MOVING THE NOVASURE® PROCEDURE INTO YOUR OFFICE

A Physician's Guide to Paracervical and Intrauterine Fundal Block

NovaSure®
Endometrial Ablation

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

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

Now, going in office 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 adminster both blocks using different medications and techniques.

The following pages represent a guide to paracervical and intrauterine fundal block techniques and local anesthesia protocols that can help you maximize 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.

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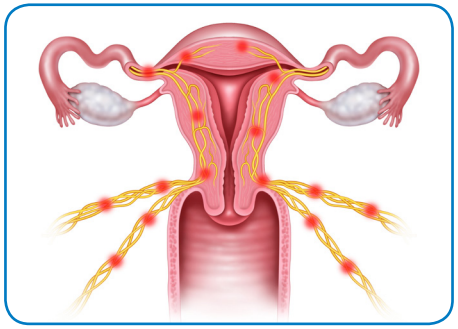
Why use a paracervical block in the office setting?

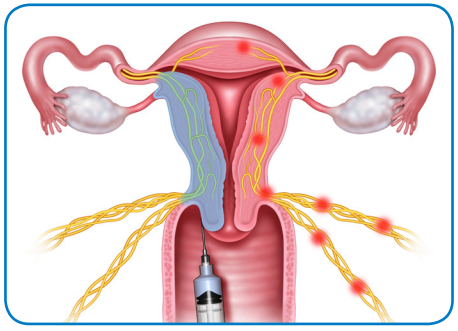
Paracervical and fundal block are local anesthetic techniques that can improve patient comfort for minor procedures in the office setting. They can be used for a variety of different office procedures, including the NovaSure endometrial ablation procedure, cervical biopsies, endometrial biopsies, and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

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

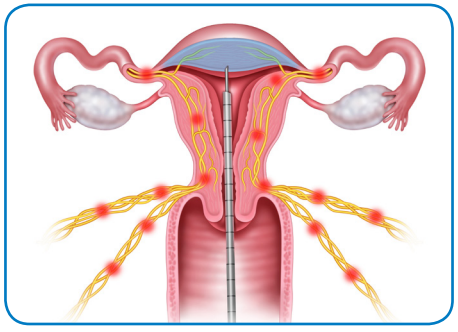
There are several protocols that describe the type of anesthetic agents to use and the locations to inject them. Understanding the blood supply and innervation of the uterus and cervix can help in planning where to safely inject the medications to achieve the best result.



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 anesthetic medication into the uterine region to block the impulses leaving the uterus.



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

NovaSure in the Office: Clinical Data

PARACERVICAL BLOCK PRIOR TO THE NOVASURE PROCEDURE

Prospective study of 33 patients to assess the safety of endometrial ablation under local anesthesia[6]

- 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 anesthesia acceptable

Prospective study of 47 patients to determine feasibility of the NovaSure procedure in the outpatient setting under local anesthesia[5]

- 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 procedure[4]

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

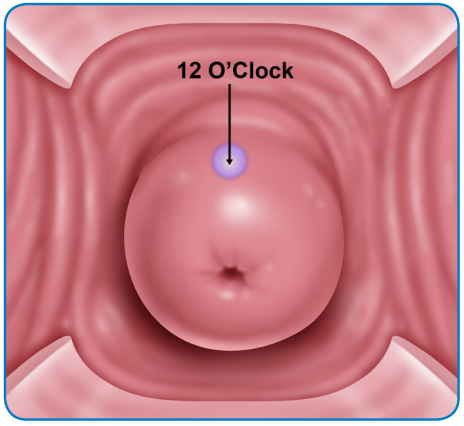
Paracervical Block Techniques including Oral Sedation Protocols

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

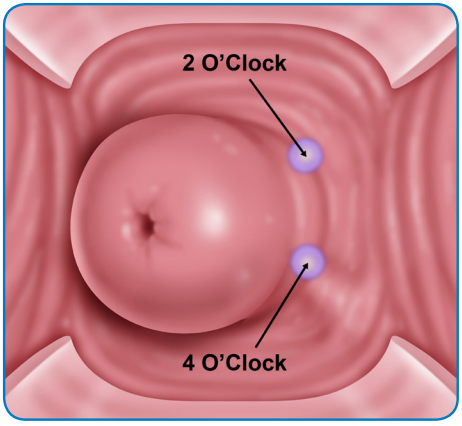
Protocols provided courtesy of the health care facilities listed. Please consult the applicable package insert for full drug prescribing information, including dosage, risks and precautions.

