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Description of Aspirators

There are two models of aspirator:

- Ipas MVA Plus®
- Single-Valve

Each aspirator has a cylinder, plunger, and valve(s). Most aspirators are clean, not sterile, when shipped.

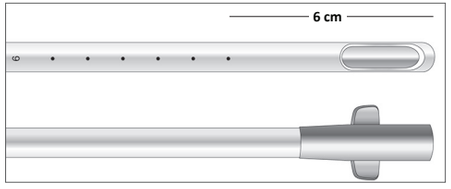
Description of Cannulae

There are three models of cannula:

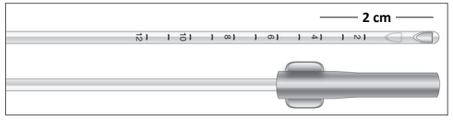
- Ipas EasyGrip® (multiple use, 4–10 and 12 mm)
- Flexible Karman (single use, 4–10 and 12 mm)
- 3 mm (single use)

Each cannula, depending on its size, has either one (9, 10, 12 mm) or two (3–8 mm) apertures.

All cannulae have either lines or dots spaced at intervals to assist in gauging depth of insertion/retraction. The Ipas EasyGrip® (pictured below) and Flexible Karman cannulae have a series of dots—the first at 6 cm from the tip and others at 1 cm intervals:



The 3 mm cannulae have a series of lines—the first line at 2 cm from the tip and others at 1 cm intervals:



Each cannula is sterilized with ethylene oxide after packaging and remains sterile until the stated expiration date, as long as the package is intact.

Compatibility of Aspirators/Cannulae

ASPIRATOR	COMPATIBLE CANNULAE
Ipas MVA Plus® (no adapter)	• Ipas EasyGrip® (all sizes) • Flexible Karman 12 mm
Ipas MVA Plus® (with adapter)	• Flexible Karman 4–10 mm • 3 mm (6 mm adapter)
Single-Valve	• Flexible Karman 4–6 mm • 3 mm

Intended Use/Indications

Aspirators and cannulae described are intended for use by trained healthcare professionals only.

All Ipas aspirators and compatible cannulae are intended for uterine aspiration/uterine evacuation in obstetrics and gynecologic patients. Clinical indications for uterine aspiration include treatment of incomplete abortion for uterine sizes up to 12 weeks from last menstrual period (LMP) and endometrial biopsy.

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

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.

Warnings

As with any invasive procedure, there is risk of infection to providers, patients, and support staff through contact with contaminants. To minimize the 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/evacuation 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 during or after procedures: uterine or cervical injury/perforation, pelvic infection, vagal reaction, incomplete evacuation, or acute hematometra. Some of these conditions can lead to secondary infertility, other serious injury, or death.

CAUTION: *Do not perform uterine aspiration/uterine evacuation until the size and position of the uterus and cervix have been determined. Large fibroids or uterine anomalies may make it difficult to determine the size of the uterus and hard to perform intrauterine procedures, including uterine evacuation.*

Precautions

Before performing uterine evacuation, 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 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, the devices should be used only with extreme caution and only in facilities where full emergency backup care is available.

Determining Appropriate Cannula Size

CAUTION: *Use a cannula size that is appropriate for the application and size of the uterus and amount of cervical dilation present. Using a cannula that is too small may result in retained tissue or loss of suction.*

For uterine aspiration/evacuation, the range of suggested cannula size relative to uterine size to be used is as follows:

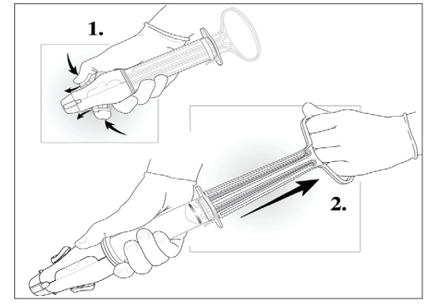
UTERINE SIZE LMP	CANNULA SIZE
4 – 6 weeks	4 – 7 mm
7 – 9 weeks	5 – 10 mm
9 – 12 weeks	8 – 12 mm

For endometrial biopsy, use a 3–4 mm cannula.

Instrument Preparation

Begin with the valve button(s) open (not depressed), the plunger inserted all the way inside the cylinder, and the collar stop locked in place (with the tabs pushed down into the holes in the cylinder).

1. Push the button(s) down and forward (simultaneously for the Ipas MVA Plus®) until you feel them lock.



2. Create a vacuum by pulling the plunger back until the plunger arms snap out and catch on the wide sides of the cylinder base.

