



HOLOGIC[®]
The Science of Sure

MOVING THE NOVASURE[®] PROCEDURE TO AN OUTPATIENT SETTING



A Guide to Paracervical and Intrauterine Fundal Block

NovaSure[®]
Endometrial Ablation

There are many benefits of moving the NovaSure® procedure to your outpatient setting for both your practice and your patient

By moving to an outpatient setting, you can reduce downtime between cases, satisfy your patients with a comfortable setting, and run your practice more efficiently and profitably.

Now, going to an outpatient setting can be even easier by fully understanding how to manage patient pain. Two common pain management techniques are the use of paracervical block and intrauterine fundal block. There are a variety of ways to administer both blocks using different medications and techniques.

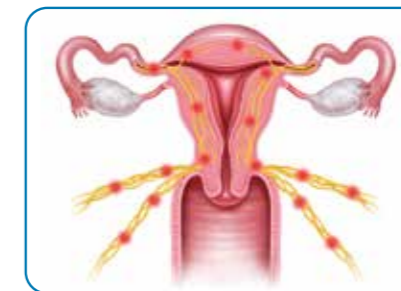
The following pages represent a guide to paracervical and intrauterine fundal block techniques and local anaesthesia protocols that can help you maximise patient comfort during a NovaSure® procedure in the office. The exact technique that you use for your patient will be a decision you make based on the specific characteristics of your patient, your comfort level, and the degree of intervention you are planning.

Why use a paracervical block in the outpatient setting?

Paracervical and fundal block are local anaesthetic techniques that can improve patient comfort for minor procedures in the outpatient setting. They can be used for a variety of different outpatient procedures, including the NovaSure® endometrial ablation procedure, cervical biopsies, endometrial biopsies, and LEEP procedures. A paracervical block is the introduction of an anaesthetic at the base of the uterus, near the cervix and the uterosacral ligaments, which blocks the pain fibres leaving the uterus.

A fundal block is the introduction of an anaesthetic into the myometrium of the uterine fundus. This type of block can be used in combination with a paracervical block to further minimise patient pain.

There are several protocols that describe the type of anaesthetic agents to use and the locations to inject them. Understanding the blood supply and innervation of the uterus and cervix can help in planning where to safely inject the medications to achieve the best result.



The sensation for pain for the patient is mainly due to impulses passing by sensory pathways down the lateral and posterior portions of the cervix, into the area of the uterosacral ligaments.



Paracervical block involves injecting anaesthetic medication into the uterine region to block the impulses leaving the uterus.



Fundal block involves injecting anaesthetic medication into the fundus to block the impulses in the upper part of the uterus.

NovaSure® in the Outpatient: Clinical Data

Paracervical Block Prior to the NovaSure® procedure

Prospective study of 33 patients to assess the safety of endometrial ablation under local anaesthesia¹

- Median pain score of 5.1 for entire procedure
- 70% of patients reported a pain score of 0 at 24 hours after procedure
- 30% of patients reported mild pain 24 hours after procedure
- 94% of patients found the NovaSure® procedure under local anaesthesia acceptable

Prospective study of 47 patients to determine feasibility of the NovaSure® procedure in the outpatient setting under local anaesthesia²

- Mean pain score of 4.1 at 30 minutes after procedure
- Mean pain score of 3.85 at 90 minutes after procedure

Paracervical Block with Fundal Block Prior to the NovaSure® procedure

Study to investigate the effectiveness of combining a paracervical block with an intramyometrial block of the fundus on perception of pain in 83 women using the NovaSure® procedure³

- 69% of patients reported a pain score of 0 during procedure
- 92% of patients reported a pain score of 2 or under during procedure

Paracervical Block Techniques including Oral Sedation Protocols

There are a number of different techniques used to administer a paracervical block or intrauterine fundal block. The following pages contain examples of local anaesthesia protocols.

