

MOVING THE NOVASURE® PROCEDURE TO AN OUTPATIENT SETTING



A Guide to Paracervical and Intrauterine Fundal Blocks



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 blocks. 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 outpatient 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.



This is a general information tool for medical professionals. The information provided may suggest a particular technique or protocol however it is the sole responsibility of the medical professional to determine which technique or protocol is appropriate. At all times, clinicians remain responsible for utilising sound patient evaluation and selection practices, and for complying with all applicable rules and regulations regarding accreditation, anesthesia, reimbursement, and all other aspects of in-office procedures. In no event shall Hologic be liable for damages of any kind resulting from your use of the information presented.

Why use a paracervical block in the outpatient setting?

The paracervical and fundal blocks 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 of pain to 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 the 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



NovaSure[®] in the outpatient: clinical data

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 out of 10, or under during procedure

A randomised, double-blinded non-inferiority trial of 96 women to assess pain during endometrial ablation performed in the outpatient setting.⁴

Participants were randomised to paracervical anaesthesia combined with hysteroscopic fundal infiltration with anaesthetics or paracervical anaesthesia combined with hysteroscopic fundal infiltration with saline.

Results: Paracervical anaesthesia without fundal anaesthesia did not establish non-inferiority to the combination of paracervical anaesthesia and fundal infiltration with anaesthetics when both primary outcome variables of pain were taken into account (Numeric Rating Scale 5.0 versus 3.9 (mean difference 1.2 (95% CI 0.1–2.2)) and Faces Pain Score 5.4 versus 4.8 (mean difference 0.6 (95% CI -0.3–1.5))).

Conclusion: This study did not confirm non-inferiority of paracervical anaesthesia without fundal anaesthesia to the combination of paracervical anaesthesia with fundal anaesthesia in the reduction of pain during endometrial ablation and therefore provides no reason to leave out fundal anaesthesia. We recommend using fundal anaesthesia combined with paracervical anaesthesia to reduce pain during endometrial ablation in the office.

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. 9
Levobupivacaine	Queen Alexandra Hospital Princess Royal Hospital	pg. 10 pg. 11
Chirocaine	Princess Royal Hospital Colchester General Hospital	pg. 11 pg. 12
Lidocaine	University Hospital Wishaw	pg. 17
Bupivacaine	Liverpool Women's Hospital Derriford Hospital	pg. 13 pg. 16

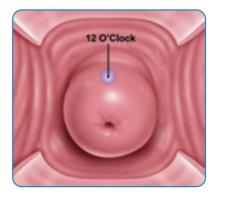
Intra and Paracervical anaesthesia regime examples

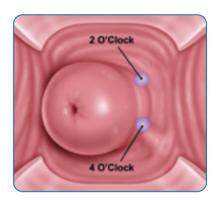
Ropivacaine	Dr. H. Skensved	pg. 9
Levobupivacaine	Queen Alexandra Hospital	pg. 10
Chirocaine	Colchester General Hospital	pg. 12
Prilocaine	Liverpool Women's Hospital	pg. 13
Lidocaine	Northampton General Hospital	pg. 15
Citanest	Northampton General Hospital	pg. 15
Scandonest	Princess Royal Hospital Derriford Hospital University Hospital Wishaw	pg.11 pg. 16 pg. 17
Local anaesthesia medication information		pg. 18

Protocols provided courtesy of the health care facilities listed. Please consult the applicable package insert for full drug prescribing information, including dosage, risks and precautions.

Paracervical Block Injection Sites

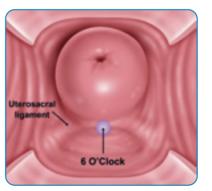
The following images represent examples of injection sites associated with the following paracervical block techniques.



