

HOLOGIC®

Nearly Two Decades
of Real World
Experience



NovaSure®
Endometrial Ablation



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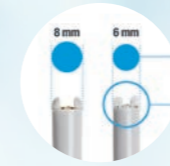
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Customised Treatment. Proven Outcomes.

The NovaSure® Endometrial Ablation System has **treated over 3 million patients** since its FDA approval and launch in 2002.



Following customer feedback, the NovaSure device design has been improved four times during the 18 years since launch, HOWEVER the technology has remained the same due to its strong safety record and proven efficacy.



Smaller

Reduced dilation, rounded tips for easier insertion.



Smarter

SmartDepth™ technology monitors and measures tissue impedance to ensure a customised depth of ablation for each patient, with the fastest average treatment time of 90 seconds.



Safe

Suctions and filters ablation by-products. Closed loop, exclusive **Moisture Transport System (MTS)** which suctions and filters the ablation by-products during the procedure.

The reduction of risk via viral spread through aerosol generating procedures has never been more important than it is today.

There is uncertainty of viral transmission via aerosolisation of particles through AGP procedures, evidence supports lower theoretical risk with hysteroscopic vs laparoscopic procedures.⁽¹⁾

With nearly two decades of clinical use and robust data, NovaSure continues to lead the GEA market. The NovaSure procedure can be performed safely and comfortably in an ambulatory setting.



Smart Depth™ Technology

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



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.



NICE recommends:

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.**

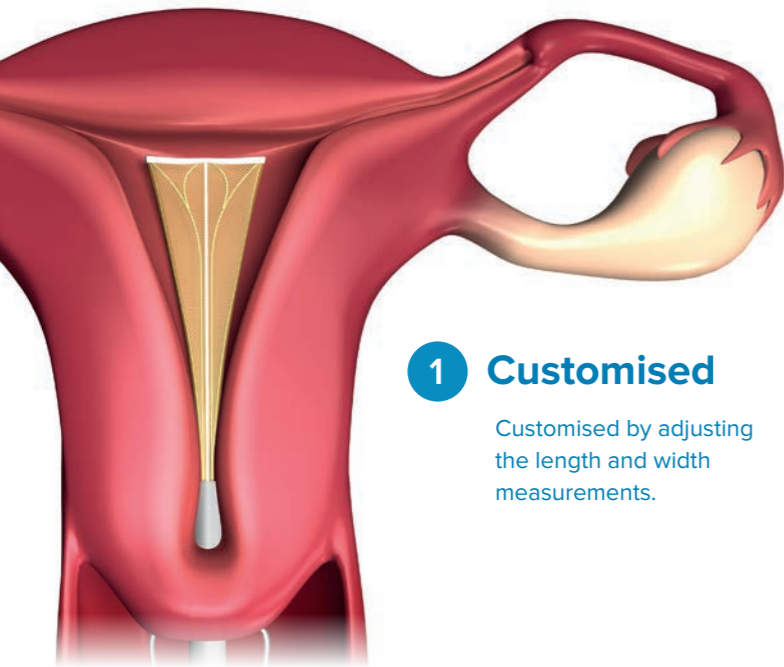
Evidence

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.⁽²⁾

How does NovaSure[®] technology work?

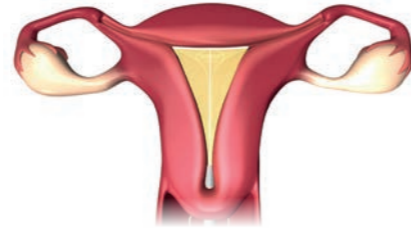
The NovaSure procedure is a safe, comfortable way to provide endometrial ablation in an average of 5 minutes or less⁽³⁾.



1 Customised

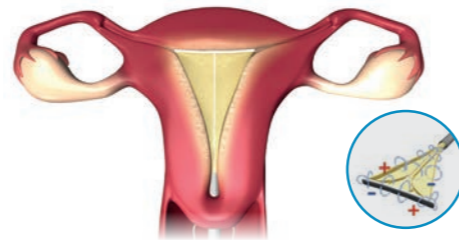
Customised by adjusting the length and width measurements.

2 Pro-active Safety Check



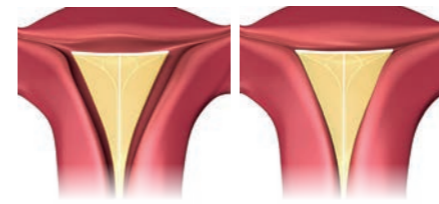
Maintaining pressure at 50mmHg for a minimum of 4 seconds to ensure the uterine cavity is intact – perforations >18 gauge needle can be detected.

