

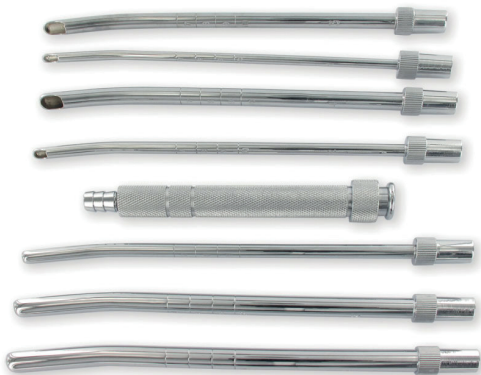


GIMA

PROFESSIONAL MEDICAL PRODUCTS

SET CANNULE ASPIRAZIONE UTERINA SET OF UTERINE SUCTION CANNULAS

Manuale d'uso User manual



- È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.
- All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.

REF 28260



Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com
Made in Pakistan



Before using set of 7uterine aspiration cannulas with one handle read instructions carefully and keep them in a safe place for future record.

Intended use:

Uterine suction aspiration cannula is used as an aspiration to remove uterine contents through the cervix. It may be used as a method of induced abortion, a therapeutic procedure used after miscarriage, or a procedure to obtain a sample for endometrial biopsy.

Brief Description:

Uterine suction aspiration cannula is used as an aspiration to remove uterine contents through the cervix. It may be used as a method of induced abortion, a therapeutic procedure used after miscarriage, or a procedure to obtain a sample for endometrial biopsy. The rate of infection is lower than any other surgical abortion procedure at 0.5%. Some sources may use the terms dilation and evacuation or "suction" dilation and curettage to refer to vacuum aspiration, although those terms are normally used to refer to distinct procedures. It can also be used as a method of induced abortion, as a therapeutic procedure after miscarriage, to aid in menstrual regulation, and to obtain a sample for endometrial biopsy. It is also used to terminate molar pregnancy.

When used as a miscarriage treatment or an abortion method, vacuum aspiration may be used alone or with cervical dilation anytime in the first trimester (up to 12 weeks gestational age). For more advanced pregnancies, vacuum aspiration may be used as one step in a dilation and evacuation procedure. Vacuum aspiration is the procedure used for almost all first-trimester abortions.

Features:

1. Uterine suction aspiration cannula has smooth surface finish.
2. Uterine suction aspiration cannula has a simple elegant design.
3. The product is easy to use.
4. The necessary skills are easy to acquire and require minimal additional training and resources.
5. Uterine suction aspiration cannula is available in various sizes i.e. Dia 5.0mm, 6.0mm, 7.0mm, 8.0mm, 9.0mm, 10.0mm, 11.0mm with one handle.

Operating Procedure:

Uterine suction aspiration cannula may be used as a method of induced abortion, as a therapeutic procedure after miscarriage, to aid in menstrual regulation, and to obtain a sample for endometrial biopsy. It is also used to terminate molar pregnancy.

Step 1: Prepare the Aspirator:

- Position the plunger all the way inside the cylinder.
- Have collar stop in place with tabs in the cylinder holes.
- Push valve buttons down and forward until they lock.
- Pull plunger back until arms snap outward and catch on cylinder base.

Step 2: Prepare the Patient

- Administer pain medication to have maximum effect when procedure begins.
- Give prophylactic antibiotics to all women, and therapeutic antibiotics if indicated.
- Ask the woman to empty her bladder.
- Conduct a bimanual exam to confirm uterine size and position.
- Insert speculum and observe for signs of infection, bleeding or incomplete abortion.

Step 3: Perform Cervical Antiseptic Prep

- Use antiseptic-soaked sponge to clean cervical os. Start at os and spiral outward without retracing areas. Continue until os has been completely covered by antiseptic.

Step 4: Perform Paracervical Block

- Paracervical block is recommended when mechanical dilatation is required with MVA.
- Administer paracervical block and place tenaculum.
- Use lowest anesthetic dose possible to avoid toxicity – foreexample, if using lidocaine, the recommended dose is less than 200 mg.

Step 5: Dilate Cervix

- Observe no-touch technique when dilating the cervix and during aspiration. Instruments that enter the uterine cavity should not touch your gloved hands, the patient's skin, the woman's vaginal walls, or unsterile parts of the instrument tray before entering the cervix.
- Use mechanical dilators or progressively larger cannulas to gently dilate the cervix to the right size.

Step 6: Insert Cannula

- While applying traction to tenaculum, insert cannula through the cervix, just past the os and into the uterine cavity until it touches the fundus, and then withdraw it slightly.

Step 7: Suction Uterine Contents

- Attach the prepared aspirator to the cannula if the cannula and aspirator were not previously attached.
- Release the vacuum by pressing the buttons.
- Evacuate the contents of the uterus by gently and slowly rotating the cannula 180° in each direction, using an in-and-out motion.
- When the procedure is finished, depress the buttons and disconnect the cannula from the aspirator. Alternatively, withdraw the cannula and aspirator without depressing the buttons.

Step 8: Inspect Tissue

- Empty the contents of the aspirator into a container.
- Strain material, float in water or vinegar and view with a light from beneath.
- Inspect tissue for products of conception, complete evacuation and molar pregnancy. If inspection is inconclusive, re-aspiration or other evaluation may be necessary.

Step 9: Perform Any Concurrent Procedures

- When procedure is complete, proceed with contraception or other procedures, such as IUD insertion or cervical tear repair.

Step 10: Process Instruments

- Immediately process or discard all instruments, according to local protocols.

Cleaning:

The Product can be cleaned by using the following method.

1. Slightly moisten a cotton swab or cloth with isopropyl or ethyl alcohol and gently wipe the surface of the product.
2. Wipe from side to side rather than in a circular motion.
3. Always clean it with proper care.

Sterilization:

After cleaning, the components can be gas-sterilized with ethylene oxide at up to 65°C. Autoclaving can also be used.

Gas Sterilization:

Gas sterilization by Ethylene oxide up to a maximum temperature of 65°C and 8 psi may be performed, which is preferred especially if sterilization is to be performed regularly.

Autoclave:

In order to perform Autoclave kindly refer to below mentioned table:

	(A) GRAVITY DISPLACEMENT STEAM	B) PRE-VACUUM STEAM
Temperature	121°C (250 °F)	134°C (270 °F)
Cycle Time	30 Min	5 Min
Dry Time	15 Min	20 Min

Caution:

- Do not insert the cannula forcefully.
- Do not use the product if it is broken.
- Do not place the product under extreme condition.
- Do not place the product under sun light or near heat. Never use abrasive cleaning agents, thinners or benzene for cleaning.
- Do not use chemicals other than isopropyl or ethyl alcohol on the product.

Recommended Operating Environment

Operation

Temperature 10°C to 40°C

Humidity 30% to 75%

Air Pressure 700hPa to 1060hPa











Altitude 0 - 13123 feet (0 - 4000 meters)

Storage and Transport

Temperature -20°C to 60°C

Humidity 10% to 90% (Without Condensation)

Air Pressure 500hPa to 1060hPa

	Caution: read instructions (warnings) carefully		Consult instructions for use
	Keep in a cool, dry place		Keep away from sunlight
	Manufacturer		Non-sterile
	Product code		Lot number
	Medical Device compliant with Regulation (EU) 2017/745		Medical Device

GIMA warranty terms

The Gima 12-month standard B2B warranty applies.