Proven
over 10 years of data and 2 million patients treated.

A Complete Guide to NovaSure Endometrial Ablation
This is a general information tool for medical professionals and is not a complete representation of the product(s)’ Instructions for Use (IFU) or Package Insert, and it is the medical professionals’ responsibility to read and follow the IFU or Package Insert. The information provided may suggest a particular technique or protocol; however, it is the sole responsibility of the medical professional to determine which technique or protocol is appropriate. At all times clinicians remain responsible for utilizing sound patient evaluation and selection practices, and for complying with applicable local, state and federal rules and regulations regarding accreditation, anesthesia, reimbursement and all other aspects of in-office procedures. In no event shall Hologic be liable for damages of any kind resulting from your use of the information presented.
Efficacy
The NovaSure procedure has proven efficacy when compared to other GEA devices, with the highest amenorrhea and highest patient satisfaction and the lowest re-intervention rates in direct head-to-head trials.

The same studies showing excellent amenorrhea rates also demonstrate high efficacy in improvement to normal bleeding levels or better.
The NovaSure procedure has been shown to improve both PMS and menstrual pain.

Re-intervention rate comparison

Five prospective studies demonstrate a single-digit re-intervention rate with the NovaSure procedure. No other global endometrial ablation (GEA) modality comes close.

The NovaSure procedure has been shown to improve both PMS and menstrual pain.

Statistically significant improvement in PMS and menstrual pain after the NovaSure procedure

(Self-rating of PMS symptoms on a scale of 0 (none) to 10 (severe))
Our Technology
Our Technology

A customized ablation
The NovaSure device provides a customized ablation during every procedure. The procedure's proven outcomes are achieved through:

1. Bi-polar RF energy
   - Four uniquely designed electrodes that form the array deliver the energy.
   - Array shape is designed to deliver the proper depth of energy.
   - Ablation profile is designed to be tapered to the uterine cavity.

2. A proactive cavity integrity assessment
   - This ensures that the cavity can hold 50 mmHg to check for a perforation.
   - Assessment is sensitive enough to detect a perforation as small as an 18-gauge needle.
Dr. Darren Housel, M.D.
Physician, Circle of Life Women's Center, Ogden, UT

“I have many patients that come back and tell me, I wish I’d done this years ago because my life is so much better. The benefits are plentiful. I have many, many hundreds of patients that tell me these things.”

3. The moisture transport system
- Vacuum draws uterine cavities into contact with the array, even those that are imperfectly shaped.
- Removes steam, moisture and other by-products of the ablation.

4. The scientific endpoint
- 50 ohms of impedance determines when ablation is complete.
- 90-second average treatment time; ablation is never more than 2 minutes.
The NovaSure system delivers comfort, control, and confidence.

- **Smooth Access™ tips** require significantly less manipulation, providing more comfort for your patient.

- **SureFit™ cervical seal** is designed from soft material providing a 70% greater coverage area, improving procedure efficiency and patient comfort.

- **Sheath material** designed to promote greater durability, especially at higher temperatures.

- **Customized ablation** is designed to deliver optimal results based on the patient’s uterine cavity length and width.

- **Ergonomic thumb tab** enables more leverage and control of the cervical collar.

- **No uterine distention** Patented Moisture Transport System maintains contact between the uterus and the array while evacuating by-products of the procedure.

- **Proactive safety** CIA Test evaluates uterine cavity integrity prior to procedure.
NovaSure RFC10 controller
The newly designed RFC10 controller has been enhanced with intuitive graphics for improved workflow.

**Advanced touchscreen interface** has responsiveness set to react to user intent and is optimized for use with or without surgical gloves.

**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 off and on.

**iFUI Procedural instructions on interface** walks the physician through corrective actions when an error message is encountered.

**Volume-controlled and mutable alarms** are perfect for in-office procedures during which a patient can be easily startled.

**Universal NovaSure compatibility** with all generations of NovaSure devices.
SureSound® uterine cavity measuring device
The SureSound device is a single use, uterine and cervical canal length measurement device consisting of an external shaft and an internal, polyethylene telescoping sound controlled by a locking deployment tab.

1/2 cm markings are easy to read and increase measurement accuracy.

Shoulder and internal lumen design allow for consistent measurement from internal cervical os to the fundus by eliminating the need to measure the cervical canal.

SureSound single-use device may reduce contamination risk compared to traditional sound.

