

TREATMENT FOR HEAVY PERIODS

This brochure is designed to assist Australian healthcare professionals when consulting with patients who are considering treatment for heavy periods. It contains information on the NovaSure[®] endometrial ablation procedure and is designed to help women make an informed choice in consultation with their doctor.

**Minimally-invasive procedure
for heavy menstrual bleeding**

NovaSure[®]
Endometrial Ablation

3 million+

Over 3 million women have been treated with the NovaSure® procedure globally.*

NovaSure endometrial ablation (EA) is a minimally-invasive surgical procedure suitable for premenopausal women with heavy periods due to benign causes, who are finished with their childbearing.¹

An endometrial ablation is recommended by the Australian Commission on Safety and Quality in Health Care (ACSQHC) as an alternative to hysterectomy for women with heavy menstrual bleeding. The ACSQHC recommends hysterectomy should only be considered when other treatment options are ineffective or unsuitable.³

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 may be right for you.

Talk to your doctor.

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

This brochure is intended to help you make an informed treatment choice and supports shared decision making in consultation with your doctor - as recommended by the Australian Government's guidelines for the treatment of Heavy Menstrual Bleeding.³

Heavy menstrual bleeding checklist

Do any of the following statements apply to you?

- I am bothered by the amount of bleeding or the pain that I have during my period
- I need to change protection every one to two hours
- My period lasts for more than seven days per cycle
- 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 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

If so, talk to your doctor about the treatment options suitable to your individual clinical needs.

The safety and efficacy of the NovaSure procedure are supported by over 15 years of clinical data and over 3 million procedures performed globally.*

* Hologic, Inc. Data on file; 2019.

Do heavy periods affect your life?

It is estimated that heavy menstrual bleeding affects one-in-five women.⁴ That means millions of women are suffering from heavy periods around the world, yet research shows less than one-third seek treatment.⁴ Many women begin to experience heavy and/or irregular bleeding in their 30s and 40s, as they get closer to menopause. Heavy periods take a physical, social, and emotional toll as well.⁴

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 events⁵
- About 80% report avoiding sex⁵
- 33% have been forced to miss work⁵

Emotional:

- 77% have depression or moodiness⁵
- 75% feel anxious⁵
- 57% report a lack of confidence during their period⁵

What is NovaSure® Endometrial Ablation?

NovaSure endometrial ablation is a minimally-invasive surgical procedure that can lighten or end your heavy period. No pills. No hormonal side effects. No incisions. The clinical study used for the approval of the NovaSure system showed the procedure resolved problem bleeding in 91% of patients.^{1,5}

- One-time procedure¹
- The treatment time usually takes less than five minutes¹
- It is typically performed with general anaesthesia in a day surgery or hospital setting
- 91% of women returned to normal, light or no periods at all^{1,5}
- 97% of patients from the initial clinical trial experienced no post-procedural pain^{1,5}
- Most women experience mild or no pain during or after the procedure¹
- There are no incisions (cuts into your body)
- It can be performed at any time during your cycle, even if you're bleeding¹
- You don't need to prepare by taking any pretreatment hormonal therapy¹

* FDA Pre Market Approval (2001)

For more information, talk to your doctor.

Choosing the right treatment for you

The Australian Commission on Safety and Quality in Health Care recommends women with heavy periods are presented with information on all treatment options to support shared decision-making.³ Your doctor will help you decide which treatment may be right for you.

NON-HORMONAL			HORMONAL		
	Medication NSAIDs or Tranexamic Acid	Minimally Invasive Surgery Endometrial Ablation	Major Surgery Hysterectomy	Oral Contraceptives	Hormone-Releasing Intrauterine Device or IUD
Description	<p>Nonsteroidal anti-inflammatory drugs (NSAIDs) are painkillers, generally available as over-the-counter medication.</p> <p>Tranexamic acid is an antifibrinolytic agent that helps block the breakdown of blood clots.¹ A prescription is required.</p>	<p>Quick and effective procedure that removes the lining of the uterus.⁷</p>	<p>Surgery to remove the uterus - a permanent option for women not responsive to other treatments.</p>	<p>Low doses of female hormones (oestrogen and/or progestin) such as birth control pills.</p>	<p>Device inserted into the uterus that releases a steady amount of progestins, which can help control bleeding.</p>
Advantages	<ul style="list-style-type: none"> • NSAIDs are suitable for milder menorrhagia² • NSAIDs can relieve painful menstrual cramps⁴ • NSAIDs and tranexamic acid only need to be taken at the time of bleeding⁴ • Some NSAIDs can reduce the amount of blood volume by up to 45%² • Tranexamic acid is shown to reduce the amount of blood flow during each period by 40–60%² 	<ul style="list-style-type: none"> • 91% of patients returned to normal or lower than normal bleeding⁸ • Typically takes less than 5 minutes⁷ • Can be performed in the hospital or a day surgery unit⁷ • Local or general anaesthetic can be used (general is mostly used in Australia and New Zealand)⁷ • Can be done at any time during the cycle without hormonal pretreatment⁷ • Recovery in 1 to 2 days⁷ • Removes lining but leaves uterus intact⁷ 	<ul style="list-style-type: none"> • Eliminates problem bleeding • Permanent 	<ul style="list-style-type: none"> • Reduces bleeding in around one-third of patients⁵ • Self-administered - taken by mouth • Contraceptive • Fertility restored when therapy is stopped 	<ul style="list-style-type: none"> • 39% efficacy after 5 years¹⁰ • Does not require taking pills • Contraceptive • Fertility restored when the IUD is removed
Disadvantages	<ul style="list-style-type: none"> • NSAIDs and tranexamic acid are associated with gastrointestinal (GI) side effects, including nausea, vomiting, diarrhoea and dyspepsia, as well as disturbances in colour vision² • NSAIDs are less effective than tranexamic acid² • Tranexamic acid can cause nausea² • Patients on tranexamic acid also run the risk of developing deep venous thrombosis (DVT)² 	<ul style="list-style-type: none"> • Only appropriate for women who do not want more children⁷ • Surgical risks associated with minimally invasive procedures⁷ • Cannot be reversed⁷ • After an ablation, your uterus is not able to properly support foetal development so some form of birth control is required⁷ 	<ul style="list-style-type: none"> • Involves major invasive surgery • Risks of complications associated with major surgery • Requires general anaesthesia • 2 to 8 week recovery time • May result in early onset of menopause with possible need for future hormone treatment¹¹ • Cannot be reversed 	<ul style="list-style-type: none"> • May take up to 3 months before they start working¹¹ • About 50% of patients experience side effects⁵ • Hormonal side effects can include depression, acne, headache, weight gain, breast tenderness, increased risk of cervical cancer¹² • Ongoing cost • Must remember to take them • 77% of women eventually progress to a surgical solution¹³ 	<ul style="list-style-type: none"> • Must be removed and replaced every 5 years • 70% of women experience intermenstrual bleeding/spotting¹⁰ • 50% of women experience hormonal side effects¹⁴ • Hormonal side effects may include depression, acne, headaches, nausea, weight gain and hair loss^{14,15} • Other potential side effects include abdominal pain, infection, and difficulty inserting the device, requiring cervical dilation¹⁶ • May take up to 6 months before it starts working¹⁷ • 42% of women require surgery within 5 years¹⁰

For more information, talk to your doctor.

How does NovaSure® work?

The NovaSure endometrial ablation (EA) procedure is proven to significantly reduce or stop problem bleeding. It does not involve removal of the uterus, which is supported by the Australian Commission on Safety and Quality Health Care in its recommendation that women should first consider surgical procedures that leave the uterus in place.³

It works by permanently removing the lining of the uterus (the part that causes the bleeding), with a delivery of radio frequency energy.¹

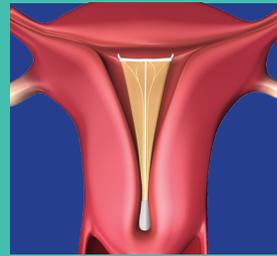
The NovaSure procedure is minimally-invasive as it does not require incisions. Treatment time is typically less than five minutes and usually requires general anaesthetic. Unlike other EA methods, the NovaSure procedure can be performed at any time during the menstrual cycle and does not require hormonal pretreatment. Patients can go home the same day and are back to work in one or two days.¹

Over 3 million women worldwide have been treated with NovaSure endometrial ablation to date.*

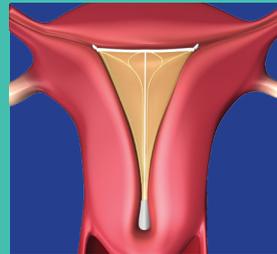


* Hologic, Inc. Data on file; 2019.