3 Impedance Controlled



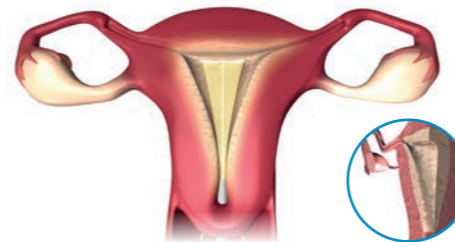
Radiofrequency energy is delivered through 4 electrodes in the array to monitor tissue impedance and terminate the procedure once 50 ohms of impedance has been reached OR after 2 minutes.

4 Moisture Transport[™] fluid removal



Moisture Transport fluid removal system draws the tissue onto the array using vacuum and removes steam, moisture and by products of the ablation.

5 Tapered Depth of Ablation



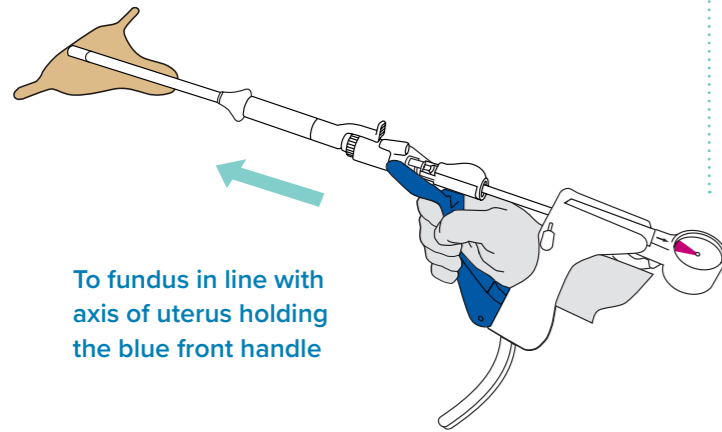
Once the ablation is complete, the uterine lining has been desiccated down to the superficial myometrium. The ablation profile depth is tapered to each patient.



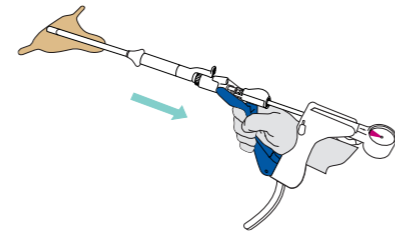
NovaSure® Seating Technique - overview*

In order to maintain superior clinical outcomes and reduce complications, the following technique should be deployed.

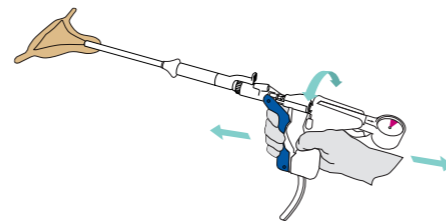
1 Advance



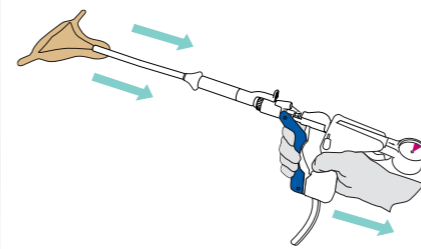
2 Withdraw



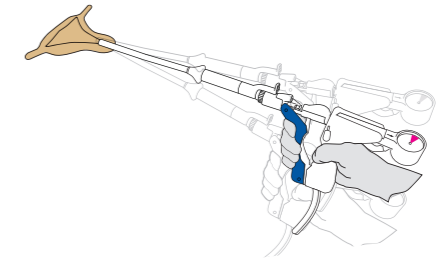
3 Rotate & Tap



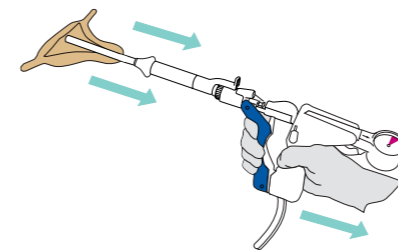
4 Lock



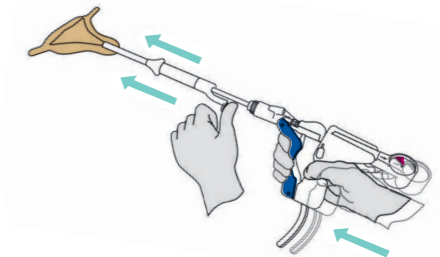
5 Cross



6 Pull back



7 Advance



*Please refer to the full operating instructions for the NovaSure Controller and Disposable Device, as well as any warnings, contraindications, and safety information www.novasure.co.uk⁽⁴⁾

NovaSure® with previous c-sections

The NovaSure device enables you to measure the cavity length and adjust the treated area.

FACT
 NO NEED TO SCAN the myometrial thickness prior to treating patients with NovaSure

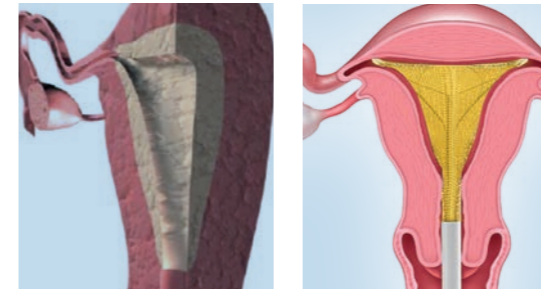


Customised and tapered depth of ablation



Clinical Question

Do I need to measure the myometrial thickness prior to treating with NovaSure?



