

NovaSure® Endometrial Ablation

Product Overview

NovaSure Endometrial Ablation System







NovaSure System Indication & Important Safety Information

NovaSure System Indication:[7]

The NovaSure system is intended to ablate the endometrial lining of the uterus in pre-menopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete.

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. Inform patients to contact you if they experience a possible side effect related to use of this product. For detailed benefit and risk information, please consult the IFU. [7]

7. NovaSure Instructions for Use.

NovaSure ADVANCED Endometrial Ablation System

Nominal 6-mm diameter

May reduce patient discomfort when undergoing the NovaSure procedure in an office setting.[10*]

Rounded Smooth Access™ tips

require less force for insertion.†



Blue front handle

aids insertion technique with visual reminder to hold only the front handle.‡

Improved cervical seal

creates an increased sealing surface within the cervical canal during proactive cavity assessment and evacuation of procedure by-products.[4]

*A hysteroscopic study has shown that narrow instrument diameter correlates with less patient discomfort during the post-procedure recovery phase.
†Based on internal bench testing that measured perceived ease of insertion through a simulated cervix of both the 6-mm and 8-mm devices. N=16 surgeon users.
‡Based on internal bench testing of a simulated procedure in a uterine model after which surgeons were asked to state their level of agreement on a Likert scale. N=16 surgeon users.

4. Hologic, Inc. Data on file;2016. DHM-05232.
10. Pluchino N, Ninni F, Angioni S, et al. Office vaginoscopic hysteroscopy in infertile women: effects of gynecologist experience, instrument size, and distention medium on patient discomfort. *J Minim Invasive Gynecol.* 2010;17(3):344-350.

NovaSure RFC10 Controller

Touchscreen interface

The advanced touchscreen interface has responsiveness set to react to user input.

Ablation timer and summary screen

The ablation timer and summary screen display cumulative running ablation time and total ablation time at the end of the procedure, as well as length, width and power level. The prior procedure data is also recoverable if the controller is powered on and off.



Universal compatibility

The new RFC10 controller is compatible with the current portfolio of NovaSure devices.

Procedural instructions on interface

With IFU procedural instructions on the interface, the RFC10 walks a physician through corrective actions when an error message is encountered.

Volume-controlled and mutable alarms

The volume-controlled and mutable alarms are perfect for in-office procedures where a patient can be easily startled.

SureSound®+ Device

Calibrate with confidence

The NovaSure system provides a customized procedure based on a patient's cavity size for a controlled ablation depth and proven outcomes. The SureSound+ device is specifically designed to precisely measure the uterine cavity with the NovaSure system in mind.



Malecot technology

helps identify the internal os with a simple click.

6-mm shaft diameter

aids in the dilation process and complements

Atraumatic tip

facilitates a smooth insertion

Easy-grip finger rings

give physicians easy control of the Malecot anchoring feature.

