

Performing Uterine Evacuation with the Ipas MVA Plus[®] Aspirator and Ipas EasyGrip[®] Cannulae: Instructional Booklet

Second Edition



For International Distribution

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In the United States and a number of other countries, Ipas EasyGrip® cannulae are labeled for single-use and should be discarded after use. Where regulations allow, these cannulae are reusable after undergoing sterilization or high-level disinfection.

Performing Uterine Evacuation with the Ipas MVA Plus® Aspirator and Ipas EasyGrip® Cannulae: Instructional Booklet



Ipas is an international nongovernmental organization that has worked for over three decades to reduce abortion-related deaths and injuries; increase women's ability to exercise their sexual and reproductive rights; and improve access to reproductive health services, including safe abortion care. Ipas's global and country programs include training, research, advocacy, distribution of reproductive health technologies and information dissemination.

Ipas manual vacuum aspiration (MVA) instruments are intended for use only by or under the supervision of a physician. This booklet provides information and directions on the use of MVA for uterine evacuation. It is designed for clinicians who have current knowledge, skills and familiarity with intrauterine procedures as outlined in the prerequisites. The information provided in this booklet, when used in conjunction with simulated practice and clinical practice with patients under the supervision of an experienced provider, prepares a clinician to perform uterine evacuation using MVA.

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Prerequisite skills

This booklet is intended for use by clinicians knowledgeable about the anatomy, physiology and medical procedures of the uterus and skilled in transvaginal intrauterine procedures such as sharp curettage, electric vacuum aspiration, IUD insertion, hysteroscopy and endometrial biopsy. Further, users of this manual need to possess the following skills:

- ▶ the ability to perform a pelvic examination
- ▶ the ability to accurately assess the size and position of a uterus, including assessing abnormalities and the duration of gestation in first-trimester pregnancies
- ▶ the ability to diagnose and manage pregnancy-related conditions and the stages of miscarriage
- ▶ demonstrated knowledge of infection-prevention techniques including standard/universal precautions, no-touch technique and processing of medical instruments
- ▶ the ability to assess the need for and provide appropriate pain management
- ▶ the ability to diagnose, stabilize and refer patients with ectopic pregnancy
- ▶ the ability to manage complications of uterine evacuation and pain medications, including incomplete evacuation, cervical and abdominal injury, uterine perforation, uterine atony, infection, failed abortion, and medication-related reactions; or the ability to stabilize the patient and establish a mechanism for referral

Section A

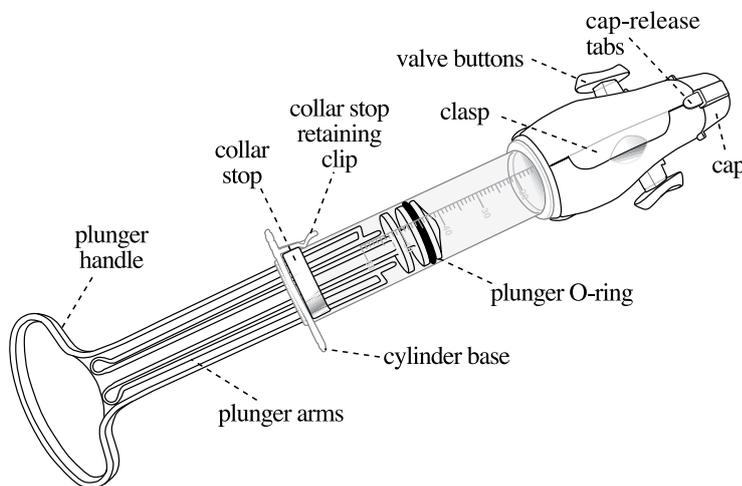
MVA Instruments

Manual vacuum aspiration, or MVA, is a safe and effective technique for uterine evacuation whose low cost, simplicity and portability make it an especially valuable reproductive health technology. More than 30 years of clinical and programmatic research in over 100 countries has shown vacuum aspiration for uterine evacuation to be safer than, and as effective as, sharp curettage, also known as dilatation and curettage, or D&C. Further, MVA offered in outpatient settings has been shown to reduce the cost and length of stay related to the procedure, when compared to sharp curettage performed in an operating theatre. MVA is also an excellent alternative to electric suction, producing an equivalent vacuum (Greenslade et al., 1993; Baird & Flynn, 2001). The World Health Organization (WHO) recommends MVA as a preferred method for uterine evacuation, including for treatment of incomplete abortion and induced abortion in early pregnancy (WHO, 2003). Additionally, there is substantial evidence that mid-level providers (for example, midwives, clinical officers, nurse practitioners, physician assistants) can perform MVA procedures safely and effectively in a range of health-care settings (Goldman, 2004; Warriner et al., 2006).

This booklet provides an overview of the Ipas MVA Plus[®] aspirator and Ipas EasyGrip[®] cannulae. For information on other Ipas MVA instruments, such as the Ipas Single-Valve aspirator, please see other Ipas instructional materials.

The Ipas MVA Plus[®] Aspirator and Ipas EasyGrip[®] Cannulae

Ipas MVA Plus[®] aspirator

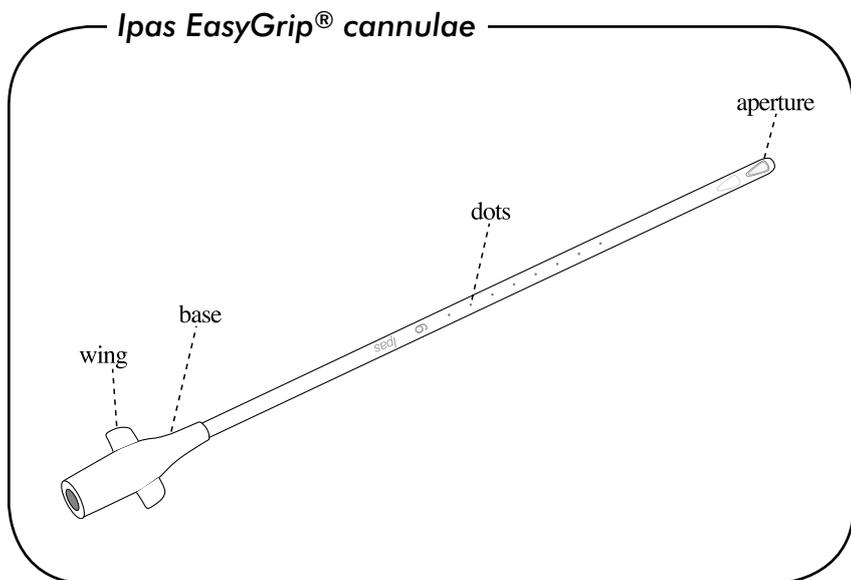


The **Ipas MVA Plus[®] aspirator** provides between 24-26 inches, or 609.6-660.4 millimeters, of mercury. It is composed of the following parts:

- ▶ a valve with a pair of buttons that control the vacuum, a cap and a removable liner
- ▶ a plunger with a plunger handle and O-ring
- ▶ a 60cc cylinder for holding evacuated uterine contents, with a retaining clip for the collar stop
- ▶ a collar stop

Ipas EasyGrip® cannulae are available in sizes 4, 5, 6, 7, 8, 9, 10 and 12mm.

- The smaller cannulae (4mm-8mm) have two opposing apertures.
- The larger cannulae (9, 10 and 12mm) have a larger single scoop aperture.

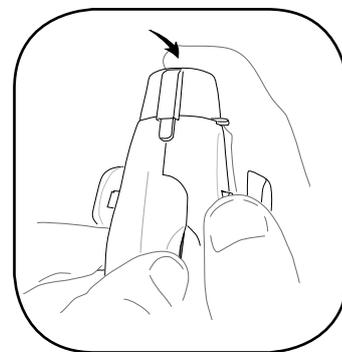
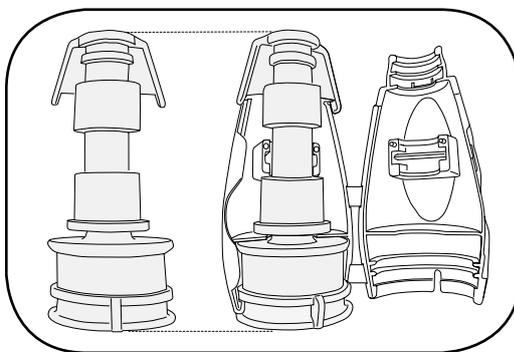


- Dots imprinted on each cannula indicate the location of the main aperture; the first dot is 6cm from the cannula tip and dots thereafter are spaced at the 1cm interval.
- Cannulae are semi-rigid and have permanently attached color-coded bases; separate adapters are not necessary. Wings on the bases aid in connection to and disconnection from the aspirator.

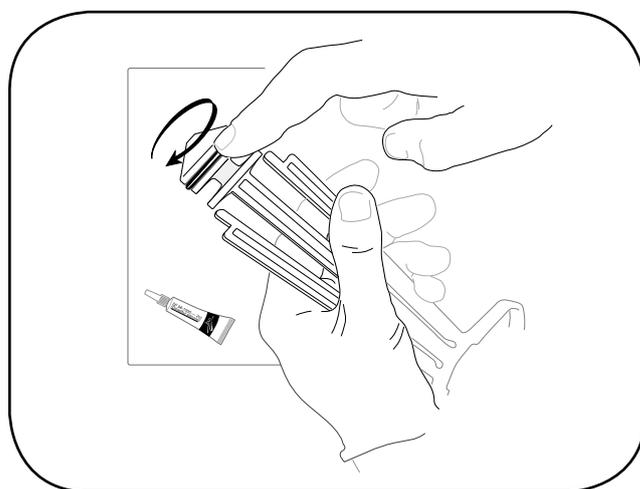
Assembly and charging of the Ipas MVA Plus® aspirator

In preparation for use, the Ipas MVA Plus® aspirator must first be charged with vacuum, as follows.

- 1** **Open the valve** and put the liner in place by aligning the internal ridges. Then close the valve until it snaps into place. Snap the cap into place on the end of the valve.

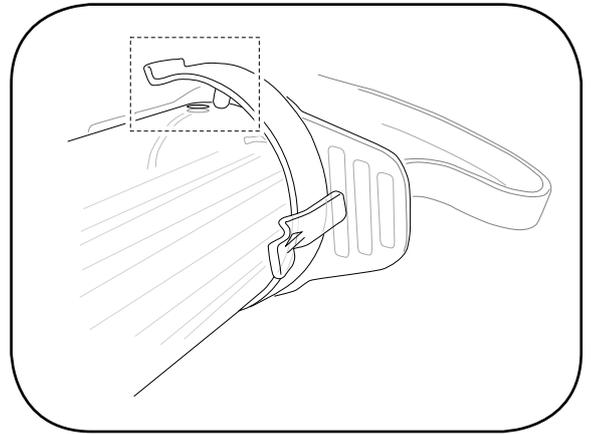


- 2** **Check the O-ring.** Ensure that the O-ring is in the groove at the tip of the plunger. Lubricate it with a single drop of lubricant, such as silicone, glycerol or liquid detergent. Never use petroleum-based products, such as petroleum jelly, on the O-ring as they can deteriorate the rubber. Take care not to over-lubricate the O-ring.

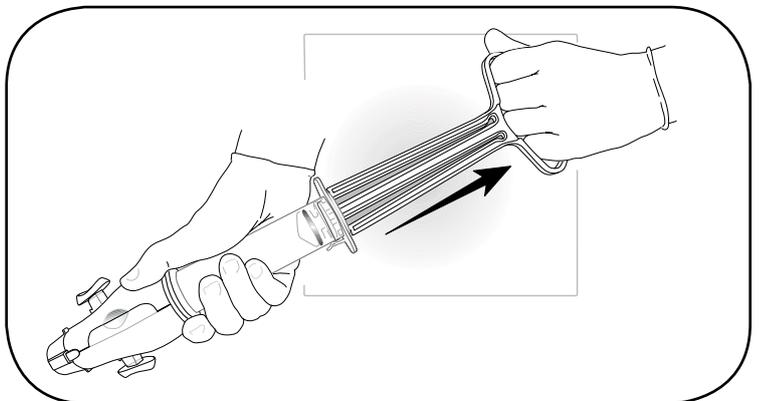
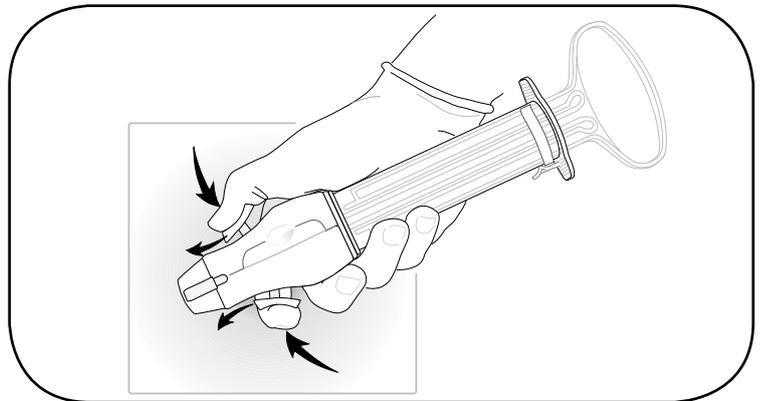


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Assemble the aspirator by pushing the cylinder into the valve, making sure that the buttons are not engaged while doing so. Push the cylinder straight into the valve. Do not twist the cylinder or valve when assembling, as this will cause the liner to dislodge and may lead to device failure. Insert the plunger all the way into the cylinder. Make sure that the buttons, the wide side of the cylinder base and the plunger handle are in alignment. Then affix the collar stop by sliding it under the retaining clip and pushing its tabs into the holes at the base of the cylinder.

**4**

Create the vacuum. First, push the buttons down and forward until you feel them snap into place. Then charge the aspirator by pulling back on the plunger until its arms snap outward and catch on the wide sides of the cylinder base. With the arms in this position, the plunger will not move forward and vacuum is maintained. Incorrect positioning of the arms could allow them to slip back into the cylinder, possibly injecting the contents of the aspirator into the uterus. Never grasp the aspirator by the plunger arms.

**5**

Check the aspirator for vacuum retention before use. After establishing the vacuum, leave the aspirator for several minutes, then release the buttons. You should hear a rush of air into the aspirator, indicating there is a vacuum. If you do not hear a rush of air, displace the collar stop, withdraw the plunger and check that the O-ring is properly placed, lubricated and free of damage and foreign bodies. Also check that the cylinder is firmly placed in the valve. Then reinsert the plunger, reposition the collar stop and retest the aspirator. If vacuum is still not retained, the aspirator cannot be used. Discard it and use another aspirator.

For more information on resolving loss of vacuum, see the Ipas instructional CD-ROM, *Performing Uterine Evacuation with the Ipas MVA Plus® Aspirator and Ipas EasyGrip® Cannulae*.

Reuse of Ipas MVA instruments

The Ipas MVA Plus[®] is a multiple-use device that requires high-level disinfection or sterilization prior to initial use and between patients. The aspirator does not need to be high-level disinfected or sterile at the time of use. Cannulae must be high-level disinfected or sterile at the time of use.