   Note: *Both plunger arms must be fully extended to the sides and secured over the edges of the cylinder. Incorrect positioning of the arms could allow them to slip back inside the cylinder, possibly injecting the contents of the aspirator back into the uterus.* ***Never grasp the aspirator by the plunger arms.***

3. Check for vacuum retention before each use by releasing the buttons. A rush of air into the aspirator should be heard indicating that a vacuum was retained.

4. If the rush of air is not heard, remove the collar stop, withdraw the plunger, and check that the plunger O-ring is free of damage and foreign bodies, properly lubricated and properly positioned in the groove. Also make sure the cylinder is firmly placed in the valve. Then create a vacuum and test it again. If a vacuum is still not retained, discard and use another aspirator.

Patient Preparation

1. Assess the size and position of the uterus by bimanual examination. Where available, ultrasound may be helpful for accurate dating when there is a discrepancy revealed by the bimanual exam, but is not a requirement for the provision of early uterine evacuation. Assess signs of infection and address them. Assess the need for pain control medication and administer as needed.
2. Insert speculum.
3. Perform cervical antiseptic prep.
4. Perform paracervical block, as appropriate.
5. Dilate the cervix, if required.

   Note: *For endometrial biopsy, cervical dilation is rarely necessary to allow passage of 3 mm cannulae, although it may be required in some instances. In some older women, particularly those who are post-menopausal, the cervix may be sufficiently stenotic that dilation and passage of a cannula is not possible in the outpatient setting.*

Uterine Aspiration/Evacuation Procedure

CAUTION: *Cannulae must be sterile when inserted into the uterus. Observe no-touch technique throughout the procedure: The parts of the instruments that enter the uterus should not touch objects or surfaces that are not sterile, including vaginal walls, before being inserted.*

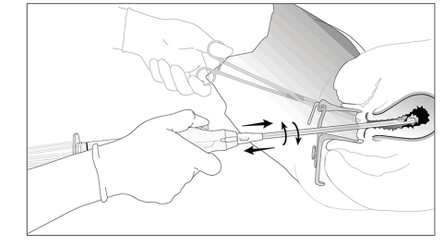
1. With the speculum inserted, hold the cervix steady with a tenaculum and gently apply traction to straighten the cervical canal.
2. Introduce the cannula gently through the cervical os into the uterine cavity. Advance the cannula slowly until it touches the fundus, then withdraw it slightly. (Rotating the cannula with gentle pressure often helps to ease insertion.)

   CAUTION: *Do not insert the cannula forcefully through the cervical os into the uterus. Forceful movements may cause uterine perforation or damage to the cervix, pelvic organs, or blood vessels. Remain alert to signs that may indicate perforation throughout the procedure and stop suction immediately if they appear.*

3. Attach the cannula (with adapter if required) to the prepared aspirator (vacuum established) by grasping the cannula firmly at the base with one hand, holding it steady. Make sure that the cannula does not move forward into the uterus as you attach the aspirator. With the other hand, hold the aspirator by the valve body. Gently rotate the aspirator and push cannula base in firmly, twisting slightly if necessary.

   Note: *As an alternate method, the cannula can be attached to the aspirator prior to insertion through the cervical os.*

4. Release the buttons on the aspirator to transfer the vacuum through the cannula into the uterus. Blood, tissue, and bubbles should begin to flow through the cannula into the aspirator.
5. For uterine evacuation, evacuate the contents of the uterus by rotating the cannula 180 degrees in each direction while using a gentle in-and-out motion.



Note: *When performing endometrial biopsy, movement of the cannula inside the uterus will vary according to the purpose of the biopsy. To take a sample, aspirate tissue by moving the cannula gently back and forth along the anterior uterine wall, then rotate the cannula and take a sample from the posterior uterine wall in the same manner. A small amount of tissue is sufficient for diagnosis in most cases.*

6. When performing uterine evacuation, if the aspirator fills up so that suction stops, depress the valve button(s) and disconnect the cannula from the aspirator. Leave the cannula inserted through the cervical os. Either replace the aspirator or empty its contents and then reattach it to the cannula.
7. If the cannula becomes clogged, ease it back toward—but not through—the external os of the cervix. The movement will often unclog the cannula. If it does not, depress the valve button(s) and disconnect the cannula from the aspirator and remove the cannula from the uterus, taking care to prevent contamination. Alternatively, withdraw the cannula and aspirator together without depressing the button(s). Remove the tissue with sterile forceps. Reestablish vacuum in the aspirator, reinsert the cannula using no touch technique and continue the procedure if necessary.

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

8. **For uterine evacuation,** the signs listed below indicate that the uterus is empty:
   - red or pink foam without tissue is seen passing through the cannula; *and*
   - a gritty sensation is felt as the cannula passes over the surface of the evacuated uterus; *and*
   - the uterus contracts around (grips) the cannula.

