

PERFORMING MANUAL VACUUM ASPIRATION (MVA)

Using the Ipas MVA Plus®, 3mm and Ipas EasyGrip® Cannulae

FOR INTERNATIONAL DISTRIBUTION

THE IPAS MVA PLUS ASPIRATOR, 3MM* AND IPAS EASYGRIP CANNULAE

To be used by trained healthcare professionals. These instructions are intended as a general guideline only, and are not to supersede institutional protocols or clinical judgement.

*The Ipas 3mm cannula is a dedicated product for endometrial biopsy.

Intended Use/Indications

The Ipas MVA Plus aspirator, 3mm and Ipas EasyGrip cannulae up to 12mm are intended for uterine aspiration/uterine evacuation in obstetrics and gynecology patients. Clinical indications for uterine aspiration with this product are:

- Treatment of incomplete abortion for uterine sizes up to 12 weeks from the last menstrual period (LMP)
- First-trimester abortion/menstrual regulation
- Endometrial biopsy

Applications for endometrial biopsy may include cases of infertility, abnormal uterine bleeding, amenorrhea, and screening for endometrial cancer or screening for endometrial infections.

Endometrial biopsy should not be performed in cases of suspected pregnancy. There are no known contraindications for treatment of incomplete abortion for uterine sizes up to 12 weeks LMP or first trimester abortion (menstrual regulation).

Precautions

Before uterine aspiration, any serious medical conditions that are present should be addressed immediately. These include shock, hemorrhage, cervical or pelvic infection, sepsis, perforation, or abdominal injury, as may occur with incomplete abortion or with clandestine abortion. Uterine aspiration is often an important component of definitive management in these cases and once the patient is stabilized, the procedure should not be delayed. History of blood dyscrasia may be a factor in the woman's care. In cases where the woman has a history of a blood-clotting disorder, the cannulae should be used only with extreme caution and only in facilities where full emergency backup care is available.

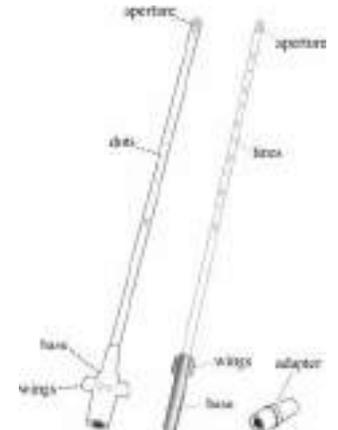
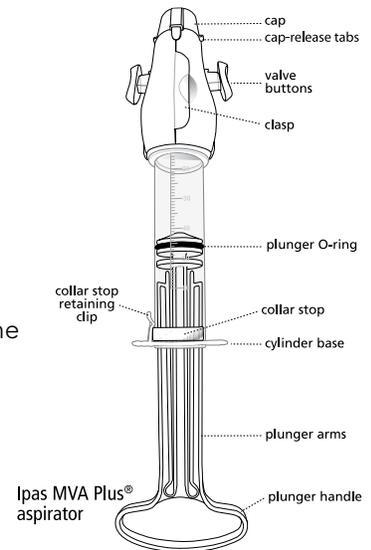
Warnings

Uterine aspiration is a procedure that involves minimal trauma to the uterus. However, in a small percentage of cases, one or more of the following may occur during or after the procedure: uterine or cervical injury or perforation, pelvic infection, vagal reaction, incomplete evacuation, or acute hematometra. Some of these conditions can lead to secondary infertility, serious injury or death.

PERFORMING THE MVA PROCEDURE

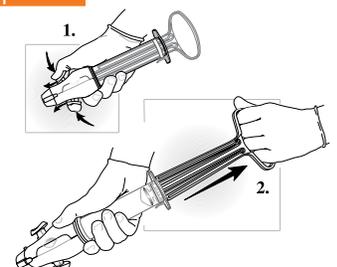
Step One: Prepare the Aspirator

- Position the plunger all the way inside the cylinder.
- Have collar stop in place with tabs in the cylinder holes.
- Push valve buttons down and forward until they lock (1).
- Pull plunger back until arms snap outward and catch on cylinder base (2).



Ipas EasyGrip cannula and Ipas 3mm cannula with adapter

Step One



Step Two



Step Two: Prepare the Patient

- Administer pain medication to have maximum effect when procedure begins.
- Give prophylactic antibiotics to all women, and therapeutic antibiotics if indicated.
- Ask the woman to empty her bladder.
- Conduct a bimanual exam to confirm uterine size and position.
- Insert speculum and observe for signs of infection, bleeding or incomplete abortion.