Ipas EasyGrip[®] cannulae are sterilized with ethylene oxide after packaging and remain sterile until the stated expiration date, as long as the package is intact. Where regulations allow, Ipas EasyGrip[®] cannulae are multiple-use devices.

For step-by-step instrument processing information, see Section C.

Replacement of Ipas MVA instruments

The Ipas MVA Plus[®] aspirator should be discarded and replaced for any of the following reasons:

- The cylinder is brittle or cracked or mineral deposits inhibit plunger movement.
- The valve parts are cracked, bent or broken.
- The buttons are broken.
- The plunger arms do not lock.
- The aspirator no longer holds a vacuum.

Ipas EasyGrip[®] cannulae should be discarded and replaced for any of the following reasons:

- The cannula has become brittle.
- The cannula is cracked, twisted or bent, particularly at the aperture.
- Cleaning the cannula does not completely remove tissue.

Uterine evacuation with MVA

Vacuum aspiration of uterine contents is a safe and effective clinical procedure. Studies report effectiveness rates of MVA procedures in excess of 98% with extremely low complication rates. Other studies demonstrate that MVA achieves greater safety than sharp curettage. Further, MVA can result in cost savings when compared to sharp curettage (*Greenslade et al., 1993; Baird & Flynn, 2001*).

Intended use/indications

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

- treatment of incomplete abortion for uterine sizes up to 12 weeks from the last menstrual period (LMP)
- first-trimester abortion (menstrual regulation)
- endometrial biopsy

Contraindications

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 performing uterine evacuation or endometrial biopsy, 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 or clandestine abortion. Uterine aspiration/uterine evacuation 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, Ipas cannulae and aspirators should be used only with extreme caution and only in facilities where full emergency back-up care is available.

Warnings

As with any invasive procedure, there is a risk of infection to providers, patients and support staff through contact with contaminants. To minimize risk, universal precautions must be observed at all times. These include using appropriate barriers (such as gloves and masks), handling waste carefully and taking precautions to prevent injuries.

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

Before the procedure

Before beginning the MVA procedure, the provider must address the following aspects of patient care: clinical assessment, counseling, pain management, voluntary informed consent, infection prevention and a management plan for complications.

Clinical assessment

A complete clinical assessment, including general history, pelvic exam, sizing and positioning of the uterus and a psycho-social assessment, should be conducted. It is more likely that a woman with an incomplete abortion will present with existing complications than will a woman coming in for an induced abortion. Therefore, women presenting for treatment of incomplete abortion or abortion complications (postabortion care) need to be assessed with particular care before the MVA procedure is performed. If signs of infection, trauma, foreign bodies or laceration are seen, they should be managed according to facility protocols and local medical standards.

Counseling

High-quality counseling provides the woman with emotional support while contributing to the effectiveness of the procedure.

Pain management

Medication for pain management should always be offered (WHO, 2003). Generally, paracervical block, analgesia and/or mild sedation and verbal reassurance are sufficient for the woman's comfort during the procedure.

Voluntary informed consent

Obtained in writing or verbally, voluntary informed consent ensures that the woman understands, and is in agreement with, her proposed treatment plan, including its benefits, risks and alternatives.

Infection prevention

When providing uterine-evacuation procedures, measures should be taken to prevent the introduction or spread of infection and disease.

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 tip of any other instrument that enters the uterus, should never touch nonsterile surfaces (including the vaginal walls) prior to insertion.

Complications management

While rare, complications are possible with MVA procedures and back-up plans for management or referral are necessary.

For step-by-step information on these topics, see the Ipas instructional CD-ROM, *Performing Uterine Evacuation with the Ipas MVA Plus® Aspirator and Ipas EasyGrip® Cannulae*.

Preparing for the procedure

1 Ensure that all necessary equipment and supplies are available.

2 Select appropriate Ipas EasyGrip[®] cannulae. It is advisable to have cannulae of several sizes available.

Using a cannula that is too small may result in retained tissue or loss of suction. While the size of cannula used depends, to some extent, on provider preference, the range of suggested sizes relative to uterine size is listed in Table 1.

Table 1

Range of cannula size relative to uterine size

| Uterine size in weeks LMP | Suggested cannula sizes |
|---------------------------|-------------------------|
| 4–6 weeks | 4–7mm |
| 7–9 weeks | 5–10mm |
| 9–12 weeks | 8–12mm |

3 Inspect instruments. Ensure that the aspirator holds a vacuum. Discard aspirators with visible cracks or defects and those that do not hold a vacuum.

For more information, see Section A.

4 Charge the aspirator. For step-by-step instructions on creating a vacuum, see Section A. If vacuum is not retained, check the O-ring and lubricate if necessary. If vacuum is still not retained, discard and use another aspirator.

No-Touch Technique

The parts of instruments that enter the uterus should not touch objects or surfaces that are not sterile, including vaginal walls, before being inserted. This is known as *no-touch technique*.

Recommended equipment and supplies:

- Private area in which to provide counseling and procedure
- Procedure table
- Strong light
- Chair/stool
- Covering for patient privacy
- Clean water
- Detergent or soap
- Cotton swabs
- MVA instruments: aspirator, cannulae of various sizes, and silicone or other suitable lubricant
- Tenaculum
- Speculum
- Sponge forceps or uterine-packing forceps
- Mechanical dilators (if not using cannulae for this purpose)
- Personal protective barriers, such as gloves and face protection
- Betadine[®] or other nonalcohol antiseptic
- Pain medications: analgesics and anxiolytics
- Paracervical block supplies: anesthetic (0.5% or 1.0% Lidocaine) without epinephrine and a 5, 10 or 20ml syringe with 21- or 22-gauge (or finer) regular or spinal needle
- Tissue inspection supplies: strainer, clear bowl, light source, forceps and water
- Agents and equipment for sterilization or HLD for instrument processing
- Supplies and equipment for the management of emergencies: intravenous infusion set and fluids (or a mechanism for stabilization and referral)

Performing the procedure

The MVA procedure can be started once all instruments and supplies are ready and the woman is prepared and has given her consent to start.

For detailed information on each of the following steps, see the Ipas instructional CD-ROM, *Performing Uterine Evacuation with the Ipas MVA Plus® Aspirator and Ipas EasyGrip® Cannulae*.

1 Confirm findings of initial examination through bimanual exam, watching for any signs of infection and treating promptly according to protocols.

2 Implement pain-management plan.

3 Perform cervical antiseptic prep.

4 Perform paracervical block, if necessary.

5 Place tenaculum and apply gentle traction if not already done with paracervical block.

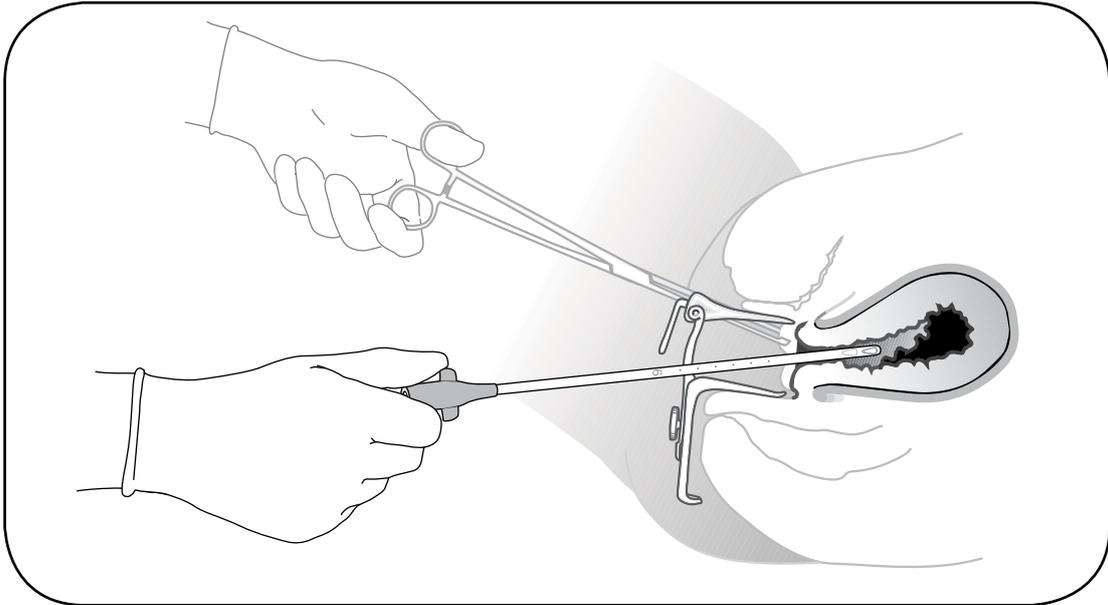
6 Dilate cervix, if necessary.

