Proven

over 14 years of data and
over 2 million patients treated.¹

A complete guide to the NovaSure® system
The NovaSure® procedure has proven efficacy when compared to other global endometrial ablation (GEA) devices, with the highest amenorrhoea and highest patient satisfaction and the lowest re-intervention rates in direct head-to-head trials. The NovaSure endometrial ablation procedure has demonstrated exceptional amenorrhoea rates in multiple long-term clinical studies. These same studies showing excellent amenorrhoea rates also demonstrate high efficacy in improvement to normal bleeding levels or better.

The NovaSure procedure uses bipolar radio frequency (RF) energy for an impedance-controlled endometrial ablation. The system has the following features:

- 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 rules and regulations regarding accreditation, anaesthesia, 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.
The power of performance

The NovaSure® procedure has proven efficacy when compared to other global endometrial ablation (GEA) devices, with the highest amenorrhoea and highest patient satisfaction and the lowest re-intervention rates in direct head-to-head trials.3,4

The NovaSure procedure amenorrhoea rates

NovaSure procedure successful reduction in bleeding

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

The same studies showing excellent amenorrhoea 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.¹⁰

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

- **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.

<table>
<thead>
<tr>
<th>NovaSure procedure surgical re-intervention rates</th>
<th>NovaSure procedure re-intervention vs hydrothermablation (HTA)</th>
<th>NovaSure procedure re-intervention vs GYNECARE THERMACHOICE® Uterine Balloon Therapy System</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Graph" /></td>
<td><img src="image2.png" alt="Graph" /></td>
<td><img src="image3.png" alt="Graph" /></td>
</tr>
</tbody>
</table>

The NovaSure procedure has been shown to improve both PMS and menstrual pain.¹⁰
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.

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.

- Busund et al. (1-year follow-up, N=46)
- Gallinat (5-year follow-up, N=107)
- Baskett et al. (1-4-year follow-up, N=200)

6-month results 1-year results 3-year results

NovaSure procedure re-intervention vs hydrothermablation (HTA)

NovaSure procedure re-intervention vs GYNECARE THERMACHOICE® Uterine Balloon Therapy System
Our technology

A customised ablation
The NovaSure® procedure provides a customised 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 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.
“The ease of use and the maximum two-minute treatment time makes it especially attractive for use in an outpatient setting. A recent survey confirmed high patient satisfaction rates of over 90%.”

Miss Narmada Katakam and Dr. Sangeeta Das
Consultant Obstetricians and Gynaecologists
Royal Bolton Hospital
Bolton, UK
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.

For OBGYNs working in multiple settings who want to treat a wide variety of patients suffering from abnormal uterine bleeding (AUB), the NovaSure device portfolio can be used for ablations safely and effectively in a hospital or office setting because it now offers two different-sized GEA devices.

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

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

“NovaSure has been my preferred endometrial ablation technique for 7 years now, because I think it offers the best balance of efficacy and safety, and can be used in the outpatient setting, where the short treatment time is particularly important.”

Mr. Keith Louden, Consultant Obstetrician and Gynaecologist
Royal Hampshire County Hospital, Winchester, UK
### The NovaSure® system delivers comfort, control, and confidence.

<table>
<thead>
<tr>
<th>Feature</th>
<th>8-mm NovaSure device</th>
<th>NovaSure ADVANCED device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sheath material</strong> is designed to promote greater durability, especially at higher temperatures.</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Customised ablation</strong> 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> provides leverage and control of the cervical collar.</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Moisture Transport™ fluid removal system</strong> 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> evaluates uterine cavity integrity before procedure.</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Nominal 6-mm sheath diameter</strong> requires approximately 6 mm of cervical dilation.</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Rounded Smooth Access™ tips</strong> require less force for insertion.*</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Improved cervical seal</strong> 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> 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.
Introducing the new SureSound®+ device

The NovaSure® system provides a customised procedure based on a patient’s cavity size, leading to a controlled ablation depth and proven outcomes. Now, there’s the SureSound+ device that’s 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.

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

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

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

Atraumatic tip facilitates a smooth insertion.

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.

Advanced touchscreen interface optimised 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.

Universal NovaSure compatibility with the portfolio of NovaSure devices.

NovaSure® RFC10 controller

The RFC10 controller has been enhanced with intuitive workflow graphics.
Introducing the new SureSound®+ device

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RFC10 controller
The RFC10 controller has been enhanced with intuitive workflow graphics.
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.

