

Frequently Asked Questions

Endometrial Biopsy using the Ipas MVA procedure

| What is Endometrial Biopsy?

Endometrial Biopsy is a safe, efficient, and cost-effective method for evaluating the endometrium. It is a minor procedure that consist of sampling a small part of the endometrium for examination. A thin tube (cannula) is inserted through the cervix into the uterus, and gentle scraping and suction are used to remove the sample.

| When should I perform an Endometrial Biopsy?

When your patient is experiencing any of the following symptoms, the evaluation of an endometrial sample can help you make a diagnosis:

- Heavy or very long menstrual periods
- Bleeding after menopause
- Irregular menstruation
- Abnormal bleeding
- Absence of bleeding
- Thickened uterine lining

| What can an Endometrial Biopsy reveal?

When your patient is experiencing one of the symptoms listed above, the following causes/conditions might be diagnosed from an Endometrial Biopsy:

- Dysfunctional uterine bleeding (DUB)
- Amenorrhea
- Endometrial cancer
- Endometrial infections
- Infertility

Endometrial Biopsy can also be used for some histology tests:

ERA®

Endometrial Receptivity Analysis Test

To determine the optimal timing for future embryo transfers, as part of fertility treatment.

E-Tegrity Test

The endometrium can be tested for the presence of substances that are important for embryo implantation.

Endometrial Pathology

The endometrium can be sampled to check for endometrial hyperplasia, and endometrial polyps¹.

Chronic Endometritis

An endometrial biopsy can be used to diagnose Chronic Endometritis, a low-grade infection of the uterine lining which can lead to miscarriage.



| What is a Manual Vacuum Aspirator?

The Ipas Manual Vacuum Aspirator is a simple, quiet, hand-held device that uses suction to sample uterine specimens for examination. The Manual Vacuum Aspirator can be used in an outpatient setting and is a comfortable and safe solution for the patient.

Why should I use the Ipas MVA for Endometrial Biopsy rather than other methods?

1

Convenience

The Ipas MVA is a simple, safe, effective and reliable method that is indicated for endometrial biopsy. It is also indicated for miscarriage management and post-abortion care.

2

Effectiveness

Compared to sharp curettage, the MVA for an endometrial biopsy is safer, less painful² and more effective than other techniques.

3


Cost Saving


Moreover, it costs 11% less and results in a hospital stay that is 27% shorter than a sharp curettage procedure³.


What do you need to perform an Endometrial Biopsy with MVA?

To practice an endometrial biopsy with MVA, you should use:

 <p>Single-Valve Aspirator</p>	<h3>Ipas Aspirators (sterile)</h3> <ul style="list-style-type: none">o Ready-to-useo Packed sterileo Latex-free plastico Comes in a pack of 10	 <p>Double-Valve Aspirator</p>
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	<h3>The 3mm Cannula for Endometrial Biopsy</h3> <ul style="list-style-type: none">o Disposable and packed sterileo Approximately 23 cm (9 in) in lengtho Latex-free
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	<h3>The Karman Flexible 4mm Cannula</h3> <ul style="list-style-type: none">o Disposable and packed sterileo Approximately 24 cm (9.5 in) in lengtho Latex-free
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	<h3>The 6mm Adaptor (for use with Double-Valve Aspirator)</h3> <ul style="list-style-type: none">o Enables the Ipas Double Valve Aspirator to be used with the 3mm and 4mm cannulao Comes in a pack of 5 unitso Packed non-sterileo Disposable or reusable where local regulations allow
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How to perform an Endometrial Biopsy with MVA⁴?

Before the procedure, make sure that your patient (see contraindications below):



is **NOT** pregnant

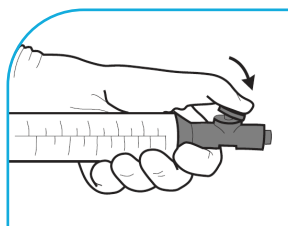


Does **NOT** take any medication that might interfere with the biopsy (blood thinners, etc.)

Preparing Ipas Cannulae and Aspirators

Instruments need to be sterile when they are inserted through the cervix. If sterility is not possible, high-level disinfection (HLD) is the only acceptable alternative. Before being inserted, the parts of dilators or cannulae that will enter the uterus should not touch objects or surfaces that are not sterile or treated with HLD, including the vaginal walls.

