

GIMA Reusable Surgical Instruments User Manual

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GIMA Reusable Surgical Instruments



Specifications

• Brand: Gima

• Warranty: 12-month standard B2B warranty

• Compliance: Medical Device complies with Directive 93/42/EEC; in accordance with MDCG 2020-2

Manufacturer: Gima S.p.A.Country of Origin: Pakistan

Product Usage Instructions

· Warnings:

 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.

• Storage:

• Store in a cool, dry place.

· Compliance:

 This medical device is compliant with Directive 93/42/EEC and in accordance with MDCG 2020-2. It shall be made compliant with Regulation (EU) 2017/745 for change of class.

• Manufacturer Information:

∘ Gima S.p.A. Via Marconi, 1 – 20060 Gessate (MI) Italy

Email: gima@gimaitaly.com / export@gimaitaly.com

• Website: www.gimaitaly.com

USING REUSABLE SURGICAL INSTRUMENTS

These instruments are intended to be used by medical practitioners who are specially trained on how to use and care of them. Incorrect use and poor or inappropriate maintenance can rapidly lead to deterioration of the instruments. The first time, and after every use it is recommended to clean, dry, and sterilize the instruments. The instruments must always be cleaned prior to sterilization. For automated cleaning use only washing equipment with approved and certified detergents. For manual cleaning use approved and certified detergents, brushes ,and running water. Always follow instructions on how to use the detergent; clean the instruments both when open and closed; rinse for 3 minutes and check that water also enters and exits the blind holes several times. Use completely demineralized water in the final rinse phase. Instruments that are not dried could suffer damage by corrosion. Always dry the instruments. After cleaning, and before sterilization it is recommended that you treat the instruments with physiologically safe oil, especially the tips, connectors, terminals, and all moving parts.

Also, make sure that the product does not come into contact with acids or other aggressive disinfectants that could corrode it. The instruments must be sterilized in an autoclave by moist heat sterilization method at 132°C for 15 minutes prior to use in surgery. It is recommended that sterilization temperatures should not exceed 137°C. The process of steam sterilization must take place in accordance with EN ISO 17664. In the context of validating the sterilization process, check the suitability of the specific measures for drying. The humidity in the container can cause the instruments to rust. Often bad, and insufficient drying, is due to the incorrect positioning of the load and the use of unsuitable types of cloths for drying. There is no advice about a maximum number of sterilization cycles, this depends largely on the state of the product. Instruments that show signs of corrosion must be discarded immediately. Always perform a visual inspection for damage or signs of wear: sharp edges must be free of dents and with continuous edges; there should be no distortion of instruments with long parts; the instruments that are part of a larger assembly must be checked together with other assembly components; always check the rotating movement of hinges, which must not have excessive play; always check that the locking systems are working. Whilst the instruments are under warranty, repairs and/or replacement of all defective parts, for reasons that are accepted by the manufacturer, are free, with the exception of costs for labor, travel, transport, packing, etc. Damage caused by improper use of the product is not covered by the warranty.

WARRANTY

GIMA WARRANTY TERMS

• The Gima 12-month standard B2B warranty applies.

WARNINGS

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.

Symbols

	GB Manufacturer
	GB Date of manufacture
NON STERILE	GB Non-sterile
<u> </u>	GB Caution: read instructions (warnings) carefully
	GB Consult instructions for use
*	GB Keep away from sunlight

**	GB Keep in a cool, dry place
REF	GB Product code
LOT	GB Lot number
MD	GB Medical Device
C€	GB Medical Device complies with Directive 93/42/EEC; in accordance with MDCG 2020-2, they shall be made compliant with Regulation (EU) 2017/745, for change of class.
UDI	GB Unique device identifier

CONTACT INFORMATION

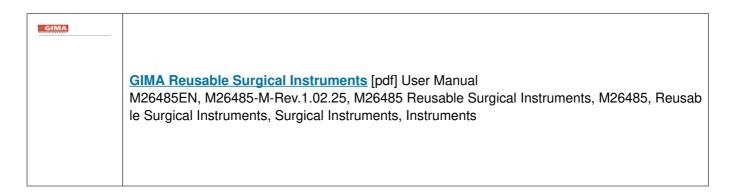
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- gima@gimaitaly.com

- export@gimaitaly.com
- www.gimaitaly.com
- · Made in Pakistan

FAQs

- Q: What is the warranty period for this product?
 - A: The product comes with a 12-month standard B2B warranty.
- Q: Where should I report serious accidents involving the product?
 - A: Serious accidents must be reported to the manufacturer and competent authority of the member state where your registered office is located.

Documents / Resources



References

• User Manual

Manuals+, Privacy Policy

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