77% of patients want to hear about the NovaSure procedure at their first visit.

Impact on Quality of Life

Answered “Always,” “Frequently,” or “Sometimes”

<table>
<thead>
<tr>
<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>
</tr>
<tr>
<td>Do you have a problem working due to your period?</td>
<td>66%</td>
</tr>
<tr>
<td>Do you spend less time at work or other activities?</td>
<td>61%</td>
</tr>
<tr>
<td>Do you feel anxious due to your period?</td>
<td>75%</td>
</tr>
<tr>
<td>Do your periods cause you to miss social activities?</td>
<td>63%</td>
</tr>
<tr>
<td>Do your periods cause you to miss athletic activities?</td>
<td>66%</td>
</tr>
<tr>
<td>Are you unable to work outside your home due to your periods?</td>
<td>33%</td>
</tr>
<tr>
<td>Do you have less energy or a total lack of energy?</td>
<td>84%</td>
</tr>
<tr>
<td>Do you experience painful periods?</td>
<td>57%</td>
</tr>
<tr>
<td>Do you have PMS symptoms?</td>
<td>65%</td>
</tr>
</tbody>
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**Patient satisfaction**

**The NovaSure® procedure as a first-line treatment option**
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### Impact on Quality of Life

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<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>
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</tr>
<tr>
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<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:

- of evaluable patients returned to normal levels of menstrual bleeding, or lower.**
- patient satisfaction was reported.¹
- of patients from the initial clinical trial would recommend the NovaSure procedure to other women.¹
- of patients from the initial clinical trial reported no post-procedural pain.²

Celebrating over 2.5 million women treated

![NovaSure Icon]
Celebrating over 2.5 million women treated

Pretreatment
12-month follow-up

Lack of confidence
Lack of energy
Difficulty with work or daily activities
Anxiety

24%
75%
10%
24%
66%
84%
16%
57%

(N=265)

Improvements in symptoms

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:

97% of evaluable patients returned to normal levels of menstrual bleeding, or lower.

Patient satisfaction was reported.

97% of patients from the initial clinical trial would recommend the NovaSure procedure to other women.

93% of patients from the initial clinical trial reported no post-procedural pain.

90%
The NovaSure procedure has the highest amenorrhoea 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.

<table>
<thead>
<tr>
<th>Average treatment time</th>
<th>NovaSure</th>
<th>THERMACHOICE</th>
<th>HTA</th>
<th>Her Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>90 seconds</td>
<td></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>✔️</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>

“The clinical results advocate bipolar high frequency ablation compared to established methods since a higher rate of amenorrhoea and a lower hysterectomy rate have been documented.”

Prof. Dr. med. Thomas Römer
Chief Physician, Gynaecologic-Obstetric Department
Evangelisches Krankenhaus
Köln-Weyertal, DE
The NovaSure procedure has the highest amenorrhoea rates in direct head-to-head trials of endometrial ablation modalities.\textsuperscript{3,4,19,20}

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

\textbf{Amenorrhoea rates (12-month follow-up)}

- NovaSure procedure: 56\%
- THERMACHoice\textsuperscript{®}: 23\%
- HTA: 43\%
- Thermablate\textsuperscript{®}: 56\%

\textbf{NovaSure procedure re-intervention vs HTA (12-month follow-up)}

- NovaSure procedure: 4% (N=160)
- HTA: 10% (N=160)

\textbf{NovaSure procedure re-intervention vs THERMACHoice\textsuperscript{®} (12-month follow-up)}

- NovaSure procedure: 3% (N=81)
- THERMACHoice\textsuperscript{®}: 7.7% (N=81)

\textsuperscript{*Statistically significant differences between groups.}

\textsuperscript{†Amenorrhoea rates for the NovaSure system (Hologic, Inc. Bedford, MA, USA) were 43\% for all patients (Group A) and 56\% for patients treated after an equipment failure was noted (Group B). Amenorrhoea rates were 8\% for both Group A and B for patients treated with thermal balloon.
Medical management
NovaSure® procedure LNG-IUS
Clinical data review

Reduction to Normal Bleeding Level
1-year follow-up (PBLAC ≤ 75)
(N=265)

Patient Satisfaction
vs Rollerball
1-year follow-up
(satisfied or very satisfied)
(N=175)