Fundal Block anaesthesia regime examples

Prilocaine with felypressin	Dr H. Skensved	pg. 8
Levobupivacaine	Queen Alexandra Hospital	pg. 9
Chirocaine	Princess Royal Hospital Colchester General Hospital	pg. 10 pg. 11
Lidocaine	Singleton & Neath Port Talbot Hospital	pg. 12

Intra and Para-Cervical anaesthesia regime examples

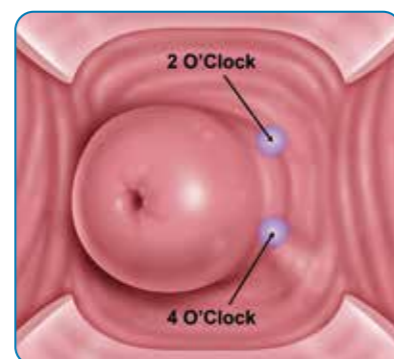
Ropivacaine	Dr. Skensved	pg. 8
Levobupivacaine	Queen Alexandra Hospital	pg. 9
Chirocaine	Colchester Hospital	pg. 11
Lignospan	Singleton & Neath Port Talbot Hospitals	pg. 12
Citanest	Kings Mill Hospital Northampton General Hospital	pg. 12 pg. 14
Lidocaine	Queen Margaret Hospital Northampton General Hospital	pg. 13 pg. 14
Local Anaesthesia Medication Information		pg. 15

Paracervical Block Injection Sites

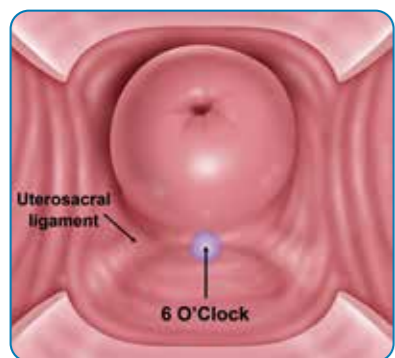
The following images represent examples of injection sites associated with the following paracervical block techniques.



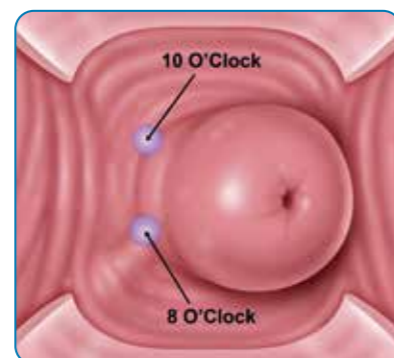
Example of an intracervical block



Example of a left paracervical block



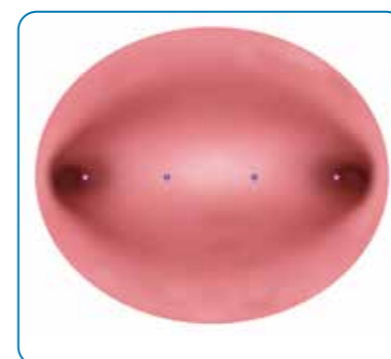
Example of a posterior paracervical and uterosacral block



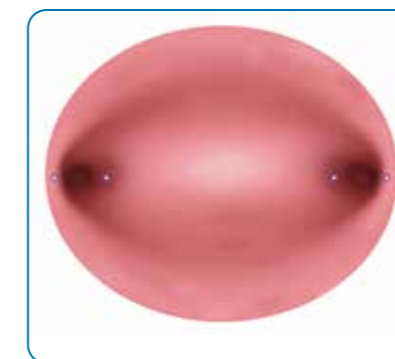
Example of a right paracervical block

Intrauterine Fundal Block Injection Sites

The following images represent examples of injection sites associated with the following intrauterine fundal block techniques.