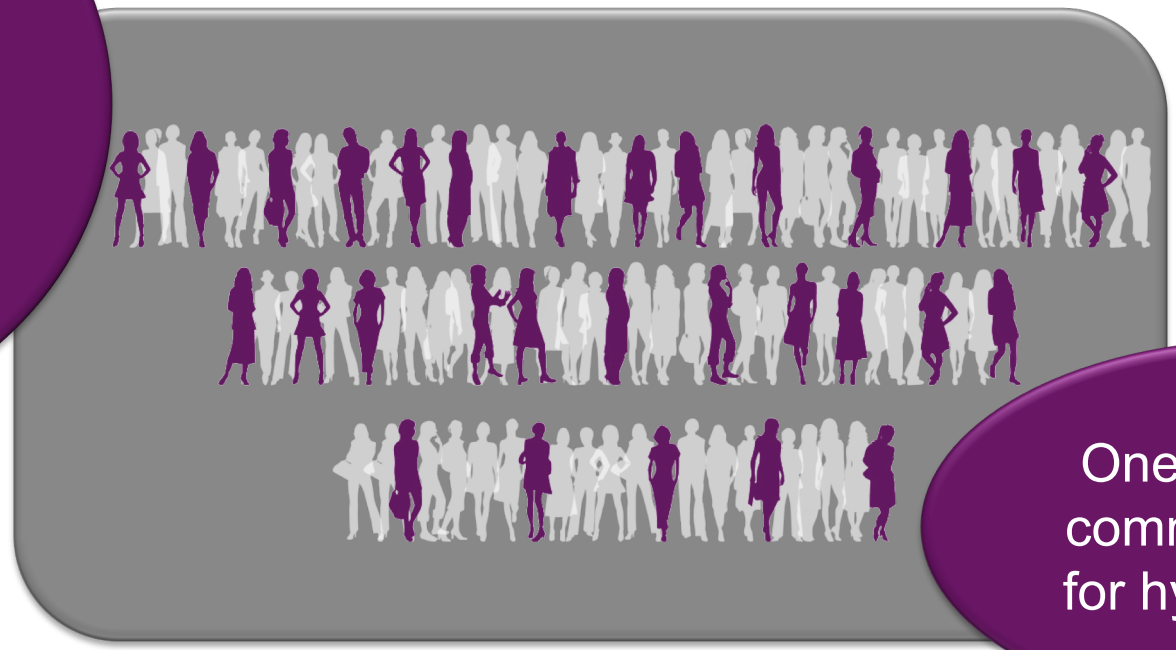
AccuLength™ window

makes accurate measurement of the uterine cavity length quick and easy.

Widespread Impact of AUB

Over 10 million[1]
American women suffer from heavy menstrual bleeding, yet
33%[2]
seek treatment each year

20%[1]
of ALL women suffer from AUB



One of the most common reasons for hysterectomy[3]

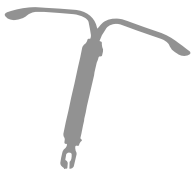
1. Centers for Disease Control and Prevention. Heavy menstrual bleeding. https://www.cdc.gov/ncbddd/blooddisorders/women/menorrhagia.html. Accessed January 30, 2017.
2. The American Congress of Obstetricians and Gynecologists. Heavy menstrual bleeding. http://www.acog.org/Patients/FAQs/Heavy-Menstrual-Bleeding. Accessed January 30, 2017.
3. Cooper J, Gimpelson R, Laberge P, Galen D, Garza-Leal JG, Scott J, Leyland N, Martyn P, Liu J. A randomized, multicenter trial of safety and efficacy of the NovaSure system in the treatment of menorrhagia. J Am Assoc Gynecol Laparosc. 2002 Nov;9(4):418-28.

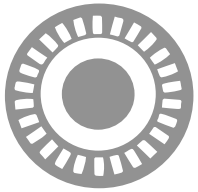
AUB Options

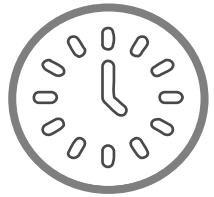
Hysterectomy	Endometrial Ablation (NovaSure procedure)	Hormone Therapy IUD	Hormone Therapy	No Management
• Invasive surgery • Eliminates bleeding • Permanent • Loss of fertility	• Minimally invasive • No pretreatment Not cycle dependent	• Contraceptive • Retain fertility • Potential hormonal side effects	• Contraceptive • Retain fertility • Potential hormonal side effects	• No change until menopause