   When the uterus is empty, depress the valve button(s) and remove the cannula from the uterus. Alternatively, withdraw the cannula and aspirator together without depressing the button(s). Disconnect the cannula from the aspirator.

   For endometrial biopsy, the instrument can be

withdrawn when an adequate amount of tissue is obtained for pathological examination. Withdraw the cannula from the uterus, then disconnect the cannula from the aspirator. The sample may be left in the aspirator to transfer for assessment.

9. Empty the contents of the aspirator into the appropriate container by releasing the buttons, squeezing the plunger arms, and pushing the plunger fully in the cylinder.
10. For uterine evacuation, inspect aspirated tissue. For pregnancy-related procedures, address any indications that 1) tissue is left in the uterus (incomplete evacuation), or 2) ectopic or molar pregnancy is present. If visual observation is not conclusive, strain the tissue, put it in water or vinegar and view it with light from beneath. Tissue left in the uterus can lead to infection or bleeding. In this situation, repeat aspiration of the uterus. If no villi or decidua are present in the tissue, take steps to rule out ectopic pregnancy, which may include ultrasound, blood samples for determination of HCG level, and / or referral.

    Note: Endometrial biopsy samples should be handled according to laboratory protocols.
11. When the procedure is complete, proceed with any contraceptive or other concurrent procedures to be conducted.

Instrument Processing

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

The Ipas MVA Plus®, and Single-Valve aspirator are labeled for multiple use and must be high-level disinfected or sterilized prior to use and after each procedure to remove contaminants. Aspirators do not need to remain high-level disinfected or sterile at the time of use.

Ipas EasyGrip® cannulae are reusable after processing where regulations allow. These cannulae require high-level disinfection or sterilization between patients and must be HLD or sterile when inserted into the uterus.

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

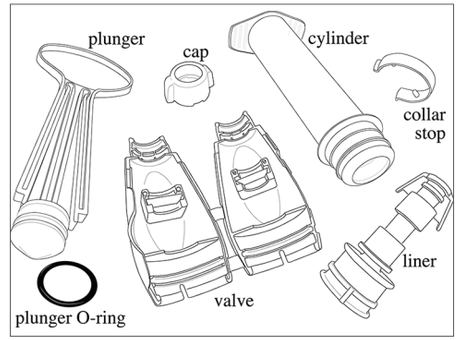
***CAUTION:** Methods of processing that are not included in these instructions may cause damage and/or discoloration to the device.*

Decontamination Soak

Following the procedure, aspirators, Ipas EasyGrip® cannulae, and adapters that are reused should be kept wet until cleaning. A disinfectant such as 0.5% chlorine solution can be used. Letting the devices dry may make it difficult to remove all contaminants.

Cleaning

Aspirators must be disassembled before cleaning and further processing. This includes removal of the plunger O-ring. Detachable adapters used with the Flexible Karman cannulae must be removed from the cannulae. Wash all surfaces thoroughly in warm water and detergent. Detergent is preferable to soap, which can leave a residue.



***CAUTION:** Do not use any pointed or sharp objects to clean the valve parts or to remove the O-ring. This could damage and prevent the device from maintaining vacuum.*

Recommended Processing Methods for Instruments

After cleaning, the Ipas MVA Plus®, the Single-Valve aspirator, Ipas EasyGrip® cannulae, and adapters (if used) must undergo high-level disinfection (HLD) or sterilization between patients to remove contaminants. Devices are then safe to use for the next procedure.

Aspirators and adapters do not need to remain high-level disinfected or sterile at the time of use.

Cannulae must be high-level disinfected or sterile at the time of use.

***CAUTION:** It is important to follow these guidelines to ensure proper processing and to avoid damage to the instruments.*

Sterilization Options

- **[Ipas MVA Plus® Aspirator, Ipas EasyGrip® cannulae and adapters only - do not autoclave Single-Valve aspirator]** Steam autoclave at 121°C/250°F for 30 minutes. Place disassembled Ipas MVA Plus® aspirator on linen, paper, or other appropriate autoclave compatible pouch with biological indicator. Steam must penetrate all surfaces. Parts should not touch and should be arranged so openings are not obstructed, permitting drainage. Ipas EasyGrip® cannulae, particularly the smaller size, may curve in the autoclave. To minimize this, package them by wrapping in paper, linen, or other appropriate autoclave compatible pouch with biological indicator, and lay the package flat along the side or on the bottom of the autoclave. Be sure no other objects in the autoclave are positioned to cause bending of the cannulae.
- **[Ipas MVA Plus, adapters, and EasyGrip® cannulae only - do not use Sporox with the Single-Valve aspirator]**

  Completely immerse disassembled parts in Sporox® II for 6 hours. Discard solution per manufacturer's instructions, or sooner, as indicated by results from Sporox test vials.
- **[all multi-use devices]** Completely immerse disassembled parts in a 2% glutaraldehyde solution (Cidex® or equivalent), 10 hours for Cidex® or per manufacturer's instructions. Items must be fully immersed. Discard solution per manufacturer's recommendations or sooner if solution becomes cloudy.

High-Level Disinfection Options

- **[Ipas MVA Plus®, adapters, and EasyGrip® cannulae only—do not boil Single-Valve aspirator]** Boil for 20 minutes. Items do not need to be fully immersed, but aspirators need to be completely disassembled. Cannulae may discolor without affecting function. Grasping hot cannulae may cause flattening. Let water cool before removing cannulae and handle by the adapter/base.
- **[Ipas MVA Plus®, adapters, and EasyGrip® cannulae only - do not use Sporox with the Single-Valve aspirator]**

  Completely immerse disassembled parts in Sporox® II for 30 minutes. Discard solution per manufacturer's instructions, or sooner, as indicated by results from Sporox test vials.
- **[all multi-use devices]** Completely immerse disassembled parts in a 0.5% chlorine solution for 20 minutes. Discard solution daily or sooner if solution becomes cloudy.
- **[all multi-use devices]** Completely immerse disassembled parts in a 2% glutaraldehyde solution (Cidex® or equivalent) per manufacturer's instructions. Discard solution per manufacturer's recommendations or sooner if solution becomes cloudy.

After Processing MVA Instruments

If chemical agents were used in processing:

- Aspirator parts can be thoroughly rinsed in clean potable water (drinking water).
- Ipas EasyGrip® cannulae are to be thoroughly rinsed in boiled water (for instruments that were HLD) or sterile water (if instruments were sterilized) after processing.
- Chemical processing agents are hazardous substances. When processing instruments, take necessary precautions such as using personal protective equipment. Refer to manufacturer's safety instructions to establish safe use.

Reassembly of Aspirators

1. **For the Ipas MVA Plus®,** 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 into place on the end of the valve.
2. **For the Single-Valve aspirator,** attach the button to the clamp and insert into the valve. With the valve button open, push and twist the valve liner through the valve into position.
3. Push the cylinder into the base of the valve. Do not twist the cylinder into the valve when assembling, as this will cause the liner to dislodge and may lead to device failure.
4. Place the plunger O-ring into the groove at the end of the plunger and lubricate it by spreading one drop of lubricant around the O-ring with a fingertip. Plunger O-rings must be lubricated when they are reassembled to function properly. Silicone (not sterile) is provided.

Storage of Instruments

Ipas MVA Plus® and Single-Valve aspirators must be high-level disinfected or sterilized after each procedure to remove contaminants. Aspirators do not need to remain high-level disinfected or sterile at the time of use. Cannulae must be HLD or sterile when inserted into the uterus. Store dry instruments at room temperature, in a clean dry container protected from contaminants, in an environment that preserves the level of processing desired. If this storage is not possible, then reprocess before next use.

When to Replace Cannulae

The Flexible Karman cannulae and the 3 mm cannulae are single use devices. Discard after one use.

When the Ipas EasyGrip® cannulae are processed using the recommended methods, the number of uses can be expected to be up to 25. Actual number of uses may vary, but should not exceed 25 times. Cannulae should be discarded and replaced if any of the following have occurred:

- The cannula becomes brittle
- The cannula becomes cracked, twisted or bent, especially at the aperture
- Tissue cannot be removed during the cleaning process

When to Replace Aspirators

When aspirators are processed using the recommended methods, the number of uses can be expected to be up to 25. Actual number of uses may vary, but should not exceed 25 times. Aspirators should be discarded and replaced if any of the following have occurred:

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

Disposal

Always follow institutional protocols on disposal of infectious waste.

***CAUTION:** Do Not Reuse Single-Use Devices.*

The Flexible Karman cannulae and the 3 mm cannulae are single-use devices. Their design and the materials of construction make them unsuitable for reprocessing.

INTERNATIONAL SYMBOLS USED ON LABELING

REF	Catalog Number	EC REP	Authorized Representative in the European Community
	Manufacturer		Date of Manufacture
	Use By		Caution, Consult Accompanying Documents
LOT	Lot Number	STERILE EO	Sterilized by Ethylene Oxide
#	Quantity/ Content		Sterile Unless Damaged or Opened
	Single-Use, Do Not Reuse		Consult Instructions For Use
	Keep Dry	xx°C xx°C	Temperature Range

These instructions are intended as a general guideline only, and are not to supersede instructional protocols or clinical judgement.

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Ipas MVA Plus	7,641,640 B2
Ipas EasyGrip	2,768,302

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