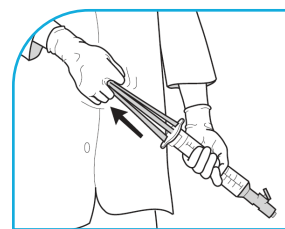
- o Have ready a 3mm or 4mm cannula and an aspirator.
- o **Inspect the aspirator.** To be effective, an aspirator must be able to hold a vacuum. Discard aspirators with any visible cracks or defects, or ones that do not hold a vacuum.
- o **Check the plunger and valve.** The plunger should be positioned all the way into the barrel and the pinch valve should be open, with the valve button out.
- o **Close the pinch valve** by pushing the button down and forward toward the aspirator tip. When closed, the valve will lock into place.



Closing the Pinch Valve on Ipas Single Valve Aspirator

- o **Prepare the aspirator** by grasping the barrel and pulling back on the plunger until the arms

of the plunger snap outward at the end of the aspirator barrel, holding the plunger in place. Check the stable positioning of the plunger arms. Both plunger arms must be fully extended to the sides and secured over the edge of the barrel. With the arms snapped in this position, the plunger will not move forward and the vacuum is maintained. Incorrect positioning of the arms could allow them to slip back inside the barrel, possibly pushing the contents of the aspirator or air into the uterus. *Never grasp the aspirator by the plunger arms.*



Creating the Vacuum

- o **Check the aspirator for vacuum tightness before use.** Leave the aspirator for several minutes with the vacuum established. Open the pinch valve by releasing the button. Air will rush into the aspirator, indicating that there was a vacuum in the aspirator. If there is not a rush of air, lubricate the o-ring with silicone and test the vacuum again. Replace the o-ring or use another aspirator if the aspirator still will not hold a vacuum.
- o **Repeat steps 3 through 6** to reestablish the vacuum at the time of the procedure.

Any instruments or parts of instruments that enter the uterus must be sterile or high-level disinfected. Observe a No-Touch Technique throughout the procedure: do not contaminate the cannula or allow the tip to touch objects or surfaces before being inserted through the cervical canal.

Step 1

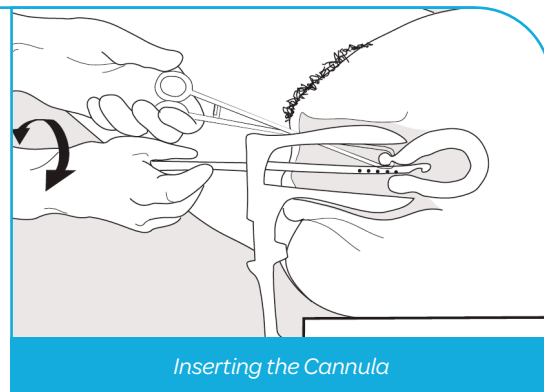
- With speculum inserted, **hold the cervix steady** with a tenaculum and gently apply traction to straighten the cervical canal.

Step 2

- **Dilate the cervix (if required).** When performing endometrial biopsy, cervical dilation is rarely necessary to allow passage of the 3mm or 4mm cannula, although it may be required in some instances. In some older women, particularly postmenopausal patients, the cervix may be so stenotic that dilation and passage of a cannula may not be possible in the outpatient setting.

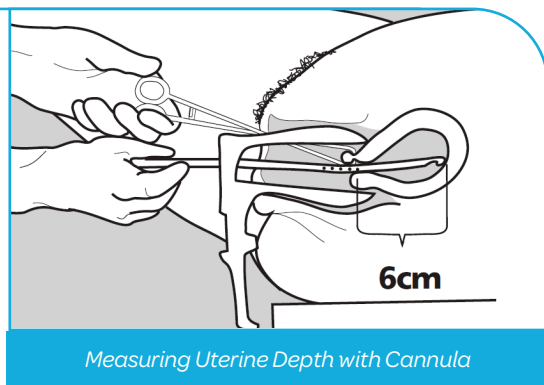
Step 3

- **Insert the cannula** gently through the cervix into the uterine cavity just past the internal os, while holding the cervix steady. Rotating the cannula with gentle pressure often helps ease insertion.