Note: Does not contain latex material in the construction or components of the device.
Dr. Robert Stevens, M.D.
Seven Hills Women’s Health Center
Medical Director, Women’s Healthcare Service Line:
The Christ Hospital, Cincinnati OH

“I’ve done hundreds of NovaSure ablation procedures and I see these patients back for their annual visits and checkups. These are among the happiest patients that we see.”
Patient Satisfaction
Patient Satisfaction

The NovaSure procedure as a first-line treatment option

Over 8.3 million women suffer from excessive menstrual bleeding, yet only 13% seek treatment each year.13 77% of patients want to hear about the NovaSure procedure at their first visit.2

<table>
<thead>
<tr>
<th>Impact on Quality of Life</th>
<th>Before NovaSure</th>
<th>After NovaSure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you lack confidence due to your period?</td>
<td>57%</td>
<td>16%</td>
</tr>
<tr>
<td>Do you have a problem working due to your period?</td>
<td>66%</td>
<td>10%</td>
</tr>
<tr>
<td>Do you spend less time at work or other activities?</td>
<td>61%</td>
<td>9%</td>
</tr>
<tr>
<td>Do you feel anxious due to your period?</td>
<td>75%</td>
<td>24%</td>
</tr>
<tr>
<td>Do your periods cause you to miss social activities?</td>
<td>63%</td>
<td>9%</td>
</tr>
<tr>
<td>Do your periods cause you to miss athletic activities?</td>
<td>66%</td>
<td>9%</td>
</tr>
<tr>
<td>Are you unable to work outside your home due to your periods?</td>
<td>33%</td>
<td>6%</td>
</tr>
<tr>
<td>Do you have less energy or a total lack of energy?</td>
<td>84%</td>
<td>24%</td>
</tr>
<tr>
<td>Do you experience painful periods?</td>
<td>57%</td>
<td>21%</td>
</tr>
<tr>
<td>Do you have PMS symptoms?</td>
<td>65%</td>
<td>36%</td>
</tr>
</tbody>
</table>
The NovaSure procedure significantly reduces debilitating menorrhagia symptoms.

Prior to NovaSure treatment, most women complained of problems associated with heavy menses, including:
- Anxiety.
- Lack of confidence.
- Difficulty with work or daily activities.
- Lack of energy.

The NovaSure procedure improves patient quality of life. In a clinical trial:
- 91% of evaluable patients returned to normal levels of menstrual bleeding, or lower.6
- 93% patient satisfaction.6
- 97% of patients from the initial clinical trial would recommend the NovaSure procedure to other women.16
- 97% of patients from the initial clinical trial experienced no post-procedural pain.16

Celebrating over two million women treated

Improvements in symptoms16

<table>
<thead>
<tr>
<th></th>
<th>Pretreatment</th>
<th>12 month follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td>75%</td>
<td>24%</td>
</tr>
<tr>
<td>Lack of confidence</td>
<td>24%</td>
<td>16%</td>
</tr>
<tr>
<td>Difficulty with work/activities</td>
<td>57%</td>
<td>10%</td>
</tr>
<tr>
<td>Lack of energy</td>
<td>84%</td>
<td>24%</td>
</tr>
</tbody>
</table>
The NovaSure procedure offers clear advantages for proven outcomes.

<table>
<thead>
<tr>
<th></th>
<th>NovaSure&lt;sup&gt;16&lt;/sup&gt;</th>
<th>ThermaChoice III&lt;sup&gt;17&lt;/sup&gt;</th>
<th>HTA&lt;sup&gt;18&lt;/sup&gt;</th>
<th>HerOption&lt;sup&gt;19&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average treatment time</td>
<td>90 seconds</td>
<td>8 minutes</td>
<td>10 minutes</td>
<td>10-34 minutes</td>
</tr>
<tr>
<td>Average procedure time</td>
<td>4.2 minutes</td>
<td>27.4 minutes</td>
<td>26.4 minutes</td>
<td>N/A</td>
</tr>
<tr>
<td>No pretreatment required</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Not cycle dependent</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

“The NovaSure procedure being done in the office is advantageous to not only the patient, but also to the physician and to the practice as a whole.”

Dr. Stephen Brown, M.D., F.A.C.O.G
President, CNY Women’s Healthcare, Syracuse, NY
The NovaSure procedure has the highest amenorrhea rates in direct head-to-head trials of endometrial ablation modalities.

The NovaSure procedure also has the lowest re-intervention rates in direct head-to-head studies with other global endometrial ablation modalities.

**Competitive analysis**
The NovaSure procedure is the most proven GEA modality in head-to-head trials.20

Amenorrhea rates

NovaSure re-intervention vs. HTA

NovaSure re-intervention vs. ThermaChoice
Medical Management
Clinical data review

There are no completed head-to-head studies comparing NovaSure endometrial ablation and LNG-IUS. Here are the clinical outcomes other studies have shown.
Long-term outcomes of oral contraceptives

Five years following initiation of oral contraceptives, the majority of women required surgical intervention to achieve bleeding control.27

Surgical intervention rates

- Surgical intervention required post-hormone therapy
- Surgical intervention required post-NovaSure

77% of women say they would have liked to have learned about the NovaSure procedure at their first consultation.12

Required treatment time to achieve outcome

- NovaSure <5 minutes
- LNG-IUS 6 months

The efficacy of the NovaSure procedure is immediate. LNG-IUS requires a lengthy 3-6 months to begin to control AUB.
Hysterectomy
Hysterectomy

While highly effective, hysterectomy has a profound impact on patients.