- Cervical dilatation is necessary when the cervical canal will not allow passage of a cannula appropriate to the uterine size.
- When required, dilatation should be done gently with progressively larger cannulae or tapered mechanical dilators, taking care not to traumatize the cervix.
- Misoprostol can also be used to ripen the cervix.

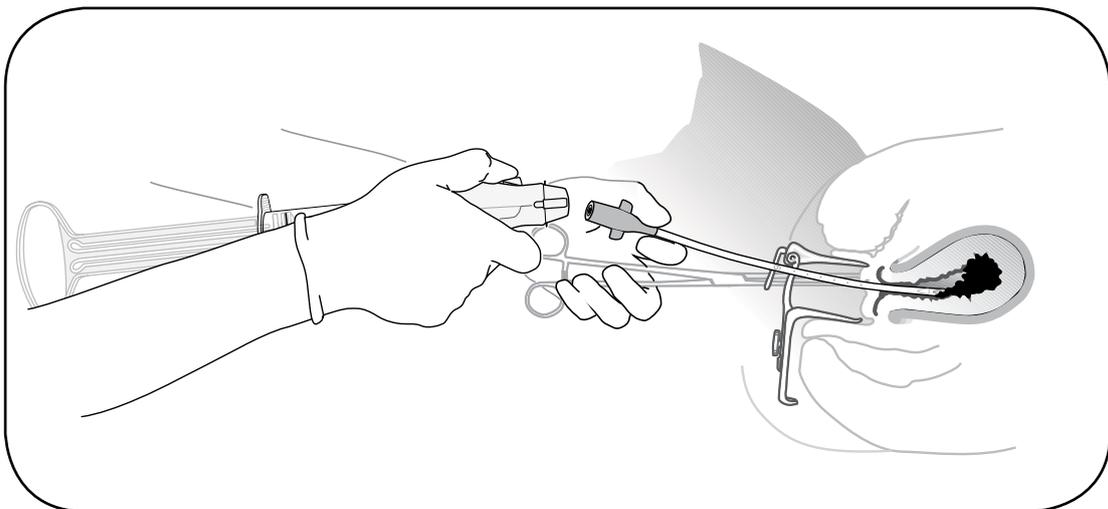
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Suction uterine contents.

- Gently introduce cannula just past the internal os. Alternatively, slowly push the cannula into the uterine cavity until it touches the fundus, then withdraw it slightly. Rotate the cannula with gentle pressure to help ease insertion.
 - Do not insert the cannula forcefully, as forceful movements may cause uterine perforation or damage to the cervix, pelvic organs or blood vessels.
 - Remain alert to signals that may indicate perforation throughout the procedure and stop suction immediately if they appear.

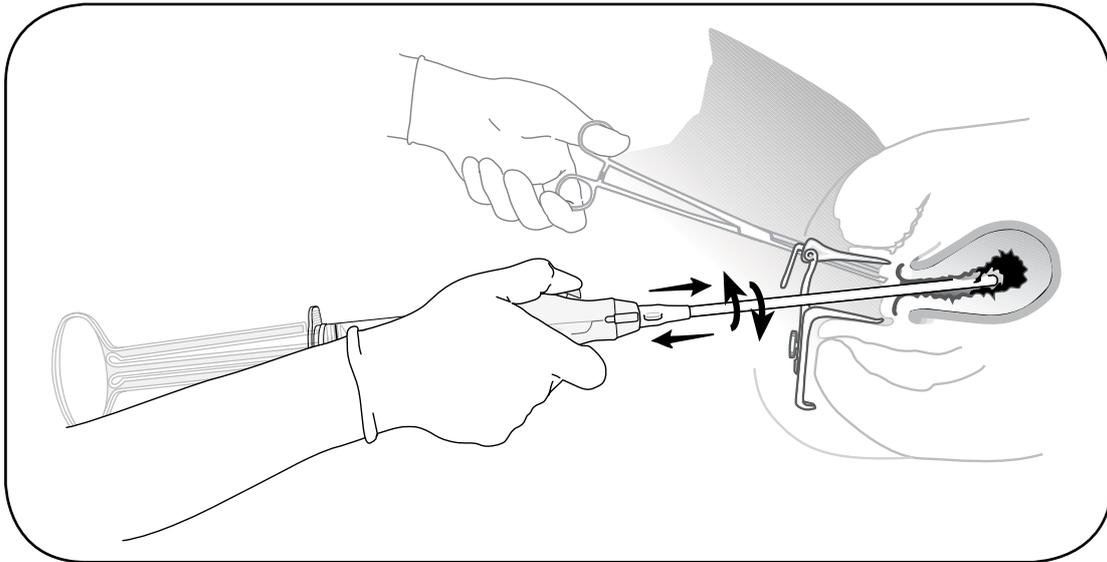


- Attach cannula to aspirator, holding the tenaculum and end of the cannula in one hand and the aspirator in the other. Take care not to push the cannula further into the uterus.



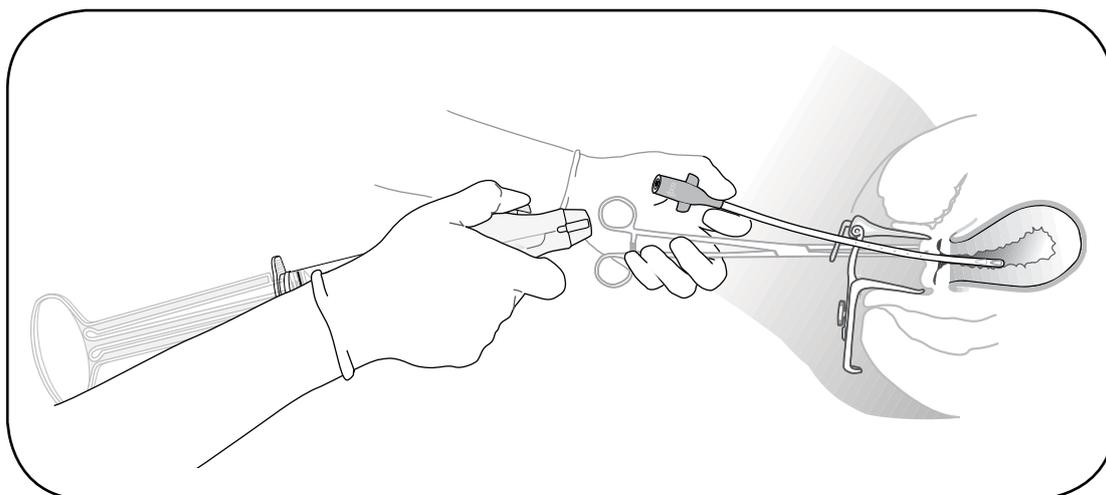
- Release vacuum by pressing the buttons in; suction will begin immediately.

