Step 3: Processing Options

The Ipas MVA Plus and any adapters used are multiple-use devices that require high-level disinfection or sterilization prior to first use and after each procedure to remove contaminants. Aspirators do not need to remain high-level disinfected or sterile for the next use.

Ipas EasyGrip cannulae require high-level disinfection (HLD) or sterilization before re-use and must be HLD or sterile when inserted into the uterus.

The Ipas 3mm cannulae are single-use devices. After use, treat and dispose as infectious waste.

High-Level Disinfect

- boil for 20 minutes.
- 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 a 2% glutaraldehyde solution (Cidex® or other equivalent solutions) for 20 minutes or per manufacturer's instructions.
- Soak completely immersed in Cidex OPA for 12 minutes.
- Soak completely immersed in Sporox®II solution for 30 minutes.

Sterilize

- Steam autoclave in linen or paper for 30 minutes at 121°C (250°F) with a pressure of 106 kPa (15 lbs/in²).
- 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.
- Soak completely immersed in a 2% glutaraldehyde solution (Cidex® or other equivalent solutions) for 10 hours. See OSHA precautions for use: www.osha.gov/SLTC/etools/hospitalhazards/glutaraldehyde/glut.html, 3/26/08.
- Soak completely immersed in a 2% glutaraldehyde (Cidex® or other equivalent solutions) for 10 hours or per manufacturers’ instructions.
- Soak completely immersed in Sporox®II solution for 6 hours.
- Place (aspirators and adapters only) in STERRAD® 100S processor for 55 minutes in an approved container.

After processing MVA Instruments

If chemical agents were used in processing, rinse all parts with either boiled water (for instruments that were HLD) or sterile water (if instrument was sterilized) after processing.

Step 4: Store or Use Immediately

Store: Store instruments in a clean, dry container protected from contaminants, in an environment that preserves the level of processing desired. Handle cannulae by the base ends. Instruments processed by wet methods (glutaraldehyde, chlorine, boiling water) should ideally be reprocessed daily.

Before Use: Reassemble, lubricate and check the vacuum 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 straight 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 another non-petroleum-based lubricant 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 the vacuum by pushing the buttons and pulling the plunger until the arms lock. Leave in this position for two to three minutes, then release the buttons. A rush of air indicates that the aspirator maintained the vacuum.
- If no rush of air is heard, 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.

U.S. Patent and Trademark Office Reg. No. Ipas MVA Plus® 2,907,186  Ipas EasyGrip® 2,768,302

Performing Manual Vacuum Aspiration (MVA) Using the Ipas MVA Plus®, Ipas 3mm and Ipas EasyGrip® Cannulae

The Ipas MVA Plus Aspirator, Ipas 3mm* and Ipas EasyGrip Cannulae

Manual vacuum aspiration, or MVA, is a technique for uterine aspiration whose low cost, simplicity and portability make it an especially valuable reproductive-health technology. Over 30 years of clinical research and use in more than 100 countries has shown vacuum aspiration to be safe and effective. MVA offered in outpatient settings has been shown to reduce the cost and length of stay related to uterine aspiration as compared to procedures performed in an operating room. MVA is also an excellent alternative to electric vacuum aspiration, producing an equivalent vacuum.1

This document provides an overview of the Ipas MVA Plus aspirator, Ipas 3mm and Ipas EasyGrip cannulae.

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

Indications

The Ipas MVA Plus aspirator, Ipas 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)
- Endometrial biopsy

Endometrial biopsy should not be performed in cases of suspected pregnancy. There are no known contraindications for other clinical indications.

Pre-existing Conditions to Consider

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. Uterine aspiration is often an important component of definitive management in these cases. Once the patient is stabilized, the procedure should not be delayed. History of blood dyscrasia may be a factor in the woman’s care.

Complications

As with any uterine aspiration procedure, one or more of the following may occur during or after the procedure: uterine or cervical injury or perforation, pelvic infection, vaginal 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 and Check Instruments

- 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 at the same time until they lock (1).
- Pull plunger back until arms snap outward and catch on cylinder base (2). This “charges” the instrument.
- Check vacuum by leaving the instrument in the “charged” position for two to three minutes, then release the buttons. A rush of air indicates that the aspirator maintained a vacuum.
- If no rush of air is heard, 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.