The NovaSure Radio Frequency technology, **tapers the depth of ablation** of the uterine cavity to ensure sufficient penetration into the myometrium for consistent results irrelevant of the patients cavity size.

The main body and fundus receive a deeper depth of ablation with a more shallow depth for the lower segment and cornua.

Maintaining suction pressure (NO distension of the cavity) for the duration of the treatment (average 90 seconds) to **control the depth of ablation**.

NovaSure product labelling does NOT mandate scanning the myometrium however it is recommended that physicians use their clinical judgement.

Evidence

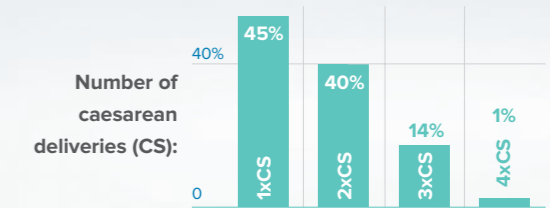
Radiofrequency Endometrial Ablation in Patients With a History of Low Transverse Caesarean Delivery.

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

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

Objective:

Compare 100 patients who had previous low transverse caesarean delivery with 94 patients with previous vaginal births who had a previous radio frequency 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.

Conclusion

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

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 the fundus).



Treating Irregular Cavities:

Moisture Transport System – irregular cavities will be suctioned onto the array of the NovaSure device using the moisture transport system. This will ensure constant contact with the myometrium to determine depth of ablation.

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 10 cm (*)
- with submucosal fibroids that distort the uterine cavity;
- with bicornuate, septate or sub-septate uteri ;
- with medical (e.g., GnRH agonist) or surgical pretreatment;
- who have undergone a previous endometrial ablation including the NovaSure endometrial ablation procedure; or,
- who are post-menopausal

Evidence

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

AUTHOR:

Thiel JA, Briggs MM, Pohlman S et al.

PUBLICATION:

Journal of Minimally Invasive Gynecology 2011; 18:S37.

Objective:

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

Methods:

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

Outcomes:

- The cases and controls were similar for age, 43.7 ± 6.0 vs 43.2 ± 5.3 years respectively..
- Body mass index (BMI) was significantly greater in the cases (31.3 ± 7.6) compared to the controls (28.3 ± 7.1)
- No adverse events were reported from either group
- There was a reduction to either light bleeding, spotting, or amenorrhoea in 80.5 % of the cases and 90.8% of the controls.

Conclusion

These retrospective results show improvement in bleeding with no serious adverse events in women with uterine sounding lengths >10 cm 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, Desaulniers 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 3 cm 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 3 cm.

* 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 10 cm⁽⁶⁾

Re-accessing the Cavity & Cancer Detection Post Ablation

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



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.

Endometrial Cancer After Endometrial Ablation vs. medical management of abnormal tissue 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

Objective

To investigate 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 yrs with AUB diagnosed between 1994 – 2010.

Interventions used – endometrial ablation, medical management or both.

Results:

A total of 234,721 women met study inclusion.

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; p 5.17).

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.

Long Term Results and Re-intervention:

Following a NovaSure procedure **86%** of women avoided having a hysterectomy at 10 years⁽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 (2 Pt 1):219-25

62% amenorrhoea
79% amenorrhoea + spotting
96% reduction in bleeding

90% avoidance of hysterectomy
10% required surgical re-intervention (3 patients)*

Follow up cohort included:



*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.

75% amenorrhoea
94% amenorrhoea + spotting
98% reduction in bleeding

97% avoidance of hysterectomy
3.8% required surgical re-intervention (3 patients)**

follow up cohort of **103 patients**

**Patient symptoms:

1. Hematometra
2. Symptomatic myoma
3. Menometrorrhagia

AFTER 10 YEARS

Dutch experience:

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

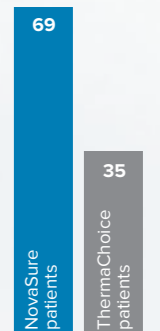
AUTHOR:
Herman MC, Penninx JP, Mol BW, Bongers MY

PUBLICATION:
BJOG 2013 Jul;120(8):966-70

73% amenorrhoea
90% reduction in dysmenorrhoea

86% avoidance of hysterectomy
14% required surgical re-intervention (10 patients)

Follow up cohort included:



Patient symptoms:

- Dysmenorrhoea (n = 1)
- Cyclic abdominal pain due to haematometra from cervical stenosis (n=1)
- Atypia of the endometrium (n = 1)
- Abdominal pain (n = 1)
- Myoma nascens (n = 1)
- Persistent heavy menstrual bleeding (n = 5)



Post Ablation Pain

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

Key Figures

< 1% Incidence of PATSS and/or hematometra⁽⁶⁾

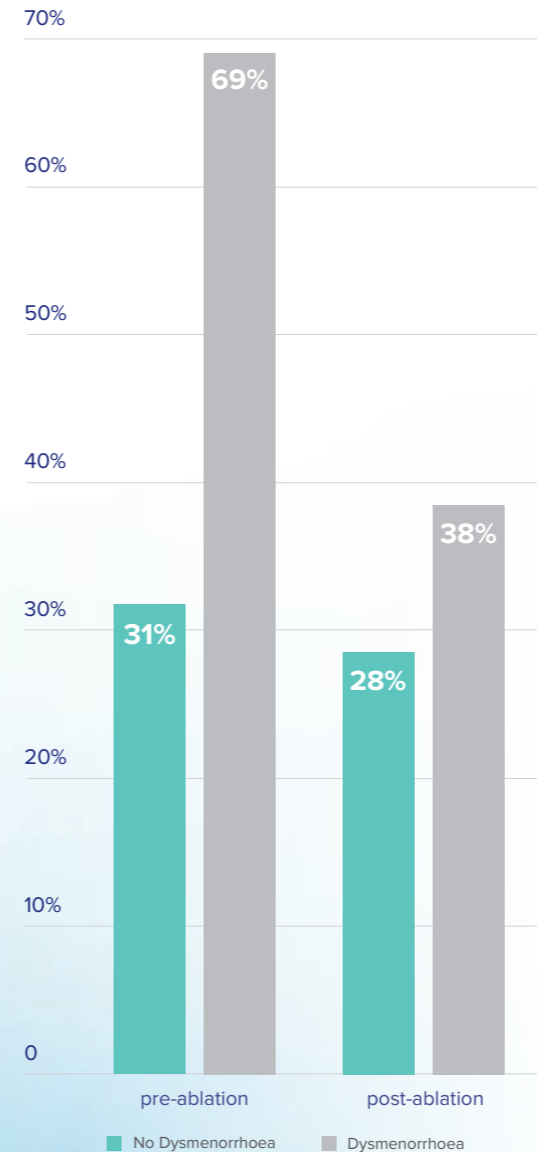
7% New dysmenorrhoea post-ablation is uncommon with only 3/44 (7%)⁽⁷⁾

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 synechiae at the cornua area post-ablation
- Occlusion of the upper endocervical canal

Key Findings⁽⁷⁾



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.

Method:

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 all premenopausal women and avoids the risks and costs associated with hysterectomy.

FACT
79%
of women aged 21-36 avoided hysterectomy
 Mean follow up 39 months⁽⁸⁾



Evidence

Hysterectomy Subsequent to Endometrial Ablation

AUTHORS:
 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.

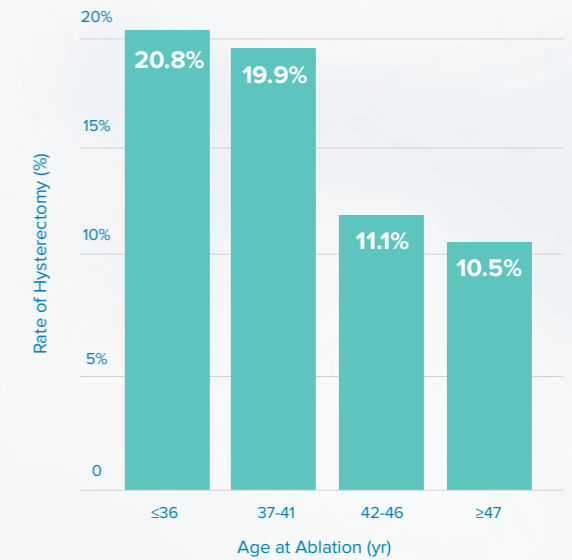
Methods:

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.

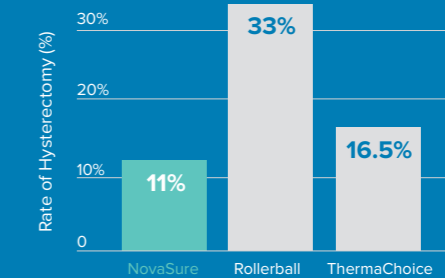
Rate of hysterectomy subsequent to endometrial ablation stratified by age at ablation



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.