- Evacuate by slowly and gently rotating cannula and aspirator 180 degrees in each direction while using an in-and-out motion. Take care not to withdraw the aperture of the cannula beyond the cervical os, as this will cause a loss of vacuum.



- Blood and tissue will be visible through the cannula and in the aspirator cylinder.
- If aspirator becomes full or vacuum is lost, disconnect it from the cannula and either replace it with another aspirator or empty its contents into a receptacle and reattach it to the cannula. **Never push aspirated contents through the cannula into the uterus.**
- If cannula removal is necessary during the procedure: Stabilize the cannula by grasping it at the base with one hand and holding it steady; with the other hand, hold the aspirator by the valve body, rotate the aspirator and gently separate it from the cannula. To insert the cannula, hold the aspirator by the valve body (not the cylinder), push the cannula base in firmly, twisting slightly if necessary.
- Check for signs of completion:
 - Red or pink foam without tissue passes through the cannula;
 - Gritty sensation as the cannula passes over the surface of the evacuated uterus;
 - The uterus contracts around the cannula;
 - The woman feels increased cramping when the uterus is empty, indicating contraction.

- When the procedure is finished, depress the buttons and disconnect the cannula from the aspirator. Alternatively, withdraw the cannula and aspirator together without depressing the buttons.



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Inspect aspirated tissue for quantity and presence or absence of products of conception (POC). Empty the contents of the aspirator into an appropriate container by ensuring the cannula is detached, releasing the buttons, squeezing the plunger arms and pushing the plunger fully into the cylinder. Keep instruments available in case re-aspiration is necessary. Inspecting aspirated tissue is extremely important since it indicates whether the evacuation was complete or whether there is the possibility of an ectopic or molar pregnancy.

If no POC are seen, the possibility of ectopic pregnancy, incomplete abortion or a complete spontaneous abortion should be considered.

- If retained tissue is suspected, repeat the aspiration.
- After determining that the procedure is complete, wipe away excess blood from the os and assess the quantity still coming from the uterus or elsewhere.
- Ensure that bleeding is minimal.
- Proceed with any concurrent procedures such as IUD insertion or tubal ligation, provided that prior informed consent was obtained and counseling was given.
- Soak instruments. Until they can be cleaned, all instruments that are to be reused should be kept wet. A solution such as 0.5% chlorine can be used.

Post-procedure care

Monitor the woman's recovery. Have the woman rest in a comfortable position. Assess and respond sensitively to her emotional state. Monitor her until she has:

- pulse and blood pressure that is normal for her
- the ability to walk and drink fluids
- normal bleeding and cramping

Provide post-procedure counseling and information. The postabortion period provides a critical opportunity to provide information on contraception, recovery, follow-up care, and other sexual and reproductive health issues. Women should be given detailed information regarding the following:

Postabortion contraception

- Women can become pregnant as soon as 10 days after the procedure.
- Contraception can help prevent pregnancy.
- Contraceptive counseling and the woman's method of choice should ideally be provided before she leaves the clinic.

HIV

- Unprotected sex may have exposed her to HIV infection.
- The earlier a woman knows her HIV status the better; if a woman is HIV-positive, she could access care and support services that can prolong and increase the quality of her life.
- Safer sexual practices, such as condom use, may reduce the risk of receiving or transmitting HIV as well as other sexually transmitted infections.
- Offer voluntary HIV counseling and testing, as well as referrals to local HIV/AIDS support groups.

Instructions for care

- instructions for taking medications
- information about routine hygiene
- information about resumption of sexual activity and contraception
- signs and symptoms requiring emergency attention
- where to seek emergency care, if needed
- list of counseling and other available services
- date, time and location of follow-up visit

Signs of a normal recovery

- Some uterine cramping can be expected over the next few days, similar to that of a normal menstrual period.
- Discomfort may be eased by mild analgesics, warm compress or bath.
- Spotting and bleeding should not exceed normal menses.
- A normal period should begin within four to eight weeks.

Signs and symptoms requiring immediate care

- fever, chills, nausea or vomiting for more than 24 hours
- cramping for more than a few days
- tenderness, pain or distention of the abdomen
- heavy bleeding (more than normal menstrual bleeding)
- foul-smelling vaginal discharge
- delay in resumption of menstrual period by more than eight weeks
- fainting or dizziness

Schedule follow-up care according to local protocols.

For more information on post-procedure care, postabortion contraception and follow-up care, see the Ipas instructional CD-ROM, *Performing Uterine Evacuation with the Ipas MVA Plus® Aspirator and Ipas EasyGrip® Cannulae*, or other Ipas training materials.

Technical difficulties during the MVA procedure

The most common technical problem seen with MVA instruments is loss of vacuum. During most MVA procedures, the vacuum remains constant until the aspirator is approximately 80% or 50ml full. However, a decrease in vacuum may occur before the aspiration is complete for several reasons. There include:

- The aspirator is full.
- The cannula is withdrawn past the external os.
- The cannula becomes clogged.

If the cylinder fills so that suction stops:

- Depress the buttons.
- Disconnect the aspirator from the cannula, leaving the cannula in place inside the uterus.
- Empty the aspirator into a container by pressing the buttons and pushing the plunger into the cylinder.
- Re-establish vacuum in the aspirator, reconnect to the cannula and resume the aspiration.

Note: Many clinicians keep a second prepared aspirator on hand during the procedure and switch aspirators if one becomes full.

If the aperture of the cannula is withdrawn from the uterus beyond the external os, remove the cannula, taking care not to contaminate it through contact with the vaginal walls or other nonsterile surfaces:

- Detach the aspirator from the cannula, empty the aspirator, then re-establish vacuum.
- Reinsert the cannula if it has not been contaminated.
- If contamination has occurred, insert another sterile or HLD cannula.

- Reconnect the aspirator, release the vacuum and continue aspiration.

If the cannula becomes clogged, a lack of tissue or bubbles flowing into the aspirator will be noted:

- Ease the cannula back toward, but not through, the cervical os.

If this does not unclog the cannula:

- Depress the buttons and disconnect the cannula from the aspirator before removing from the uterus, or withdraw the cannula without depressing the buttons.
- Remove tissue from the opening in the cannula using sterile/HLD forceps, taking care not to contaminate the cannula.
- Reinsert the cannula using no-touch technique.
- Reattach the aspirator and continue the procedure.

Note: Never try to unclog the cannula by pushing the plunger back into the cylinder.

Other reasons why the aspirator might not hold a vacuum are:

- incorrect assembly
- a defective aspirator
- the need for a larger cannula to create a tighter seal in the cervix

What happens if...

Buttons won't engage

- Check that the liner is not twisted.
- Make sure that you push the buttons down and forward toward the lip of the aspirator.
- Use enough force to click buttons into place.
- Buttons must be pressed at the same time.

Valve body won't close

- Make sure that the liner is in the correct position — that the internal ridges are aligned and the liner tabs fit into the notches of the valve body.
- Make sure autoclaving temperature is 121°C/250°F.

Plunger is hard to pull

- Lubricate the O-ring with one drop of silicone or nonpetroleum-based oil, such as vegetable oil; rub the oil around the O-ring and move the plunger back and forth in the barrel.
- Check for mineral deposits.
 - If so, rinse with vinegar or soak in water and wash well to remove the mineral deposits.

