GIMA

PROFESSIONAL MEDICAL PRODUCTS

# *PINZA BIOPSIA*
# *BIOPSY FORCEPS*

**Manuale d'uso - User manual**

**REF** **819-600-01 (Gima 29421)**
**819-610-01 (Gima 29422)**


Medical Devices (Pvt) Ltd
Wazirabad Road, Ugoki,
Sialkot - Pakistan
Made in Pakistan

EC REP Obelis s.a. Bd Général Wahis 53
B- 1030 Brussels

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


*M29421-M Rev.0-12.23*

**29421 - BIOPSY FORCEPS 3,5x8 mm CUP JAWS 420 mm**
**29422 - BIOPSY FORCEPS 4 mm CUTTING JAWS 420 mm**

**ATTENTION**
The operator/user must carefully read and understand this manual thoroughly to keep the product performance durable and reliable for a long period. Failure to understand and observe any warning statement in this manual could lead to patient sever injuries. Check that the product is in perfect conditions.

## *OPERATING INSTRUCTIONS*

Biopsy forceps are brought exactly to the target site in the gastric mucosa. The jaws are then used to cut the sample from the tissue. It is necessary to accurately position the jaws on the lesion to ensure the best sample. This may be done by rotating the jaws, or it may be necessary to approach the lesion tangentially. Biopsy forceps with jaws that operate independently will assist the tangential approach.
It is important that the sample is cut cleanly from the patient and not torn out, as this minimizes bleeding and ensures a sample of maximum quality. After the sample is obtained, it is retained within the biopsy forceps cup to ensure safe passage up the endoscope channel. Care should be taken when retracting the biopsy forceps from the channel not to damage the endoscope. This is particularly the case when retracting through the bending section of the endoscope.

The instrument has got the following major features:
- Stainless steel construction making it durable, easier to clean and disinfect with conventional solutions.
- Precisely finished smooth cutting edges.
- Ergonomically formed handle which is comfortable to hold.
- Single handle for all types of forceps.
- Shaft rotatable through 360 degrees.

**Precautions**
- Repairs shall only be carried out by qualified persons.
- Check the correct operation of the device before use.
- Use only original parts and accessories.

## *Cleaning procedure*

Immediately after use, the biopsy forceps should be rinsed under cool running tap water until all visible soil is removed. Ensure that all hard-to-reach areas are flushed with the running tap water. Immerse biopsy forceps in a presoak enzymatic cleaner solution, prepared in accordance to manufacturer's recommendations for a minimum of two minutes.
Remove device from enzymatic cleaner solution and rinse with lukewarm running tap water for a minimum of one minute to remove all residues and visible soils. Then, immerse device in enzymatic detergent. Brush thoroughly using a soft bristle brush, while ensuring that in all hard-to-reach areas visible soils / residues are removed. Dry with lint-free, clean cloth or filtered pressurized air. Follow with HIGH LEVEL DISINFECTION or STEAM STERILIZATION PROCEDURE.

**Disinfection**
Soaking in solutions or in a sterilized thermochemical washer up to 93°C may perform disinfection. Manufacturer's instructions regarding duration and concentration of solutions should be strictly adhered. After disinfection, rinse thoroughly in sterile water and dry with a clean lint-free cloth.

**Cold Soak Solution**
To achieve a high-level disinfection, Cidex®OPA or 2.4% Glutaraldehyde solution may be used according to manufacturer's instructions. Dry with lint-free, clean cloth or filtered pressurized air. Reassemble all parts and test the product for proper functioning.

Do not immerse biopsy forceps in Bleach, Betadine or Potassium Hydroxide solutions. Doing so will severely damage instruments. Also avoid metal to metal contact after soaking. The biopsy forceps should be rinsed under sterile water to remove chemical residues and dried with lint-free clean cloth or filtered pressurized air.

**Sterilization**
Before performing any of the procedures described below, the biopsy forceps should be cleaned as described in the cleaning Procedure.
**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.

**Steam Sterilization**
Steam Sterilization can also be performed. Insert device in appropriate autoclave pouch.

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

**Note**
Do not exceed temperature of 135°C and pressure of 28 psi.

Flash autoclaving and hot air sterilization should be avoided as these processes will damage the instrument.

## *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

## *Precautions*

To avoid any unwanted event follow the instructions/precautions as written
a) Read the label before loosening packing.
b) Store in clean environment and preserve at comfortable temperature.
c) Only qualified medical personnel should use it.
d) Use protective gloves and wash hands with anti germs and anti bacterial soap before operating any medical operation.
e) Use properly to increase the shelf life of the instrument. Avoid placing the instrument for a long time in salty or humid atmosphere.

**Warning**
a) Don't use the equipment in case it is damaged, apply to you retailer.
b) If the Handle has rusted then don't use it.

**Shelf life: 5 years**

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|---|---|---|---|---|---|
| REF | Product code | | Manufacturer | | Date of manufacture |
| LOT | Lot number | CE | Medical Device complies with Directive 93/42/EEC | | |
| | Keep in a cool, dry place | | Caution: read instructions (warnings) carefully | | |
| | Keep away from sunlight | EC REP | Authorized representative in the European community | | |
| | Consult instructions for use | | Imported by | | |

**GIMA WARRANTY TERMS**
The Gima 12-month standard B2B warranty applies.