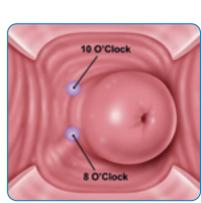


Example of an intracervical block

Example of a left paracervical block



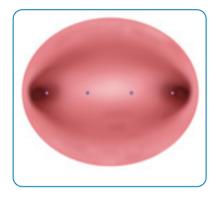
Example of a posterior paracervical and uterosacral block

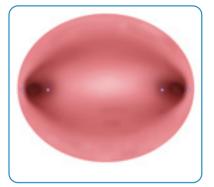


Example of a right paracervical block

Intrauterine Fundal Block Injection Sites

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





Skensved (2012)³ and Gardner (2016)⁵ injection sites

Skensved (2012)³ injection sites

Dr H. Skensved, Consultant Gynaecologist, Denmark³

Medication	Dosage
Pre-procedure	
Naproxen	500mg
Procedure	
Paracervical block*Inject a total of 40ml Ro	pivacaine 2mg/ml, 10ml at 3, 5, 7 and 9 o'clock

Fundal block

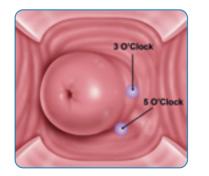
• Inject 4ml of Citanest[®] (30mg prilocaine/0.54µg felypressin per millilitre) into the fundal wall. 1ml placed medial to each tubal ostia; 2ml injected with 1ml on either side of the midline of fundus. Inject 4ml of Citanest (30mg prilocaine/0.54µg felypressin per millilitre) into the fundal wall. 1ml placed medial to each tubal ostia; 2ml injected with 1ml on either side of the midline of fundus.

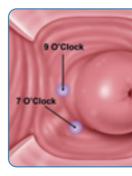
Post-procedure

Naproxen

250mg

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





As referenced above

Time Course

2 hours pre-procedure

k respectively.

4 and 8 hours post-procedure



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

Medication	Dosage	Time Course
Pre-procedure		
Paracetamol	1g PO	1-2 hours pre-procedure
Diclofenac	100mg PO	1-2 hours pre-procedure
Tramadol	50-100mg PO	1-2 hours pre-procedure
Ondansetron (Zofran®)	4mg PO	1-2 hours pre-procedure
Procedure		

Paracervical block

- Inject 2ml Levobupivacaine 0.25% in the anterior lip of cervix and use a tenaculum to manipulate the cervix
- Inject 4ml Levobupivicaine 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 repeatly down the track of each injection site

Fundal block

- Inject 2ml 0.25% Levobupivicaine 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. Ensure the injection is in the myometrium not the endometrium.

This is a guide for "standard patients" (approx 70kg). For small stature patients, reduce the dose appropriately.

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 & Mr. N. Biswas, Consultant Obstetrician & Gynaecologist, The Princess Royal Hospital, UK⁶

Medication	Dosage	Tin
Pre-procedure		
Diclofenac (Tramadol 100mg orally replaces diclofenac if contraindicated)	100mg PO	Ora
Oramorph	10mg PO	Ora
Odansetron	4mg	Ora

Intra-procedure

- 3 ampules Scandonest 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)

TOP TIP

 \checkmark If you have small hands then use a 2.5ml Luer Lock Syringe twice as its quite high pressure to squeeze a 5ml syringe

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

- 4ml Levobupivacaine
- 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)

ne Course

- rally 1 hour prior to the procedure
- rally 1 hour prior to the procedure
- rally 1 hour prior to the procedure

Mr F. Alfhaily, Consultant Gynaecologist, East Suffolk & North East NHS Foundation Trust / Colchester Site, UK⁷

Medication	Dosage	Time Course
Pre-procedure		
Paracetamol	1g	PO
lbuprofen	400mg	PO (unless contraindicated)
Intra-procedure		

Paracervical

• 2.5mg/ml Chirocaine 5 x 8ml injections (total 40mls) using yellow spinal needle

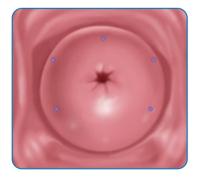
Intra-fundal

2ml of 2.5mg/ml Chirocaine injected into the fundus at 4-5 sites (depending on the technique) hysteroscopically using a cook cystoscopic needle

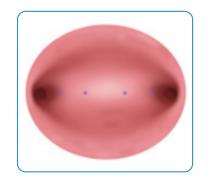
Post-procedure

NOTE: Very rarely required Paracetamol	1g	4 hourly post-procedure (max 4g in 24hrs, patients own medication)
lbuprofen	400mg	8 hourly post-procedure (patients own medication)

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



Paracervical



Intra-fundal

Mr. A. Soltan, Consultant Obstetrician & Gynaecologist, Liverpool Women's Hospital, UK⁸

Medication	Dosage
Pre-procedure	
Diclofenac (If patients do not want rectal suppository offer oral Ibuprofen 600g tablets instead)	100mg rectal sup
Paracetamol	1g oral
Ondansetron	4mg oral
Intra-procedure	
 Prilocaine 3% for cervical block (usually 3 ampoules; Option to position 12, 2, 5, 7, 10 (1/2 amp each positio then intracervically) + at 6:00 o'clock (intracervically) Bupivacaine 0.25% (or 0.5% diluted) for fundal block Entonox could be given as needed during the ablation 	n) or preferred opt (10-20mls dependi
Post-procedure (All PRN, options to consider as follo	ws)

Buscopan	20mg oral
Codeine	30-60mg
Ondansetron (If patient is nauseous/sick)	4mg
Tramadol (rarely needed)	50-100mg
Ibuprofen (If NSAIDS not administered prior to procedure consider)	400mg

If patients are unable to take NSAIs offer Codeine 30-60mg or Tramadol HCL 50-100mg 30-60 minutes prior to the procedure. Antibiotics are not routinely given because the risk of uterine / pelvic infection is low (<1:200). However, if patients are on immunosuppressants or other relevant risk factors prophylactic antibiotics may given. If difficult cervical dilatation anticipated consider 800 Mcg misoprostol administration.

Time Course

ppository 30-60mins pre-procedure

30-60mins pre-procedure

30-60mins pre-procedure

- administer intra-cervically option use only 12:00 (top for volsellum and

ding on cavity size)

QDS

Professor. J. Clark, Consultant Obstetrician & Gynaecologist, Birmingham Women's Hospital, UK⁹

Medication	Dosage	Time Course
Pre-procedure		
Co-codamol 30/500	2 tabs orally	
lbuprofen	800mg orally	
Ondansetron or Cyclizine	8mg orally 50mg orally	
Intra-procedure		
Nil routineOffered inhalational and	algesia with nitrous oxide or methoxy	flurane (Penthrox)
Post-procedure (All PRN, bu	t usually only one dose of any of these pharmace	auticals required)
Morphine	10-20mg orally or intramuscularly	2-4 hourly PRN
Stemetil	12.5mg intramuscularly	6-8 hourly PRN

Ms. G. Smith, Nurse Consultant, Northampton General Hospital, UK¹⁰

Medication	Dosage
Pre-procedure	
Diclofenac PR	100mg
Paracetamol	1g Oral
Diazepam	5mg Oral
Cyclizine	50mg Oral
Intra-procedure	

• 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 are advised to take analgesics for at least 24 hours post-procedure

Time Course

1-1.5 hours before procedure, stat dose

Mr. P. Scott, Consultant Obstetrician & Gynaecologist, Derriford Hospital, UK¹¹

	Time Course
1g	1hr pre-procedure
400mg	
625mg	
donest 3% into the	cervix
asts longer than Lig	nocaine) to the fundus in 4 areas - 2mls each
ms needle	
ć	400mg 625mg donest 3% into the asts longer than Lig

TTO of 100mls Oramorph 10mls

2 hourly / PRN if needed

Dr. Mihai Gherghe, Consultant Gynaecologist, University Hospital Wishaw, Scotland, UK¹²

Medication	Dosage	Time Course
Pre-procedure		
Ibuprofen (Alternative: Diclofenac 100mg PO)	800mg PO	
Paracetamol (Alternative if allergic to NSAIDS: Co-codamol 30/500mg x2 PO)	1000mg PO	30 – 45 min prior to procedure
Ondansetron	4mg PO	
Buscopan	20mg PO	
Intra-procedure		

Para-cervical block

3 ampules Scandonest 3%, 2.2mls each To be administered via dental syringe at 12, 3, 5, 7 and 9 o'clock in equal doses

Uterine Fundal block

6mls Lidocaine 1% (alternative: Chirocaine 2.5mg/mls, 6mls) To be administered using Cooks (Williams) needle via Storz Bettochi scope 10mls luer lock syringe filled to 6mls 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)

Inhalational Nitrous Oxide at the patient's discretion if there are no contra-indications

Post-procedure

At home - Patient to take own analgesia as needed

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

Local anaesthesia medication information

Medication	Onset of action	Duration of Action in Isolation	Maximum Dosage Guidelines (total cumulative infiltrative injection dose per procedure*)
Lidocaine ^{13,14,15}	1-3 min	30-120 min	3-4.5mg/kg not to exceed 300mg per dose
Lidocaine with epinephrine ^{13,14,15}	1-3 min	120-240 min	6-7mg/kg not to exceed 500mg per dose
Bupivacaine ^{13,14,15}	2-10 min	120-175 min	2-2.5mg/kg not to exceed 175mg per dose
Bupivacaine with epinephrine ^{13,14,15}	2-10 min	180-480 min	2.5-3mg/kg not to exceed 225mg per dose
Procaine ^{13,14}	-	20-30 min	7-10mg/kg not to exceed 1000mg total dose
Chloroprocaine ^{13,14}	6-12 min	30-60 min	10-12mg/kg not to exceed 800mg per dose
Chloroprocaine with epinephrine ^{13,14}	6-12 min	60-90 min	14mg/kg; not to exceed 1000mg per dose
Prilocaine ¹⁴	<2 min	120 min approx	 Body weight <70kg: 8mg/kg not to exceed 500mg Body weight >70kg: 600mg
Ropivacaine ^{13,14}	3-5 min	120-240 min	2-3mg not to exceed 225mg per dose
Mepivacaine ^{13,14}	3-20 min	45 - 90 min	4.5-5mg/kg not to exceed 400mg per dose
Prilocaine with felypressin ^{16,17}	2-3 min	45-120 min	Not to exceed 300mg
Levobupivacaine ^{13,15}	-	180-360 min	2mg/kg not to exceed 150mg per dose
Levobupivacaine with epinephrine ^{13,15}	-	180-360 min	2-3mg/kg

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 selection¹⁸

- 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

* 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% = 10mg/ml, epi 1:100,000 =.01mg/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.

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 appropriate¹⁹

- Abnormalities of major organ systems, and stability and optimisation of any medical illness
- Difficult airway, morbid obesity and/or obstructive sleep appoea
- 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 safety¹⁸

- 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

Monitoring and Equipment¹⁸

- 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 Transfers¹⁸

- 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





NovaSure[®] SmartDepth[™] technology gives Healthcare Professionals the confidence to perform safe and effective endometrial ablations – for every patient.



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 SureClear[™] fluid removal system provides constant tissue contact with the array through integrated suction while simultaneously removing steam, blood, and other by-products.



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.

Instructions for use per product MAN-07653: The controller automatically calculates the optimal power level (W) required for the treatment of the uterine cavity, based on uterine size.





Local analgesia animation -Maxima Medical Centre, NL:



Fundal block anaesthetic technique:



For more information. please visit:

▶ gynsurgicalsolutions.co.uk

▶ wearwhiteagain.co.uk

Or contact us:

▶ ukgynsurgical@hologic.com

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*Based on commercial data from Hologic Inc., units shipped from 2004-2018.

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