Step Two: Prepare the Patient
- Ask the woman to empty her bladder.
- Conduct a bimanual exam to confirm uterine size and position.
- Insert speculum.

Step Three: Perform Cervical Antiseptic Prep
- Clean cervical os with antiseptic.
- Follow No-Touch Technique: no instrument that enters the uterus can contact contaminated surfaces before being inserted through the cervix.

Step Four: Perform Paracervical Block
- Perform paracervical block as appropriate.
- Using local protocols, administer paracervical block and place tenaculum.
- Use lowest anesthetic dose possible to avoid toxicity. If using lidocaine, the recommended dose is less than 200 mg/person.

Step Five: Dilate Cervix
- If the cervix is insufficiently dilated, use mechanical dilators or progressively larger cannulae to dilate.
- Dilate the cervix to allow a cannula approximate to the uterine size to fit snugly through the os.

Step Six: Insert Cannula
- Note: Ipas 3mm and Ipas EasyGrip cannulae have been sterilized with ethylene oxide and will remain sterile until the stated expiration date, as long as their package is intact. Ipas 3mm cannulae should be discarded after a single use.
- While applying traction to the tenaculum, insert the 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.
* For endometrial biopsy, use the Ipas 3mm cannula with an adapter.

Step Seven: Suction Uterine Contents
- Attach the cannula to the prepared aspirator.
- Release the vacuum by pressing the buttons.
- Evacuate the contents of the uterus by gently and slowly rotating the cannula 180 degrees in each direction while using a gentle in-and-out motion.
- For endometrial biopsy, aspirate tissue by moving the cannula gently back and forth along the uterine wall, taking the appropriate sample.
- When finished, depress the buttons and withdraw the instruments.
* For endometrial biopsy, withdraw instruments when an adequate amount of tissue is obtained.

NOTE: If more than one aspirator is required to empty the uterus:
(1) Detach the cannula from the aspirator, leaving the cannula in place. Empty the aspirator, recharge it and carefully reattach it to the cannula. Resume evacuation.
OR
(2) Have a second aspirator readily available if more than one aspirator is needed.

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.
- Inspect tissue for products of conception by straining material or floating material in water or vinegar and viewing with a light from beneath.

Step Nine: Perform Any Concurrent Procedures
- When the procedure is complete, proceed with any contraception or other concurrent procedures, such as IUD insertion.

Step Ten: Process Instruments
- Process the aspirator, EasyGrip cannulae and adapters according to site protocols.

Processing the Ipas MVA Plus Aspirator, Ipas EasyGrip Cannulae and Adapters

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 aspirators, EasyGrip cannulae and adapters that will be reused should be kept wet until cleaning. Letting them dry may make it difficult to completely remove all contaminants. Using a 0.5% chlorine solution is an option. See OSHA precautions for use: www.osha.gov/SLTC/healthguidelines/chlorine/recognition.html, 03/26/08.

Caution: Instruments are not safe to handle with bare hands until cleaned.

Step 2: Clean aspirators, EasyGrip cannulae and adapters thoroughly in warm water and detergent, not soap. Wear gloves and face protection.
- If tissue is trapped in the tip of a cannula, flush water through the cannula repeatedly or use a cotton-tipped probe, soft brush or soft cloth to gently remove material.
- 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 clasps. Place right thumb alongside the right valve button and 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. Displace the plunger O-ring by squeezing its sides and rolling it into the groove below.

Do not use pointed or sharp objects to clean the valve parts or remove the O-ring. This could cause damage and prevent the device from maintaining vacuum.
- Instruments must be completely clean before further processing. If unable to remove blood or tissue from instruments during cleaning despite repeated attempts, discard the instrument.

Note: Ipas 3mm and Ipas EasyGrip cannulae have been sterilized with ethylene oxide and will remain sterile until the stated expiration date, as long as their package is intact. Ipas 3mm cannulae should be discarded after a single use. If inspection is inconclusive, reappraisal may be necessary. If indicated, follow clinic protocols to rule out ectopic pregnancy.

