Proven

over 15 years of data and
over 2.5 million patients treated.¹

A complete guide to the NovaSure® system
The NovaSure® system uses bipolar radio frequency (RF) energy for an impedance-controlled endometrial ablation.

- Requires no hormonal pretreatment
- Average ablation time is approximately 90 seconds
- Compatible with local and/or IV sedation protocols
- Cavity integrity assessment safety test
- Controlled ablation depth with RF energy impedance threshold
- 6-mm-diameter option designed with in-office procedures in mind

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 power of performance
The NovaSure® procedure has proven efficacy when compared to other global endometrial ablation (GEA) devices, with high rates of amenorrhea and success in direct head-to-head trials.\textsuperscript{3,4}

![NovaSure procedure amenorrhea rates](chart1)

![NovaSure procedure successful reduction in bleeding](chart2)

The NovaSure endometrial ablation procedure has demonstrated exceptional amenorrhea rates in multiple long-term clinical studies.

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.

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

Before and After:
- **PMS**:
  - Before: 7.4
  - After: 3.2

- **Menstrual Pain**:
  - Before: 7.3
  - After: 2.8

4-6-month follow-up Self-rating (N=36) of PMS symptoms on a scale of 0 (none) to 10 (severe)

**Re-intervention rate comparison**

Five prospective studies demonstrate a single-digit re-intervention rate with the NovaSure® procedure. No other GEA modality has the NovaSure procedure’s record of effectiveness.
Our technology
A customized ablation

The NovaSure® procedure provides a customized ablation during every procedure. The procedure’s proven outcomes are achieved through:

1. **Bipolar RF energy**
   - Four uniquely designed electrodes that form the array deliver the energy.
   - Array shape is designed to deliver the appropriate depth of ablation.
   - 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.11
   - Assessment is sensitive enough to detect a perforation as small as an 18-gauge needle.12
3 **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.

4 **The scientific endpoint**
- Ablation is complete when impedance reaches 50 ohms.
- 90-second average treatment time; ablation is never more than 2 minutes.

"With the safety checks that are in place with the NovaSure technology, it really makes you feel confident that you’re doing the right thing in a safe environment."

Dr. Sony Singh
Department of Obstetrics and Gynecology
The Ottawa Hospital/University of Ottawa
Ottawa, ON
The NovaSure® system continues to innovate to best serve OBGYNs and the patients they treat. Design enhancements may expand potential patient population and simplify the procedure.

With two sizes available, the NovaSure devices are designed for use by OBGYNs who want to treat a variety of patients suffering from abnormal uterine bleeding (AUB) in the hospital and office settings.

NovaSure CLASSIC device

NovaSure ADVANCED device

The NovaSure ADVANCED device has the same efficacy and safety of the NovaSure system with a smaller 6-mm diameter.

- Treat patients who may have a narrow cervical os using less cervical dilation
- Simplify the GEA procedure with easier insertion*

“NovaSure comes out with very high levels of satisfaction. Certainly, within our own studies within my hospital that we’ve published, we have levels of satisfaction between 80% and 100%.“¹⁴

Dr. Francis Gardner
Department of Gynecology
Queen Alexandra Hospital
Portsmouth, UK

*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.
The NovaSure® system delivers comfort, control, and confidence.

<table>
<thead>
<tr>
<th>Feature</th>
<th>NovaSure CLASSIC device</th>
<th>NovaSure ADVANCED device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sheath material</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>is designed to promote greater durability, especially at higher temperatures.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Customized ablation</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>is designed to deliver optimal results based on the patient’s uterine cavity length and width.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ergonomic thumb tab</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>provides leverage and control of the cervical collar.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Moisture Transport™ fluid removal system</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>maintains contact between the uterus and the array while evacuating by-products of the procedure without distending the endometrium.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Proactive cavity integrity assessment</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>evaluates uterine cavity integrity before procedure.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Nominal 6-mm sheath diameter</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>requires approximately 6 mm of cervical dilation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Rounded Smooth Access™ tips</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>requires less force for insertion.*</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Improved cervical seal</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>creates an increased sealing surface within the cervical canal during proactive cavity integrity assessment and evacuation of procedure by-products.†</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Blue front handle</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>aids insertion technique with a visual reminder to hold only the front handle.‡</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Internal bench testing of simulated cervix; perceived ease of insertion of both 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.
NovaSure® RFC10 controller
The RFC10 controller has been enhanced with intuitive workflow graphics.