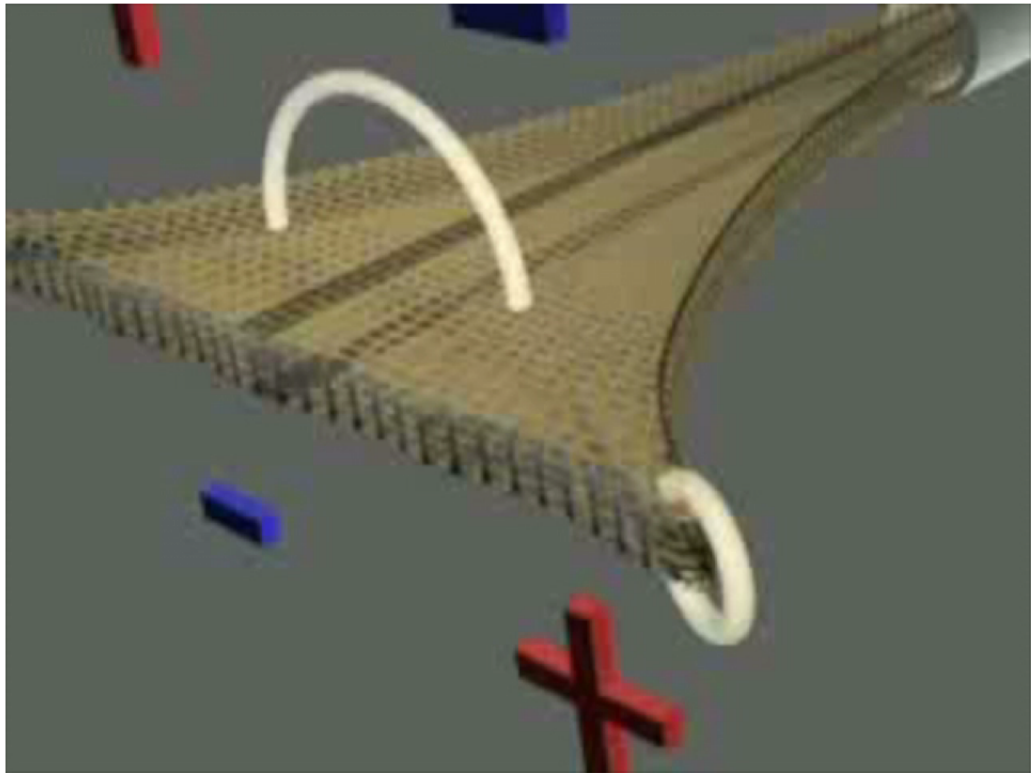




NovaSure Technology

Bipolar Radiofrequency Energy

- Four uniquely designed electrodes form the array & deliver the energy
- Ablation profile is designed to be tapered to the uterine cavity



NovaSure Technology

Patented Proactive Cavity Integrity Assessment (CIA)

- Ensures that the cavity can hold 50 mmHg pressure to check for a perforation
- Assessment is sensitive enough to detect a perforation as small as an 18 gauge needle[13]