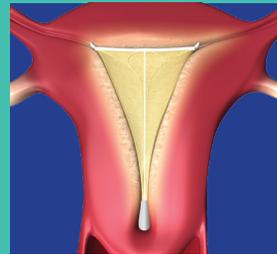
The NovaSure Procedure



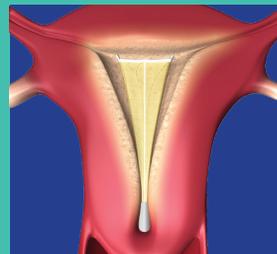
Your doctor opens your cervix (the opening to the uterus), inserts a slender wand, and extends a triangular-shaped netted device into the uterus.



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



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



The netting 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.

For more information, talk to your doctor.



Frequently asked questions

Is the NovaSure procedure right for me?

Your doctor can help you decide if NovaSure is right for you. Women with heavy or long-lasting periods who are finished having children may be candidates. Your doctor may perform diagnostic tests to be sure there is no other cause for your heavy periods.

Can I still become pregnant after the NovaSure procedure?

Because NovaSure 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 are sexually active. A pregnancy after an ablation is very dangerous for both the mother and the foetus, since the uterine lining would not be able to properly support foetal development. It's very important to talk to your doctor about what birth control you will use after the NovaSure 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 EA procedures are making a hole in the uterus, bleeding, infection, bradycardia, injury to organs within the abdomen or around the uterus or complications leading to serious injury or death. These problems are very rare.⁸ Tell your doctor if you have a cardiac pacemaker or any other electrical device in your body.

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

Every woman is different. Plan to give your body about three months to fully heal on the inside and resume a 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.

What to expect: After the procedure

As with any medical procedure, your doctor will give you specific postoperative instructions to follow. The information in this brochure is intended only to describe what many women typically experience and should not be regarded as a substitute for your doctor's advice. Remember, every woman is different.

The first 24 hours

- Right after the procedure and for the next day or so, some women experience slight cramping. Others don't feel any discomfort at all. Most cramps can be relieved with over-the-counter pain medicines.
- Some women may feel nauseous or vomit as a result of anaesthesia
- Watery and/or bloody discharge may begin
- You may feel tired and need to rest

Just in case...

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 isn't relieved by over-the-counter pain medication or other prescribed medicine
- Nausea, vomiting, shortness of breath, or dizziness
- Bowel or bladder problems
- A greenish vaginal discharge (reddish, yellowish, or brownish is normal)

What to expect: The next few weeks

How you'll feel

Most women will feel back to normal within a day or two of the procedure. Any cramps should subside, and the lingering effects of any anaesthesia should be gone. If it makes you more comfortable, you can continue to take over-the-counter pain medicine. Some women may still feel tired from time to time for a while afterwards. If this does happen, don't worry-any remaining symptoms should disappear as soon as your body is fully healed.

Returning to normal activities

After the first 24 hours, your doctor will probably give you approval to return to most light-to-moderate activities. As a rule, your body's comfort level will tell you how much you're ready to do. For heavier activities, such as vigorous exercise or heavy lifting, your doctor may want you to wait a bit longer. If you feel tired or start to get cramps, you may need to slow down a bit.

What to avoid

Though you may feel better shortly after your procedure, it will take your body a few weeks to fully heal on the inside. Your doctor may tell you to limit certain activities (such as taking a bath, swimming, or sex) for a week or two to avoid risk of infection. Be sure to follow instructions no matter how good you're feeling. If your symptoms persist you should contact your doctor immediately.

A word about discharge after the NovaSure procedure:

You may have a watery and/or bloody discharge after your NovaSure procedure. It could start anywhere from immediately after the procedure to a couple of weeks afterwards. The discharge might last only briefly or continue for up to a couple of months. It could even come and go, and may increase after certain activities.

Why? It's because the inside of your uterus, which has been treated to stop your heavy bleeding, is healing. This is quite normal and can be expected with any endometrial ablation procedure.

What does the discharge look like? It may be watery, bloody, or the two mixed together. Reddish, brownish, or yellowish discharge is normal. As you heal, it may even change in appearance. When you are fully healed, the discharge should stop completely.

When to call your doctor: If your discharge is greenish in color or if it is bright red for a long time. These could be signs of an infection.

Taking care of yourself

As with any surgical procedure, minor or major, the healthier and less stressed you are, the easier it will be for your body to heal. Good nutrition (with perhaps a daily multivitamin) will help make sure your body has the building blocks it needs to heal. Getting enough sleep, with a little extra rest when necessary, can help too. And though it may be easier said than done, try to avoid putting yourself under too much stress.

