

# Ipas Manual Vacuum Aspirator Technology



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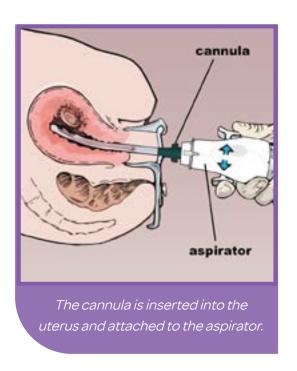
# What is a Manual Vacuum Aspirator?

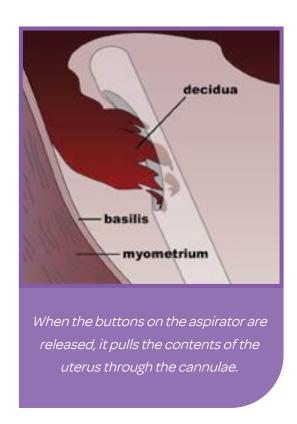
manual vacuum aspirator is a simple, reliable, hand-held device that is used to remove contents from the uterus. Manual vacuum aspirators are used around the world by healthcare providers with basic skills training. The Ipas MVA, was invented in its modern form in the 1970s by Ipas to evacuate the uterus safely while using minimal resources and causing

minimal discomfort to the woman. The MVA revolutionized abortion care and miscarriage management around the world because of its efficacy, safety, simplicity, ease-of-use, and affordability. The MVA gained rapid and widespread adoption from providers eager to bypass operating theaters and make use of the MVA's suitability for outpatient settings.

### How does it work?

A manual vacuum aspirator works by removing the contents of the uterus by suction.





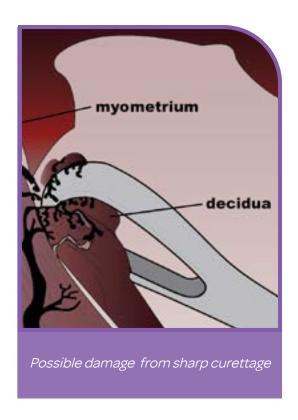
## Indications for the Ipas MVA

The Ipas MVA is indicated for management of all types of spontaneous and induced abortion, as well as for treatment of abortion complications such as incomplete abortion or for post-abortion care. Spontaneous abortion is also called miscarriage or early pregnancy loss.

The Ipas MVA is also indicated for menstrual regulation and endometrial biopsy. Reasons for performing an endometrial biopsy include diagnosing abnormal uterine bleeding or amenorrhea, and screening for endometrial cancer or endometrial infections.



## Why should I use MVA?



M anual vacuum aspiration is a safe and highly effective way to remove uterine contents; it is as effective as electrical vacuum aspiration (EVA)<sup>1</sup> but requires a much lower up-front investment.

In comparison with dilation and curettage (D&C; also known as sharp curettage), the MVA reduces blood loss, pain, infection, and procedure time.<sup>2</sup> Vacuum aspiration is also associated with fewer major and minor complications than D&C.<sup>3</sup> Extensive experience shows vacuum aspiration is highly accepted by women and improves access to and quality of safe abortion care while reducing its cost.<sup>4</sup>

### When should I use MVA?

A trained provider can use an MVA to remove contents from the uterus in accordance with local regulations, including the following common reasons:



Induced abortion



Incomplete abortion



Post-abortion care



Miscarriage management or early pregnancy loss (EPL)



Menstrual regulation



Endometrial biopsy



### **Endorsements From The Industry**

V acuum abortion (both MVA and EVA) is recommended over D&C by the World Health Organization and the International Federation of Gynecology and Obstetrics.

Most major professional obstetric and gynecological groups, like the American College of Obstetricians and Gynecologists (ACOG) and the Royal College of Obstetricians & Gynaecologists (RCOG), have issued similar position statements.



"Vacuum aspiration is the recommended technique of surgical abortion for pregnancies of up to 12 to 14 weeks of gestation... Dilatation and sharp curettage (D&C), if still practiced, should be replaced by vacuum aspiration." Strength of recommendation: STRONG

Safe abortion: technical and policy guidance for health systems. Geneva: World Health Organization, 2012, 2nd edition.



"Evacuate the uterus with vacuum aspiration or medications, not sharp curettage (also known as dilatation and curettage or D&C)."

Consensus Statement on Uterine Evacuation.

London: International Federation of Gynecology & Obstetrics. July 12, 2011.



# Key advantages of the MVA

The MVA also transforms service delivery and availability by saving significant financial and human resources.