Step 4

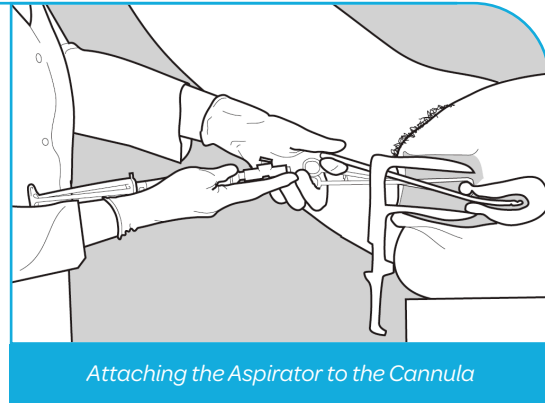
- **Push the cannula slowly into the uterine cavity** until it touches the fundus. Note the uterine depth by the dots visible on the cannula. The dot nearest the tip of the cannula is 6cm from the tip, and the other dots are at 1cm intervals.



After measuring the uterine size, withdraw the cannula slightly.

Step 5

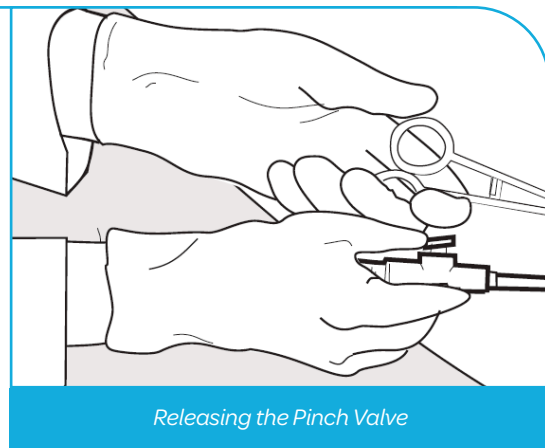
o **Attach the prepared aspirator** (vacuum established) to the cannula. With the index and thumb of one hand, hold the end of the cannula, and with the other fingers the tenaculum. Hold the aspirator with the other hand. Make sure that the cannula does not move forward into the uterus as you attach the aspirator.



Some providers prefer to attach the aspirator to the cannula before inserting the cannula through the cervical os.

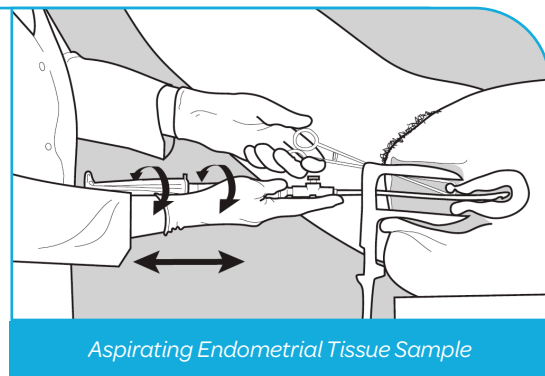
Step 6

o **Release the pinch valve** on the aspirator to transfer the vacuum through the cannula to the uterus. Blood, tissue and bubbles should begin to flow through the cannula into the aspirator.



Step 7

o Movement of the cannula inside the uterus may vary according to the purpose of the biopsy. Aspirate tissue sample by moving the cannula gently and slowly back and forth within the anterior uterine cavity, without going beyond the internal os. Then rotate the cannula and reinsert it until it touches the uterine fundus and aspirate the tissue sample from the posterior cavity in the same manner. In the case of hemostatic curettage (biopsy), move the cannula gently and slowly back and forth within the entire

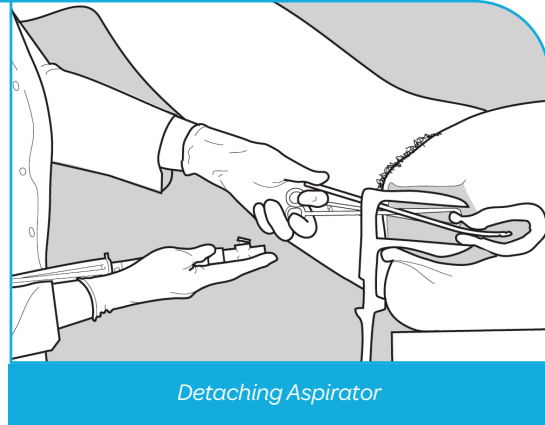


uterine cavity, rotating the aspirator as you do so. It is important not to withdraw the cannula apertures beyond the cervical os during the procedure.

- While the vacuum is established and the cannula is in the uterus, **never grasp the aspirator by the plunger arms** to ensure that they do not move from their locked position on the rim of the barrel. Accidentally allowing the plunger to slip back into the aspirator may push tissue or air back into the uterus, possibly causing complications.

Step 8

- **Complete the procedure.** The procedure may be quicker and produce less discomfort than biopsy with metal curettes, and is complete as soon as an adequate amount of tissue is obtained for pathological examination. Withdraw the cannula from the uterus. If the cannula is detached from the aspirator immediately following withdrawal, empty the contents of the aspirator into a fixative solution by opening the valve and pushing the plunger to eject aspirated tissue. If the cannula is not detached immediately following withdrawal from the uterus, the cannula may be used



to draw fixative into the aspirator, mixing the fixative with the aspirated tissue. Then the cannula is detached from the aspirator and the aspirated tissue is emptied into a specimen bottle containing fixative.

Prepare and deliver specimen in accordance with local laboratory requirements. (Do not reinsert the cannula into the uterus after flushing with fixative.)

Step 9

- **Decontaminate** and process all instruments appropriately.

Manual vacuum aspiration is a procedure that involves minimal trauma to the uterus and cervix. However, in a small percentage of cases, one or more of the following complications may occur: uterine or cervical perforation, hypotension, vagal reaction, pelvic infection, or air embolism. Some of these conditions can lead to secondary infertility or other serious injury, or, in some cases, death.

| What is the recovery time?

Recovery time is very short with an MVA procedure; the patient should be kept in observation for half an hour after the procedure and be recommended to rest for the rest of the day.

| What are the benefits of using the Ipas MVA for Endometrial Biopsy⁵?

Moreover, studies confirmed the following advantages of using the DKT WomanCare Global Endometrial Biopsy Kit (aspirator + cannula + adaptor):

- It's a simple, safe and effective technique for Endometrial Biopsy
- Highly comfortable procedure
- Enables aspiration of 'long strip (thread) like tissues' that are less mixed with blood, therefore increased accuracy (adequate samples above 97%)
- Shorter operating time (5 min) with least complications.
- The use of MVA yielded more adequate specimen thus higher accuracy in diagnostic results.
- Less pain, less blood loss and less cramping.
- Outpatient procedure.

| What are the contraindications of Endometrial Biopsy?

There are a few absolute contraindications for endometrial biopsy⁶:

- Pregnancy
- Acute pelvic inflammatory disease
- Acute cervical infection
- Acute vaginal infection
- Cervical cancer



| References

¹ Source: <https://www.academiawomenshealth.com/endometrial-pathology-hyperplasia-and-endometrial-polyps/>

² Kitiyodom S. The adequacy of endometrial sampling: comparison between manual vacuum aspiration and metal curettage method. *J Med Assoc Thai.* 2015;98(6):523-527.

³ Foster-Rosales A, Koontz SL, Molina de Perez O, Leon K. Cost savings of manual vacuum aspiration for endometrial sampling in El Salvador. *Contraception.* 2003 Nov;68(5):353-7. doi: 10.1016/j.contraception.2003.08.007. PMID: 14636939.

⁴ Forrest C. Greenslade, Ph.D.; José David Ortiz Mariscal, M.D.; Marian Abernathy, MPH. Endometrial Sampling Technologies for the Office or Clinic. *Resources for Women's Health.* Volume 1, Number 1, October 1997.

⁵ Greenslade Ph.D, F., Ortiz Mariscal, M.D., J. and Abernathy, MPH, M., 1997. Endometrial Sampling Technologies For The Office Or Clinic. 1st ed.

⁶ Will AJ, Sanchack KE. Endometrial Biopsy. [Updated 2020 Jun 28]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK541135/>



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