Advanced touchscreen interface
with responsiveness set to react to user input.

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.

IFU procedural instructions on interface
walk the physician through corrective actions when an error message is encountered.

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

Universal compatibility
with the portfolio of NovaSure devices.
Introducing the new SureSound®+ device
The NovaSure® system provides a customized procedure based on a patient’s cavity size, leading to a controlled ablation depth and proven outcomes. The SureSound+ device is designed to precisely measure the uterine cavity with the NovaSure system in mind.

**AccuLength™ window**
makes accurate measurement of the uterine cavity length quick and easy.

**Malecot technology**
helps identify the internal os with a simple click.

**Easy-grip finger rings**
give physicians easy control of the Malecot anchoring feature.

**6-mm shaft diameter**
aids in the dilation process and complements the NovaSure ADVANCED device.

**Atraumatic tip**
facilitates a smooth insertion.
Patient satisfaction
The NovaSure® procedure as a first-line treatment option

Over 10 million American women suffer from heavy menstrual bleeding, yet only 33% seek treatment each year. 77% of patients want to hear about the NovaSure procedure at their first visit.

### Impact on Quality of Life

<table>
<thead>
<tr>
<th>Question</th>
<th>Before NovaSure procedure</th>
<th>After NovaSure procedure</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 the NovaSure procedure, 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 clinical trials:

- 91% of evaluable patients returned to normal levels of menstrual bleeding, or lower.\(^a\)
- 93% patient satisfaction was reported.\(^b\)
- 97% of patients from the initial clinical trial would recommend the NovaSure procedure to other women.\(^c\)
- 97% of patients from the initial clinical trial reported no pain up to 24 hours post-procedure.\(^d\)

Improvements in symptoms\(^{18}\)

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Pretreatment</th>
<th>12-month follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td>24%</td>
<td>76%</td>
</tr>
<tr>
<td>Lack of confidence</td>
<td>16%</td>
<td>57%</td>
</tr>
<tr>
<td>Difficulty with work/activities</td>
<td>10%</td>
<td>66%</td>
</tr>
<tr>
<td>Lack of energy</td>
<td>24%</td>
<td>84%</td>
</tr>
</tbody>
</table>

Celebrating over 2.5 million women treated\(^{17}\)
GEA technologies
The NovaSure® procedure offers clear advantages for proven outcomes.

<table>
<thead>
<tr>
<th></th>
<th>NovaSure®</th>
<th>THERMACHOICE®</th>
<th>HTA®</th>
<th>Her Option®</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 hormonal pretreatment required</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Not cycle-dependent</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
</tbody>
</table>

“With devices like NovaSure, the procedure time is so short that you know you’re going to be able to help many patients in that short amount of time.”

Dr. Sony Singh
Department of Obstetrics and Gynecology
The Ottawa Hospital/University of Ottawa
Ottawa, ON
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 GEA modalities.

**Amenorrhea rates (12-month follow-up)**

- NovaSure®: 56%
- THERMACHOICE®: 23%
- HTA: 43%
- Thermablate®: 11%

**Hysterectomy after the NovaSure procedure vs. after hydrothermablation (HTA)**

- NovaSure®: 5%
- HTA: 10%

**NovaSure procedure re-intervention vs THERMACHOICE® (12-month follow-up)**

- NovaSure®: 2.4%
- THERMACHOICE®: 7.7%

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*Statistically significant difference between groups.