#### Delivery in the outpatient setting:



The MVA is quiet, portable, and electricity-free, so it can be set up quickly in outpatient settings and used with local anesthesia.<sup>5</sup> This frees up operating theaters for acute cases and avoids risks related to general anesthesia.

# Task-shifting from specialists to other providers:



Nurses, midwives, and other primary healthcare providers can safely and effectively perform uterine evacuations with basic skills training.<sup>6</sup> This improves service availability and optimizes human resource allocation.

#### Customer-centric care:



The MVA uses different sized cannulae based on gestational term, which reduces the need for dilation and can be less damaging to the cervix. The MVA also yields readily identifiable products of conception thus avoiding a "curette check" that risks harming the uterus.<sup>7</sup>

# How is the Ipas aspirator different from other aspirators?

The Ipas aspirators (the Ipas MVA Plus®, the Ipas Double Valve Aspirator, and the Ipas Single Valve Aspirator) are the most-widely distributed manual vacuum aspirators in the world.8 They hold quality certifications from some of the most demanding regulators and have been marketed in over 100 countries for more than 40 years.

In addition to their longstanding reputation for quality, the Ipas MVA Plus® and the Ipas Single Valve Aspirators are proven to be reusable up to 25 times. The Ipas EasyGrip® cannula is likewise proven to be reusable up to 25 times.<sup>9</sup>

Because they can be reused 25 times, the Ipas MVA Plus® and Ipas EasyGrip® cannulae offer the **best value of any manual vacuum aspirators** available in the market. Other aspirators are not reusable and so can only be used once before disposal.

Table 1: Advantages of Ipas MVA Plus® aspirator and EasyGrip® cannulae against other MVA products.

	Ipas MVA Plus® and EasyGrip® cannulae	Other Aspirators and cannulae
Autoclaveable	$\checkmark$	X
Reusable up to 25 times	$\checkmark$	X
Listed with the US FDA	$\checkmark$	X
CE marked	$\checkmark$	SOME



# Why are there different types of lpas aspirators?

There are three types of Ipas aspirator to respond to specific customer needs:



# **<b>§Ipas** MVAPIus<sup>®</sup>

The Ipas MVA Plus® is the most advanced MVA in the world¹o: specifically designed for reuse, it can be disassembled for easy cleaning, is compatible with cannulae sizes 4-10mm and 12mm, and is the only MVA in the world that tolerates heated methods (i.e. autoclave or boiling water) for processing.



# **∛lpas** Double-Valve Aspirator

The Ipas Double Valve Aspirator is compatible with cannulae sizes 4-10mm and 12mm but is designed for customers who prefer single use. This is ideal for markets where reuse of medical devices is not allowed or for customers whose clinical protocols instruct disposal of MVA devices after use.



# **Ipas** Single-Valve Aspirator

The Ipas Single Valve Aspirator is reusable when processed via heat-free methods but only fits cannulae sizes 4-6mm. However, the Ipas Single Valve Aspirator does not need an adaptor to be used with the special 3mm Endometrial Biopsy cannula.



# Why are there different sizes of cannulae and what can they be used for?

There are different sizes of cannulae in order to remove the products of conception more quickly. As more time passes since a woman's last menstrual period (LMP), the products of conception become larger. Because of this, cannulae with larger diameters are better for removing more contents.

The larger sized Ipas cannulaes (9mm, 10mm, 12mm) are specially designed with a single large "scoop" aperture (opening) on the side in order to pass products of conception from later gestational ages more easily.

Providers select the cannula size based on the woman's gestational age, which is an indicator of the volume of pregnancy tissue. The table below is a guide to selecting a cannula of the right diameter, but providers should always exercise their clinical judgment when deciding how to perform a uterine evacuation.



Table 2: Approximate cervical dilation based on gestational age

Gestational age (weeks)	Cannula diameter (mm)
4-6 weeks	4-7 mm
7-9 weeks	7-9 mm
10-12 weeks	9-12 mm



# What is the difference between an Ipas EasyGrip® and a Flexible Karman cannulae?

The two cannula types serve the same essential function: evacuating the uterus. However, there are three distinctions between the Ipas EasyGrip® cannulae and the Flexible Karman cannulae

#### Reusable:

In countries where reuse is permitted, Ipas EasyGrip® cannulae can be reused up to 25 times after proper processing. The softer, more flexible plastic of the Karman cannulae is not designed to withstand reprocessing and is limited to single-use.