Paracervical Block Injection Sites

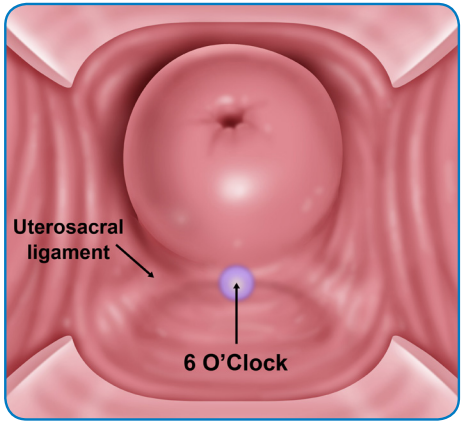
The following images represent examples of injection sites associated with the following paracervical block techniques.



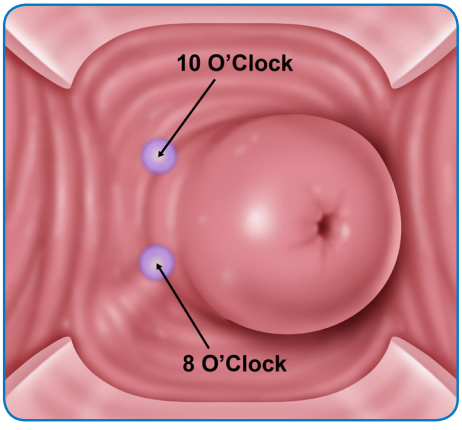
Example of an intracervical block



Example of a left paracervical block



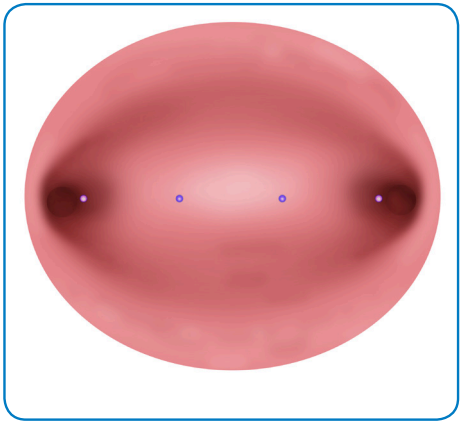
Example of a posterior paracervical and uterosacral block



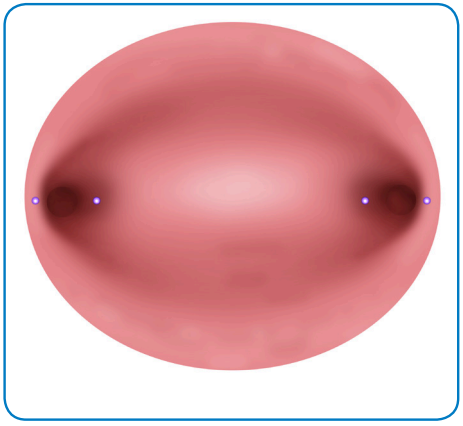
Example of a right paracervical block

Intrauterine Fundal Block Injection Sites

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



Skensved (2012) and Gardner (2016) injection sites



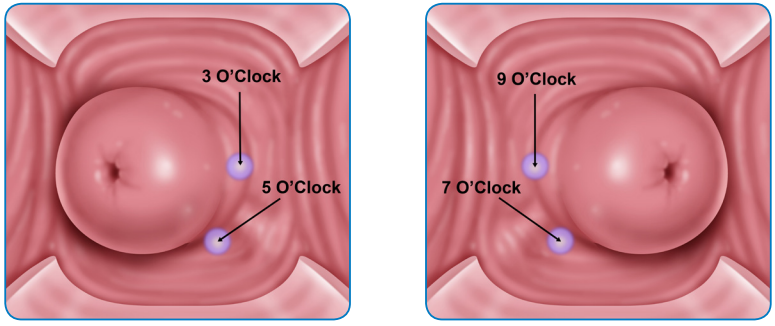
Skensved (2016) injection sites

DR. SKENSVED, CONSULTANT GYNAECOLOGIST[4]