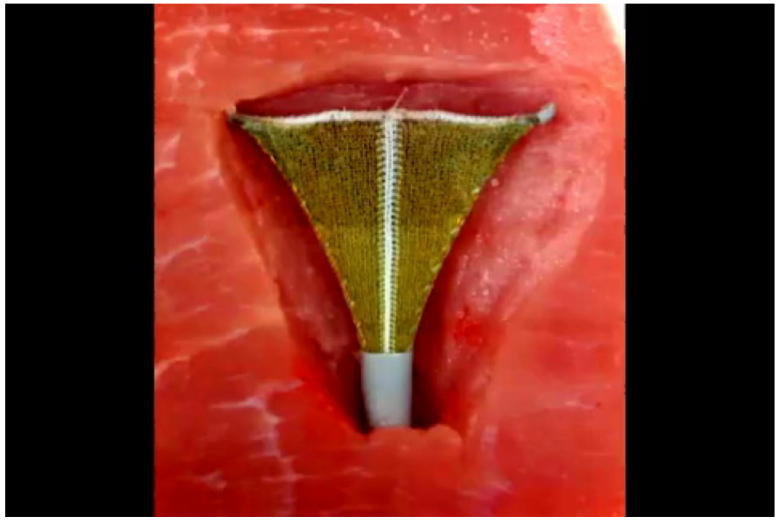


11. Hologic, Data on File, DHM-03752.

NovaSure Technology

Moisture Transport™ Fluid Removal System

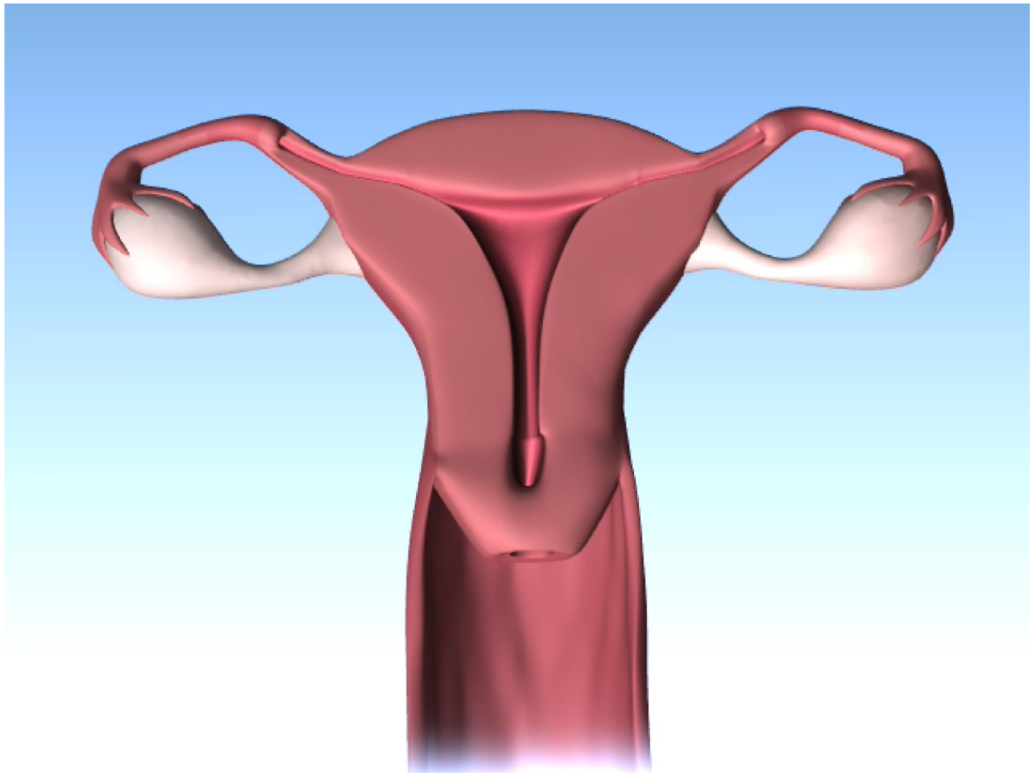
- Vacuum draws the uterine cavity into contact with the array, even those that are imperfectly shaped
- Removes steam, moisture, and other by-products of the ablation



NovaSure Technology

Impedance-based Scientific Endpoint

- 50 ohms of impedance determines when ablation is complete[14]
- 90-second average treatment time[9]; ablation is never more than 2 minutes[9]



7. NovaSure Instructions for Use.
12. Hologic, Inc. Data on file, PPR-00011.

Advantages of NovaSure Ablation

Improve quality of life

Minimally Invasive

97% avoidance of hysterectomy[11]



9. Gallinat A. An impedance-controlled system for endometrial ablation: five-year follow-up of 107 patients. J Reprod Med. 2007;52(6):467-472.

Advantages of the NovaSure Procedure

Proven Outcomes

- Low re-intervention rate (2.8 - 8.2%)[6]
- High amenorrhea rate (30-75%)[6]
- 93% patient satisfaction rate[7]
- 91% of evaluable patients returned to normal menstrual bleeding levels or lower[13]

Advanced Technology

- Consistent depth of ablation, regardless of endometrial thickness
- Customized to uterine cavity size
- No need for pretreatment and cycle independent[7]

Safe and Comfortable

- Average 90-second treatment time & less than 5 min procedure time[7]
- No uterine distention, low post-operative pain[7]
- Feasible to perform in the office setting[5]

5. Clark TJ, Samuels N, Malick S, Middleton L, Daniels J, Gupta J. Bipolar radiofrequency compared with thermal balloon endometrial ablation in the office: a randomized controlled trial. Obstet Gynecol. 2011;117(5):1228.
6. Ten-year literature review of global endometrial ablation with the NovaSure® device. Gimpelson RJ.Int J Womens Health. 2014 Mar 11;6:269-80. doi: 10.2147/IJWH.S56364. eCollection 2014.
7. NovaSure Instructions for Use.
13. Sabbah R et al. J Minim Invasive Gynecol. 2006;13(5):467-71.