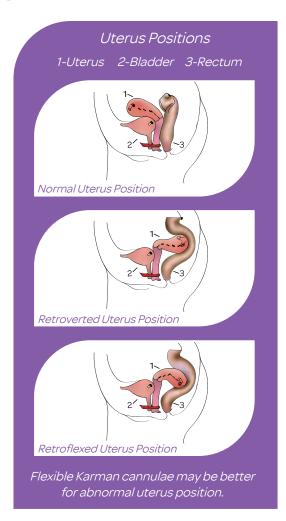
#### Greater rigidity:

Ipas EasyGrip® cannulae are semi-rigid and provide greater tactile feedback. This is useful for feeling the gritty sensation that indicates an evacuated uterus.

However, the pliability of Flexible Karman cannulae may be preferable for clients with retroverted or retroflexed uterus.

#### Permanently integrated adaptors:

Ipas EasyGrip® cannula feature color-coded winged adaptors that make identification and handling easier.







## Reusability

The Ipas MVA delivers unrivalled value because the low, up-front cost of the device is divided over 25 uses.

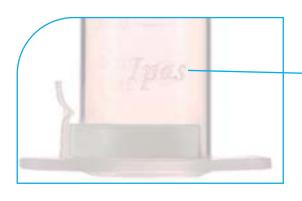
With the availability of simple disinfection methods like boiling water, the effective cost per procedure is very low and enhances patient access to high-quality care by making safe uterine evacuation services more available and affordable.



# Why can I reuse some Ipas MVA products and not others?

You can reuse certain Ipas MVA products because they are made of durable, high-quality plastics and parts that can withstand repeated reuse. The Ipas MVA Plus®, Ipas Single Valve Aspirator, and Ipas EasyGrip® cannulae are tested under rigorous conditions for reuse up to 25 times. No other MVA has been tested for reuse.





Raised
"Ipas"
imprint
on
MVA Plus

To make sure you are purchasing a reusable MVA that can withstand repeated use, look for the raised "Ipas" imprint on your aspirator or cannula and make sure your MVA packaging does not include the "single use" symbol. To make sure your MVA is reusable, refer to the manufacturer's instructions or ask your WomanCare Global representative for further details.

# Which Ipas MVA products can I reuse?

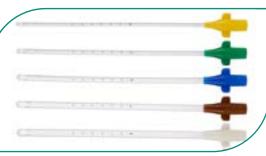
he following Ipas MVA products are reusable:



## **∛lpas** MVAPlus®

The MVA Plus® was engineered with the following features to enable easy cleaning and processing:

- Clear fluid path without ridges or crevices to avoid fluid or material traps.
- Can be fully disassembled with a removable valve liner so that all surfaces are accessible for direct cleaning,
- Heat-tolerant plastics that can withstand boiling or steam autoclaving without warping or melting.
- Adhesion-resistant plastics prevent fluids or materials from sticking to the device or components during procedures.



## **∛lpas** EasyGrip®

The Ipas EasyGrip® cannulae was designed with the following to enable reuse:

- Heat-tolerant plastics that can withstand boiling or steam autoclaving
- Permanently integrated adaptors to facilitate handling during processing



#### **♦ Ipas** Single-Valve Aspirator

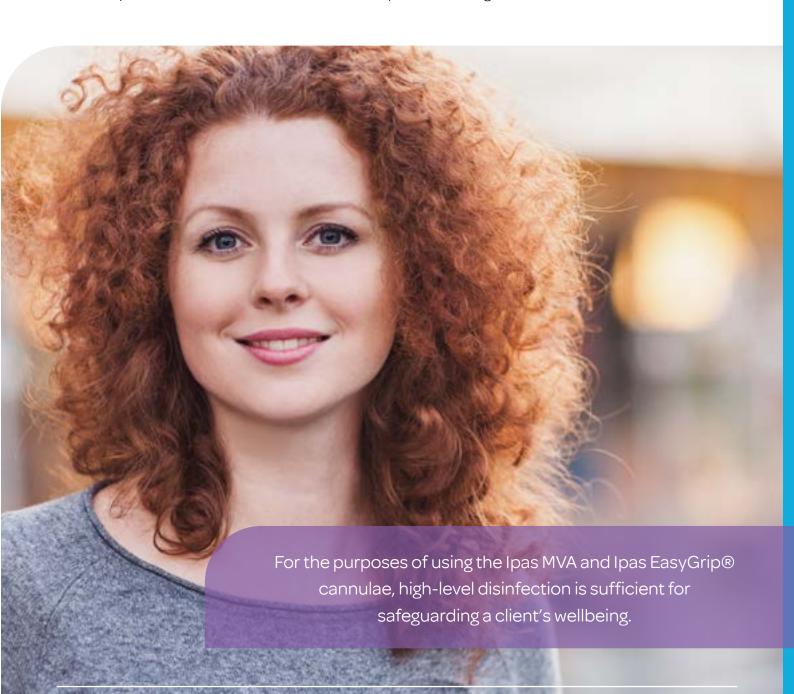
The Ipas Single Valve Aspirator was designed for reprocessing via heat-free methods only:

- Can be fully disassembled with a removable valve liner so that all surfaces are accessible for direct cleaning.
- Heat-free chemical soaks can be used to achieve high-level disinfection (HLD) or sterilization.