Skensved (2012)⁴ and Gardner (2016)⁵ injection sites

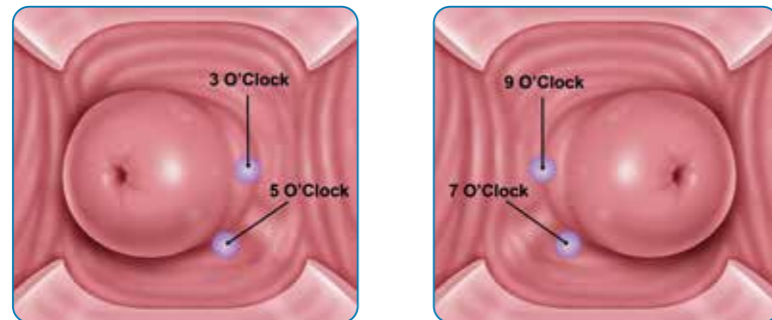


Skensved (2016)⁴ injection sites

Dr H. Skensved, Consultant Gynaecologist, Denmark⁴

Medication	Dosage	Time Course
Pre Procedure		
Ibuprofen	600 mg	2 hours pre-procedure
Acetaminophen	1300 mg (sustained relief formula) PO	2 hours pre-procedure
Procedure		
Paracervical block		
<ul style="list-style-type: none"> Inject a total of 40ml Ropivacaine 2mg/ml, 10ml at 3, 5, 7 and 9 o'clock respectively. 		
Fundal block		
<ul style="list-style-type: none"> Inject 1ml of Prilocaine 30mg/ml, Felypressin 0.54 µg/mL (3% Citanest® DENTAL with Octapressin®) above and below each ostia for a total of 4ml per patient. 		
Post Procedure		
Ibuprofen	600 mg	4 and 8 hours post-procedure
Acetaminophen	1300 mg sustained relief formula PO	4 and 10-12 hours post-procedure
Codeine	25 mg	Bedtime
First post-procedure day		
Acetaminophen	1300 mg (sustained relief formula) PO PRN	Do not exceed 3900 mg within 24 hours

Paracervical block to be administered 10 minutes before the NovaSure® procedure.



As referenced above

Mr. F. Gardner, Consultant Obstetrician & Gynaecologist, Queen Alexandra Hospital, UK⁵

Medication	Dosage	Time Course
Pre Procedure		
Paracetamol	1 g PO	1-2 hours pre-procedure
Diclofenac	100 mg PO	1-2 hours pre-procedure
Tramadol	50-100 mg PO	1-2 hours pre-procedure
Ondansetron (Zofran®)	4 mg PO	1-2 hours pre-procedure
Procedure		
Paracervical block		
<ul style="list-style-type: none"> Inject 2ml Levobupivacaine 0.25% in the anterior lip of cervix and use a tenaculum to manipulate the cervix. Inject 4ml Levobupivacaine 0.25% at 11 and 1 o'clock. Inject 5ml Levobupivacaine 0.25% at 9, 3, 8, 4, 7 and 5 o'clock. Use a 35mm needle with a normal syringe to aspirate prior to injecting repeatedly down the track of each injection site. 		
Fundal block		
<ul style="list-style-type: none"> Inject 2ml 0.25% Levobupivacaine adjacent to the tubal ostia and 1cm medially on each side (Total of 4 injections). The first injection should be just lateral to the tubal ostia but if this is not possible it should be just medial. Use a separate 2ml syringe for each fundal injection, changing the syringes when the tip of the needle is still in the myometrium to avoid flash back of the saline distension medium. <p>Ensure the injection is in the myometrium not the endometrium.</p>		
<p>This is a guide for "standard patients" (approx 70 kg). For small stature patients, reduce the dose appropriately.</p>		

Acetaminophen is recognised as a replacement for Paracetamol. Avoidance of patient dehydration and starvation is important to reduce perioperative complications of vasovagal attack and nausea or vomiting.

**Mr. M. Underwood, Consultant Obstetrician & Gynaecologist,
The Princess Royal Hospital, UK**

Medication	Dosage	Time Course
Pre Procedure		
Diclofenac (Tramadol 100mg orally replaces diclofenac if contraindicated)	100mg PO	Orally 1 hour prior to the procedure
Oramorph	10mg PO	Orally 1 hour prior to the procedure
Odansetron	4mg	Orally 1 hour prior to the procedure
Intra-procedure		
<ul style="list-style-type: none"> • 3 ampules Citanest – cervical block • Fundal block administration: 5ml luer lock syringe overfilled holds ~6ml of Chirocaine. • Administered using Cooks (Williams) needle. • 2ml near left ostia, 1ml just to left of midline, 1ml just to right of midline and 2ml next to right ostia (2-1-1-2ml) 		
<p>TOP TIP If you have small hands then use a 2.5ml luer lock syringe twice as its quite high pressure to squeeze a 5ml syringe</p>		
Post-procedure		
In hospital - Oramorph PRN (rarely needed)		
At home - Patient to take own meds at home if needed – Ibuprofen / Paracetamol - recommended 4 hours post procedure		

FUNDAL BLOCK CARDEX (if using 5f Operative Channel Scope – Storz Bettocchi or equivalent)

- Standard cervical block equipment

PLUS

- 1 x 10ml Ampule of Chirocaine 2.5mg/ml (only ~6ml required)
- 1 x 5ml Luer Lock Syringe (overfilled to ~6ml)
- 1 x Williams Cystoscopic Injection Needle (Code: 090001 – Cook Medical)
- Needle goes down a 5f operative channel on a scope (Storz Bettocchi Scope or equivalent)

FUNDAL BLOCK CARDEX (if using 5f Operative Channel Scope – Storz Bettocchi or equivalent)

- Standard cervical block equipment

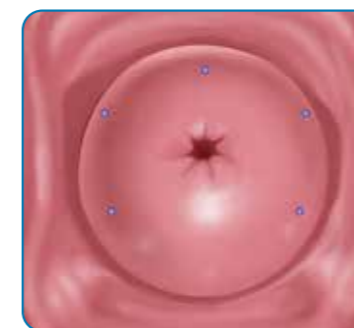
PLUS

- 1 x 10ml Ampule of Chirocaine 2.5mg/ml (only ~6ml required)
- 1 x 5ml Luer Lock Syringe (overfilled to ~6ml)

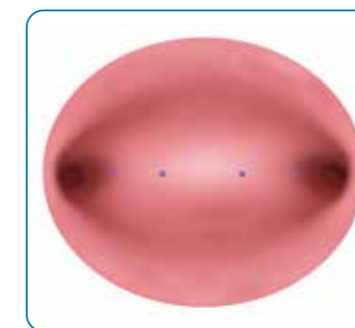
**Mr F. Alfhaily, Consultant Gynaecologist,
East Suffolk and North East NHS Foundation Trust / Colchester Site, UK**

Medication	Dosage	Time Course
Pre Procedure		
Paracetamol	1g	PO
Ibuprofen	400mg	PO (unless Contraindicated)
Intra-procedure		
<p>Paracervical</p> <ul style="list-style-type: none"> • 2.5mg/ml Chirocaine 5x8ml injections (total 40mls) using yellow spinal needle <p>Intra-fundal</p> <ul style="list-style-type: none"> • 2ml of 2.5mg/ml Chirocaine injected into the fundus at 4 sites hysteroscopically using a cook cystoscopic needle. 		
Post-procedure		
NOTE: Very rarely required		
Paracetamol	1g	4 hourly post procedure (max 4g in 24hrs, patients own medication)
Ibuprofen	400mg	8 hourly post procedure (patients own Medication)

This is not given routinely but only given if patient did not take pre-operatively or if required.



Paracervical



Intra-fundal

**Mr. P. Flynn, Consultant Obstetrician & Gynaecologist,
Singleton & Neath Port Talbot Hospitals, UK**

Medication	Dosage	Time Course
Pre Procedure		
Ibuprofen	400mg	1 hour before appointment
If NSAID intolerant: Co-codamol 30/500	2 tabs	1 hour before appointment (advised not to drive)
Cyclizine	50mg	30 mins before procedure
Intra-procedure		
Paracervical block: Lignospan or Scandanest	2 amps	Prior to hysteroscope introduction
Intrauterine (Fundal) block: Lidocaine 2%	4 x 1ml aliquots via Williams needle	After initial survey and before cervical dilation
Post-procedure		
Ibuprofen tabs	400mg	TDS PRN
If NSAID intolerant: Co-codamol 30/500	1-2 tabs	QDS PRN

Mr. S. Vindla, Consultant Obstetrician & Gynaecologist, King's Mill Hospital, UK

Medication	Dosage	Time Course
Pre Procedure		
Paracetamol 500mg P.O	2	1hr pre procedure
Cyclizine 25mg P.O	1	1hr pre procedure
Diclofenac 100mg P.R	1	1hr pre procedure
Intra-procedure		
Citanest and Octapressin 2.2 mls vial	Up to 3 into cervix	Immediately prior to procedure
Post-procedure		
Paracetamol	500mg 1-2 up to 8 in 24 hrs	TTO
Naproxen	250mg 1 up to 3 in 24 hrs	TTO

Mr. J. Clark, Consultant Obstetrician & Gynaecologist, Birmingham Women's Hospital, UK

Medication	Dosage	Time Course
Pre Procedure		
Voltarol or Ibuprofen	100mg PR 800 mg PO	1 hour before
Paracetamol	1g orally	
Cyclizine	50 mg orally	
Intra-procedure		
Nil routine Recourse to inhalational Nitrous Oxide at the patients discretion		
Post-procedure (All PRN, but usually only one dose of any of these pharmaceuticals required)		
Dihydrocodeine	30-60mg orally	6 hourly, PRN
Morphine	10-20mg orally or intramuscularly	2-4 hourly PRN
Stemetil	12.5mg intramuscularly	6-8 hourly PRN

Dr. S. Monaghan, Consultant Obstetrician & Gynaecologist, Queen Margaret Hospital, Scotland

Medication	Dosage	Time Course
Pre Procedure		
Paracetamol	1g	1hr pre-procedure
Ibuprofen	400mg	1hr pre-procedure
Or Tramadol	50mg	1hr pre-procedure (patient advised must not drive home)
Intra-procedure		
Lidocaine 6ml injected into cervix		
Post-procedure		
Ibuprofen	400mg	tid if required
Tramadol	50mg	bd if required

Ms. G. Smith, Nurse Consultant Northampton General Hospital, UK

Medication	Dosage	Time Course
Pre Procedure		
Diclofenac PR	100mg	1-1.5 hours before procedure, stat dose
Paracetamol	1g Oral	
Diazepam	5mg Oral	
Cyclizine	50mg Oral	
Intra-procedure		
<ul style="list-style-type: none"> Prilocaine 3% with Felypressin (Citanest) or Lidocaine Hydrochloride 2% w/v. Adrenaline (Epinephrine) tartrate expressed in base 1/80,000w/v.3 vials, Infiltration of the cervix 		
Post-procedure		
Patients advised to take analgesics for at least 24 hours post procedure		



Important Reminder:

While the information provided in this guide may describe a particular technique or protocol, it is not intended as a requirement to use this technique or protocol. It is the sole responsibility of the treating medical practitioner to determine which specific technique and/or protocol to employ for any given patient based on their professional medical judgment. It is also the treating medical practitioner's sole responsibility to determine if his or her practice is suitable for performing endometrial ablation and any associated pain management protocol in an outpatient setting.

Local Anaesthesia Medication Information

Medication	Usual Concentration	Usual Volume (ML)	Onset	Duration of Action	Maximum Dosage Guidelines (total cumulative infiltrative injection dose per procedure*)
Lidocaine ⁶	1%	5-20	slow (3-5 min)	Medium (30-60 min)	4.5mg/kg not to exceed 300 mg
Lidocaine with epinephrine ⁶	1%, epi 1:100,000 or 1:200,000	5-20	slow (3-5 min)	Long (120-360 min)	7mg/kg
Bupivacaine ⁶	0.25-0.5%	5-20	slow	Long (120-240 min)	2.5mg/kg not to exceed 175mg total dose
Bupivacaine with epinephrine ⁶	0.25-0.5%, epi 1:100,000 or 1:200,000	5-20	slow	Long (180-420 min)	Not to exceed 225mg total dose
Procaine ⁶	2%	5-20	fast-acting	Short (15-60 min)	7 mg/kg not to exceed 350-600mg
Chlorprocaine ⁶	2%	5-20	fast-acting	Short (15-30 min)	11 mg/kg not to exceed 800 mg total dose
Chlorprocaine with epinephrine ⁶	2%, epi 1:100,000 or 1:200,000	5-20	fast-acting	Short (15-30 min)	14 mg/kg; not to exceed 1000mg
Prilocaine ⁶	1%	5-20	slow	Medium (30-90 min)	<ul style="list-style-type: none"> Body weight <70kg: 8mg/kg not to exceed 500mg Body weight >70kg: 600mg
Ropivacaine ⁶	0.2-0.5%	5-20	slow	Long (120-360 min)	5 mg not to exceed 200 mg for minor nerve block
Mepivacaine ⁶	1%	5-20	slow	Medium (45-90 min)	7 mg/kg not to exceed 400mg
Prilocaine with felypressin ⁷	3%	1-5	fast-acting	Medium (45-120 min)	Not to exceed 300mg
Levobupivacaine ^{8, 9}	.25-.75%	28-60 ML	slow (10-15 min)	Long (3-12 hours)	Not to exceed 2.5mg/kg
Levobupivacaine with epinephrine ^{8, 10}	.25-.75%	28-60 ML	slow (10-15 min)	Long (4-12 hours)	Not to exceed 3.0mg/kg

* Nondental use, administer by small incremental doses. Administer the smallest dose and concentration required to achieve desired effect avoid rapid injection. Drug mg/mL concentration is calculated by moving the decimal point one place to the right on the percentage. Ex. Lidocaine 1% = 10 mg/mL, epi 1:100,000 =.01 mg/mL. General guidelines: All administrative agents should be accompanied by intermittent aspiration to avoid inadvertent intravascular injection.

Please consult the applicable package insert for full drug prescribing information, including dosage, risks and precautions.

Anaesthesia Considerations for Outpatient-Based Procedures

It is important to review applicable laws, regulations and guidelines for outpatient surgery to ensure that you are safely and effectively setting up your office. These guidelines may vary from country to country and locally, so you should consult with your local medical regulatory authority that govern outpatient-based procedures to learn which regulations apply to your practice.

For your reference, the following organisations have established outpatient surgery guidelines:

- The Royal College of Obstetricians and Gynaecologists
- The Royal College of Anaesthetists
- The British Society for Gynaecological Endoscopy
- The European Society for Gynaecological Endoscopy

Patient and Procedure Selection³

- The medical practitioner should be satisfied that the procedure to be undertaken is within the scope of practice of the health care practitioners and the capabilities of the facility.
- The procedure should be of a duration and degree of complexity that will permit the patient to recover and be discharged from the facility.
- Patients who by reason of pre-existing medical or other conditions may be at undue risk for complications should be referred to an appropriate facility for performance of the procedure and the administration of anaesthesia.

Please refer to local guidance

The following is a partial list of specific factors that should be taken into consideration when deciding whether anaesthesia in the outpatient setting is appropriate¹⁰

- Abnormalities of major organ systems, and stability and optimisation of any medical illness.
- Difficult airway, morbid obesity and/or obstructive sleep apnoea.
- Previous adverse experience with anaesthesia and surgery, including malignant hyperthermia.
- Current medications and drug allergies, including latex allergy.
- Time and nature of the last oral intake.
- History of alcohol or substance use or abuse.
- Presence of a vested adult who assumes responsibility specifically for accompanying the patient from the outpatient setting.

Facility and Safety³

- Facilities should comply with all applicable federal, state and local laws, codes and regulations pertaining to fire prevention, building construction and occupancy, accommodations for the disabled, occupational safety and health, and disposal of medical waste and hazardous waste.
- Policies and procedures should comply with laws and regulations pertaining to controlled drug supply, storage and administration.

Please refer to local guidance

Monitoring and Equipment³

- At a minimum, all facilities should have a reliable source of oxygen, suction, resuscitation equipment, the ability to provide positive pressure ventilation and emergency drugs.
- There should be sufficient space to accommodate all necessary equipment and personnel and to allow for expeditious access to the patient, anaesthesia machine (when present) and all monitoring equipment.
- All equipment should be maintained, tested and inspected according to the manufacturer's specifications.
- Back-up power sufficient to ensure patient protection in the event of an emergency should be available.
- In any location in which anaesthesia is administered, there should be appropriate anaesthesia apparatus and equipment which allow monitoring consistent with ASA "Standards for Basic Anesthetic Monitoring" and documentation of regular preventive maintenance as recommended by the manufacturer.

Emergencies and Transfers³

- All facility personnel should be appropriately trained in and regularly review the facility's written emergency protocols.
- There should be written protocols for cardiopulmonary emergencies and other internal and external disasters, such as fire.
- The facility should have medications, equipment and written protocols available to treat malignant hyperthermia when triggering agents are used.
- The facility should have a written protocol in place for the safe and timely transfer of patients to a pre-specified alternate care facility when extended or emergency services are needed to protect the health or well-being of the patient.

Please refer to local guidance

NovaSure[®]
Endometrial Ablation



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



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.

Per Product IFU AW-03935: The controller automatically calculates the optimal power level (W) required for the treatment of the uterine cavity, based on uterine size.



**For more information,
please visit:**

▶ gynsurgicalsolutions.com

▶ novasure.co.uk

Wear white again. [CO.UK](http://www.wearwhiteagain.co.uk)
HOLOGIC® Campaign

Or contact us:

▶ ukgynsurgical@hologic.com

References: **1.** Penninx JP, Mol BW, Bongers MY. Endometrial Ablation with Paracervical Block. J Reprod Med. Oct 2009; 54(10):617-620 **2.** Kalkat RK, Cartmill SV. NovaSure endometrial ablation under local anaesthesia in an outpatient setting: an observational study. J Obstet Gynaecol 2011;31:152–155. **3.** American Society of Anesthesiologists. Guidelines for Office-based Anesthesia (Approved by the ASA House of Delegates on October 13, 1999; last amended on October 21, 2009; and reaffirmed on October 15, 2014). <https://www.asahq.org/standards-and-guidelines/guidelines-for-office-based-anesthesia>. Accessed: 30.10.19. **4.** Skensved, Henrik. 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. Gynecological Surgery. 2012; 9 (2) pp 207-212. **5.** M. Davey, F.J.E Gardner. Paracervical Block with Fundal Infiltration (PBFi) provides superior pain control compared with Intracervical Block (IB) for NovaSure® Endometrial Ablation, a prospective audit. Department of Gynaecology, Queen Alexandra Hospital, Portsmouth, PO6 3LY. Presented at the RCOG World Congress, 2016. <https://www.epostersonline.com/rcog2016/node/8162>. Accessed: 30.10.19. **6.** eMedicine, Toxicity, Local Anesthetics. Available at <http://emedicine.medscape.com/article/819628-overview>. Accessed: 30.10.19. **7.** Data Sheet: 3% Citanest® DENTAL with Octapressin®. Available at <http://www.medsafe.govt.nz/profs/datasheet/c/Citanestwithoctapressininj.pdf>. Accessed: 30.10.19. **8.** Pharmacology of regional anaesthesia. Available at <http://www.frca.co.uk/article.aspx?articleid=100816>. Accessed: 30.10.19. **9.** Maximum Recommended Local Anaesthetic Doses for Adults. Available at <https://www.nuh.nhs.uk/download.cfm?doc=docm93jjjm4n5742>. Accessed: 30.10.19. **10.** Massachusetts Medical Society. Office-Based Surgery Guidelines. 2011; 1-66. <http://www.massmed.org/officebasedsurgery/#.XbnBKniCeM8>. Accessed: 30.10.19