Endometrial biopsy samples should be handled according to laboratory protocols.
Step Two: Prepare the Patient
- Ask the woman to empty her bladder.
- Conduct a bimanual exam to confirm uterine size and position.
- Insert speculum.

Step Three: Perform Cervical Antiseptic Prep
- Clean cervical os with antiseptic.
- Follow No-Touch Technique: no instrument that enters the uterus can contact contaminated surfaces before being inserted through the cervix.

Step Four: Perform Paracervical Block
- Perform paracervical block as appropriate.
- Using local protocols, administer paracervical block and place tenaculum.
- Use lowest anesthetic dose possible to avoid toxicity. If using lidocaine, the recommended dose is less than 200 mg/person.

Step Five: Dilate Cervix
- If the cervix is insufficiently dilated, use mechanical dilators or progressively larger cannulae to dilate.
- Dilate the cervix to allow a cannula approximate to the uterine size to fit snugly through the os.

Step Six: Insert Cannula
- Note: Ipas 3mm and Ipas EasyGrip cannulae have been sterilized with ethylene oxide and will remain sterile until the stated expiration date, as long as their package is intact. Ipas 3mm cannulae should be discarded after a single use.
- While applying traction to the tenaculum, insert the 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 cannula to the prepared aspirator.
- Release the vacuum by pressing the buttons.
- Evacuate the contents of the uterus by gently and slowly rotating the cannula 180 degrees in each direction while using a gentle in-and-out motion.
- For endometrial biopsy, aspirate tissue by moving the cannula gently back and forth along the uterine wall, taking the appropriate sample.
- When finished, depress the buttons and withdraw the instruments.
- For endometrial biopsy, wash handling instruments when an adequate amount of tissue is obtained.

NOTE: If more than one aspirator is required to empty the uterus:
(1) Detach the cannula from the aspirator, leaving the cannula in place. Empty the aspirator, reattach it and carefully reattach it to the cannula. Resume evacuation.

OR
(2) Have a second aspirator readily available if more than one aspirator is needed.

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.
- Inspect tissue for products of conception by straining material or floating material in water or vinegar and viewing with a light from beneath.

Step Nine: Perform Any Concurrent Procedures
- When the procedure is complete, proceed with any contraception or other concurrent procedures, such as IUD insertion.

Step Ten: Process Instruments
- Process the aspirator, EasyGrip cannulae and adapters according to site protocols.

---

Processing the Ipas MVA Plus Aspirator, Ipas EasyGrip Cannulae and Adapters

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 aspirators, EasyGrip cannulae and adapters that will be reused should be kept wet until cleaning. Letting them dry may make it difficult to completely remove all contaminants. Using a 0.5% chlorine solution is an option. See OSHA precautions for use: www.osha.gov/SLTC/healthguidelines/chlorine/recognition.html, 03/26/08.

Caution: Instruments are not safe to handle with bare hands until cleaned.

Step 2: Clean aspirators, EasyGrip cannulae and adapters thoroughly in warm water and detergent, not soap. Wear gloves and face protection.
- If tissue is trapped in the tip of a cannula, flush water through the cannula repeatedly or use a cotton-tipped probe, soft brush or soft cloth to gently remove material.
- 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 right thumb alongside the right valve button and 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. Displace the plunger O-ring by squeezing its sides and rolling it into the groove below.

Do not use pointed or sharp objects to clean the valve parts or remove the O-ring. This could cause damage and prevent the device from maintaining vacuum.
- Instruments must be completely clean before further processing. If unable to remove blood or tissue from instruments during cleaning despite repeated attempts, discard the instrument.
Step 3: Processing Options

The Ipas MVA Plus and any adapters used are multiple-use devices that require high-level disinfection or sterilization prior to first use and after each procedure to remove contaminants. Aspirators do not need to remain high-level disinfected or sterile for the next use. Ipas EasyGrip cannulae require high-level disinfection (HLD) or sterilization before re-use and must be HLD or sterilized when inserted into the uterus. The Ipas 3mm cannulae are single-use devices. After use, treat and dispose as infectious waste.