Amenorrhea rates for the NovaSure system were 43% for all patients treated and 56% for patients treated after an equipment failure was corrected. Amenorrhea rate was 8% for patients treated with thermal balloon.
Medical management
Medical management

Clinical data review

There are no completed head-to-head studies comparing NovaSure procedure 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.\textsuperscript{31}

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{surgical-intervention-rates.png}
\caption{Surgical intervention rates}
\end{figure}

77\% of women say they would have liked to have learned about the NovaSure\textsuperscript{®} procedure at their first consultation.\textsuperscript{18}

\textbf{Required treatment time to achieve outcome}

- NovaSure procedure <5 minutes\textsuperscript{2}
- LNG-IUS 6 months\textsuperscript{29}

The efficacy of the NovaSure procedure is immediate. LNG-IUS requires a lengthy 3-6 months to begin to control AUB.\textsuperscript{29}
Hysterectomy
Hysterectomy

The NovaSure® procedure is a cost-effective, safe, and simple alternative to hysterectomy.

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

Emotional and physical effects include:
- Lengthy recovery time
- Home and work life may be limited for 4-6 weeks
- Post-operative pain
- Psychological distress

Surgical complications, including:
- Blood clots
- Infection
- Excessive bleeding
- Damage to urinary tract
- Bladder damage
- Bowel damage

Hysterectomy imposes a high cost on the healthcare system.

The NovaSure procedure avoids additional intervention.  
97% avoidance of hysterectomy at 5 years

Avoided hysterectomy
Required hysterectomy

Average treatment costs

(N=107)
Choosing the right treatment pathway

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

<table>
<thead>
<tr>
<th>NovaSure procedure</th>
<th>Hysterectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>Permanent surgical option for women not responsive to other treatments</td>
</tr>
<tr>
<td>Simple, safe procedure that removes uterine lining while preserving the uterus to reduce or eliminate bleeding</td>
<td></td>
</tr>
<tr>
<td><strong>Advantages</strong></td>
<td>Eliminates problem bleeding</td>
</tr>
<tr>
<td>For 91% of women, menstrual bleeding is dramatically reduced or stopped</td>
<td></td>
</tr>
<tr>
<td>One-time, five-minute procedure</td>
<td></td>
</tr>
<tr>
<td>Can be done in your office</td>
<td></td>
</tr>
<tr>
<td>Rapid recovery</td>
<td></td>
</tr>
<tr>
<td><strong>Disadvantages</strong></td>
<td>One-time procedure</td>
</tr>
<tr>
<td>Only appropriate for women who have completed childbearing</td>
<td></td>
</tr>
<tr>
<td>Requires anesthesia: local or general</td>
<td></td>
</tr>
<tr>
<td>Non-reversible—loss of fertility</td>
<td></td>
</tr>
<tr>
<td>Risk of complications associated with minimally invasive procedure</td>
<td></td>
</tr>
<tr>
<td>Cost</td>
<td></td>
</tr>
<tr>
<td>Involves major invasive surgery</td>
<td></td>
</tr>
<tr>
<td>Risk of complications associated with major surgery</td>
<td></td>
</tr>
<tr>
<td>Requires general or regional anesthesia</td>
<td></td>
</tr>
<tr>
<td>2-8-week recovery time</td>
<td></td>
</tr>
<tr>
<td>Non-reversible—loss of fertility</td>
<td></td>
</tr>
</tbody>
</table>
The NovaSure® procedure
The clear advantage for proven outcomes
The NovaSure procedure is a safe, comfortable way to provide endometrial ablation in an average of 5 minutes or less.²

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. The NovaSure system delivers bipolar RF energy until the ablation is complete in approximately 90 seconds.²

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

INDICATION

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

CONTRAINDICATIONS

The NovaSure® impedance controlled endometrial ablation system is contraindicated for use in:

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