- Brush with a soft brush, if needed.
- Check for build-up of debris on the O-ring and head of plunger from insufficient cleaning.
 - If so, use warm water and a residue-free detergent to remove build-up.
 - A nonabrasive brush can be used to aid in build-up removal.
- Check for worn or deteriorated O-ring. If condition is questionable, replace.
- Check for use of a non-Ipas replacement O-ring.
- Make sure autoclaving is not performed with plunger inside cylinder.
- Make sure autoclave is set at 121°C/250°F. If condition persists, cold processing is recommended.

Plunger pulls out of the cylinder

- Make sure that the collar stop is in place and the pins are fully engaged.

Vacuum is not established

- Remove the collar stop, withdraw the plunger and check that the O-ring is free of damage or foreign material.
- Make sure that the O-ring is properly lubricated and properly positioned in the groove on the plunger head.
- Make sure the cylinder is firmly placed in the valve.
- Make sure that the liner is not torn or damaged.
- Make sure that the valve closes completely and is not warped.
- Make sure O-ring was not replaced with one from a source other than Ipas.
- Make sure that the buttons are locked into place before pulling the plunger back.

Fluid path appears blocked

- Open the valve body and check that the valve liner is not twisted.
- Remove the valve liner and ensure that it is clean and intact.

Mineral deposits appear to be building up in the cylinder or on the valve hinges

- Soak the instrument briefly in vinegar and brush with a soft brush as needed; rinse with clean water.
- If you cannot remove the deposits, replace the aspirator.

The device becomes misshapen in the autoclave

- Check that the temperature setting on the steam autoclave is at 121°C (250°F) and that the instrument is in the autoclave for 30 minutes at 106kPa (15lbs/in²).
- Do not use a “flash” (higher settings for shorter periods of time) setting.
- Replace the aspirator if it has become misshapen.

Possible complications

Complications are rare with MVA procedures on uterine sizes of less than 12 weeks LMP, particularly when performed by trained providers. Risks with MVA are significantly lower than those with sharp curettage procedures and full-term delivery.

Table 2 lists complications that may be seen during or after an MVA procedure. The risk of complications increases with greater uterine size, although complications are rare. Some of these conditions can lead to secondary infertility, serious injury or death. Providers of MVA procedures should also be aware that a vagal reaction (fainting) may occur.

Table 2

Possible complications in women undergoing MVA procedures

| Signs and symptoms | Diagnosis |
|---|---|
| Vaginal bleeding; uterus smaller than expected; less tissue than expected; abdominal pain; signs of infection | Incomplete evacuation, retained tissue |
| Torn or lacerated cervix; heavy vaginal bleeding; vaginal bleeding after evacuation; sudden excessive pain; rapid heart rate; falling blood pressure; instruments pass further than expected; fat, bowel or omentum in aspirate | Cervical or abdominal injury, uterine perforation |
| Vaginal bleeding; large, soft uterus | Uterine atony |
| Fever; chills; foul-smelling discharge; lower abdominal pain; prolonged vaginal bleeding; uterine tenderness | Pelvic infection |
| Positive pregnancy test; continued signs of pregnancy; no POC upon tissue inspection | Failed abortion |
| Respiratory distress; rash; swollen face; metallic taste; ringing in ears; disorientation; seizures; slurred speech | Medication-related reaction |
| Hard, enlarged, blood-filled uterus hours/days after the procedure; pelvic pain; scant vaginal bleeding | Acute hematometra |
| Inability of blood to clot; serosanguinous bleeding | Disseminated intravascular coagulation (DIC) |
| Less tissue than expected; difficult dilatation and cannula insertion | Asherman's Syndrome |

For more information, see the Ipas instructional CD-ROM, *Performing Uterine Evacuation with the Ipas MVA Plus® Aspirator and Ipas EasyGrip® Cannulae*.

Section C

Processing the Ipas MVA Plus[®] aspirator and Ipas EasyGrip[®] cannulae

The removal of microorganisms from instruments to make them safe for use on patients is known as instrument processing. Standard (or universal) precautions for infection prevention must always be followed when processing MVA and other medical instruments. This section covers the steps for processing the Ipas MVA Plus[®] aspirator and Ipas EasyGrip[®] cannulae: decontamination, soak, cleaning, sterilization or high-level disinfection (HLD), and storage.

Decontamination soak

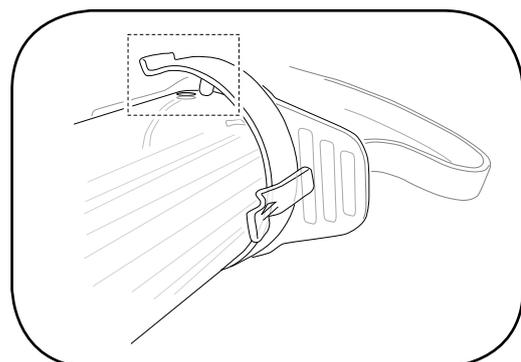
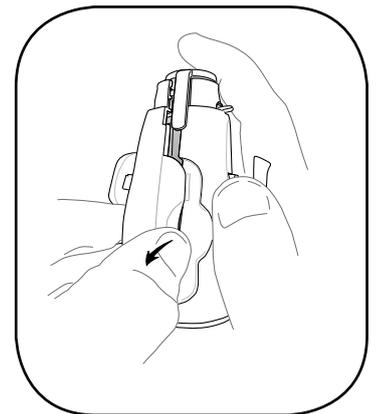
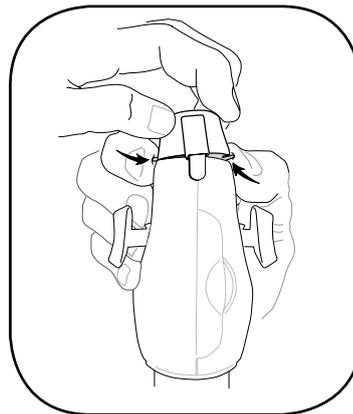
Following the procedure, all MVA instruments that are to be reused should be kept wet until cleaning; letting them dry may make it impossible to completely remove all contaminants. A disinfectant, such as 0.5% chlorine solution can be used. Immerse the instruments completely, making sure to draw the solution inside both the cannula and the aspirator. **Aspirators and adapters are not safe to handle with bare hands until clean.**



Cleaning

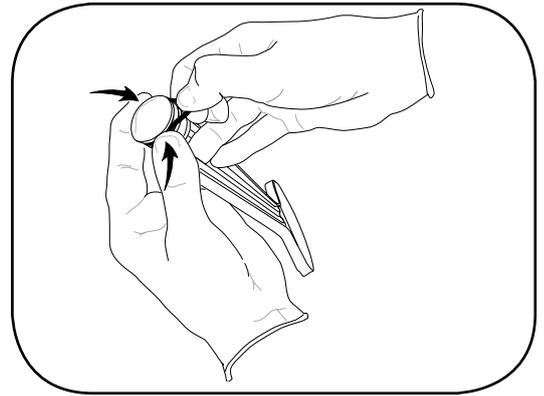
After the decontamination soak, the aspirator must be disassembled for cleaning:

- Pull the cylinder out of the valve.
- Disassemble the valve by pressing down on the cap-release tabs, with the other hand, pull the cap off.
- 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.
- Disengage the collar stop by sliding it sideways under the retaining clip or remove

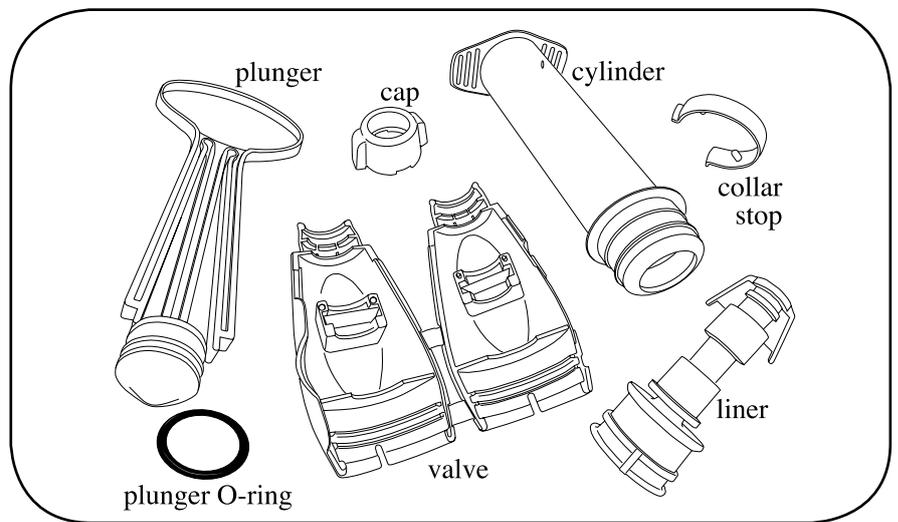


it completely.