Types of ablation



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

The benefit of offering NovaSure to your patients

FIRST-LINE: The recent MIRA study showed that 35% of women who were treated with LNG-IUS, required re-intervention within 2 years vs. 20% treated with NovaSure.⁽⁹⁾

39%

of LNG-IUS were removed within the study group during the 24 month of follow up⁽⁹⁾

27%

in the LNG-IUS study group, ultimately received a surgical intervention • **24% underwent NovaSure[®]**

FACT

81%

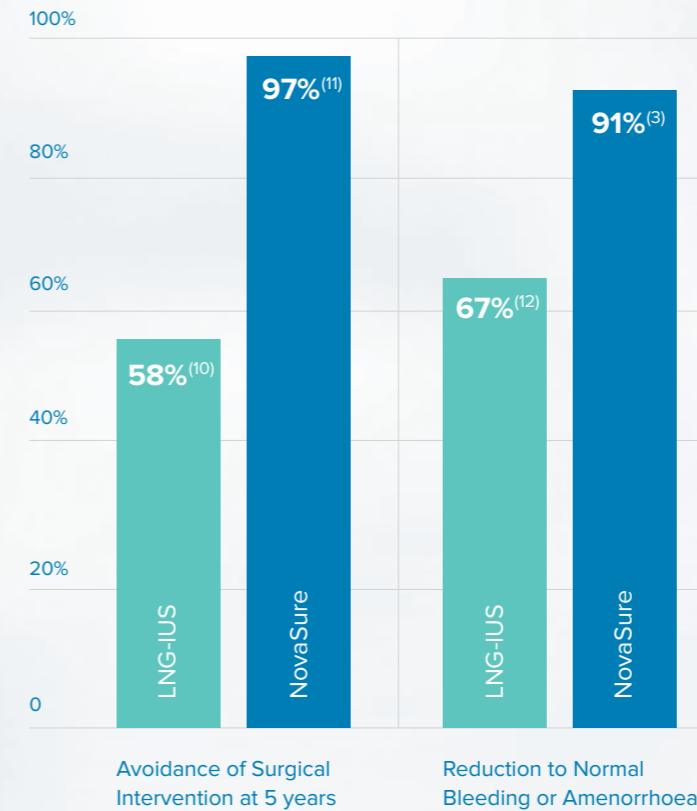
of women treated with NovaSure were satisfied at 3 months and 86% at 6 months compared to 44% satisfaction with LNG-IUS at 3 months and 59% at 6 months⁽⁹⁾

Heavy Menstrual Bleeding Guidelines NG88 2018⁽²⁾

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.**

Comparison

LNG-IUS Effectiveness vs. NovaSure



Women who discontinued use of LNG-IUS

70%

cited inter-menstrual bleeding⁽¹⁰⁾

32%

reported Heavy bleeding⁽¹⁰⁾

36%

discontinued LNG-IUS at 2 years⁽¹³⁾

30%

had hormonal problems⁽¹⁰⁾

Hormonal side effects included depression, acne, headache and weight gain⁽⁴⁾

Additional benefits of NovaSure include:

