamic acid prescribing information [https://www.amringusa.com/wp-content/uploads/2022/01/Amring\\_Pharmaceuticals\\_Inc\\_TRANEXAMIC\\_ACID\\_USP\\_Tablets.pdf](https://www.amringusa.com/wp-content/uploads/2022/01/Amring_Pharmaceuticals_Inc_TRANEXAMIC_ACID_USP_Tablets.pdf) Accessed 02-15-22 14. Singh RH, Blumenthal P. Hormonal management of abnormal uterine bleeding. *Clin Obstet Gynecol.* 2005; 48:337-352. 15. The American College of Obstetricians and Gynecologists. Frequently Asked Questions, Gynecologic Problems. ACOG. 2011; FAQ162.