# What is the difference between sterilization and high-level disinfection?

5 terilization and high-level disinfection are both acceptable methods of decontamination to safeguard patient safety. Sterilization is the complete elimination of all micro-organisms in or on an instrument, while high-level disinfection leaves only a small number of bacterial spores. This means sterilization is harder to perform than high-level disinfection.



# How can I sterilize or high-level disinfect my Ipas MVA equipment?

There are "heated" and "heat-free" methods for disinfecting your MVA equipment. Be careful to follow the instructions for your product: only the Ipas MVA Plus® and EasyGrip® cannulae can withstand such heated methods.

Table 3: Methods of Sterilization and High-Level Disinfection

#### **HEATED METHODS**

For Ipas MVA Plus® and Ipas EasyGrip® only

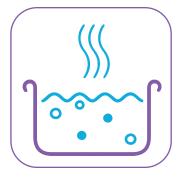


#### **HEAT-FREE METHODS**

For all reusable lpas devices



• Steam autoclave at 121 C for 30 min



 Boil for 20 min. Wait for the water to cool before removing cannulae and handle only by the adaptor/base



- Soak in 0.5% chlorine solution for a minimum of 20 minutes
- Soak in 2% glutaraldehyde solution (e.g. Cidex) for a minimum of 20 minutes or manufacturer's recommendations
- Soak in 7.5% hydrogen peroxide solution (e.g. Sporox II) for a minimum of 30 minutes
- Thoroughly rinse with disinfected or sterile water after processing



### Useful Terms to Know

Some useful definitions of technical or medical terms included in this brochure:

#### Spontaneous abortion:

Unintentional termination of pregnancy (also called a miscarriage). The incidence of 2 or 3 consecutive spontaneous abortions is known as recurrent abortion or recurrent pregnancy loss.

#### Missed abortion:

When the pregnancy has stopped developing but before any products of conception are expelled or there is any bleeding. Left untreated, this would eventually result in a spontaneous abortion with symptoms like bleeding.

#### Inevitable abortion:

Vaginal bleeding or rupture of the membranes accompanied by dilation of the cervix.

#### Endometrial biopsy:

A medical procedure that involves taking a tissue sample of the lining of the uterus for diagnostic purposes.

#### Incomplete abortion:

Expulsion of some, but not all, products of conception. The Ipas MVA turns incomplete abortions into complete abortions by removing all products of conception.

#### Post-abortion care:

Emergency treatment for complications related to spontaneous or induced abortions; usually includes completing the uterine evacuation with MVA or medications. May include offers of contraception to prevent future unintended pregnancy and connections with other needed services (i.e. STI testing, etc.).

#### Induced abortion:

Intentional termination of pregnancy.

#### Menstrual regulation:

Uterine evacuation without laboratory or ultrasound confirmation of pregnancy for women who report recent delayed menses.





<sup>1</sup>Goldberg, A.B. et al. (2004). Manual versus electric vacuum aspiration for early first-trimester abortion: a controlled study of complication rates. Obstet Gynecol. 2004; 103:101–7.

<sup>2</sup>Verkuyl, D. A., & Crowther, C. A. (1993). Suction v. conventional curettage in incomplete abortion: A randomised controlled trial. S. Afr. Medical Journal, 83(1), 13-15.

<sup>3</sup>Cates, W., Grimes, D.A. & Schulz, K.F. (2000) Abortion surveillance at CDC – creating public health light out of political heat. American Journal of Pre-





<sup>6</sup>Barnard, S et al. (2015) Doctors or mid level providers for abortion. Cochrane Database of Systematic Reviews, 7(CD011242).

<sup>7</sup>Edwards, J., & Carson, S.A. (1997). New technologies permit safe abortion at less than six weeks' gestation and provide timely detection of ectopic gestation. American Journal of Obstetrics and Gynecology, 176(5), 1101-1106.

<sup>8</sup>Girvin, S. & Ruminjo, J. (2003). An evaluation of manual vacuum aspiration instruments. International Journal of Gynecology & Obstetrics, 83 (2), 219-232.

<sup>9</sup>Powell, B. & Kapp, N. (2019). Validation of instrument reprocessing methods for the Ipas manual