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: Inject a total of 40 mL ropivacaine 2 mg/mL, 10 ml at 3, 5, 7 and 9 o'clock respectively. Fundal block: Inject 1 mL of Prilocaine 30 mg/mL, felypressin 0.54 µg/mL (3% Citanest® DENTAL with Octapressin®) above and below each ostia for a total of 4 mL 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.

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.



As referenced above

DR. ARRINGTON AT SOUTHWEST WOMEN'S HEALTHCARE ASSOCIATES

Medication	Dosage	Time Course
Pre Procedure		
Ibuprofen	800 mg PO	Q8 hours for 48 hours prior to procedure
Misoprostol (Cytotec®)	200 mg vaginally	6am and 6pm day prior to procedure
Alprazolam (Xanax®)	1 mg PO x 1	60-90 minutes before procedure
Oxycodone/acetaminophen (Percocet®)*	5/325 2 tabs PO x 1	60-90 minutes before procedure
Promethazine (Phenergan®)	25 mg PO x 1	60-90 minutes before procedure
Ketorolac (Toradol®)	30 mg IM	45-60 minutes before procedure
Procedure		
**0.5% ropivacaine (Naropin®) 30 cc mixed with 20 cc Saline. Use a 10 or 20 cc syringe with 22 gauge needle (needle extender helps) to inject 10 cc at 4, 8, 10, and 2 o'clock. Try to avoid 3 and 9 o'clock as it is proximal to the uterine vessels. The block is placed just medial to the cervico-vaginal reflection and is to be placed deep into the uterine musculature.		
Post Procedure		
Azithromycin (Zithromax®)	1 g PO to prevent infection	Upon returning home from procedure

*Should not be taken on an empty stomach.
**Paracervical block to be administered 20 minutes before NovaSure procedure.

DR. PELEKANOS AT FORBES REGIONAL HOSPITAL

Medication	Dosage	Time Course
Pre Procedure		
Ibuprofen (Motrin®)	800 mg	Take 1 Q8 hours starting 2 days before procedure – take 1 morning of procedure with breakfast
Oxycodone/acetaminophen (Percocet®)*	7.5 mg/325 mg	Given 1 hour prior to procedure
Alprazolam (Xanax®)	2 mg 1 PO	Given 1 hour prior to procedure
Ondansetron (Zofran®)	4 mg 1 PO	Given 1 hour prior to procedure
Ketorolac (Toradol®)	60 mg IM gluteal	Given 15-20 minutes prior to procedure
Procedure		
0.5% ropivacaine 30 cc mixed with 15 cc normal saline. Inject 2-3 cc at 12 o'clock prior to single tooth tenaculum placement. Try to use allis clamps to prevent bleeding. Use a needle extender and inject 10 cc at 2, 4, 8, and 10 o'clock.		
Post Procedure		
Oxycodone/acetaminophen (Percocet®)	7.5 mg/325 mg	Q4 hours day of procedure
Ibuprofen (Motrin®)	800 mg	Q8 hours for 12 to 24 hours post procedure into next day
Promethazine (Phenergan®) suppository (if needed)	25 mg	To be used only if patient is nauseated (to enable patient to take the Percocet as directed)

*Paracervical block administered 7-10 minutes prior to procedure.

DR. CORSI AT ASSOCIATED OB GYN

Medication	Dosage	Time Course
Pre Procedure		
Diazepam (Valium®)	10 mg	1 hour prior to procedure
Acetaminophen/hydrocodone (Norco®)	7.5 mg / 325 mg	1 hour prior to procedure
Ketorolac (Toradol®)	60 mg IM	1 hour prior to procedure
Procedure		
1.0% mepivacaine (Polocaine®). Inject 3 cc at 12 o'clock prior to single tooth tenaculum placement. Inject 10 cc superficial and deep (half superficial, then half deep) in each uterolsacral ligament at approximately 5 and 7 o'clock. Inject 7 cc in parametrium at 2 and 10 o'clock. Inject 3 cc at 6 o'clock.		
Post Procedure		
Ibuprofen (Motrin®)	600 mg	Q6 hours day after procedure
Acetaminophen/hydrocodone (Norco®)	7.5 mg	Q6 hours day after procedure

DR. GARDNER AT QUEEN ALEXANDRA HOSPITAL[11]

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: Inject 2 ml levobupivacaine 0.25% in the anterior lip of cervix and use a tenaculum to manipulate the cervix. Inject 4 ml levobupivicaine 0.25% at 11 and 1 o'clock. Inject 5 ml levobupivacaine 0.25% at 9, 3, 8, 4, 7 and 5 o'clock. Use a 35 mm needle with a normal syringe to aspirate prior to injecting repeatly down the track of each injection site. Fundal block: Inject 2 ml 0.25% levobupivicaine adjacent to the tubal ostia and 1 cm 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 2 ml 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 70 kg). For small stature patients, reduce the dose appropriately.		

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

11. *Paracervical Block with Fundal Infiltration (PBFI) provides superior pain control compared with Intracervical Block (IB) for NovaSure Endometrial Ablation, a prospective audit.* M. Davey, F.J.E Gardner. Department of Gynaecology, Queen Alexandra Hospital, Portsmouth, PO6 3LY. *Presented at the RCOG World Congress, 2016.

BASINKI AND JURAN, LLC[9]

Medication	Dosage	Time Course
Pre Procedure		
Ibuprofen	400 mg PO	Q8 hours day before procedure; stop morning of procedure
Misoprostol (Cytotec®)	200 mcg PO	Night before and morning of procedure
Ondansetron (Zofran®)	8 mg PO	3 hours prior to procedure
Ketorolac (Toradol®)	30 mg IV/nasal, 60 mg IM	1 hour prior to procedure
Promethazine (Phenergan®)	25 mg PO	1 hour prior to procedure
Diazepam (Valium®)	10 mg PO	1 hour prior to procedure
Hydrocodone/oxycodone	7.5 mg PO	1 hour prior to procedure
Procedure		
Combine 20 mL lidocaine 1% (total 200 mg, max 4.5 mg/kg), 10 mL of ropivacaine (Naropin®) 0.5% (total 50 mg, max 3 mg/kg), and 30 cc normal saline. Inject 1-2 cc at the 12 and 6 o'clock positions in cervix at areas of tenaculum placement. Grasp cervix at 6 o'clock position and lift cervix to expose uterosacral ligaments. Inject 10 cc into each uterosacral ligament in the posterior cervical fornix at the 4 and 8 o'clock positions. Grasp cervix at the 12 o'clock position. Inject 15 cc into each lateral fornix at the 3 and 9 o'clock positions*. *Injections are at the cervical-vaginal reflection and not into the cervical paremchyma approximately 2-3 mm below the mucosa.		

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

9. Basinski CM, Price P, Burkhart J, Johnson J. Safety and Effectiveness of NovaSure® Endometrial Ablation After Placement of Essure® Micro-Inserts. *Journal of Gynecologic Surgery.* 2012; 28(2):1-6.

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 physician 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 physician's sole responsibility to determine if his or her practice is suitable for performing endometrial ablation and any associated pain management protocol in an office setting.

Local Anesthesia Medication Information

Medication	Usual Concentration	Usual Volume (mL)	Onset	Duration of Action	Maximum Dosage Guidelines (Total Cumulative Infiltrative Injection Dose per Procedure*)
Lidocaine[1]	1%	5-20	slow (3-5 min)	Medium (30-60 min)	4.5 mg/kg not to exceed 300 mg
Lidocaine with epinephrine[1]	1%, epi 1:100,000 or 1:200,000	5-20	slow (3-5 min)	Long (120-360 min)	7 mg/kg
Bupivacaine[1]	0.25-0.5%	5-20	slow	Long (120-240 min)	2.5 mg/kg not to exceed 175 mg total dose
Bupivacaine with epinephrine[1]	0.25-0.5%, epi 1:100,000 or 1:200,000	5-20	slow	Long (180-420 min)	Not to exceed 225 mg total dose
Procaine[1]	2%	5-20	fast-acting	Short (15-60 min)	7 mg/kg not to exceed 350-600 mg
Chloroprocaine[1]	2%	5-20	fast-acting	Short (15-30 min)	11 mg/kg not to exceed 800 mg total dose
Chloroprocaine with epinephrine[1]	2%, epi 1:100,000 or 1:200,000	5-20	fast-acting	Short (15-30 min)	14 mg/kg; not to exceed 1000 mg
Prilocaine[1]	1%	5-20	slow	Medium (30-90 min)	Body weight <70 kg: 8 mg/kg not to exceed 500 mg Body weight >70 kg: 600 mg
Ropivacaine[1]	0.2-0.5%	5-20	slow	Long (120-360 min)	5 mg not to exceed 200 mg for minor nerve block
Mepivacaine[1]	1%	5-20	slow	Medium (45-90 min)	7 mg/kg not to exceed 400 mg
Prilocaine with felypressin[7]	3%	1-5	fast-acting	Medium (45-120 min)	Not to exceed 300 mg
Levobupivacaine[8, 10]	.25-.75%	28-60 mL	slow (10-15 min)	Long (3-12 hours)	Not to exceed 2.5 mg/kg
Levobupivacaine with epinephrine[8, 10]	.25-.75%	28-60 mL	slow (10-15 min)	Long (4-12 hours)	Not to exceed 3.0 mg/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.

Anesthesia Considerations for Office-Based Procedures

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

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

- American College of Surgeons (ACS)
- American Society of Anesthesiologists
- Professional liability insurers
- State regulatory agencies

Patient and Procedure Selection[3]

- The physician 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 anesthesia.

The following is a partial list of specific factors that should be taken into consideration when deciding whether anesthesia in the office setting is appropriate[2]

- Abnormalities of major organ systems, and stability and optimization of any medical illness.
- Difficult airway, morbid obesity and/or obstructive sleep apnea.
- Previous adverse experience with anesthesia 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 office.

Facility and Safety[3]

- 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 Equipment[3]

- 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, anesthesia 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 anesthesia is administered, there should be appropriate anesthesia 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 Transfers[3]

- 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.

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References: 1. eMedicine, Toxicity, Local Anesthetics. Available at http://emedicine.medscape.com/article/819628-overview. Accessed September 21, 2016. **2.** Massachusetts Medical Society. Office-Based Surgery Guidelines. 2011; 1-66. **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). **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.** Kalkat RK, Cartmill SV (2011) Novasure endometrial ablation under local anaesthesia in an outpatient setting: an observational study. J Obstet Gynaecol 31:152–155. **6.** Penninx JP, Mol BW, Bongers MY. Endometrial Ablation with Paracervical Block. *J Reprod Med.* Oct 2009; 54(10):617-620. **7.** Data Sheet: 3% Citanest® DENTAL with Octapressin®. Available at http://www.medsafe.govt.nz/profs/datasheet/c/Citanestwithoctapressininj.pdf. Accessed November 2, 2016. **8.** Pharmacology of regional anaesthesia. Available at http://www.frca.co.uk/article.aspx?articleid=100816. Accessed November 2, 2016. **9.** Basinski CM, Price P, Burkhart J, Johnson J. Safety and Effectiveness of NovaSure® Endometrial Ablation After Placement of Essure® Micro-Inserts. *Journal of Gynecologic Surgery.* 2012; 28(2):1-6. **10.** Maximum Recommended Local Anaesthetic Doses for Adults. Available at https://www.nuh.nhs.uk/handlers/downloads.ashx?id=60942. Accessed November 8, 2016. **11.** *Paracervical Block with Fundal Infiltration (PBFI) provides superior pain control compared with Intracervical Block (IB) for NovaSure Endometrial Ablation, a prospective audit.* M. Davey, F.J.E Gardner. Department of Gynaecology, Queen Alexandra Hospital, Portsmouth, PO6 3LY. *Presented at the RCOG World Congress, 2016.

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