- Pull the plunger completely out of the cylinder.
- Displace the O-ring by squeezing its sides and rolling it down into the groove below. Do not use any pointed or sharp objects to remove the O-ring. This could cause damage and prevent the device from maintaining a vacuum.
- Do not attempt to remove the base from Ipas EasyGrip® cannulae.



- Wash all instrument surfaces thoroughly in warm, water and detergent. Detergent is preferable to soap, which may leave a residue.
- If tissue or dried blood is trapped inside the cannula, flush it with water repeatedly or use a cotton-tipped probe or soft cloth to remove it.



- Ascertain that the apertures are clear of visible material.
- If you are unable to remove all visible matter from inside the cannula, discard and replace it.
- Clean the cylinder, plunger and valve pieces using a soft bristle brush. Do not use sharp objects as these can cause damage, preventing the instrument from maintaining vacuum.
- Clean each piece until, upon careful inspection, no tissue or blood is visible. Holding the instrument parts up to a light source can help with this inspection.
- Rinse each part thoroughly in clean water.

HLD or Sterilization

After cleaning, the Ipas MVA Plus® and Ipas EasyGrip® cannulae must undergo high-level disinfection or sterilization between patients to remove contaminants. Devices are then safe to use for the next procedure. Aspirators do not need to remain high-level disinfected or sterile for the next use. Cannulae must be high-level disinfected or sterile at the time of use. The following is a list of processing methods our devices will withstand.

HLD in a 0.5% chlorine solution

- After cleaning, items must be soaked for 20 minutes.
- Completely immerse disassembled parts in a nonmetal container.
- After processing, rinse all parts with boiled water.

HLD by boiling

- After cleaning, items must be boiled for 20 minutes.
- Disassembled parts do not need to be fully immersed.
- Cannulae may discolor without affecting function.
- Grasping hot cannulae may cause flattening. Let water cool before removing cannulae and handle by the adapter/base end.

HLD in Cidex® OPA

- After cleaning, items must be soaked for 12 minutes.
- Completely immerse disassembled parts.
- Discard solution 14 days or sooner as indicated by Cidex® OPA solution test strips.
- After processing, rinse all parts with boiled water.

HLD or sterilize in Sporox® II

- After cleaning, items must be soaked for 30 minutes for HLD or 6 hours for sterilization.
- Completely immerse disassembled parts.
- Discard solution 21 days or sooner as indicated by results from Sporox® test vials.
- After processing, rinse all parts with boiled water for HLD or sterile water for sterilization.

HLD or sterilization in a 2% glutaraldehyde solution, such as Cidex®

- After cleaning, items must be soaked for 20 minutes for HLD or 10 hours for sterilization.
- Completely immerse disassembled parts.
- Usually discard solution 14 days after mixing or sooner if solution becomes cloudy.
- After processing, rinse all parts with boiled water for HLD or sterile water for sterilization.
- For other glutaraldehyde solutions, follow manufacturers' instructions

Sterilization using a steam autoclave

121°C at 106 kPa · 250°F at 15 lbs/in² · 30 minutes

- Package disassembled instruments by wrapping in paper or linen, and lay the package flat along the side or bottom of the autoclave. Ipas EasyGrip[®] cannulae, particularly the smaller sizes, may curve in steam autoclaves.
- Steam must penetrate all surfaces. Parts should not touch and should be arranged so openings are not obstructed, permitting drainage. The collar stop must be completely removed.
- Do not use other autoclave settings. Specifically, do not use higher settings for shorter periods of time (also known as “flash autoclaving”).
- Bring to room temperature before use.

Sterilization using the STERRAD[®] 100S processor

- Ipas MVA Plus[®] aspirator only
- Place disassembled instruments along with a chemical indicator strip in an approved tray or peel pouch.
- Processing time is 55 minutes.

Processing tips

- When processing the aspirator with liquid agents, make sure the parts are rinsed thoroughly in boiled/sterile water. When processing agents are allowed to dry on the devices, the plunger does not move easily in the cylinder. When chlorine is not rinsed sufficiently, it may also cause the valve hinges to wear prematurely.
- When the cylinder becomes cloudy or pitted due to processing, soak the cylinder for a few minutes in vinegar, then clean the inside with a soft brush. Rinse in clean water.
- Devices must be completely disassembled prior to cleaning. It is important to remove the O-ring from the plunger prior to cleaning and make sure lubricants are removed during cleaning.

Table 3

Common methods of high-level disinfecting (HLD) or sterilizing the Ipas MVA Plus[®] aspirator and Ipas EasyGrip[®] cannulae

| | | Ipas MVA Plus [®] aspirator | Ipas EasyGrip [®] cannulae |
|--|------------------------|---|--|
| HIGH- LEVEL DISINFECT | Chlorine | YES | YES |
| | Boiling | YES | YES |
| | Cidex [®] OPA | YES | YES |
| | Glutaraldehyde | YES | YES |
| | Sporox [®] II | YES | YES |
| S T E R I L I Z E | Steam autoclave | YES | YES |
| | Glutaraldehyde | YES | YES |
| | STERRAD [®] | YES | NO |
| | Sporox [®] II | YES | YES |

Table 4

**Instructions for processing the
Ipas MVA Plus[®] aspirator and
Ipas EasyGrip[®] cannulae**

NOTE: After cleaning, the Ipas MVA Plus[®] and Ipas EasyGrip[®] cannulae must undergo high-level disinfection or sterilization between patients to remove contaminants. Devices are then safe to use for the next procedure. Aspirators do not need to remain high-level disinfected or sterile for the next use. Ipas EasyGrip[®] cannulae are reusable after processing where regulations allow. Cannulae must be high-level disinfected or sterile at the time of use.

| METHOD | AGENT | TIME | PRECAUTIONS |
|-----------------------------|--|------------------------------------|---|
| HIGH-LEVEL DISINFECT | Chlorine* Dilute to 0.5% | 20 minutes | Items must be fully immersed. Discard solution daily or sooner if solution becomes cloudy. After processing, rinse all parts with boiled water. |
| | Boiling water | 20 minutes | Items do not need to be fully immersed. Cannulae may discolor without affecting function. Grasping hot cannulae may cause flattening. Let water cool before removing cannulae and handle by the adapter/base end. |
| | 2% Glutaraldehyde* (Cidex[®]) Follow manufacturer's instructions for mixing | 20 minutes | Items must be fully immersed. Discard solution 14 days after mixing or sooner if solution becomes cloudy. Do not use below 25°C (77°F). After processing, rinse all parts with boiled water. |
| | Glutaraldehyde* (other solutions) Follow manufacturer's instructions for mixing | Follow manufacturer's instructions | Items must be fully immersed. Usually discard solution 14 days after mixing or sooner if solution becomes cloudy. After processing, rinse all parts with boiled water. |
| | Cidex[®] OPA* | 12 minutes | Items must be fully immersed. Discard solution 14 days or sooner as indicated by Cidex [®] OPA solution test strips. After processing, rinse all parts with boiled water. |
| | Sporox[®] II* | 30 minutes | Items must be fully immersed. Discard solution 21 days or sooner as indicated by results from Sporox [®] test vials. After processing, rinse all parts with boiled water. |

| METHOD | AGENT | TIME | PRECAUTIONS |
|-----------|--|---|--|
| STERILIZE | <p>Steam autoclave*</p> | <p>Sterility is achieved at 121°C (250°F) for 30 minutes with pressure of 106kPa (15lbs/in²).</p> <p>Do not use other autoclave settings. Specifically, do not use higher settings for shorter periods of time (known as "flash autoclaving").</p> | <p>Steam must penetrate all surfaces. Parts should not touch and should be arranged so openings are not obstructed, permitting drainage.</p> <p>Ipas EasyGrip[®] cannulae, particularly the smaller sizes, may curve in steam autoclaves. To minimize this, package them and the disassembled aspirators by wrapping in paper or linen and lay flat.</p> <p>The Ipas MVA Plus[®] collar stop must be completely removed (not held with the retaining clip).</p> <p>Bring to room temperature before use.</p> |
| | <p>2% Glutaraldehyde* (Cidex[®])</p> <p>Follow manufacturer's instructions for mixing.</p> | <p>10 hours</p> | <p>Items must be fully immersed. Discard solution 14 days after mixing or sooner if solution becomes cloudy. Do not use below 25°C (77°F). After processing, rinse all parts with sterile water</p> |
| | <p>Glutaraldehyde* (other solutions)</p> <p>Follow manufacturer's instructions for mixing.</p> | <p>Follow manufacturer's instructions</p> | <p>Items must be fully immersed. Usually discard solution 14 days after mixing or sooner if solution becomes cloudy. After processing, rinse all parts with sterile water.</p> |
| | <p>STERRAD[®] 100S processor</p> <p><i>(Ipas MVA Plus[®] aspirator only)</i></p> | <p>55 minutes</p> | <p>Place the disassembled aspirator along with a chemical indicator strip in an approved tray or peel pack.</p> |
| | <p>Sporox[®] II</p> | <p>6 hours</p> | <p>Items must be fully immersed. Discard solution 21 days or sooner as indicated by results from Sporox[®] test vials. After processing, rinse all parts with sterile water.</p> |

* Liquid 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.

Storage of Ipas EasyGrip® cannulae

Once Ipas cannulae have been HLD or sterilized, this status must be maintained until they are used, as cannulae must be HLD or sterile when inserted into the uterus. Cannulae should be kept in dry, HLD or sterile containers with tight-fitting lids and protected from dust and other contaminants. Ideally, cannulae that have been processed by wet methods like glutaraldehyde, chlorine or boiling should be reprocessed daily.

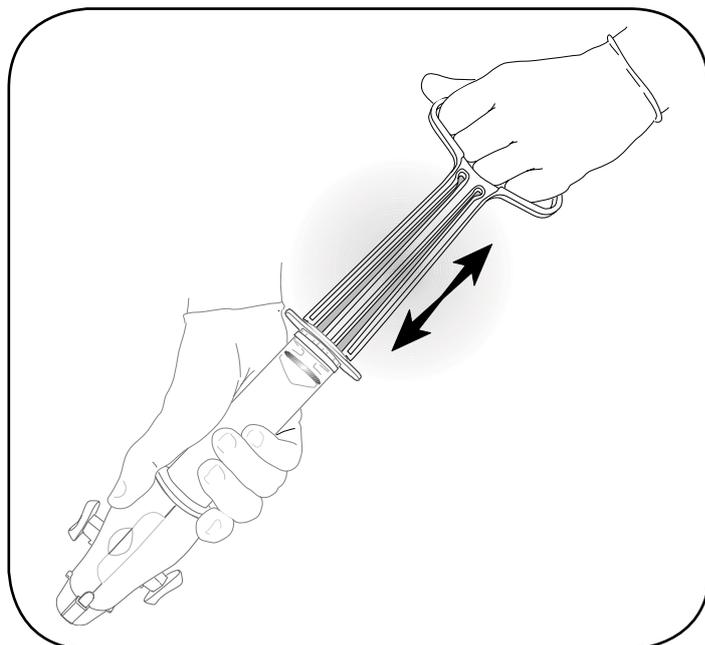
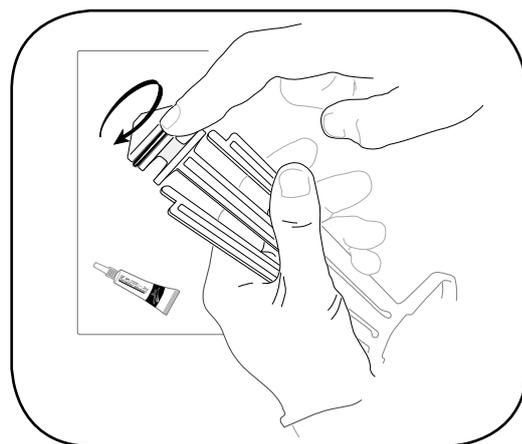
- Keep only a small number of cannulae in each container.
- Reprocess if not used within two days.
- Use HLD or sterile forceps to remove cannulae by their base ends.
- Avoid touching other cannulae in the container.
- Clean and process the transfer forceps and storage container every day or two.



Reassembly and storage of the Ipas MVA Plus® aspirator

The Ipas MVA Plus® aspirator must be HLD or sterilized prior to first use and after each procedure. Aspirators do not need to remain HLD or sterile for the next use. The Ipas MVA Plus® aspirator should be stored assembled, lubricated and ready for use.

- Reposition the O-ring.
- Place one drop of silicone (or other nonpetroleum-based lubricant) on the O-ring, spreading it with a fingertip.
- Reassemble the valve by putting the liner in place, closing the valve and snapping the cap into place.
- Reassemble the aspirator and lubricate it by pushing the plunger in and out several times.
- Keep in dry container with a tight-fitting lid, protected from dust and other contaminants, in an environment that preserves the level of processing desired.
- Check the vacuum before each use.



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Coming in 2008: Ipas will launch an e-learning site, IpasUniversity or www.IpasU.org. Courses relating to the Ipas MVA Plus® and its safe use will be available to learners to take at their convenience.

Ipas quality and safety

Ipas is committed to producing the highest-quality MVA instruments available. All Ipas MVA instruments (aspirators, cannulae and Denniston dilators) are listed with the United States Food and Drug Administration (USFDA). Our facility is registered with the FDA.

Ipas's quality system has been certified compliant for ISO 13485 (International Standards for Medical Devices) by the British Standards Institute (BSI). Ipas MVA instruments were awarded the CE

Mark per the Medical Device Directive 93/42/EEC. This certification is required for sale of products in member countries of the European Union.

Ipas will replace or repair, free of charge, either directly or through its distributors worldwide, any of our products that are found to be faulty by reason of poor craftsmanship or materials. This guarantee does not cover defects arising from accident, neglect or misuse.

How to order Ipas products

In addition to MVA aspirators and cannulae, Ipas products include Denniston plastic cervical dilators and anatomical pelvic models for training.

For information about ordering MVA instruments or other Ipas products, to receive information about the MVA distributor in your area or to become a distributor, please contact:

Ipas Customer Service

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Chapel Hill, NC 27514 USA

Tel: 919.960.6453

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