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Double-Valve Aspirator

Description of Aspirators

This IFU covers one (1) model of aspirator:

- Double-Valve Aspirator *(DVS-SU, DVS-S10)*

The Double-Valve Aspirator is a single-use device. Each aspirator has a cylinder, plunger, and valve(s). Each aspirator is sterilized with ethylene oxide after packaging and remains sterile until the stated expiration date, as long as the package is intact. Each aspirator has a holding capacity of 60cc's, and a suction capacity of 24-26 inches (609.6mm - 660.4mm) of mercury.

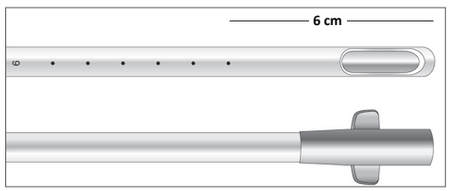
Description of Cannulae

There are three models of cannula:

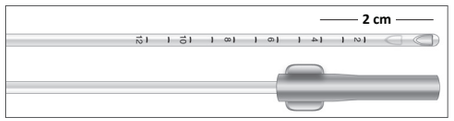
- Ipas EasyGrip® (multiple use, 4–10 and 12 mm)
- Flexible Karman (single use, 4–10 and 12 mm)
- 3 mm (single use)

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
Double-Valve	• Ipas EasyGrip Cannulae (all sizes) • 3mm (with adaptor) • Flexible Karman, 4mm to 10mm (with adaptor)

Intended Use/Indications

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

All aspirators and cannuale are intended for uterine aspiration/uterine evacuation in obstetrics and gynecologic patients. Clinical indications for uterine aspiration with product are: treatment for incomplete abortion for uterine sizes up to 12 weeks from last menstrual period (LMP), first trimester abortion (menstrual regulation), and endometrial biopsy.

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

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)

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 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 abortion or with 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, 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:

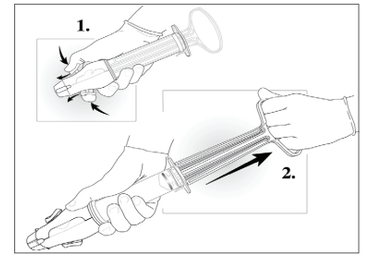
UTERINE SIZE LMP	CANNULA SIZE
4 – 6 weeks	4 – 7 mm
7 – 9 weeks	5 – 10 mm
9 – 12 weeks	8 – 12 mm

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 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.
5. Select and have available appropriate cannula(e). The cannula(e) should remain in the original sealed package until ready for use. Inspect the cannula(e) packaging prior to use. If packaging is damaged, do not use the cannula(e) as the sterility may be compromised.

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.*

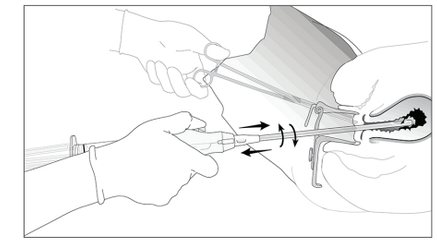
1. With the speculum inserted, hold the cervix steady with a tenaculum and gently apply traction to straighten the cervical canal.
2. Introduce the cannula gently through the cervical os into the uterine cavity. Advance the cannula slowly until it touches the fundus, then withdraw it slightly. (Rotating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

   F**or 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 double-valve aspirator is a single-use device. The design and materials of construction make them unsuitable for reprocessing. Reuse of this device could pose a risk of infection to providers, patients and support staff, device failure or patient injury.

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

Recommended Processing Methods for Instruments

After cleaning, 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 next procedure.

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 EasyGrip® cannulae and adapters only - do not autoclave Double-Valve aspirator]**
  Steam autoclave at 121°C/250°F for 30 minutes. Place cannulae and/or adapters 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 bottom of the autoclave. Be sure no other objects in the autoclave are positioned to cause bending of the cannulae.

- **[Ipas EasyGrip® cannulae and adapters only - do not use Sporox with Double-Valve aspirator]**
  Completely immerse cannulae and/or adapters in Sporox® II for 6 hours. Discard solution per manufacturer's instructions, or sooner, as indicated by results from Sporox test vials.

- **[Ipas EasyGrip® cannulae and/or adapters only]**
  Completely immerse cannulae and/or adapters 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 EasyGrip® cannulae and adapters only - do not boil Double-Valve aspirator]**
  Boil for 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.

- **[Ipas EasyGrip® cannulae and adapters only - do not use Sporox with Double-Valve aspirator]**
  Completely immerse cannulae and/or adapters in Sporox® II for 30 minutes. Discard solution per manufacturer's instructions, or sooner, as indicated by results from Sporox test vials.

- **[Ipas EasyGrip® cannulae and/or adapters only]**
  Completely immerse cannulae and/or adapters in a 0.5% chlorine solution for 20 minutes. Discard solution daily or sooner if solution becomes cloudy.

- **[Ipas EasyGrip® cannulae and/or adapters only]**
  Completely immerse cannulae and/or adapters 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:

- 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.

Storage of Instruments

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

Disposal

Always follow institutional protocols on disposal of infectious waste.

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

The Flexible Karman cannulae and the 3mm 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.

WomanCare Global
1640 Roanoke Blvd.
Salem, VA 24153 USA
www.dktwomancare.org

EC REP Donawa LifeScience Consulting
Piazza Albania, 10
00153 Rome, Italy

U.S. Patent and Trademark Office Registration Number:

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

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