65%

reduction in patients reporting dysmenorrhoea⁽⁹⁾

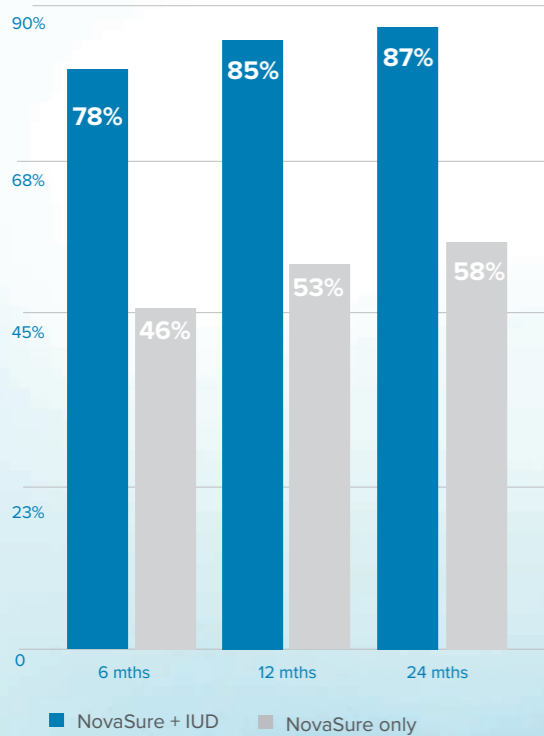
45%

reduction in patients reporting PMS⁽⁹⁾

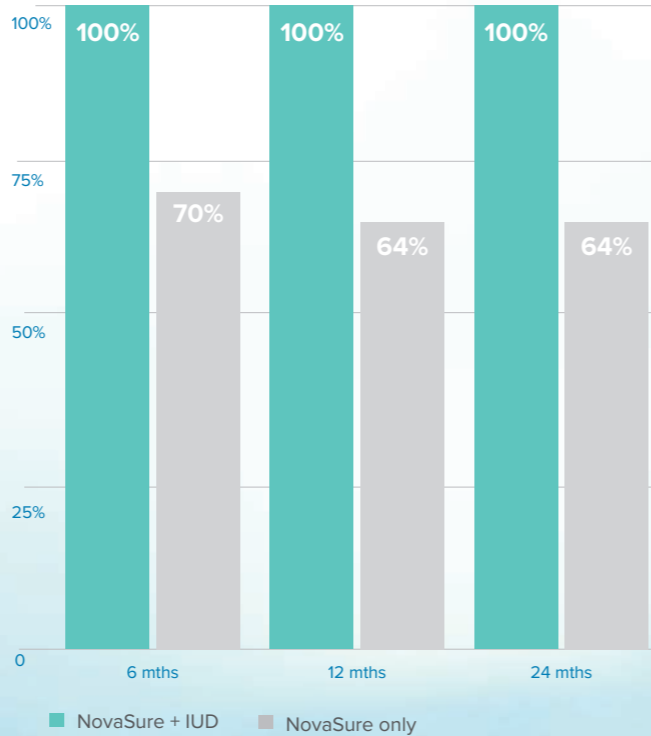
NovaSure® combined with LNG-IUS

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

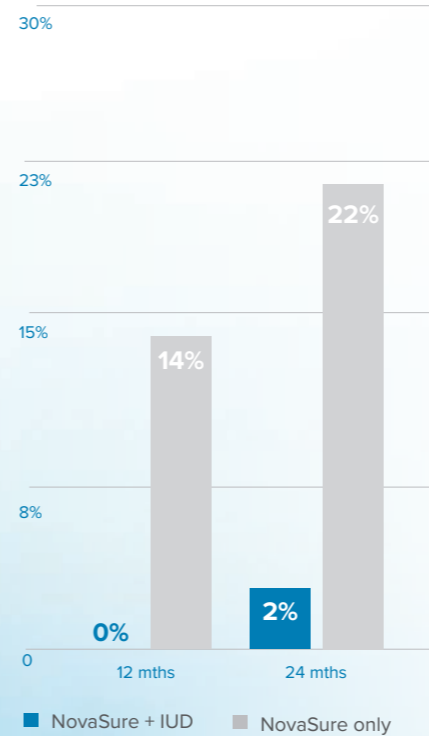
Amenorrhoea



Dysmenorrhoea



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.

AUTHORS:
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).

Methods:

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:

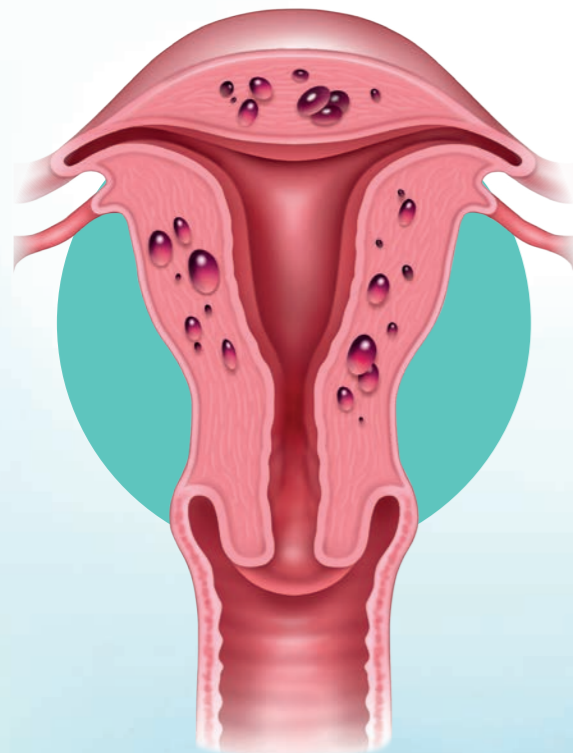
Follow-up results for patients with combined NovaSure + IUD vs. NovaSure alone.

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

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.



Key Figures

92%

of patients were satisfied with the NovaSure procedure⁽¹⁵⁾

56%

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

Evidence

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

AUTHOR:
Phillip 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).

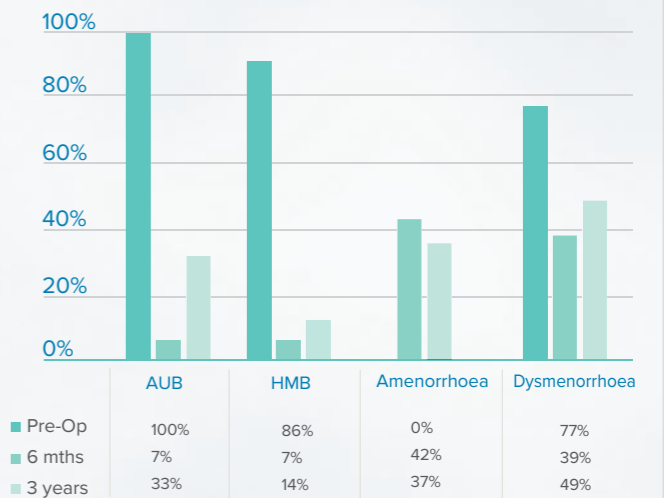
Inclusion criteria were symptomatic adenomyosis resistant to drug therapy (dysmenorrhoea and abnormal uterine bleeding (AUB)), for whom NovaSure GEA was considered.

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.

NovaSure® vs. Hysterectomy

Offering NovaSure in outpatients further reduces **costs** and **complications** whilst maintaining **results**.



Patient Satisfaction

81%

NovaSure at 10 years⁽⁴⁾

97%

Hysterectomy at 12 years⁽¹⁶⁾

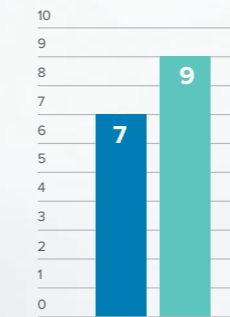
1:25,000 risk of perforation with NovaSure⁽¹⁷⁾

Endometrial Ablation vs. Hysterectomy

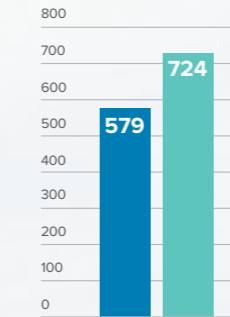
	Abdominal Hysterectomy	Vaginal Hysterectomy	Laparoscopic Hysterectomy	Endometrial Ablation
Length of Stay	3-7 days ⁽¹⁸⁾	<1-4 days ⁽¹⁹⁾	<1-2 days ⁽¹⁹⁾	<24 hours ⁽²⁰⁾
Return to Normal Activity	6-8 weeks ⁽²¹⁾	3-6 weeks ⁽²²⁾	3-6 weeks ⁽²²⁾	24 hours ⁽²⁰⁾
Laparotomy Incision	Yes	No	No	No
Laparoscopic Incision	No	No	Yes	No

Adverse Events⁽²²⁾

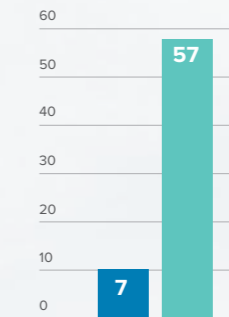
Number of studies reviewed



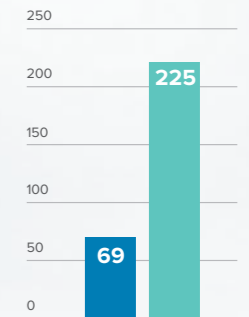
Total Number of Patients



Major Complications



Minor Complications



■ Ablation ■ Hysterectomy

“While hysterectomy is the most effective treatment for AUB, it carries the highest risk for adverse events”⁽²²⁾

NovaSure[®] performed in an ambulatory setting

Offering NovaSure under local anaesthesia has been proven to be safe, effective and well tolerated.



Evidence

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 (2 Pt 1):219-25.

Feasibility, Pain and acceptability of Office Endometrial Ablation.

Procedure:

- Duration of endometrial ablation **5.7 mins**
- Duration of entire procedure **12.4 mins**
- Pain during procedure **VAS 7.7**
- Pain 1 hour post procedure **VAS 5.1**
- Pain on discharge **VAS 2.5**

93% recommend procedure to friend (6 months follow up)

Conclusion

Office endometrial ablation using the bipolar radiofrequency procedure is feasible and effective.

Paracervical Block with Fundal Infiltration (Global Local) provides superior pain control compared with Intracervical Block for NovaSure Endometrial Ablation, a prospective audit.

AUTHOR:

M. Davey, F.J.E Gardner.

PUBLICATION:

Presented at RCOG World Congress 2016*.

NovaSure Endometrial ablation comparing intra-cervical vs. para-cervical with fundal injection anaesthesia protocols

Outcomes:

Procedure times in seconds – 104 Intra cervical vs. 108 para-cervical with fundal injection.

Pain scores:

- Intra-cervical block mean 5.9 (range 2-10)
- Para-cervical with fundal injection mean 1.1 (range 0-6)

Conclusion

Outpatient Novasure ablation pain score is dramatically lower using Paracervical block with fundal infiltration versus intracervical block.

*Source: <https://epostersonline.com/rcog2016/node/8162?view=true>

Global-local anaesthesia: combining paracervical block with intramyometrial prilocaine in the fundus significantly reduces patients' perception of pain during radio-frequency endometrial ablation (Novasure) in an office setting.

AUTHOR:

Skevnsved H.

PUBLICATION:

Gynecol Surg 9, 207–212 (2012)

Introducing the fundal block anaesthesia protocol has been shown to further reduce discomfort in combination with an intra / para cervical block.

