

Proven

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



A complete guide to the NovaSure® system

NovaSure®



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

- Requires no hormonal pretreatment²
- Average ablation time is approximately 90 seconds²
- Compatible with local and/or IV sedation protocols²
- 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 utilising sound patient evaluation and selection practices, and for complying with applicable local, state, and federal 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.

NovaSure®

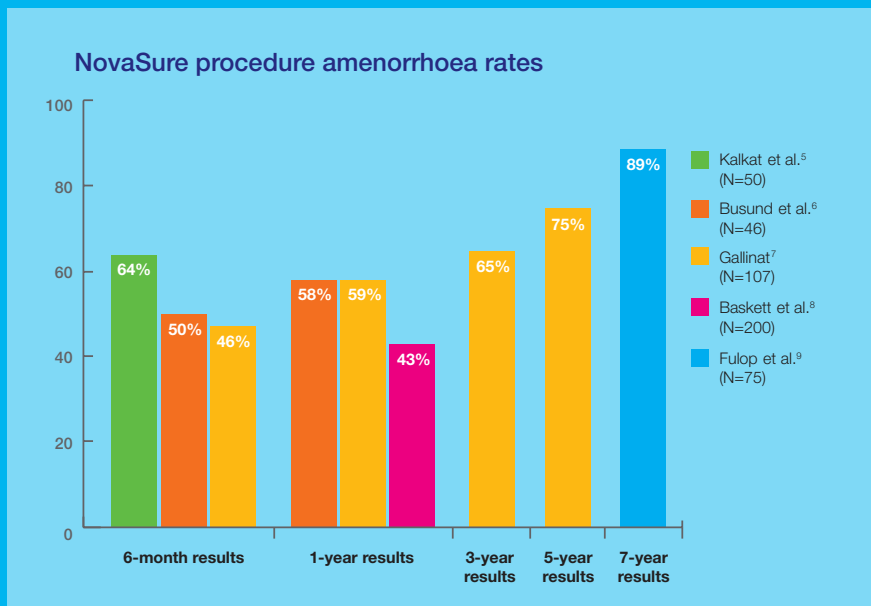


Efficacy

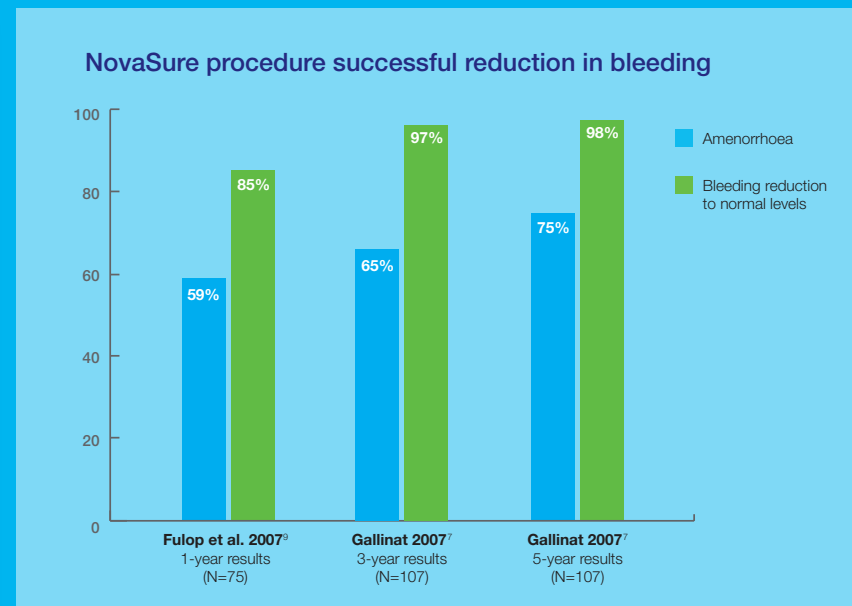
Efficacy

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}



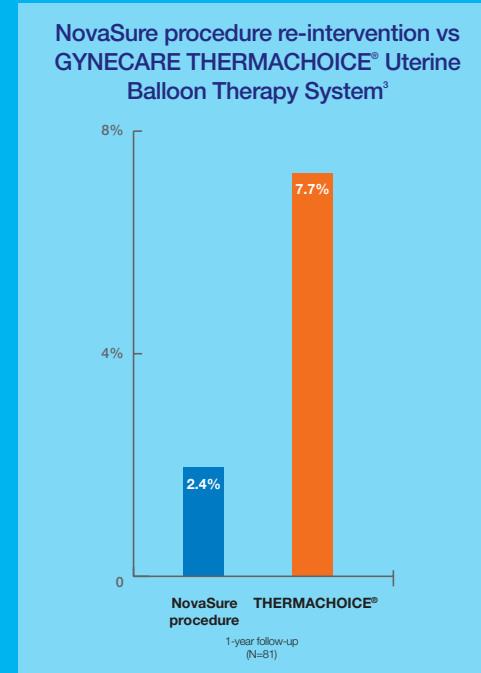
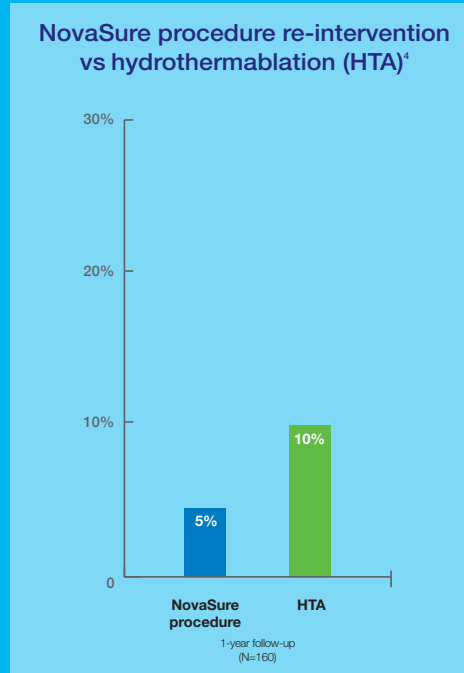
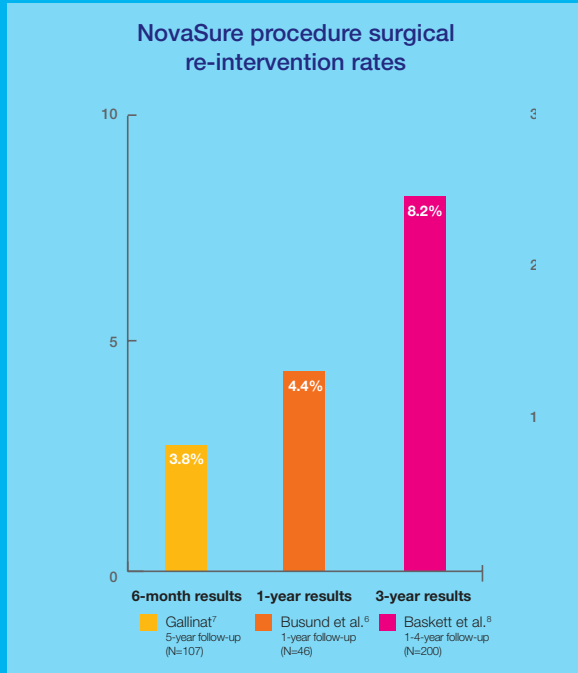
The NovaSure endometrial ablation procedure has demonstrated exceptional amenorrhoea rates in multiple long-term clinical studies.



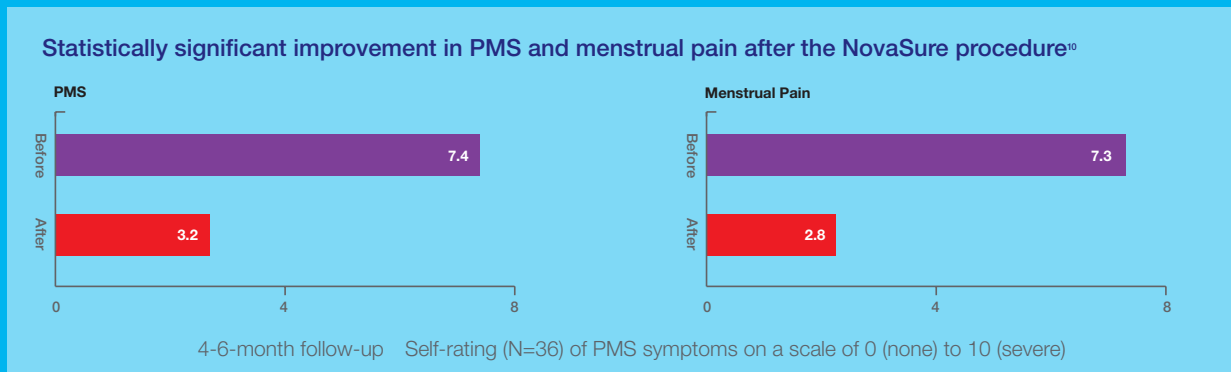
The same studies showing excellent amenorrhoea rates also demonstrate high efficacy in improvement to normal bleeding levels or better.

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.



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



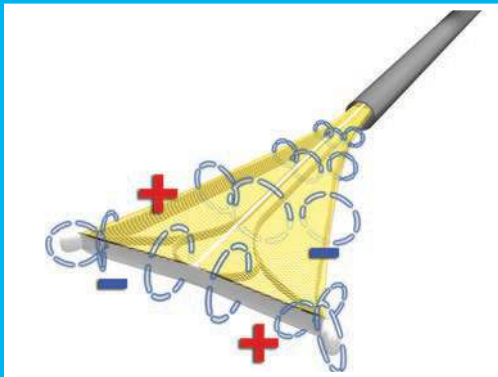


Our technology

Our technology

A customised ablation

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



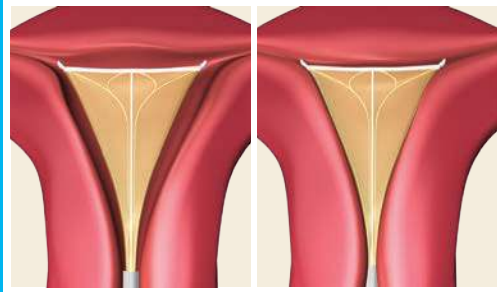
1 Bipolar RF energy

- 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.



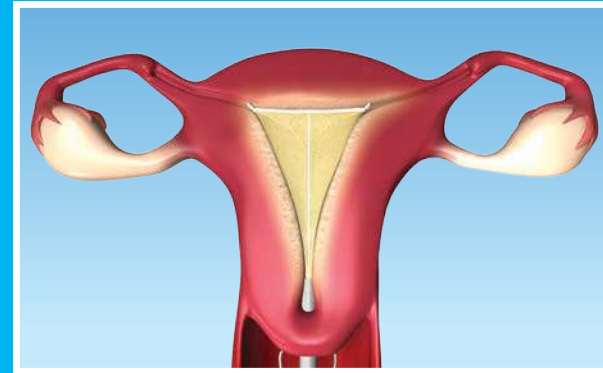
2 A proactive cavity integrity assessment

- 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.



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

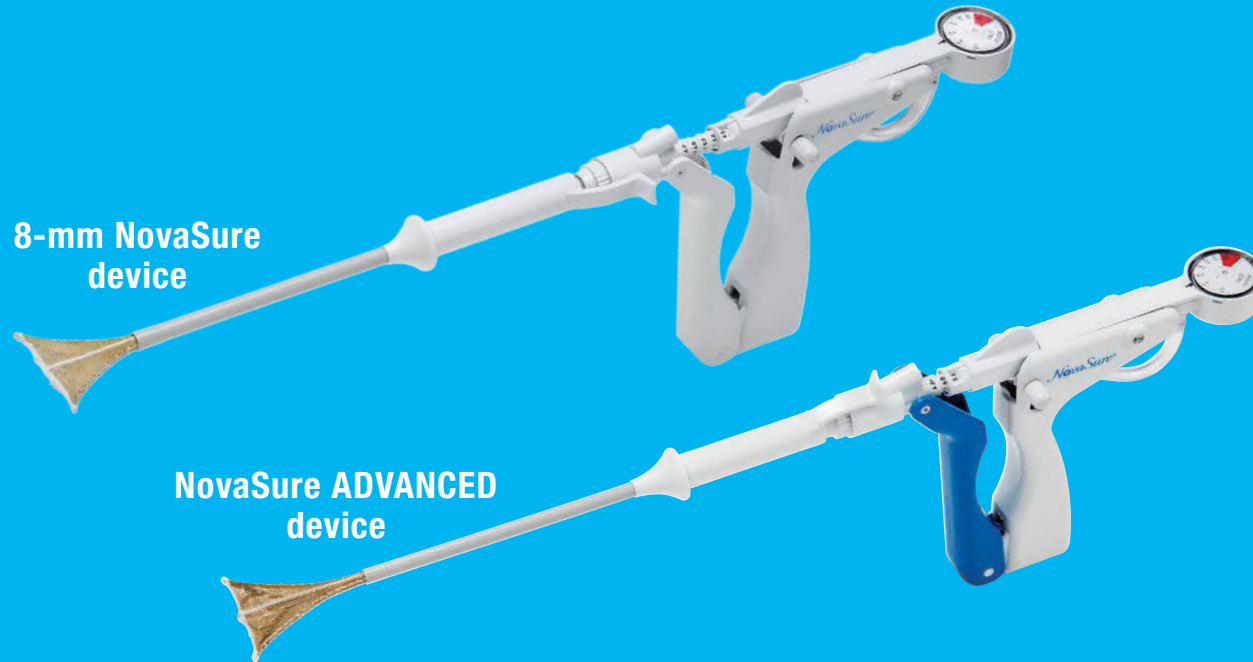
- Ablation is complete when impedance reaches 50 ohms.
- 90-second average treatment time; ablation is never more than 2 minutes.²

“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%.”²

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.



8-mm NovaSure device

NovaSure ADVANCED device

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 Loudon, Consultant Obstetrician and Gynaecologist
Royal Hampshire County Hospital, Winchester, UK

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



Feature¹⁴

8-mm NovaSure device

NovaSure ADVANCED device

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



Customised ablation is designed to deliver optimal results based on the patient's uterine cavity length and width.



Ergonomic thumb tab provides leverage and control of the cervical collar.



Moisture Transport™ fluid removal system maintains contact between the uterus and the array while evacuating by-products of the procedure without distending the endometrium.



Proactive cavity integrity assessment evaluates uterine cavity integrity before procedure.



Nominal 6-mm sheath diameter requires approximately 6 mm of cervical dilation.



Rounded Smooth Access™ tips require less force for insertion.*



Improved cervical seal creates an increased sealing surface within the cervical canal during proactive cavity integrity assessment and evacuation of procedure by-products.



Blue front handle aids insertion technique with a visual reminder to hold only the front handle.†



*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

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.



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 NovaSure compatibility

with the portfolio of NovaSure devices.

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.



NovaSure

Step 2 3 5

	Length	Power	Width
+	5.5 cm	121 Watts	4.0 cm
-			
?	✓		Array

DISPOSABLE
DEVICE

Patient satisfaction

Patient satisfaction

The NovaSure® procedure as a first-line treatment option

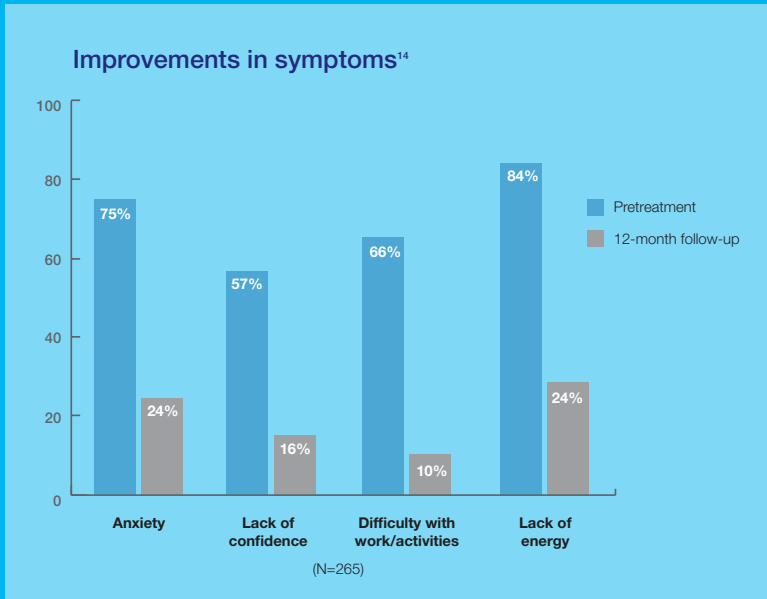
Over 8.3 million women suffer from excessive menstrual bleeding, yet only 13% seek treatment each year.¹² 77% of patients want to hear about the NovaSure procedure at their first visit.¹³

Impact on Quality of Life ¹⁴		
Answered “Always,” “Frequently,” or “Sometimes”	Before NovaSure Procedure	After NovaSure Procedure
Do you lack confidence due to your period?	57%	16%
Do you have a problem working due to your period?	66%	10%
Do you spend less time at work or other activities?	61%	9%
Do you feel anxious due to your period?	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 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%

The NovaSure® procedure significantly reduces debilitating menorrhagia symptoms.

Prior to the NovaSure procedure, most women complained of problems associated with heavy menses, including¹⁴:

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

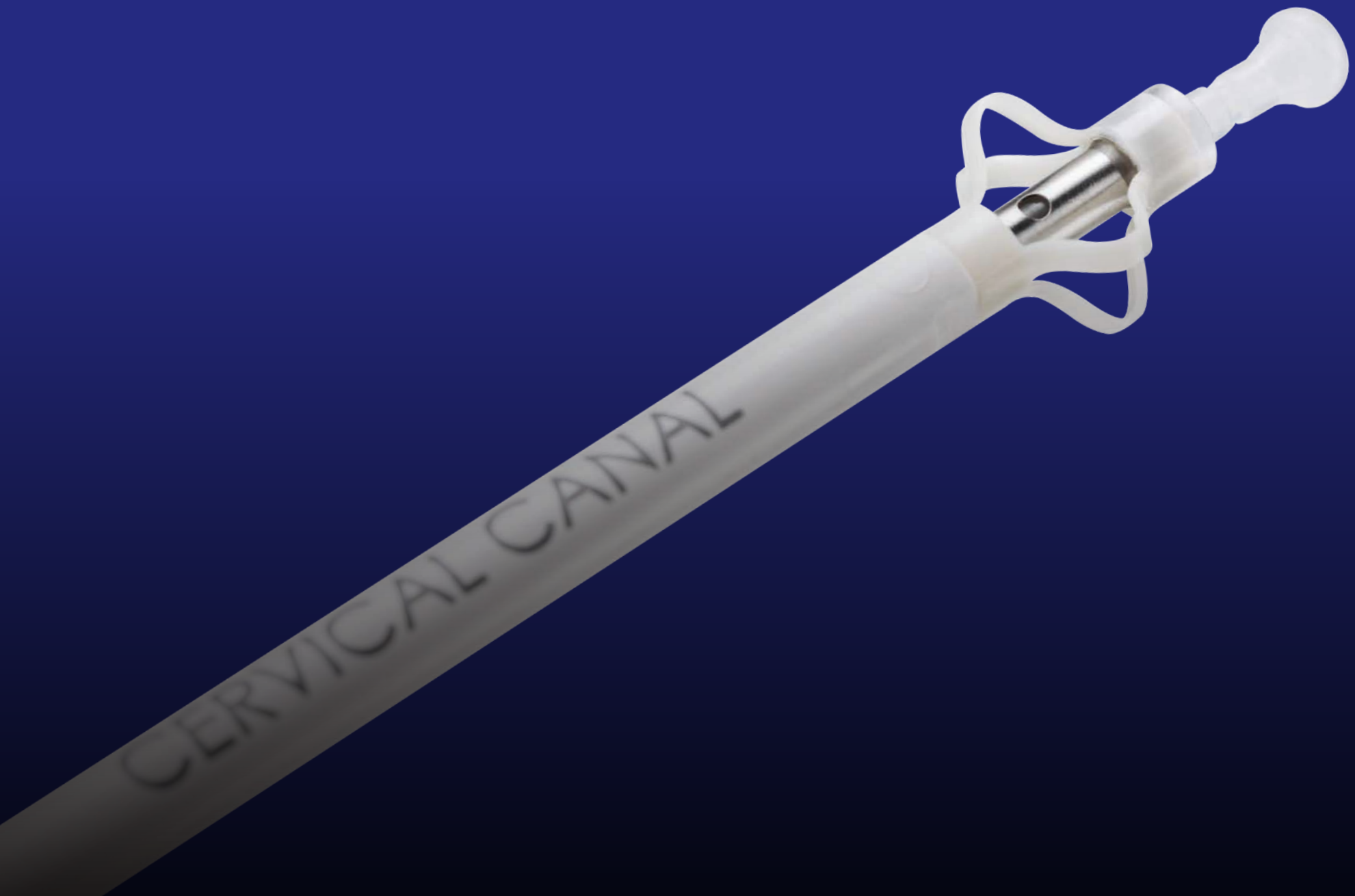


The NovaSure procedure improves patient quality of life.¹⁴ In clinical trials:

- 90% of evaluable patients returned to normal levels of menstrual bleeding, or lower.¹⁴
- 93% patient satisfaction was reported.²
- 97% of patients from the initial clinical trial would recommend the NovaSure procedure to other women.¹⁴
- 97% of patients from the initial clinical trial reported no post-procedural pain.²

Celebrating over 2.5 million women treated





GEA technologies

GEA technologies

The NovaSure® procedure offers clear advantages for proven outcomes.

	NovaSure ²	THERMACHOICE ^{®15}	HTA ¹⁶	Her Option ^{®17}
Average treatment time	90 seconds	8 minutes	10 minutes	10-34 minutes
Average procedure time	4.2 minutes	27.4 minutes	26.4 minutes	N/A
No pretreatment required	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not cycle dependent	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

“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.”

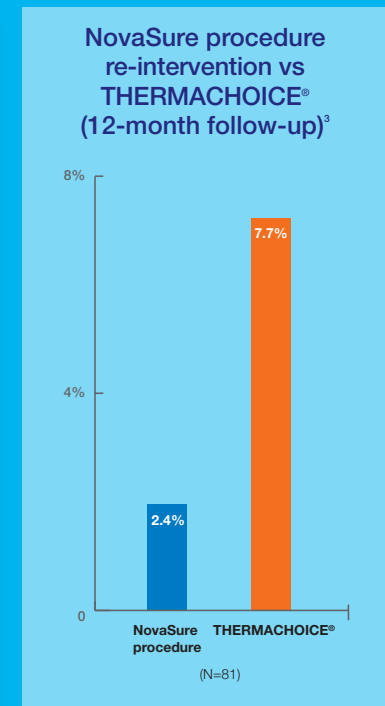
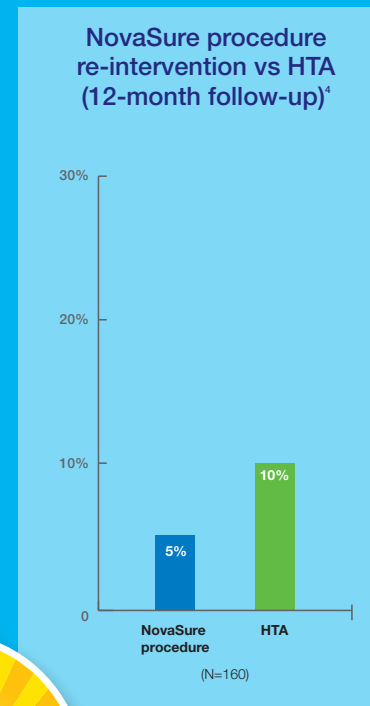
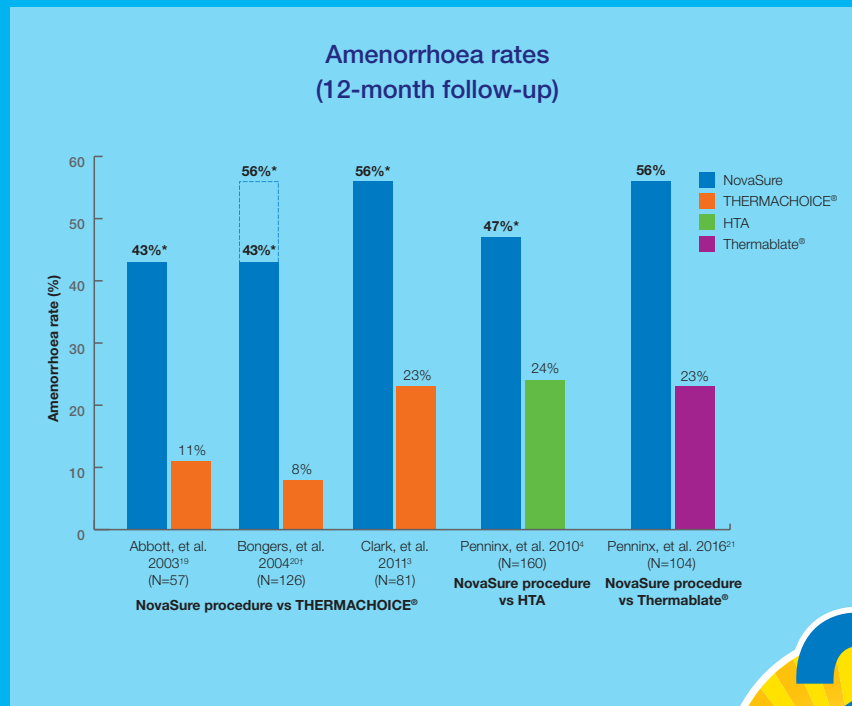
Prof. Dr. med. Thomas Römer
Chief Physician, Gynaecologic-Obstetric Department
Evangelisches Krankenhaus
Köln-Weyertal, DE

Competitive analysis

The NovaSure® procedure has proven effective in multiple head-to-head trials.¹⁸

The NovaSure procedure has the highest amenorrhoea rates in direct head-to-head trials of endometrial ablation modalities.^{3,4,19,20}

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



*Statistically significant differences between groups.

†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.





NovaSure®

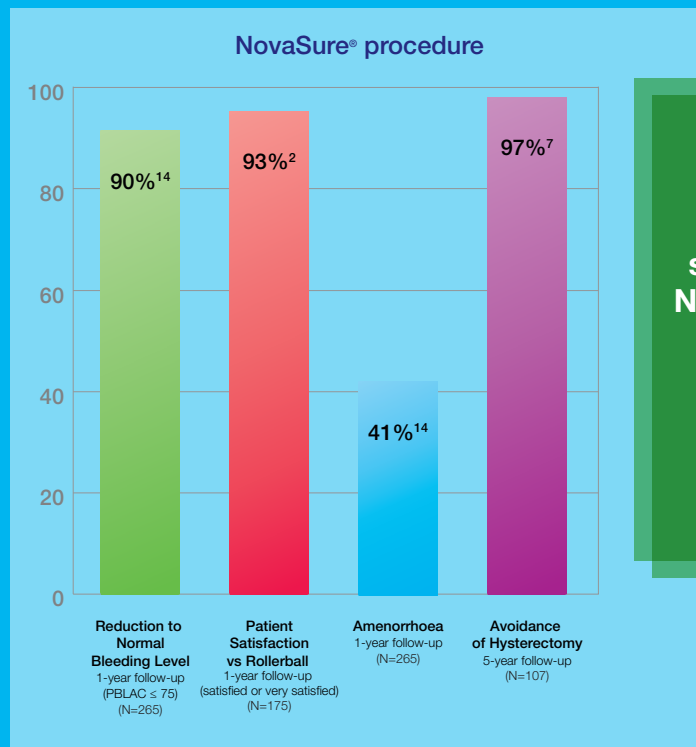


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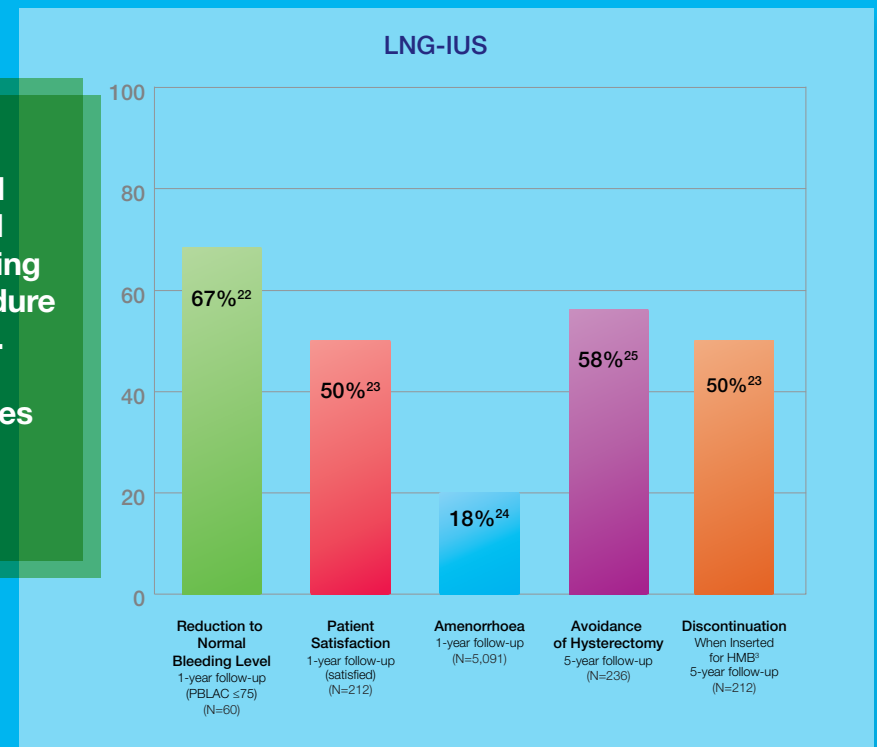
Medical management

Medical management

Clinical data review

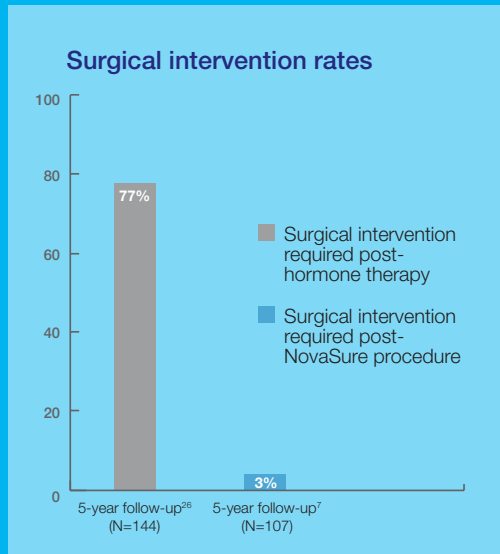


There are no completed head-to-head studies comparing NovaSure procedure and LNG-IUS. Here are the clinical outcomes other studies have shown.



Long-term outcomes of oral contraceptives

Five years following initiation of oral contraceptives, the majority of women required surgical intervention to achieve bleeding control.²⁶



77%

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

Required treatment time to achieve outcome



The efficacy of the NovaSure procedure is immediate. LNG-IUS requires a lengthy 3-6 months to begin to control AUB.²⁴

FOOT
SWITCH



HOLOGIC®

HOLOGIC.

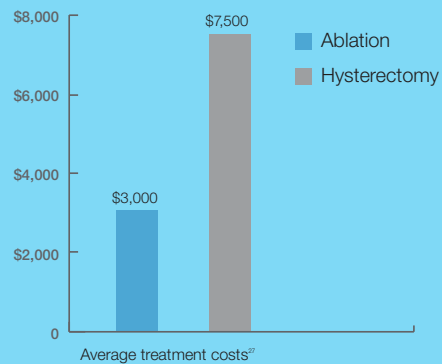


Hysterectomy

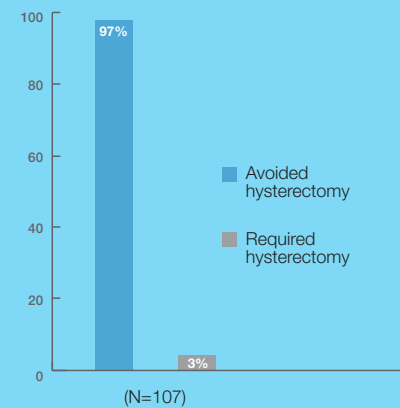
Hysterectomy

The NovaSure® procedure 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.⁷
97% avoidance of hysterectomy at 5 years



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

Emotional and physical effects include²⁸:

- 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

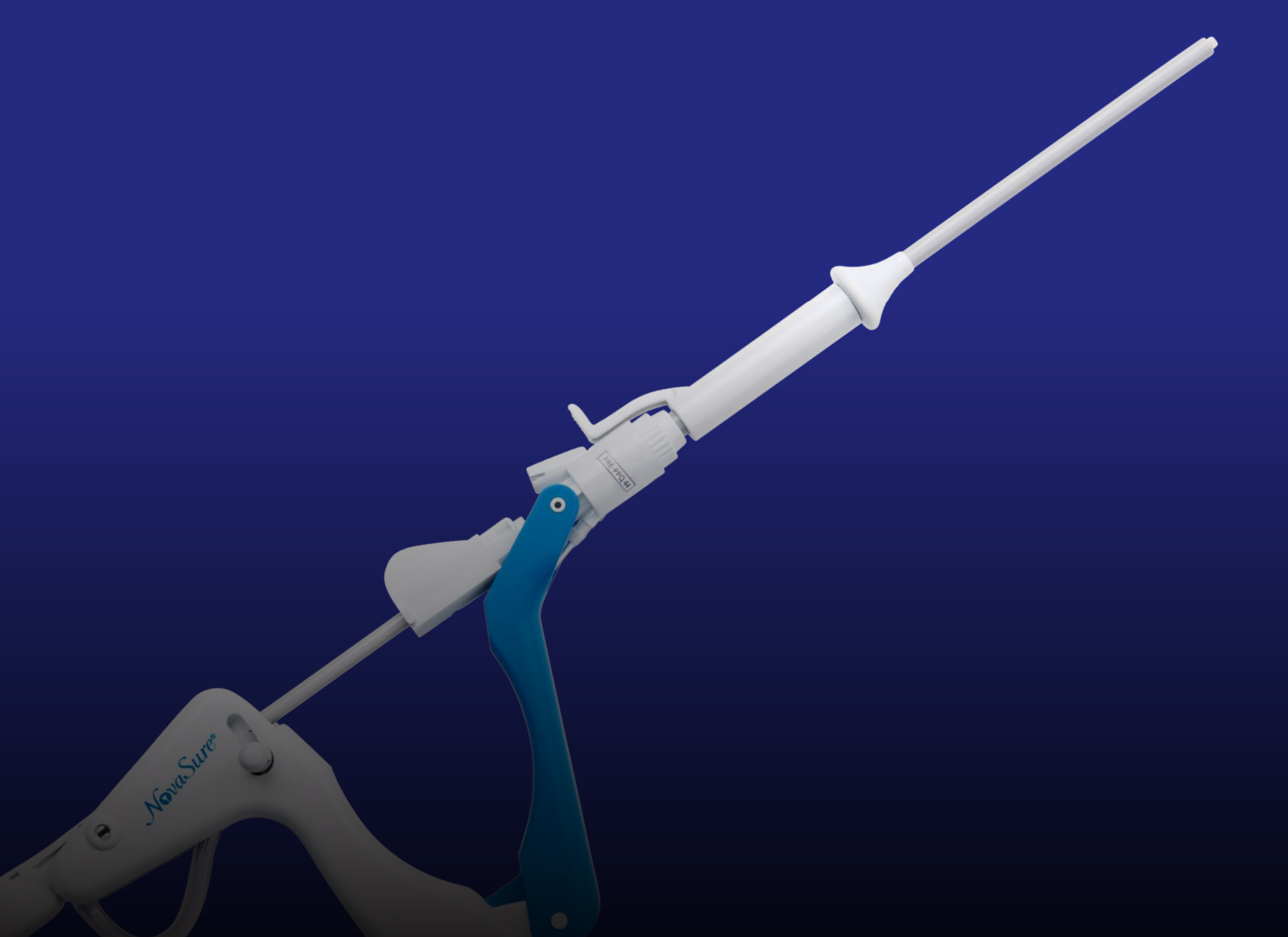
Surgical complications, including²⁸:

- Blood clots
- Infection
- Excessive bleeding
- Damage to urinary tract
- Bladder damage
- Bowel damage
- Loss of ovarian function

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.

	NovaSure procedure	Hysterectomy
Description	Simple, safe procedure that removes uterine lining while preserving the uterus to reduce or eliminate bleeding	Permanent surgical option for women not responsive to other treatments
Advantages	<ul style="list-style-type: none"> • For 90% of women, menstrual bleeding is dramatically reduced or stopped¹⁴ • One-time, five-minute procedure² • Can be done in your office • Rapid recovery 	<ul style="list-style-type: none"> • Eliminates problem bleeding • One-time procedure
Disadvantages	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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 treatment²⁸ • Non-reversible — loss of 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 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 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 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.

For more information, visit novasure.com/hcp/novasure-device

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