What to expect: The next few months and beyond

Okay, so the big question: how long until you know what your periods will be like, or if you'll even get them at all? Of course, it's different for every woman, and we know you're eager to see and enjoy your results. But you should plan to give your body about three months to fully heal and resume its normal cycle. After that, you and your doctor should be able to tell how well the procedure has worked for you.

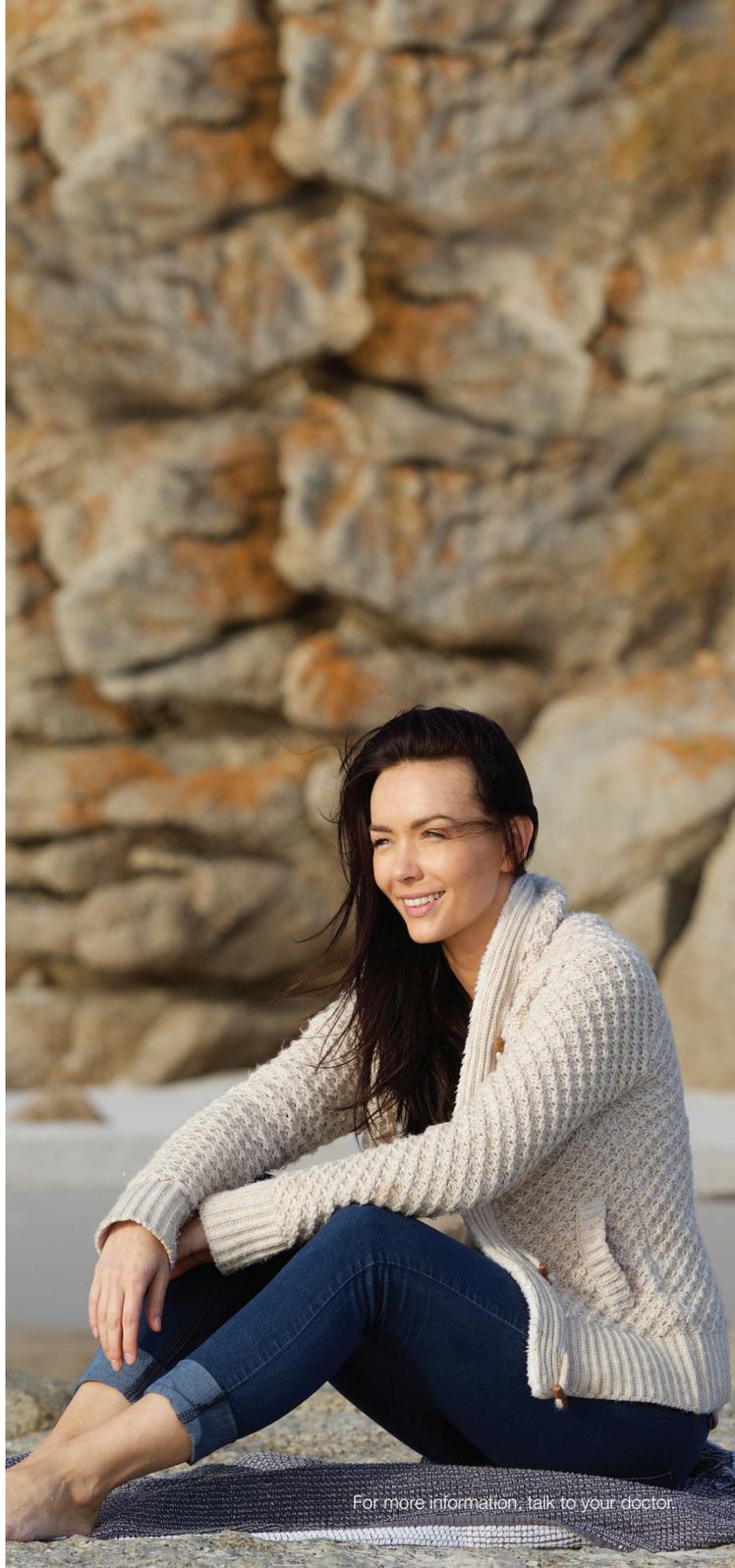
What about PMS?

Another benefit many women enjoy after the NovaSure procedure is a relief of PMS symptoms. In the NovaSure clinical trial, approximately 50% of women reported a reduction in PMS and painful periods (dysmenorrhea).²

Don't forget birth control, even if your periods stop completely

Because NovaSure 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. And a pregnancy after an ablation is very dangerous for both the mother and the foetus, since the uterine lining would not be able to properly support foetal development. So if you haven't already, be sure to talk to your doctor about birth control.