Amenorrhoea
1-year follow-up
(N=265)

Avoidance of Hysterectomy
5-year follow-up
(N=107)

Reduction to Normal Bleeding Level
1-year follow-up (PBLAC ≤ 75)
(N=60)

Patient Satisfaction
1-year follow-up
(satisfied)
(N=212)

Amenorrhoea
1-year follow-up
(N=5,091)

Avoidance of Hysterectomy
5-year follow-up
(N=236)

Discontinuation When Inserted for HMB3
5-year follow-up
(N=212)

There are no completed head-to-head studies comparing NovaSure procedure and LNG-IUS. Here are the clinical outcomes other studies have shown.
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.26

77% of women say they would have liked to have learned about the NovaSure® procedure at their first consultation.13

Surgical intervention rates

The efficacy of the NovaSure procedure is immediate. LNG-IUS requires a lengthy 3-6 months to begin to control AUB.24
Five years following initiation of oral contraceptives, the majority of women required surgical intervention to achieve bleeding control. Long-term outcomes of oral contraceptives indicate that 77% of women say they would have liked to have learned about the NovaSure® procedure at their first consultation. Surgical intervention rates are as follows: 3% for 5-year follow-up (N=144) and 77% for 5-year follow-up (N=107). The efficacy of the NovaSure procedure is immediate. LNG-IUS requires a lengthy 3-6 months to begin to control AUB. Required treatment time to achieve outcome:

- NovaSure <5 minutes
- LNG-IUS 6 months
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.

### Choosing the right treatment pathway

<table>
<thead>
<tr>
<th>NovaSure procedure</th>
<th>Hysterectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td></td>
</tr>
<tr>
<td>Simple, safe procedure that removes uterine lining while preserving the uterus to reduce or eliminate bleeding</td>
<td>Permanent surgical option for women not responsive to other treatments</td>
</tr>
</tbody>
</table>

#### Advantages of NovaSure procedure
- For 90% of women, menstrual bleeding is dramatically reduced or stopped.
- One-time, five-minute procedure.
- Can be done in your office.
- Rapid recovery.
- Eliminates problem bleeding.

#### Disadvantages of NovaSure procedure
- Only appropriate for women who have completed childbearing.
- Requires anaesthesia: local or general.
- Non-reversible — loss of fertility.
- Risk of complications associated with minimally invasive procedure.
- Cost.

#### Advantages of 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.
  - Possible need for future hormone treatment due to early onset of menopause.
  - Psychological distress.
- Surgical complications, including:
  - Blood clots.
  - Infection.
  - Excessive bleeding.
  - Damage to urinary tract.
  - Bladder damage.
  - Bowel damage.
  - Loss of ovarian function.

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

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

#### Hysterectomy imposes a high cost on the healthcare system.

<table>
<thead>
<tr>
<th>Average treatment costs ($)</th>
<th>Ablation</th>
<th>Hysterectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>$3,000</td>
<td></td>
<td>$7,500</td>
</tr>
<tr>
<td>$7,500</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$2,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$2,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$8,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$6,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$4,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$2,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$4,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$100</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Hysterectomy imposes a high cost on the healthcare system.
- Hysterectomy imposes a high cost on the healthcare system.
- Avoided hysterectomy
- Required hysterectomy
  - Avoided hysterectomy: 97%
  - Required hysterectomy: 3%
  (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.

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<th>NovaSure procedure</th>
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</tr>
</thead>
</table>
|            | • For 90% of women, menstrual bleeding is dramatically reduced or stopped\(^a\)  
• One-time, five-minute procedure\(^b\)  
• Can be done in your office  
• Rapid recovery | • Eliminates problem bleeding  
• One-time procedure |

<table>
<thead>
<tr>
<th>Disadvantages</th>
<th>NovaSure procedure</th>
<th>Hysterectomy</th>
</tr>
</thead>
</table>
|               | • Only appropriate for women who have completed childbearing  
• Requires anaesthesia: local or general  
• Non-reversible — loss of 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 anaesthesia  
• 2-8-week recovery time  
• May result in early onset of menopause/possible need for future hormone treatment\(^a\)  
• Non-reversible — loss of fertility |
The NovaSure® procedure
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 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.

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 sterilisation 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 foetus.
- 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 caesarean 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 an 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.