



# GIMA

PROFESSIONAL MEDICAL PRODUCTS

## CANNULA DI ASPIRAZIONE "BIERER" S/S BIERER ASPIRATION TUBE

### Manuale d'uso User manual



**ATTENZIONE:** 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.

**ATTENTION:** 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** 28262 - 28264



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**Intended use:**

Bierer aspiration curette is 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:**

- The suction tube is used inside the tube near the tip existing at the front side and is made of stainless steel.
- The tubular adapter is used to attach with the handle through assembling and has knurling at its back for the attachment of rubber pipe onto it. The tubular adapter material is stainless steel.
- The front end tip is used at the front end of tube that has the conical shape and is made of stainless steel.
- The locking ring is used for locking the handle with the tubular adapter and it is made of stainless steel.
- The tube is attached to the suction tube via the handle and its material is stainless steel. The sizes are 8mm (code 28262) and 12mm (code 28264).
- The handle is made of stainless steel material and has diamond knurling onto it and further it has attachment with the tubular adapter through the locking ring.
- The O-ring is used inside the tube for proper fitting of the tube and the tubular adapter.
- The steel wire is used inside the tube for proper fitting of the tube with the tubular adapter and the other wire is used at the front end of the tube that is used for cleaning purpose.

**Features:**

- Aspiration curette has smooth surface finish.
- Bierer aspiration curette has a simple elegant design.
- The product is easy to use.
- Aspiration tube is available in various sizes i.e. 8 & 12mm.

**Operating Procedure:**

Aspiration curette is an outpatient procedure that generally involves a clinic visit of several hours. The procedure itself typically takes less than 15 minutes. Suction is created with either an electric pump (electric vacuum aspiration or EVA) or a manual pump (manual vacuum aspiration or MVA).

A hand-held 25cc or 50cc syringe can function as a manual pump. Both methods use the same level of suction and so can be considered equivalent in terms of effectiveness and safety.

The clinician may first use a local anaesthetic to numb the cervix. Then, the clinician may use instruments called “dilators” to open the cervix, or sometimes medically induce dilation with drugs. Finally, a sterile cannula is inserted into the uterus and attached via tubing to the pump. The pump creates a vacuum which empties uterine contents.

After a procedure for abortion or miscarriage treatment, the tissue removed from the uterus is examined for completeness. Expected contents include the embryo or foetus, as well as the decidua, chorionic villi, amniotic fluid, amniotic membrane and other tissue.

Post-treatment care includes brief observation in a recovery area and a follow-up appointment approximately two weeks later. These would tend to include tests for infection in case any biological material was not properly removed.

Additional medications used in vacuum aspiration include NSAID analgesics that may be administered already the day before the procedure, as well as misoprostol on the preceding day for cervical ripening.

### **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:

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

### **Caution:**

- Make sure product is intact & in its proper shape before use.
- While engaging the product make sure it is properly secured.
- 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.

## **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.