NovaSure[®]
Endometrial Ablation



For more information, talk to your doctor.

Talk to your doctor to learn more about the NovaSure procedure and to determine if it is suitable to your individual clinical needs.



Add practice details here

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 the NovaSure device, please contact your physician.

References

1. NovaSure® Instructions for Use. Bedford, MA: Hologic, Inc. 2. Gallinat A. An Impedance-Controlled System for Endometrial Ablation: Five-Year Follow-up of 107 Patients. *J Reprod Med.* 2007;52(6):467–472. 3. Heavy Menstrual Bleeding Clinical Care Standard, Australian Commission on Safety and Quality in Health Care, October 2017. 4. National Women's Health Resource Center. Survey of Women Who Experience Heavy Menstrual Bleeding. Hologic data on file; 2005. 5. 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(4):418–428. 6. Centers for Disease Control and Prevention. Heavy menstrual bleeding. <https://www.cdc.gov/ncbddd/blooddisorders/women/menorrhagia.html>. Accessed April 07, 2017. 7. Backman T, et al. Length of use and symptoms associated with premature removal of levonorgestrel intrauterine system: a nation-wide study of 17,360 users. *BJOG* 2000;107:335–9. 8. Gimpelson RJ. Ten-year literature review of global endometrial ablation with the NovaSure device. *Int J Womens Health.* 2014;6:269–280.

References - Treatment Chart Options

1. Mayo Clinic. Tranexamic Acid. Available at www.mayoclinic.org/drugs-supplements/tranexamic-acid/oral-route/description/drg-20073517. Accessed February 2016. 2. Panesar K, "Managing Menorrhagia", *US Pharmacist.* 2011;36(9):56–61. 3. PubMed Health, Informed Health Online. Treatment options for heavy periods. June 2013. Available at www.ncbi.nlm.nih.gov/pubmedhealth/PMH0072477/. Accessed February 2016. 4. Mayo Clinic. Menorrhagia (heavy menstrual bleeding). Available at www.mayoclinic.org/diseases-conditions/menorrhagia/basics/treatment/con-20021959. Accessed February 2016. 5. Munro M G, Abnormal Uterine Bleeding, Cambridge University Press. First published 2010. ISBN 978-0-521-72183-7. 6. 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(4):418–428. 7. NovaSure® Instructions for Use. Bedford, MA: Hologic, Inc. 8. Gallinat A. An Impedance-Controlled System for Endometrial Ablation: Five-Year Follow-up of 107 Patients. *J Reprod Med.* 2007;52(6):467–472. 9. Cooper KG, 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. 10. Hurskainen R, et al. Clinical outcomes and costs with the levonorgestrel-releasing intra-uterine system of hysterectomy for treatment of menorrhagia: randomized trial 5-year follow-up. *JAMA* 2004; 291:1456–1463. 11. ACOG Committee on Practice Bulletins. ACOG Practice Bulletin: Endometrial Ablation. *Obstet Gynecol* 2007;109(5):1233–48. 12. Yasmin Prescribing Information. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; 2007. 13. Cooper KG, 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):1222–1228. 14. Backman T, et al. Length of use and symptoms associated with premature removal of levonorgestrel intrauterine system: a nation-wide study of 17,360 users. *BJOG* 2000;107:335–9. 15. Mirena Prescribing Information. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; 2007. 16. Istre O, et al. Treatment of menorrhagia with levonorgestrel intrauterine system versus endometrial resection. *Fertil Steril* 2001. 17. Busfield RA, Farquhar CM, Sowter MC, et al. A Randomised Trial Comparing the Levonorgestrel Intrauterine System and Thermal Balloon Ablation for Heavy Menstrual Bleeding. *BJOG.* 2006;113(3):257–263.

PP-00079-AUS-EN Rev.003 © 2019 Hologic, Inc. All rights reserved. Hologic, NovaSure and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. Views and opinions expressed herein by third parties are theirs alone and do not necessarily reflect those of Hologic. This information is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshow, it is not always possible to control where such materials appear. Mirena is a trademark of Bayer. All other trademarks are property of their respective owners.

† Testimonials appearing in this brochure are from real patients, they did not receive any valuable consideration from Hologic. They are individual experiences, reflecting real life experiences of those who have used Hologic products.

Hologic (Australia and New Zealand) Pty Ltd, Level 3, 2-4 Lyon Park Rd, Macquarie Park NSW 2113. Tel. +61 2 9888 8000. ABN 95 079 821 275.

NovaSure®
Endometrial Ablation