High-Level Disinfect
- **Boil** for 20 minutes.
- 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 a 2% glutaraldehyde solution (Cidex® or other equivalent solutions) for 20 minutes or per manufacturer’s instructions.
- Soak completely immersed in Sporox® II solution for 12 minutes.
- Soak completely immersed in Sporox® II solution for 30 minutes.

**Sterilize**
- **Steam autoclave** in linen or paper for 30 minutes at 121°C (250°F) with a pressure of 106 kPa (15 lbs/in²). **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.
- Soak completely immersed in a 2% glutaraldehyde solution (Cidex® or other equivalent solutions) for 10 hours. See OSHA precautions for use: www.osha.gov/SLTC/etools/hospitalhazards/glutaraldehyde/glut.html, 3/26/08.
- Soak completely immersed in a 2% glutaraldehyde (Cidex® or other equivalent solutions) for 10 hours or per manufacturers’ instructions.
- Soak completely immersed in Sporox® II solution for 6 hours.
- Place (aspirators and adapters only) in STERRAD® 1005 processor for 55 minutes in an approved container.

After processing MVA Instruments
If chemical agents were used in processing, rinse all parts with either boiled water (for instruments that were HLD) or sterile water (if instrument was sterilized) after processing.

**Step 4: Store or Use Immediately**
Store: Store instruments in a clean, dry container protected from contaminants, in an environment that preserves the level of processing desired. Handle cannulae by the base ends. Instruments processed by wet methods (glutaraldehyde, chlorine, boiling water) should ideally be reprocessed daily.

**Before Use:** Reassemble, lubricate and check the vacuum 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 on to the end of the valve. Push the cylinder straight 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 another non-petroleum-based lubricant 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 the vacuum by pushing the buttons and pulling the plunger until the arms lock. Leave in this position for two to three minutes, then release the buttons. A rush of air indicates that the aspirator maintained the vacuum.
- If no rush of air is heard, 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.

U.S. Patent and Trademark Office Reg. No. Ipas MVA Plus® 2,907,186; Ipas EasyGrip® 2,786,382

Performing Manual Vacuum Aspiration (MVA) Using the Ipas MVA Plus®, Ipas 3mm and Ipas EasyGrip® Cannulae

**The Ipas MVA Plus Aspirator, Ipas 3mm® and Ipas EasyGrip Cannulae**

Manual vacuum aspiration, or MVA, is a technique for uterine aspiration whose low cost, simplicity and portability make it an especially valuable reproductive-health technology. Over 30 years of clinical research and use in more than 100 countries has shown vacuum aspiration to be safe and effective. MVA offered in outpatient settings has been shown to reduce the cost and length of stay related to uterine aspiration as compared to procedures performed in an operating room. MVA is also an excellent alternative to electric vacuum aspiration, producing an equivalent vacuum.1

This document provides an overview of the Ipas MVA Plus aspirator, Ipas 3mm and Ipas EasyGrip cannulae.

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

**Indications**

The Ipas MVA Plus aspirator, Ipas 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)
- Endometrial biopsy

Endometrial biopsy should not be performed in cases of suspected pregnancy. There are no known contraindications for other clinical indications.

**Pre-existing Conditions to Consider**

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. Uterine aspiration is often an important component of definitive management in these cases. Once the patient is stabilized, the procedure should not be delayed. History of blood dyscrasia may be a factor in the woman’s care.

**Complications**

As with any uterine aspiration procedure, one or more of the following may occur during or after the procedure: uterine or cervical injury or perforation, pelvic infection, vaginal 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 and Check Instruments**
- 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 at the same time until they lock (1).
- Pull plunger back until arms snap outward and catch on cylinder base (2). This “charges” the instrument.
- Check vacuum by leaving the instrument in the “charged” position for two to three minutes, then release the buttons. A rush of air indicates that the aspirator maintained a vacuum.
- If no rush of air is heard, 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.