Emotional and physical effects include:
- Lengthy recovery time.\(^{29}\)
- Home and work life may be limited for 4-6 weeks.
- Post-operative pain.
- Possible need for future hormone treatment due to early onset of menopause.
- Psychological distress.

Surgical complications, including:\(^{29}\)
- Blood clots.
- Infection.
- Excessive bleeding.
- Damage to urinary tract.
- Bladder damage.
- Bowel damage.
- Loss of ovarian function.

NovaSure endometrial ablation is a cost-effective, safe and simple alternative to hysterectomy.

NovaSure endometrial ablation is a cost-effective, safe and simple alternative to hysterectomy.

Hysterectomy imposes a high cost on the healthcare system.

The NovaSure procedure avoids additional intervention.\(^{1}\)
97% avoidance of hysterectomy at 5 years

Hysterectomy imposes a high cost on the healthcare system.

Average treatment costs\(^{28}\)

<table>
<thead>
<tr>
<th></th>
<th>Ablation</th>
<th>Hysterectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0</td>
<td>$3,000</td>
<td>$7,500</td>
</tr>
<tr>
<td>$2,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$4,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$6,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$8,000</td>
<td></td>
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</tr>
</tbody>
</table>

Avoided hysterectomy

<table>
<thead>
<tr>
<th></th>
<th>Avoided hysterectomy</th>
<th>Required hysterectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>$2,000</td>
<td>97%</td>
<td>3%</td>
</tr>
<tr>
<td>$3,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$4,000</td>
<td></td>
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<tr>
<td>$5,000</td>
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<td>$6,000</td>
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<tr>
<td>$7,000</td>
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<tr>
<td>$8,000</td>
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</tr>
</tbody>
</table>

Hysterectomy imposes a high cost on the healthcare system.

While highly effective, hysterectomy has a profound impact on patients.
Choosing the right treatment pathway

There are a number of treatment options available for abnormal uterine bleeding (AUB). The chart below highlights the advantages and disadvantages of the NovaSure procedure compared to hysterectomy.

<table>
<thead>
<tr>
<th>NovaSure endometrial ablation</th>
<th>Hysterectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>Simple, safe procedure that removes uterine lining while preserving the uterus to reduce or eliminate bleeding</td>
</tr>
</tbody>
</table>
| **Advantages** | • For 90% of women, menstrual bleeding is dramatically reduced or stopped  
• One-time, five-minute procedure  
• Can be done in your office, usually for the cost of a copay  
• Rapid recovery | • Eliminates problem bleeding  
• One-time procedure |
| **Disadvantages** | • Only appropriate for women who have completed childbearing  
• Requires anesthesia: local or general  
• Non-reversible - lose fertility  
• Risk of complications associated with minimally invasive procedure | • Cost  
• Involves major invasive surgery  
• Risk of complications associated with major surgery  
• Requires general or regional anesthesia  
• 2 to 8-week recovery time  
• May result in early onset of menopause/possible need for future hormone treatment  
• Non-reversible – lose fertility |
The NovaSure Procedure
NovaSure procedure steps and contraindications

The clear advantage for proven outcomes
The NovaSure procedure is a safe, comfortable way to provide endometrial ablation in an average of 5 minutes.

1. The NovaSure electrode array expands to conform to the contours of each patient’s uterine cavity.

2. Cavity integrity assessment is performed using a small amount of CO₂.

3. NovaSure endometrial ablation delivers bipolar RF energy until the ablation is complete in approximately 90 seconds.¹⁶

4. The electrode array is retracted to facilitate easy removal, leaving the uterine lining desiccated down to the superficial myometrium.
Contraindications

NovaSure is contraindicated for use in patients who:

- Are pregnant or want to become pregnant in the future; pregnancies following ablation can be dangerous for both mother and fetus.
- Have known or suspected endometrial carcinoma (uterine cancer) or pre-malignant conditions of the endometrium, such as unresolved adenomatous hyperplasia.
- Have any anatomic condition (e.g., history of previous classical Cesarean section or transmural myomectomy) or pathologic condition (e.g., long-term medical therapy) that could lead to weakening of the myometrium.
- Have active genital or urinary tract infection at the time of the procedure (e.g., cervicitis, vaginitis, endometritis, salpingitis or cystitis).
- Have an intrauterine device (IUD) currently in place.
- Have a uterine cavity length less than 4 cm (the minimum length of the electrode array is 4 cm; treatment of a shorter uterine cavity will result in thermal injury to the endocervical canal).
- Have a uterine cavity width less than 2.5 cm, as determined by the width dial of the NovaSure disposable device following deployment.
- Have active pelvic inflammatory disease.

Indications

NovaSure is intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive bleeding) due to benign causes, for whom childbearing is complete.

Important Safety Information:

NovaSure is for premenopausal women with heavy periods due to benign causes who are finished childbearing. Pregnancy following NovaSure can be dangerous. NovaSure is not for those who have or suspect uterine cancer, have an active genital, urinary or pelvic infection or an IUD. NovaSure 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.
References: