

# SIGMOIDOSCOPIO

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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.

**REF** 819-098-12 (GIMA 29410)  
819-096-16 (GIMA 29411)  
819-094-21 (GIMA 29412)

819-092-21 (GIMA 29413)  
819-090-21 (GIMA 29414)



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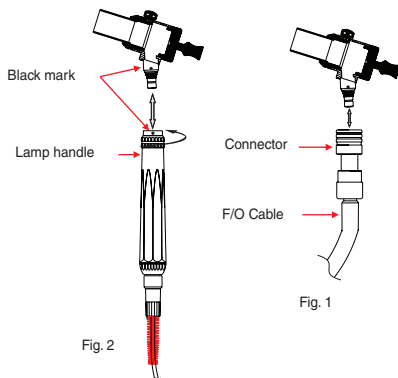


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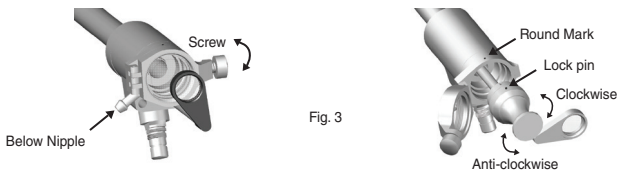


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Loosen the sealing screw and open the window, insert the obturator in the sigmoidoscope by aligning the top of the sigmoidoscope chamber, if required, connect an insufflation bulb to sigmoidoscope head. Lock the obturator by turning the head clockwise & anti-clockwise as shown in fig. 3. Apply a lubricant to the cone and insert in anal passage way. Unlock the obturator by aligning the pin and round mark again and pull out the obturator. Now the instrument is ready for use. Turn on the light to light up on the passage and perform examination and treatment. The plain glass window can be opened and closed at any time. The instrument can be made airtight by gently tightening the screw. If magnification of the object is required, insert the loupe into one of the holes provide. Both swivel to allow the window to be opened or closed.



**Important**

Window can be used as a protection against any unwanted material falling inside the sigmoidoscope. So if the examination is not being conducted and the sigmoidoscope is still inserted, it is highly recommended to close the window.

**INSUFFLATION BULB (NOT INCLUDED IN THE PRODUCT) COD. 29427**

**Use of the rubber insufflation bulb**

Always use the Hygiene Filter (2) when connecting the rubber insufflation (1) bulb to the Proctoscope / Anoscope / Sigmoidoscope. These filters are intended for single use only and prevent internal contamination of the rubber insufflation bulb. For this, connect the transparent hose (3) to the insufflation port

on the Proctoscope / Anoscope / Sigmoidoscope. Control the connection between the transparent hose and the Hygiene Filter. If it isn't securely attached, fix it more tightly. Then connect the Hygiene Filter to the rubber insufflation bulb.

**Caution!** Don't disassemble the insufflation bulb.

**Caution! Infection!** The use of the instrument without the Hygiene Filter may lead to contamination of the rubber insufflation bulb and thereby to an infection of the following patients.

Therefore, always use the filter. If you have forgotten to use the filter, replace the rubber insufflation bulb. If there is a risk of contamination inside the twin bellow insufflator, the twin bellow insufflator has to be replaced and disposed.

**Risk of allergic shock:** The rubber double bellows contain natural rubber latex. Do not use it in patients with a latex allergy.

**Caution! Infection!** The filter is a single use product. If it is reused, the risk of infection increases. The filter is not suitable for being cleaned, disinfected and sterilized.



### **Cleaning / Disinfection of insufflation bulb**

1. Residues and other deposits must be removed immediately after use to avoid any residues drying on to the surface
2. Autoclave is not recommended, this may damage the insufflation bulb
3. Use surface cleaner e.g. Isopropyl alcohol (IPA), for the disinfection of insufflation bulb.

## **CARE AND MAINTENANCE OF OBTURATOR**

### **Cleaning**

Clean immediately after use to prevent the drying-on of residues. We recommend washing with a soft brush and soapy or plain water. If machine washing or chemical cleaners are used, the manufacturer's instructions regarding duration and concentration must be followed. No ultrasonic cleaning. After cleaning, rinse thoroughly with demineralised water and dry at 65°C max.

### **Disinfection**

We recommend soaking in disinfectant or thermochemical disinfection at up to 65°C in a washer sterilizer. Adhere strictly to manufacturer's instructions regarding concentration and duration. After disinfection, rinse with sterile water and wipe dry with a sterile cloth.

## **STERILIZATION**

After cleaning the components can be gas-sterilized with ethylene oxide at up to 65°C. Autoclaving can be used occasionally, but repeated autoclaving will reduce light transmission and life expectancy of the optical fibers. Flash autoclaving and hot air sterilization are not recommended.

### **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

### Recommended operating environments

Operation	Temperature	10°C - 35°C
	Humidity	30% - 75%
	Air pressure	700 hPa – 1060 hPa
Altitude		0-13123 feet (0-4000 meters)
Storage & Transport	Temperature	-20°C - 50°C
	Humidity	10% - 90% (without condensation))
	Air pressure	500 hPa – 1060 hPa

### INDEX OF SYMBOLS

	Caution: read instructions (warnings) carefully		Medical Device compliant with Regulation (EU) 2017/745
	Keep in a cool, dry place		Keep away from sunlight
	Product code		Lot number
	Manufacturer		Date of manufacture
	Consult instructions for use		Medical Device
	Imported by		Authorized representative in the European community

### GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.