



GIMA

PROFESSIONAL MEDICAL PRODUCTS

SPECULUM CUSCO ISOLATO – MEDIO **S.S. CUSCO SPECULUM - MEDIUM INSULATED**

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.

M29763-M-Rev.0-07.20

REF 29763



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MD



DESCRIPTION/INTENDED USE:

These devices are reusable and are supplied non-sterile. Process through cleaning and sterilization prior to initial use.

REUSE:

We guarantee our products to withstand a minimum of 20 sterilization cycles when sterilized in accordance with the validated instructions contained herein. Care in use and handling can extend useful life.

CONTRAINDICATIONS:

These devices should never be used when:

- There is visible evidence of damage to the exterior of the device.
- These devices fail the inspection described herein.
- In the presence of flammable gases, liquids, and/or oxygen enriched environments.

SAFETY TIPS:

- Always place unused accessories in a safe insulated location such as a holster when not in use.
- Inspect and test each device before each use.
- Discard devices that have reached their life expectancy.

INSPECTION:

- These devices should be inspected before and after each use.
- Visually examine the devices for obvious physical damage including:
 - Cracked, broken or otherwise distorted part.
 - Broken or significantly bent connector ..
 - Corrosion or misalignment condition.

CLEANING:

Remove any obvious debris accumulated during use from the device with a soft, non-metallic instrument cleaning brush plus mild detergent and sterile purified water solution. Rinse thoroughly with sterile, purified water until free of detergent residual and debris, then thoroughly dry using a sterile wipe, (Do not fully immerse in fluids).

PRECAUTIONS:

- Do not scrape or scrub coated surface with abrasives.
- Do not use cervical brush to clean smoke tube.
- Do not overlap instruments in sterilization tray.
- Do not soak coated instruments in CIDEX or other caustic cold sterilization solutions.
- Do not use bleach.
- Do not place coated instruments in ultrasonic cleaner.

STERILIZATION:







Position these instruments separately or place in a container so as to prevent instrument from contacting each other or other instruments.

- **Steam:** Steam autoclave at 250°F (121°C) for 30 minutes.
- **Flash:** Steam autoclave at 275°F (134°C) for 10 minutes.
- **Gas (ETO):** Follow manufacturer’s guide for the unit which you are using.
- **Pre-Vac:** Steam autoclave at 270°-273°F (132°-135°C), Exposure Time (4 minutes), Dry Time (20 minutes)

Do not handle the device until it is thoroughly cooled. For maximum life of the product ETO sterilization is recommended.

STORAGE & HANDLING:

These devices must be stored in a clean, cool and dry area. Protect from mechanical damage & direct sun light. Handle with extreme care.

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

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.