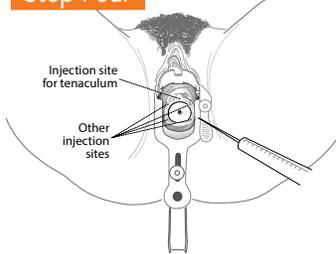
Step Three



Step Three: Perform Cervical Antiseptic Prep

- Use antiseptic-soaked sponge to clean cervical os. Start at os and spiral outward without retracing areas. Continue until os has been completely covered by antiseptic.

Step Four



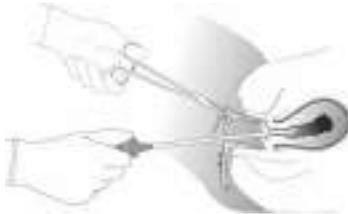
Step Four: Perform Paracervical Block

- Paracervical block is recommended when mechanical dilatation is required with MVA.
- Perform paracervical block with 1% lidocaine, 20cc. Inject 2cc into the cervix at the tenaculum site. Inject the remaining 18cc in equal doses at the cervicovaginal junction at 2, 4, 8 and 10 o'clock. Always aspirate before injecting to prevent intravascular injection of lidocaine.

Step Five: Dilate Cervix

- Observe no-touch technique when dilating the cervix and during aspiration. Instruments that enter the uterine cavity should not touch your gloved hands, the patient's skin, the woman's vaginal walls, or unsterile parts of the instrument tray before entering the cervix.
- Use mechanical dilators or progressively larger cannulae to gently dilate the cervix to the right size

Step Six



Step Six: Insert Cannula

- While applying traction to tenaculum, insert cannula through the cervix, just past the os and into the uterine cavity until it touches the fundus, and then withdraw it slightly.
- Do not insert the cannula forcefully.

Step Seven: Suction Uterine Contents

- Attach the prepared aspirator to the cannula if the cannula and aspirator were not previously attached.
- Release the vacuum by pressing the buttons.
- Evacuate the contents of the uterus by gently and slowly rotating the cannula 180° in each direction, using an in-and-out motion.
- When the procedure is finished, depress the buttons and disconnect the cannula from the aspirator. Alternatively, withdraw the cannula and aspirator without depressing the buttons.

Step Eight: Inspect Tissue

The MVA procedure is not complete until products of conception have been inspected and confirmed.

- Empty the contents of the aspirator into a container.
- Strain material, float in water or vinegar and view with a light from beneath.
- Inspect tissue for products of conception, complete evacuation and molar pregnancy.
- If inspection is inconclusive, reaspiration or other evaluation may be necessary.

Step Eight



Step Nine: Perform Any Concurrent Procedures

- When procedure is complete, proceed with contraception or other procedures, such as IUD insertion or cervical tear repair.

Step Ten: Process Instruments

- Immediately process or discard all instruments, according to local protocols.

Signs that indicate the uterus is empty:

- Red or pink foam without tissue is seen passing through the cannula.
- A gritty sensation is felt as the cannula passes over the surface of the evacuated uterus.
- The uterus contracts around or grips the cannula.
- The patient complains of cramping or pain, indicating that the uterus is contracting.

BASICS OF INFECTION PREVENTION

- Wash hands immediately before and after every patient contact.
- Consider all blood and body fluids from all patients to be potentially infectious.
- Use personal protective barriers (gloves, gowns, face protection, shoes) when contact with blood or other body fluids is expected.
- Avoid skin punctures, especially when handling needles.
- Use *No-Touch Technique*: The tip of the cannula, or the tip of any other instrument that enters the uterus, should never touch nonsterile surfaces (including the vaginal walls) prior to insertion.

Step 1: Decontamination soak

Immediately following the procedure, all Ipas MVA Plus Aspirators and Ipas EasyGrip Cannulae that will be reused should be kept wet until cleaning. A disinfectant such as a 0.5% chlorine solution can be used.

CAUTION: Aspirators and cannulae are not safe to handle with bare hands until cleaned.

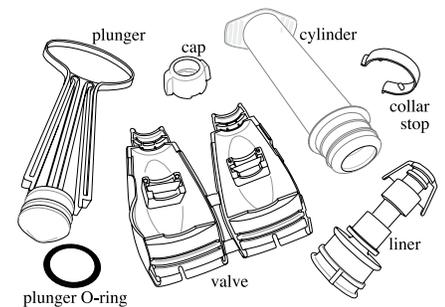
Step 2: Clean and Disassemble Instruments