What to Expect After a NovaSure Procedure

Immediately after the NovaSure procedure, some women experience the following symptoms:

- Cramping
- Mild pain
- Nausea and/or vomiting
- A watery or bloody discharge*

Most women can resume normal activities within a day or so.

Very few patients experience complications following the NovaSure procedure. 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)

*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 couple of months.

Impact on Quality of Life

Impact on Quality of Life[3]		
Answered “Always,” “Frequently” or “Sometimes”	Before the NovaSure procedure	After the NovaSure procedure
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%

3. Cooper J, Gimpelson R, Laberge P, Galen D, Garza-Leal JG, Scott J, Leyland N, Martyn P, Liu J. A randomized, multicenter trial of safety and efficacy of the NovaSure system in the treatment of menorrhagia. J Am Assoc Gynecol Laparosc. 2002 Nov;9(4):418-28.

Over 2.5 Million Patients Treated

The NovaSure procedure has been a safe, effective, and proven choice for more than 2.5 million[8] women over the past 15 years





8. Hologic, Inc. Data on file; 2016. Based on units shipped from 2004-2016.

EQUIPMENT & DEMONSTRATION

References

1. Centers for Disease Control and Prevention. Heavy menstrual bleeding. https://www.cdc.gov/ncbddd/blooddisorders/women/menorrhagia.html. Accessed January 30, 2017.
2. The American Congress of Obstetricians and Gynecologists. Heavy menstrual bleeding. http://www.acog.org/Patients/FAQs/Heavy-Menstrual-Bleeding. Accessed January 30, 2017.
3. Cooper J, Gimpelson R, Laberge P, Galen D, Garza-Leal JG, Scott J, Leyland N, Martyn P, Liu J. A randomized, multicenter trial of safety and efficacy of the NovaSure system in the treatment of menorrhagia. J Am Assoc Gynecol Laparosc. 2002 Nov;9(4):418-28.
4. Hologic, Inc. Data on file;2016. DHM-05232.
5. Clark TJ, Samuels N, Malick S, Middleton L, Daniels J, Gupta J. Bipolar radiofrequency compared with thermal balloon endometrial ablation in the office: a randomized controlled trial. Obstet Gynecol. 2011;117(5):1228.
6. Ten-year literature review of global endometrial ablation with the NovaSure® device. Gimpelson RJ.Int J Womens Health. 2014 Mar 11;6:269-80. doi: 10.2147/IJWH.S56364. eCollection 2014.
7. NovaSure Instructions for Use.
8. Hologic, Inc. Data on file; 2016. Based on units shipped from 2004-2016.
9. Gallinat A. An impedance-controlled system for endometrial ablation: five-year follow-up of 107 patients. J Reprod Med. 2007;52(6):467-472.
10. Pluchino N, Ninni F, Angioni S, et al. Office vaginoscopic hysteroscopy in infertile women: effects of gynecologist experience, instrument size, and distention medium on patient discomfort. *J Minim Invasive Gynecol*. 2010;17(3):344-350.
11. Hologic, Data on File, DHM-03752.
12. Hologic, Inc. Data on file, PPR-00011.
13. Sabbah R et al. J Minim Invasive Gynecol. 2006;13(5):467-71.

*A hysteroscopic study has shown that narrow instrument diameter correlates with less patient discomfort during the post-procedure recovery phase.
†Based on internal bench testing that measured perceived ease of insertion through a simulated cervix of both the 6-mm and 8-mm devices. N=16 surgeon users.
‡Based on internal bench testing of a simulated procedure in a uterine model after which surgeons were asked to state their level of agreement on a Likert scale. N=16 surgeon users.

Rev. 001 ©2017 Hologic, Inc. Hologic, AccuLength, Moisture Transport, NovaSure, Smooth Access, and SureSound are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries.