

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 to allow the suction or drainage of biological fluids from the uterus. Use is limited to outpatient procedure, under the supervision of qualified healthcare personnel, and it is not intended for diagnostic or therapeutic purposes.

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. The procedure itself typically takes less than 15 minutes. Suction is created with a manual pump (manual vacuum aspiration or MVA). A hand-held 25cc or 50cc syringe can function as a manual pump.

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.

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:

	(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:

- 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
	Unique device identifier		Authorized Representative in Swiss
	Authorized Representative in the UK		

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.