Outcomes:

Pain scores 60 seconds into active NovaSure Endometrial ablation:

- **92%** of participants scored between VAS 0-2

69% scored VAS 0

Conclusion

Combining a traditional paracervical block with a transhysteroscopic injection of local anaesthesia into the subendometrial myometrium of the fundus of the uterus significantly reduces women's perception of pain during radio-frequency impedance-controlled endometrial ablation.

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

If your patient meets the following criteria...

- ✓ Impact 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

References: 1. Zhang W, Du RH, Li B, et al. Molecular and serological investigation of 2019-nCoV infected patients: implication of multiple shedding routes. *Emerg Microbes Infect.* 2020;9(1):386-9. 2. NICE Heavy Menstrual Bleeding Guidelines Ng88:B:Evidence reviews for management of heavy menstrual bleeding. <https://www.nice.org.uk/guidance/ng88/evidence/b-management-pdf-4782293102-3>. Cooper J, Gimpelson R, Laberge P, et al. A randomized, multicenter trial of safety and efficacy of the NovaSure System in the treatment of menorrhagia. *J Am Assoc Gynecol Laparosc.* 2002; 9:418-428 4. NovaSure Instructions for Use. https://gynsurgicalsolutions.com/wp-content/uploads/2019/06/AW-09898-001_009_01_NovaSure_ADVANCED_device.pdf last accessed Jan 2020 5. Herman MC, Penninx JP, Mol BW, Bongers MY. Ten-year follow-up of a randomised controlled trial comparing bipolar endometrial ablation with balloon ablation for heavy menstrual bleeding. *BJOG* 2013 Jul;120(8):966-70 6. Gimpelson RJ. Ten-year literature review of global endometrial ablation with the NovaSureR device. *Int J Womens Health.* 2014 Mar 11;6:269-80 7. Wyatt SN, Banahan T, Tang Y, et al. Effect of Radiofrequency Endometrial Ablation on Dysmenorrhoea. *J Minim Invasive Gynecol.* 2016 Nov - Dec;23(7):1163-1166. 8. Shavell VI, Diamond MP, Senter JP, et al. Hysterectomy Subsequent to Endometrial Ablation. *J Minim Invasive Gynecol.* 2012 Jul-Aug;19(4):459-64 9. Beelen, P, van den Brink, M, Herman J, et al; Levonorgestrel-releasing intrauterine system versus endometrial ablation for heavy menstrual bleeding. *AJOG.* Aug 2020; DOI:10.1016/j.ajog.2020.08.016 10. Hurskainen R, Teperi J, Rissanen P, et al. Clinical outcomes and costs with the levonorgestrel-releasing intrauterine system of hysterectomy for treatment of menorrhagia: randomized trial 5-year follow-up. *JAMA* 2004;291:1456-1463 11. Gallinat A. An impedance-controlled system for endometrial resection: Five-year follow up on 107 patients. *J Reprod Med.* 2007; 52:467-472 12. Istre O, et al. Treatment of menorrhagia with levonorgestrel intrauterine system versus endometrial resection. *Fertil Steril.* 2001;76:304-309; 13. Gupta J, Kai J, Middleton L, et al. Levonorgestrel intrauterine system versus medical therapy for menorrhagia. *N Engl J Med.* 2013;368(2):128-137. 14. Mirena [package insert] Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; 2007. 15. Philip CA, Le Mitouard M, Maillat L; et al. Evaluation of NovaSure® global endometrial ablation in symptomatic adenomyosis: A longitudinal study with a 36 month follow-up. *Eur J Obstet Gynecol Reprod Biol.* 2018 Aug;227:46-51 16. Cooper K, Breeman S, Scott NW, et al. Laparoscopic supracervical hysterectomy compared with second-generation endometrial ablation for heavy menstrual bleeding: the HEALTH RCT Health Technol Assess. 2019 Sep;23(53):1-108. 17. Wortman M. Endometrial ablation: past, present, and future. Part II. *Surg Technol Int.* 2018 Nov 11;33:161-177 18. Warren L, Ladapo JA, Borah BJ, et al. Open abdominal versus laparoscopic and vaginal hysterectomy: Analysis of a large United States payer measuring quality and cost of care. *J Minim Invasive Gynecol.* 2009;16(5):581-588 19. Weinberg L, Rao S, Escobar PF. Robotic surgery in gynecology: An updated systematic review. *Obstet Gynecol Int.* 2011;2011:852061. 20. Sanders BH. Endometrial ablation for menorrhagia: Will this procedure become a mainstay of treatment? *Can Fam Physician.* 1992;38:157-160 21. Falcone T, Paraiso MF, Mascha E. Prospective randomized clinical trial of laparoscopically assisted vaginal hysterectomy versus total abdominal hysterectomy. *Am J Obstet Gynecol.* 1999;180(4):955-962 22. Matteson KA, Abed H, Wheeler TL, et al. A systematic review comparing hysterectomy with less invasive treatments for abnormal uterine bleeding. *J Minim Invasive Gynecol.* 2012 Jan; 19(1): 13-28

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