

NovaSure®
Endometrial Ablation



Nearly Two Decades of

**Real World
Experience**



Explore Real World Data

Select a section to view →

Smart Depth™ Technology

NovaSure Smart Depth™ technology gives Healthcare Professionals the confidence to perform safe and effective endometrial ablations – for every patient.



NovaSure®
Endometrial Ablation

Smart Depth™
Technology

C-section

Post Ablation
scarring / cancer

Larger & Irregular
Cavities

Re-Intervention

Post ablation pain

Younger Women

NovaSure vs. LNG-IUS

NovaSure + LNG-IUS

Adenomyosis

Hysterectomy

Contact



NovaSure®

Nearly Two Decades of Real
World Experience

Quick

Average treatment time **90 seconds**¹

Safe

1:25,000 risk of perforation²

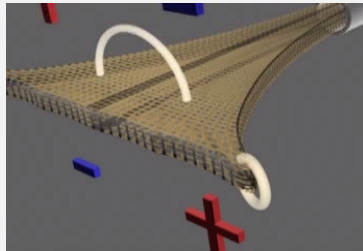
Effective

92.8% patient satisfaction³

Proven

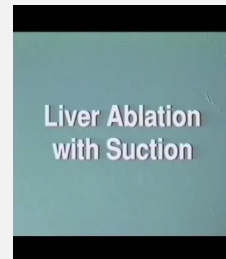
80 peer reviewed publications

Smart Depth™ Technology benefits



Smart

The technology **continuously monitors and measures tissue impedance** and calculates the optimal power level required for the treatment of the cavity - based on uterine size.



Unique

Our unique Moisture Transport® fluid removal system provides **constant tissue contact with the array through integrated suction** while simultaneously removing steam, blood, and other by-products.



Safe

The Cavity Integrity Assessment (CIA) is a **built-in safety test that confirms uterine cavity integrity**, giving you the confidence to perform a safe and effective ablation for every patient.

What do NICE recommend for Endometrial Ablation?

✓ Recommendation:

When selecting a second generation technique, providers should select 1 that is **expected to deliver outcomes at least equivalent to those from radiofrequency endometrial ablation.**

The Evidence:

The evidence from the network meta-analysis **favoured radiofrequency endometrial ablation as a preferential second generation endometrial ablation technique for the outcomes of blood loss and satisfaction.**

The committee agreed that when selecting a second generation technique, providers should select 1 that is expected to deliver outcomes at least equivalent to those from radiofrequency endometrial ablation.⁽⁴⁾

NovaSure with Previous C-sections

Clinical question...

Do I need to measure the myometrial thickness prior to treating with NovaSure for patients who have had a previous or multiple lower segment caesarean section?

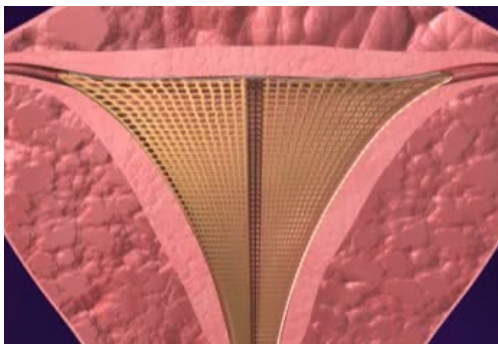
Answer...

No need to scan the myometrial thickness prior to treating patients with NovaSure ⁽¹⁾

Resources

The NovaSure[®] Radio Frequency technology, tapers the depth of ablation of the uterine cavity to ensure sufficient penetration into the myometrium for consistent results.

[▶ Click on a video below to watch how NovaSure technology works](#)



Video 1
Ablation



Video 2
Side Section

Fact

NOT contra-indicated to treat patients with multiple previous C-sections⁽¹⁾

NOTE: NovaSure is contra-indicated for patients with previous classical caesarean

Evidence

Radiofrequency Endometrial Ablation in Patients With a History of Low Transverse Caesarean Delivery.

AUTHOR:
Adkins RT, Bressman PL, Bressman PB, et al

PUBLICATION:
J Minim Invasive Gynecol.
2013 Nov-Dec;20(6):848-52

[Read more ▶](#)

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Radiofrequency Endometrial Ablation in Patients with a History of Low Transverse Caesarean Delivery.

AUTHOR:

Adkins RT, Bressman PL,
Bressman PB, et al

PUBLICATION:

J Minim Invasive Gynecol.
2013 Nov-Dec;20(6):848-52

Objective:

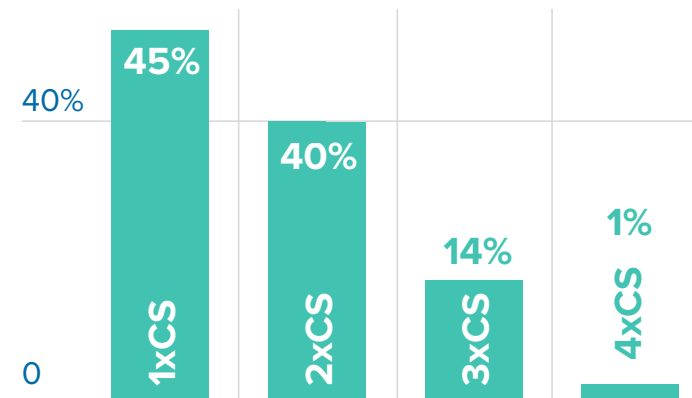
Compare 100 patients who had previous low transverse caesarean delivery with 94 patients with previous vaginal births who had a previous radiofrequency ablation performed.

Key Findings:

The NovaSure proactive Cavity Integrity Assessment Test detected incomplete healing of a Caesarean Section scar and avoided any complications. The ablation procedure was not performed, and the patient was discharged.

NO perforations were reported.

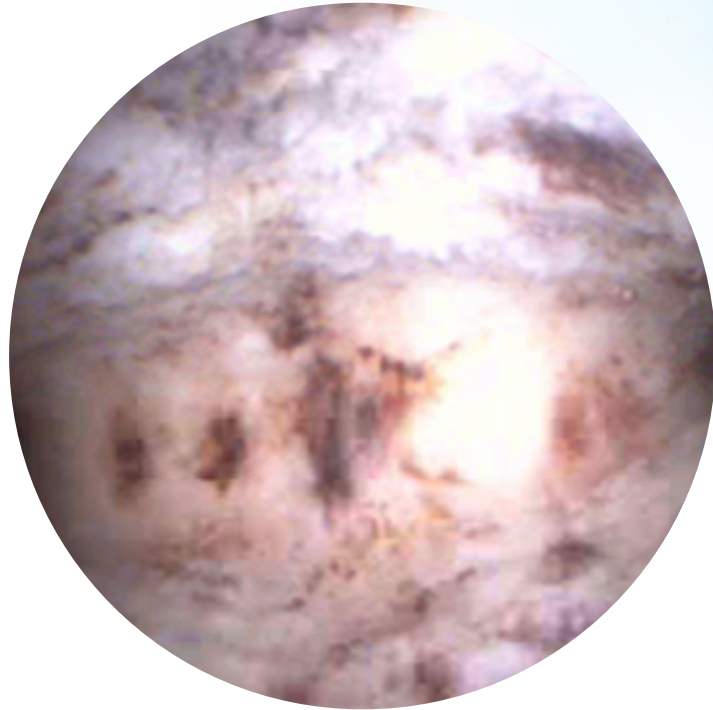
Number of caesarean deliveries (CS):



Conclusion

The efficacy and safety of endometrial ablation are comparable in women with or without a history of caesarean delivery.

Re-accessing the Cavity & Cancer Detection Post Ablation



NovaSure provides **effective results** whilst not increasing risk or delaying diagnosis of cancer

Evidence

Is endometrial ablation protective against endometrial cancer? A retrospective observational study

AUTHOR:
Singh M, Hosni MM, Jones S

PUBLICATION:
Gynecology and Obs (2016); May; 293(5):1033-7

[Read more ▶](#)

The Issue of Scarring Post-Ablation: The Data.

AUTHOR:
Lukes, AS, Evantash EG

PUBLICATION:
Contemp OB/GYN. 2012 Nov;(Suppl):1-3

[Read more ▶](#)

Endometrial cancer after endometrial ablation vs. medical management of abnormal uterine bleeding

AUTHOR:
Dood R L, Gracia C R, Sammel M D et al

PUBLICATION:
Journal of Minimally Invasive Gynecology. 2014 Sep-Oct; 21(5): 744-752

[Read more ▶](#)

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▶ **Post Ablation
scarring / cancer**

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Is endometrial ablation protective against endometrial cancer? A retrospective observational study

AUTHOR:

Singh M, Hosni MM,
Jones S

PUBLICATION:

Gynecology and Obs (2016); May;
293(5):1033-7

Objective:

Evaluate the potential risk of endometrial ablation masking the presence or delay the diagnosis of endometrial cancer.

Methods:

A retrospective observational study was conducted at Bradford Teaching Hospitals. The study included all women who had different types of endometrial ablative procedures in the period of January 1994 to December 2011.

Results:

Over 18 years period, 1521 women had endometrial ablative procedures for dysfunctional uterine bleeding. During their long-term follow-up, none of the women developed endometrial cancer later in life. This incidence is much lower than the lifetime risk of endometrial cancer in the general population (RR 0.0135; 95% CI 0.0007 -0.2801; P=0.0054).

Conclusion

This is the largest study to examine the long-term incidence of endometrial cancer in women who had endometrial ablative procedures. It shows that the development of endometrial cancer does not seem to be associated with endometrial ablative procedures.

[Read more](#) ▶

Evidence

The issue of Scarring Post-Ablation: The data

AUTHOR:

Lukes, AS, Evantash EG

PUBLICATION:

Contemp OB/GYN. 2012 Nov.
(Suppl):1-3

Objective:

To address concerns around scarring post-ablation by reviewing published scientific literature.

Findings:

Re-intervention Post Global Endometrial Ablation (GEA):

- Main indications include bleeding, pain, or both
- Hysterectomy rates for GEA range from 2-21%
- Hysterectomy rates for NovaSure specifically range from 2-9.8%

Evaluating the Cavity Post GEA:

- There is no published data that demonstrates any difference in post-ablation scarring between the different types of GEA

devices.

- Evaluation methods include: Endometrial Sampling, TVUS, SIS, Hysteroscopy, MRI

Endometrial Cancer After GEA:

- Retrospective studies have shown that no long-term increased incidence of endometrial cancer exists for women with previous endometrial ablation.

Conclusion

The need for re-intervention after GEA is very low.

- Evaluating the cavity post ablation, in most cases this can be done successfully.
- Based on available data, there is no increased incidence of endometrial cancer or evidence of masking to delay diagnosis in patients who have had an endometrial ablation.

[Read more](#) ▶

Evidence

Endometrial cancer after endometrial ablation vs. medical management of abnormal uterine bleeding.

AUTHOR:

Dood RL, Gracia C R,
Sammel M D et al

PUBLICATION:

Journal of Minimally Invasive Gynecology.
2014 sept-Oct; 21 (5): 744-752

Objective:

To compare whether endometrial ablation is associated with increased risk or delayed diagnosis of endometrial cancer compared to medical management of abnormal uterine bleeding.

Methods:

- ▶ Multi centred retrospective cohort study - **495 outpatient general practitioner practices in the UK**
- ▶ Cohort included women >25 years with AUB diagnosed between 1994-2010
- ▶ Interventions used - endometrial ablation, medical management or both

Results:

234,721 women met study inclusion in total

4776 underwent endometrial ablation

229,945 received medical management

- ▶ During a median observation period of 4.07 years, endometrial cancer developed in 3 women in the ablation group and 601 in the medical management group (ablation hazard ratio, 0.45; 95% confidence interval, 0.15-1.40; p5.17)
- ▶ Median time to diagnosis 237 days - ablation group / 299 days in the medical management group

Conclusion

No difference was observed in endometrial cancer rates and there was no delay in diagnosis when comparing endometrial ablation vs. medical management

[Read more](#) ▶

Novasure with Larger Cavity Size and Submucosal Fibroids

NovaSure has the capability to safely and effectively treat a range of different cavity sizes

Treating Larger Cavities:

The NovaSure device array can be adjusted up to 6.5cm in length and is able to treat larger cavities. The device sheath is capable of reaching up to 12cm sound length* (to reach fundus).⁽¹⁾



Evidence

Evaluation of NovaSure Endometrial Ablation in Women with Uterine Sounding Lengths >10cm

AUTHOR:
Thiel JA, Briggs MM, Pohlman S et al

PUBLICATION:
J Obstet Gynaecol Can. 2014 Jun;36(6):491-497

[Read more ▶](#)

Evidence

Use of the NovaSure Impedance Controlled Endometrial Ablation System in Patients with Intracavitary disease: 12-month follow-up results of a prospective, single-arm clinical study

AUTHOR:
Sabbah R, Desauiniers G.

PUBLICATION:
The Journal of Minimally Invasive Gynecology 2006;13:467-471

[Read more ▶](#)

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Post ablation pain

Younger Women

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* NovaSure instructions for use. Precautions: The safety and effectiveness of the NovaSure system has not been fully evaluated in patients with a uterine sound measurement greater than 10cm

Novasure with Larger Cavity Size and Submucosal Fibroids

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Evaluation of NovaSure Endometrial Ablation in Women with Uterine Sounding Lengths >10cm

AUTHOR:

Thiel JA, Briggs MM,
Pohlman S et al

PUBLICATION:

J Obstet Gynaecol Can.
2014 Jun;36(6):491-497

Objective:

Evaluate procedure outcomes and adverse events in women with uterine sounding lengths >10cm who underwent a NovaSure[®] endometrial procedure.

Method:

- **188** premenopausal women with a history of menorrhagia
- **87** procedures with a uterine sounding length >10cm
- **101** controls with a uterine sounding length ≤10cm
- Retrospective case-control study

Outcomes:

- The case and controls were similar for age, 44 ± 6.0 vs 43.3 ± 5.5 years respectively
- Body mass index (BMI) was significantly greater in the cases (30.2 ± 7.4) compared to the controls (27.5 ± 6.8)
- No adverse events were reported from either group
- There was a reduction to either light bleeding, spotting, or amenorrhoea in 86% of the cases and 93% of the controls

Conclusion

These retrospective results show improvement in bleeding with no serious adverse events in women with uterine sounding lengths >10cm who underwent a NovaSure endometrial ablation procedure.

Use of the NovaSure Impedance Controlled Endometrial Ablation System in Patients with Intracavitary disease: 12-month follow-up results of a prospective, single-arm clinical study

AUTHOR:

Sabbah R, Desauiniers G.

PUBLICATION:

The Journal of Minimally
Invasive Gynecology
2006;13:467-471

Study methods and populations:

65 women with menometrorrhagia with confirmed (type I and II) submucous myomas up to 3cm with and without polyps. Patients were not pre-treated and the procedure was not timed to the menstrual cycle.

Outcomes:

Twelve-month results demonstrated that the NovaSure System was effective in reducing excessive uterine blood loss, success (defined as reduction to normal bleeding) was observed in:

- Reduction to normal bleeding - **95% of patients**
- Amenorrhoea - **69% of patients**
- No intraoperative or postoperative adverse events reported
- **95% patient satisfaction**

Conclusion

Clinical results of this study demonstrate that the NovaSure System is safe and effective in treatment of patients with menometrorrhagia caused by intracavitary disease up to 3cm.

Novasure Long Term Results and Re-Intervention



86%

of women avoided a hysterectomy after 10 years following a NovaSure Procedure⁽⁵⁾

Evidence

AFTER 5 YEARS

UK experience:

**Bipolar Radiofrequency Compared with Thermal Balloon Ablation in the office
A Randomized Controlled Trial**

AUTHOR:

Smith PP, Malick S, Clark JT

PUBLICATION:

Obstet Gynecol. 2014 Aug;124 (2pt t):219-25

German experience:

An impedance-controlled system for endometrial ablation: five-year follow-up of 107 patients

AUTHOR:

Gallinat A.

PUBLICATION:

J Reprod Med. 2007;52(6):467-472

AFTER 10 YEARS

Dutch experience:

Ten-year follow-up of a randomised trial comparing bipolar endometrial ablation with balloon ablation for heavy menstrual bleeding.

AUTHOR:

Herman MC, Penninx JP, Mol BW, Bongers MY

PUBLICATION:

BJOG 203 Jul;120(8):966-70

[Read all case studies ▶](#)

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Post ablation pain

Younger Women

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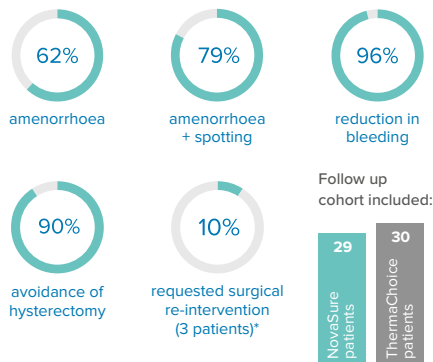
Evidence

AFTER 5 YEARS

UK experience:

Bipolar Radiofrequency Compared with Thermal Balloon Ablation in the office A Randomized Controlled Trial

AUTHOR: *Smith PP, Malick S, Clark JT*
PUBLICATION: *Obstet Gynecol. 2014 Aug;124 (2pt t):219-25*



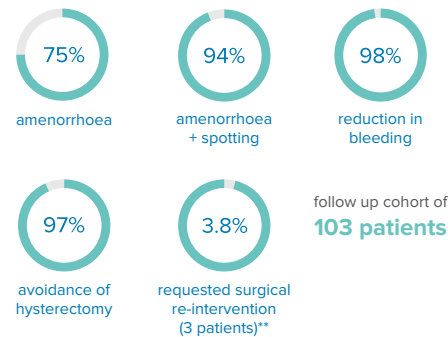
*Patient symptoms:

1. Cyclical pelvic pain
2. Offensive watery vaginal discharge
3. Persistent heavy menstrual bleeding

German experience:

An impedance-controlled system for endometrial ablation: five-year follow-up of 107 patients

AUTHOR: *Gallinat A.*
PUBLICATION: *J Reprod Med. 2007;52(6): 467-472*



**Patient symptoms:

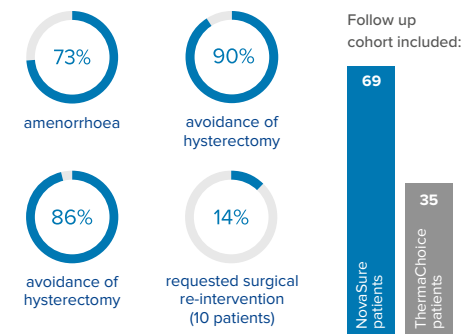
1. Hematometra
2. Symptomatic myoma
3. Menometrorrhagia

AFTER 10 YEARS

Dutch experience:

Ten-year follow-up of a randomised trial comparing bipolar endometrial ablation with balloon ablation for heavy menstrual bleeding

AUTHOR: *Herman MC, Penninx JP, Mol BW, Bongers MY*
PUBLICATION: *BJOG 203 Jul;120(8): 966-70*

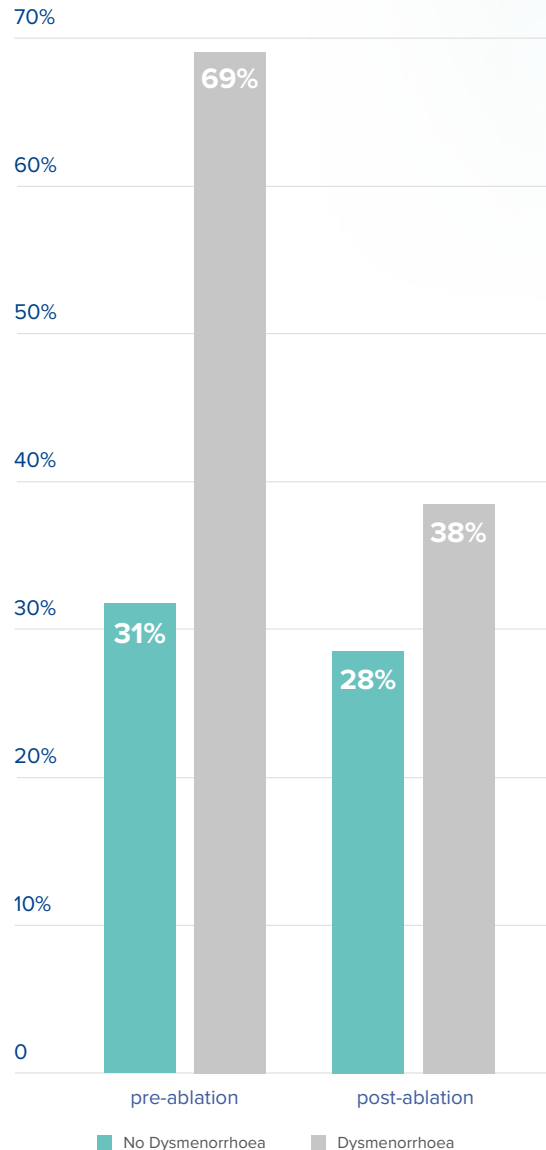


Patient symptoms:

1. Dysmenorrhoea (n=1)
2. Cyclic abdominal pain due to hematometra from cervical stenosis (n=1)
3. Atypia of the endometrium (n=1)
4. Abdominal pain (n=1)
5. Myoma nascens (n=1)
6. Persistent heavy menstrual bleeding (n=5)

Post Ablation Pain

Key Findings⁽⁶⁾



< 1%

Incidence of PATSS and/or hematometra⁽⁶⁾

7%

New dysmenorrhoea post-ablation is uncommon with only 3/44 (7%)⁽⁷⁾

50%

Nearly 50% of women with pre-ablation pain/dysmenorrhoea can expect to see resolution of pain⁽⁷⁾

Potential Causes

- PATSS and Hematometra
- Previous tubal occlusion
- Previous tubal ligation
- Contracture or synechia at the cornua area post-ablation
- Occlusion of the upper endocervical canal

Evidence

Effect of Radiofrequency Endometrial Ablation on Dysmenorrhoea.

AUTHOR:
Wyatt SN, Banahan T, Tang Y, et al.

PUBLICATION:
J Minim Invasive Gynecol. 2016 Nov - Dec;23(7):1163-1166.

[Read more ▶](#)

Smart-Depth[™]
Technology

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▶ Post ablation pain

Younger Women

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Key

Evidence

Effect of Radiofrequency endometrial Ablation on Dysmenorrhoea.

AUTHOR:

Wyatt SN, Banahan T Tang Y, et al.

PUBLICATION:

J Minim Invasive Gynecol. 2016 Nov - Dec;23(7):1163-1166.

Objective:

Determine rates of dysmenorrhoea after NovaSure in patients with pre-ablation dysmenorrhoea and in patients without pre-ablation dysmenorrhoea

Methods:

Retrospective cohort study with diverse patient population

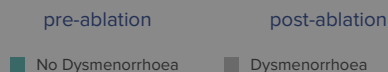
- 100 patients with pre-ablation dysmenorrhoea (69%)
- 44 patients without pre-ablation dysmenorrhoea (31%)

Results:

38% experienced dysmenorrhoea after ablation (55% improvement)

New dysmenorrhoea post-ablation is uncommon with only **3/44 (7%)**

Nearly 50% of women with pre-ablation pain/dysmenorrhoea can expect to see resolution of pain

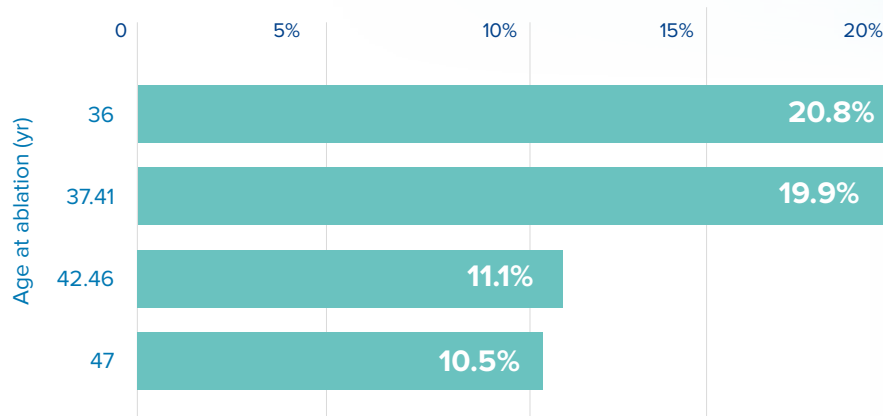


NovaSure for Younger Women

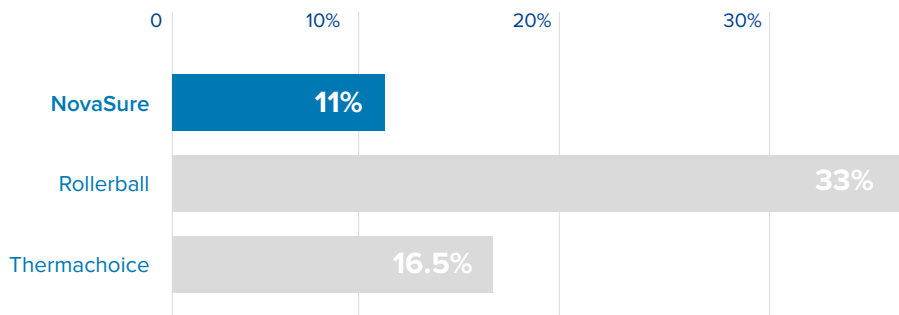
NovaSure[®] provides effective results for women of all ages and avoids the risks and costs associated with hysterectomy

Key Findings⁽⁸⁾

Rate of hysterectomy subsequent to endometrial ablation stratified by age at ablation



Types of ablation



Fact

79%
of women aged 21-36
avoided hysterectomy⁽⁸⁾

mean follow up 39 months¹

Evidence

Hysterectomy Subsequent to Endometrial Ablation

AUTHOR:

Shavell VI, Diamond MP, Senter JP, et al

PUBLICATION:

J Minim Invasive Gynecol.
2012 Jul-Aug;19(4):459-64

[Read more](#) ▶

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Hysterectomy Subsequent to Endometrial Ablation

AUTHOR:

Shavell VI, Diamond MP, Senter JP, et al

PUBLICATION:

J Minim Invasive Gynecol. 2012 Jul-Aug;19(4):459-64

Objective:

To estimate the incidence of and factors associated with hysterectomy subsequent to endometrial ablation

Methods:

A retrospective cohort study evaluated 1169 women who underwent an endometrial ablation between Jan 2003 and June 2010 with a minimum follow up of 9 months.

Results:

13.4% of women underwent a hysterectomy subsequent to an endometrial ablation

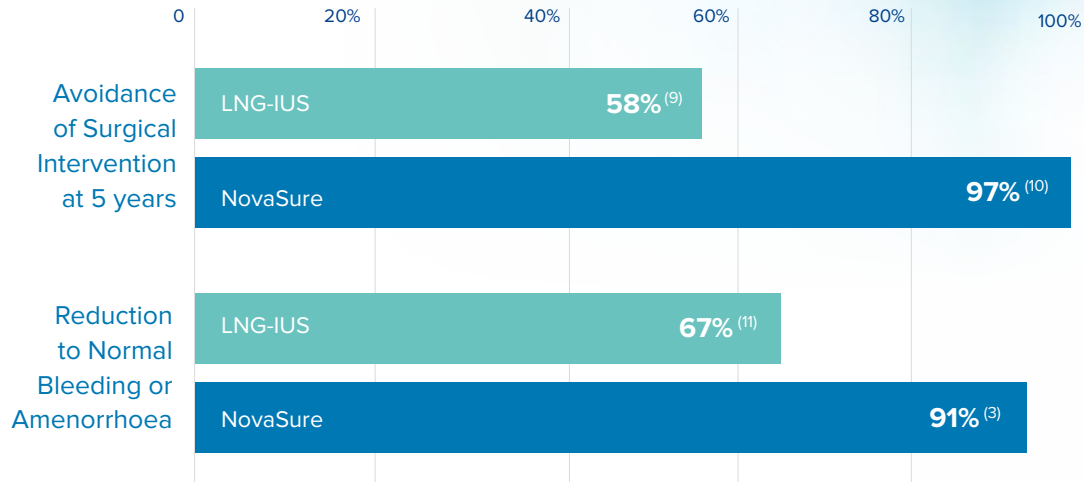
Conclusion

With a mean follow up of 39 months, younger women had an increased likelihood of hysterectomy. Rate and time of hysterectomy was associated with type of ablation performed.

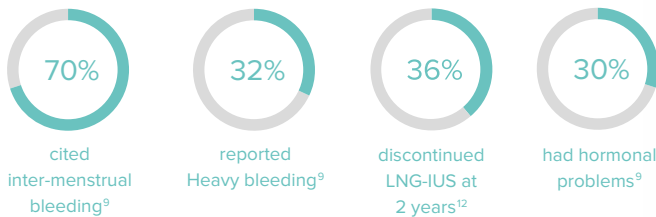
[Read more](#) ▶

Patient choice for HMB: NovaSure[®] compared to LNG-IUS

LNG-IUS Effectiveness vs. NovaSure

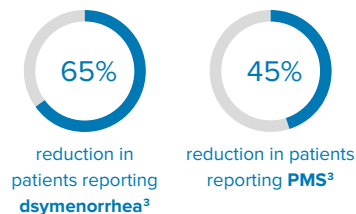


Women who discontinued use of LNG-IUS



Hormonal side effects included depression, acne, headache and weight gain¹³

Additional benefits of NovaSure include:



✓ Patient Choice

77%

of patients wish they had been offered Endometrial Ablation at their first doctors visit⁽¹⁴⁾

☰ Guidelines

Heavy Menstrual Bleeding Guidelines NG88 2018

The National Institute of Clinical Excellence recommends that healthcare professionals advise every woman with HMB about the treatments that are right for her, with a clear focus on the woman's choice.

[Read more](#) ▶

🔍 Evidence

Women's preferences for the levonorgestrel intrauterine system versus endometrial ablation for heavy menstrual bleeding

AUTHOR:

van den Brink MJ, Beelen P, Herman MC, et al.

PUBLICATION:

Eur J Obstet Gynecol Reprod Biol. 2018 Sep;228:143-147

[Read more](#) ▶

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✓ Patient Choice

NovaSure[®]
Endometrial Ablation

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Women's preference for the levonorgestrel intrauterine system vs. endometrial ablation for heavy menstrual bleeding.

AUTHOR:

van den Brink MJ, Beelen P,
Herman MC, et al

PUBLICATION:

*Eur J Obstet Gynecol Reprod
Biol.* 2018 Sep;228: 143-147

Objective:

Women's preferences for treatment of heavy menstrual bleeding (HMB) are important in clinical decision-making. Our aim was to investigate whether women with HMB have a preference for treatment characteristics of the levonorgestrel intrauterine system (LNG-IUS) or endometrial ablation and to assess the relative importance of these characteristics

Method:

A discrete choice experiment was performed in general practices and gynaecology outpatient clinics in the Netherlands. Women with HMB were asked to choose between hypothetical profiles containing characteristics of LNG-IUS or endometrial ablation

Characteristics included:

Choice	Treatment A	Treatment B
Procedure performed by gynaecologist or general practitioner	General Practitioner	Gynaecologist
Reversibility of procedure	Yes	No
Probability of dysmenorrhoea	1%	10%
Probability of irregular bleeding	15%	0%
Additional use of contraception	No	Yes
Need to repeat the procedure after five years	Yes	No
Treatment containing hormones	Yes	No

Read more ▶

Contact

Patient choice for HMB: NovaSure[®] compared to LNG-IUS

✓ Patient Choice

NovaSure[®]
Endometrial Ablation

Evidence (continued)

165 women completed the questionnaire

36 (22%) patients were recruited from general practices

129 (78%) patients were recruited from Gynaecology outpatient clinics.

- ▶ The characteristic found most important was whether a treatment contains hormones
- ▶ **Women preferred a treatment without hormones, a treatment with the least side effects, and no need for a repeat procedure or additional contraception.**
- ▶ Women completing the questionnaire at the Gynaecology outpatient clinic differed from women in primary care in their preference for a definitive treatment to be performed by a gynaecologist.

Conclusion

Whether or not a treatment contains hormones was the most important characteristic influencing patient treatment choice for HMB. Participants preferred characteristics that were mostly related to endometrial ablation, but were willing to trade-off between characteristics

dsymenorrhoea³

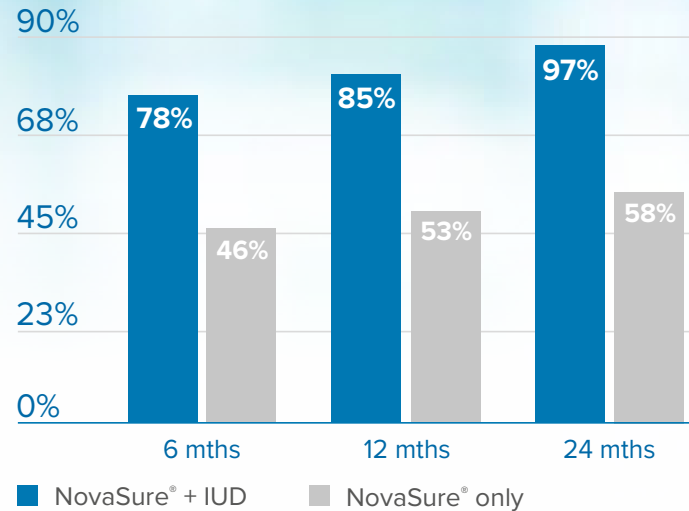
Read more ▶

Contact

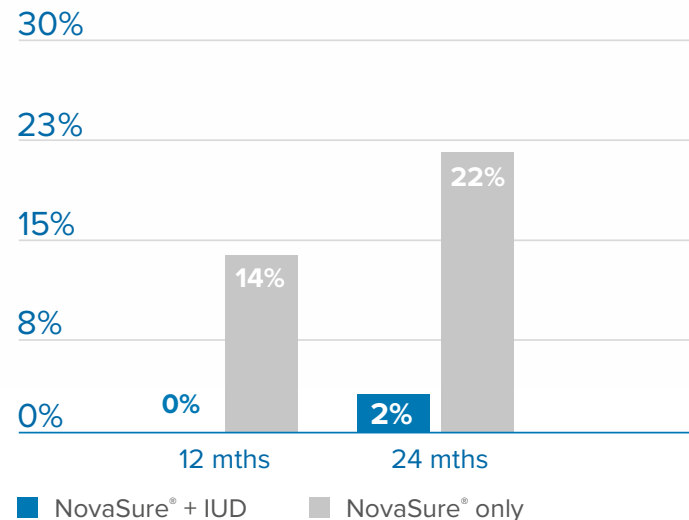
NovaSure combined with LNG-IUS

Combining use of NovaSure with LNG-IUS has shown to be more effective in achieving amenorrhoea, alleviating dysmenorrhoea and reducing re-interventions

Amenorrhoea



Re-intervention



Evidence

Comparison of combined bipolar radiofrequency impedance-controlled endometrial ablation with levonorgestrel intrauterine system versus bipolar radiofrequency endometrial ablation alone in women with abnormal uterine bleeding

AUTHOR:
Zhao H, Yang B, Feng L; et al

PUBLICATION:
J Minim Invasive Gynecol. 2019 Jun 12. pii: S1553-4650(19)30265-1

[Read more](#) ▶

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Comparison of combined bipolar radiofrequency impedance-controlled endometrial ablation with levonorgestrel intrauterine system versus bipolar radiofrequency endometrial ablation alone in women with abnormal uterine bleeding

AUTHOR:

Zhao H, Yang B, Feng L;
et al

PUBLICATION:

J Minim Invasive Gynecol. 2019 Jun
12. pii: S1553-4650(19)30265-1

Objective:

To evaluate the efficacy of the combination of bipolar radiofrequency impedance-controlled endometrial ablation (NovaSure[®]) and levonorgestrel intrauterine system (LNG-IUS, Mirena) placement in comparison with NovaSure[®] endometrial ablation alone in patients with abnormal uterine bleeding (AUB).

Method:

Retrospective study of 246 women (1:1 match established yielding 41 patients in each group) treated with NovaSure alone or NovaSure[®] with immediate IUD placement from 2013-2016.

Design:

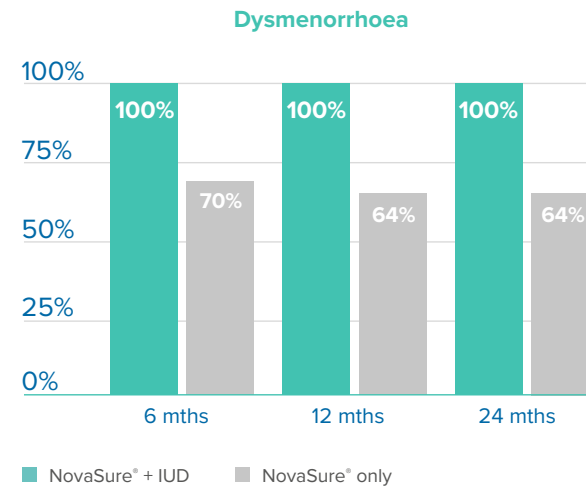
A retrospective propensity score matching study

Setting:

Beijing Tiantan Hospital, Capital Medical University, Beijing, China

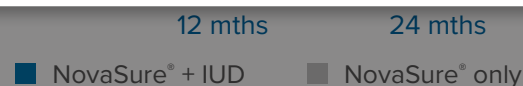
Results:

Follow-up results for patients with combined NovaSure[®] + IUD vs. NovaSure[®] alone:



Conclusion

For women with AUB, the combination of NovaSure[®] endometrial ablation and LNG-IUS is more effective than NovaSure[®] alone in achieving amenorrhoea, alleviating dysmenorrhoea and reducing re-interventions



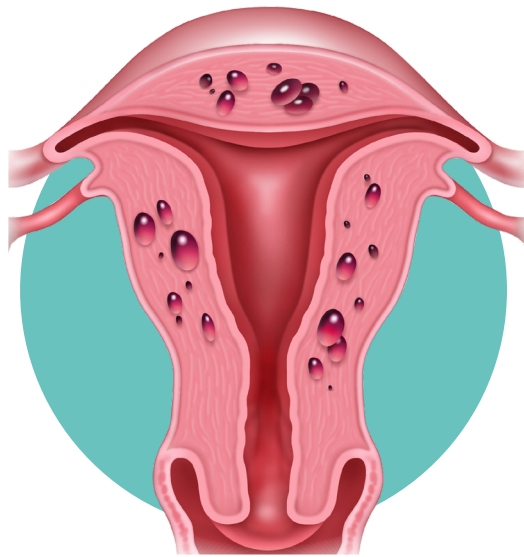
NovaSure for patients with Adenomyosis

Effective treatment

NovaSure is effective in the treatment of painful and hemorrhagic symptoms associated with adenomyosis in both the short and long term.

However, efficacy in controlling bleeding seems to decrease over time.

Nevertheless, it appears to be a good alternative to hysterectomy in this indication, especially in patients close to menopause⁽¹⁵⁾.



92%

of patients were satisfied with the NovaSure procedure⁽¹⁵⁾

56%

of patients who had hysterectomy remained satisfied by NovaSure⁽¹⁵⁾

! **Note:** The presence of adenomyosis cannot reliably predict GEA failure¹⁶

Evidence

Evaluation of NovaSure global endometrial ablation in symptomatic adenomyosis: A longitudinal study with a 36 month follow-up

AUTHOR:
Philip CA, Le Mitouard M, Maillet L; et al

PUBLICATION:
Eur J Obstet Gynecol Reprod Biol. 2018 Aug; 227:46-51

[Read more](#)

Evidence

Effects of undiagnosed deep adenomyosis after failed NovaSure endometrial ablation.

AUTHOR:
Mengerink BB, van der Wurff AAM, ter Haar JF, et al.

PUBLICATION:
JMIG. 2015;22(2):239-244.

[Read more](#)

Smart-Depth™
Technology

C-section

Post Ablation
scarring / cancer

Larger & Irregular
Cavities

Re-Intervention

Post ablation pain

Younger Women

NovaSure vs. LNG-IUS

NovaSure + LNG-IUS

Adenomyosis

Hysterectomy

Contact

Evidence

Evaluation of NovaSure[®] global endometrial ablation in symptomatic adenomyosis: A longitudinal study with a 36 month follow-up

AUTHOR:

Philip CA, Le Mitouard M, Maillet L; et al.

PUBLICATION:

Eur J Obstet Gynecol Reprod Biol. 2018 Aug;227:46-51

Objective:

To evaluate the efficacy of NovaSure[®] radiofrequency global endometrial ablation (GEA) in adenomyosis.

Design:

A monocentric longitudinal cohort (Lyon, France).

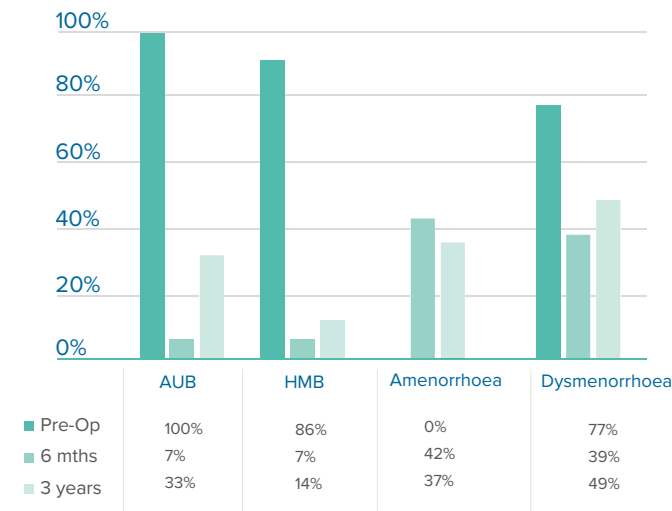
Inclusion criteria were symptomatic adenomyosis resistant to drug therapy (dysmenorrhoea and abnormal uterine bleeding (AUB)), for whom NovaSure[®] GEA was considered.

The diagnosis of adenomyosis was based on ultrasound and/or MRI criteria.

A questionnaire evaluating the symptoms was proposed to each patient before GEA and postoperatively at 6 months and 3 years.

Results:

- A significant decrease of dysmenorrhoea was observed with an improvement in 20 patients (60.6%) at 6 months and 17 patients (51.5%) at 3 years.
- 8 patients (19%) had a hysterectomy during the study.
- Patients were 92% satisfied with the procedure.
- No major postoperative complication was reported after using NovaSure.



Conclusion

NovaSure[®] is effective in the treatment of painful and hemorrhagic symptoms associated with adenomyosis in both the short and long term. However, efficacy in controlling bleeding seems to decrease over time. Nevertheless, it appears to be a good alternative to hysterectomy in this indication, especially in patients close to menopause.

! **Note:** The presence of adenomyosis cannot reliably predict GEA failure¹⁵

[Read more](#)

Evidence

Effect of undiagnosed deep adenomyosis after failed NovaSure endometrial ablation.

AUTHOR:

Mengerink BB, van der Wurff AAM, ter Haar JF, et al.

PUBLICATION:

JMIG. 2015;22(2):239-244.

Objective:

Determine the prevalence of adenomyosis and deep adenomyosis after NovaSure endometrial ablation in hysterectomy specimens after NovaSure endometrial ablation failure.

Design:

- Prospective observational study in the Netherlands
- Women who underwent hysterectomy for menorrhagia and/or dysmenorrhoea after failure of NovaSure – between 2007-2011
- Compared to women underwent hysterectomy between Jan 2005 – April 2009

213 patients underwent NovaSure
22 failed (10%)
45% had adenomyosis

173 patients control group with hysterectomy
43% had adenomyosis

Deep adenomyosis (>2.5mm endometrial penetration)

- ▶ **41%** of NovaSure failures
- ▶ **21%** of control group

Conclusion

Deep adenomyosis after failed NovaSure endometrial ablation was present in a significant number of patients. It is not clear whether adenomyosis is induced by endometrial ablation or whether it causes endometrial ablation failure.

! **Note:** The presence of adenomyosis cannot reliably predict GEA failure¹⁵

[Read more](#) ▶

NovaSure vs. Hysterectomy

Offering NovaSure in outpatients further reduces costs and risks whilst maintaining results

Cost Effective

- **Endometrial ablation performed under general anaesthesia**
The initial cost of endometrial destruction is lower than that of hysterectomy but, because retreatment is often necessary*, the cost difference narrows over time⁽¹⁷⁾.
- **Endometrial ablation performed under local anaesthesia** can provide further cost benefits.

* **82%-91%** fewer interventions / re-intervention with NovaSure versus hysterectomy⁽¹⁸⁾

Recovery

Hysterectomy is associated with a longer operating time and recovery period⁽¹⁷⁾

Patient Satisfaction

81%

NovaSure at 10 years⁽⁴⁾

97%

Hysterectomy at 12 years⁽¹⁹⁾

1:25,000 risk of perforation with NovaSure⁽²⁾

Complications^(17,20)

Most adverse events, both major and minor, were more likely after hysterectomy with minor complications up to 7% and major up to 4%⁽²¹⁾

Pre-discharge:

- Ureter damage 1:100⁽²²⁾
- Sepsis
- Blood transfusion (more common with laparoscopic vs. vaginal hysterectomy)
- Pyrexia
- Vault and wound haematoma

Post-discharge:

Infection rates ranging from:

- 10.5% abdominal, 13% vaginal, 9% laparoscopic⁽²⁰⁾
- **5% NovaSure**⁽²³⁾
- Venous thromboembolism 1% - 12%⁽²⁰⁾
- Injury to GU Tract 1-2%, GI Tract 0.1-1%⁽²⁰⁾

Longer term:

- Pelvic floor repair 5% by 30 years⁽²⁴⁾
- Salpingo-oophorectomy



Read more about Endometrial Ablation vs. Hysterectomy



Smart-Depth™
Technology

C-section

Post Ablation
scarring / cancer

Larger & Irregular
Cavities

Re-Intervention

Post ablation pain

Younger Women

NovaSure vs. LNG-IUS

NovaSure + LNG-IUS

Adenomyosis

► **Hysterectomy**

Contact

Evidence

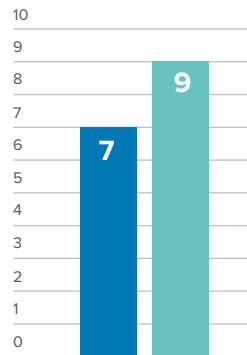
Endometrial Ablation vs. Hysterectomy

	Abdominal Hysterectomy	Vaginal Hysterectomy	Laparoscopic Hysterectomy	Endometrial Ablation
Length of Stay	3-7 days ⁽²⁵⁾	<1-4 days ⁽²⁶⁾	<1-2 days ⁽²⁶⁾	<24 hours ⁽²⁷⁾
Return to Normal Activity	6-8 weeks ⁽²⁸⁾	3-6 weeks ⁽²⁹⁾	3-6 weeks ⁽²⁹⁾	24 hours ⁽²⁷⁾
Laparotomy Incision	Yes	No	No	No
Laparoscopic Incision	No	No	Yes	No

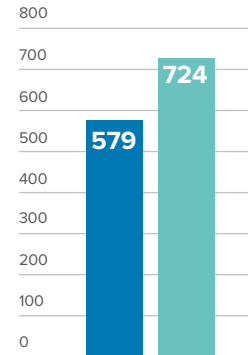
Evidence (continued)

Endometrial Ablation vs. Hysterectomy Adverse Events

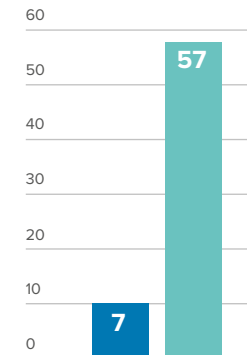
Number of studies reviewed



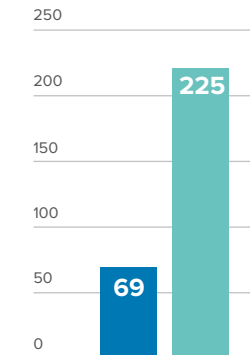
Total Number of Patients



Major Complications



Minor Complications



■ Ablation ■ Hysterectomy

“While hysterectomy is the most effective treatment for AUB, it carries the highest risk for adverse events”⁽²⁹⁾

If your patient meets the following criteria...

- ✓ HMB impacts on quality of life
- ✓ Completed childbearing
- ✓ Does not wish to have hormones
- ✓ Preference to retain her uterus
- ✓ Alternative contraception
- ✓ Offer her NovaSure®

Get It Right First Time with NovaSure®

REDUCE re-intervention and avoid hysterectomy

REDUCE burden on theatres

REDUCE adverse events

INCREASE patient satisfaction

INCREASE referrals

For more information, please visit:

▶ novasure.co.uk

▶ gynsurgicalsolutions.com

▶ *Wear white again.* [co.uk](http://wearwhiteagain.co.uk)
HOLOGIC® Campaign

or email us at:

▶ ukgynsurgical@hologic.com

◀ [Back to contents](#)

Please refer to the full operating instructions for the NovaSure Controller and Disposable Device, as well as any warnings, contraindications, and safety information.

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Please refer to the
warnings, cautions, and
contraindications section of the
instructions for use.

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