- Clean all instrument surfaces thoroughly in warm water and preferably detergent, not soap. Wear gloves and face protection.
- Disassemble the aspirator by pulling the cylinder out of the valve. Remove the cap by pressing down the cap-release tabs with one hand and pulling off the cap with the other hand.
- Open the hinged valve by pulling open the clasp. Place the right thumb alongside the right valve button and the left thumb on the valve latch. With the left thumb, pull up and to the left on the valve latch while pushing down and out on the valve body with the right thumb. Remove the valve liner.
- Disengage the collar stop by sliding it sideways under the retaining clip, or remove the collar stop completely.
- Pull the plunger completely out of the cylinder. Displace plunger O-ring by squeezing its sides and rolling it into the groove below.
- Instruments must be completely clean before further processing. If tissue is trapped in the tip of a cannula, flush water through the cannulae repeatedly or use a cotton-tipped probe, soft brush or soft cloth to gently remove material. If unable to remove blood or tissue during cleaning despite repeated attempts, discard the instrument.

CAUTION: Do not use any pointed or sharp objects to clean the valve parts or to move the O-ring. This could cause damage and prevent the aspirator from maintaining a vacuum.

Step 3: Processing Options

The Ipas MVA aspirator does not directly touch the woman's body. However, when it is used, the cylinder fills with blood. There is the potential risk that some contaminants from a previous woman could be introduced to another woman if the MVA aspirator is not fully processed (soaked, cleaned and sterilized or HLD) between each use. Therefore, after cleaning, the Ipas MVA Plus must undergo high-level disinfection or sterilization between patients to remove contaminants. Once processed, the aspirator may be kept in a clean container. Aspirators must be completely disassembled for all processing methods. Ipas EasyGrip Cannulae require HLD or sterilization before re-use and must be HLD or sterile when inserted into the uterus. Chemical processing agents are hazardous substances. When processing instruments, take necessary precautions, such as using personal protective equipment. Refer to the manufacturer's safety instructions to establish safe use.



For optimal infection prevention, items should be processed using a method that provides the highest level of effectiveness. Use one of the following methods, listed in order of effectiveness:

Sterilize

- Steam autoclave in linen or paper for 30 minutes at 121°C (250°F). DO NOT USE OTHER AUTOCLAVE SETTINGS, SPECIFICALLY DO NOT USE HIGHER SETTINGS (“FLASH AUTOCLAVING”). Lay package flat in the autoclave to avoid bending of cannulae.
- Place Ipas MVA Plus Aspirator in STERRAD® 100S processor for 55 minutes in an approved tray or peel pack, along with a chemical indicator strip.
- Soak completely immersed in 2% glutaraldehyde solution (Cidex® or equivalent) for 10 hours or per manufacturers instructions.
- Soak completely immersed in Sporox® II solution for 6 hours.

High-Level Disinfect

- Boil for 20 minutes. Grasping hot cannulae may cause flattening. Let water cool before removing cannulae and handle by the adapter/base.
- Soak completely immersed in a 0.5% chlorine solution for 20 minutes. Change chlorine solution daily or sooner if solution becomes cloudy.
- Soak completely immersed in 2% glutaraldehyde solution (Cidex® or equivalent) for 20 minutes or per manufacturers instructions.
- Soak completely immersed in Sporox® II solution for 30 minutes.

After Processing MVA Instruments

- If chemical agents were used in processing, Ipas EasyGrip Cannulae are to be thoroughly rinsed with either boiled water (for instruments that were HLD) or sterile water (if instrument was sterilized) after processing. Ipas MVA Plus Aspirator parts can be thoroughly rinsed in clean potable water (drinking water).

Step 4: Store or Use Immediately

Storage

- Store instruments in a clean, dry container protected from contaminants, in an environment that preserves the level of processing desired. Keep only a small number of instruments in each container. Handle cannulae by the base ends. Instruments processed by wet methods should ideally be reprocessed daily.

Assembly and Use

- Before use, reassemble, lubricate and check vacuum capability of the aspirator.
- Place the valve liner in position inside the valve by aligning the internal ridges. Close the valve until it snaps in place. Snap the cap onto the end of the valve. Push the cylinder into the base of the valve without twisting.
- Place the plunger O-ring in the groove at the end of the plunger and lubricate it by spreading one drop of lubricant around the O-ring with a fingertip. Silicone or other non-petroleum-based lubricants can be used. Squeeze the plunger arms and insert the plunger fully into the cylinder. Move the plunger in and out to lubricate the cylinder. Insert the tabs of the collar stop into the holes in the cylinder.
- Check vacuum by pushing the buttons down until they lock, and pulling the plunger back until the plunger arms lock. Leave in this position for two to three minutes, then release buttons. A rush of air indicates that the aspirator maintained the vacuum.
- If you do not hear the rush of air, remove the plunger. Check the plunger O-ring and instrument for foreign particles and cracks. If the aspirator still loses vacuum, it should be discarded.