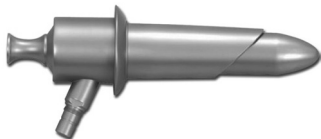


ANOSCOPIO ANOSCOPE



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 819-080-15 (GIMA 29400)
819-082-20 (GIMA 29401)

819-084-25 (GIMA 29402)
819-524-00 (GIMA 29403)



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Read these instructions carefully before using the anoscope and keep them in a safe place for future reference.

Attention

The operator/user must carefully read and understand this manual thoroughly to keep the product performance durable and reliable for longer period.

After opening the packaging, first of all it is necessary to check all the components against the standard configuration. Check that they are all present and in perfect conditions.

Indications for use

Anoscope is an instrument primarily used for examination and treatment of the anal passage.

Feature

These anoscopes have annular F/O illumination hence the anal passage is evenly illuminated for easier examination.

These anoscopes can be powered either with a powerful 120 watt Halogen light source, or by a more compact and economical 6.0 volt lamp handle. These anoscopes are made from 18/8 type stainless steel making them rust proof and most stable under cleaning and disinfection process.

Cautions

Anoscope must be inserted with obturator, securely fitted to it. The cone on these anoscope must be lubricated with suitable lubricant before use.

Usage

Check that all parts are correctly attached before usage. All anoscopes are supplied with ACMI and Wolf connection. The instrument must be used by qualified medical personnel within a professional health facility. A STORZ connector is also supplied in the package, allowing multiple connect ability options.

Attach a F/O cable to a light source and then attach the coupling adaptor to the proximal end of the

adaptor on this anoscope as shown in fig. 1.

If a light source is not available, a lamp handle with a direct main adaptor and a 6.0 volt halogen lamp can be used as shown in fig. 2. An add-on type F/O handle can also be used with the F/O cable which can then act as the handle for these anoscope. Align the black mark on the handle with a similar mark on the anoscope to achieve proper locking. The handle is locked onto the anoscope by twisting the knob towards right. For unlocking, twisting the knob towards left and pull down the handle.

Attach the Tube to the front side of head exclusively for anoscope with 90° direction of view only and make sure tube is firmly screwed in as illustrated in Fig 3.

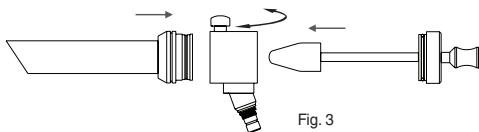
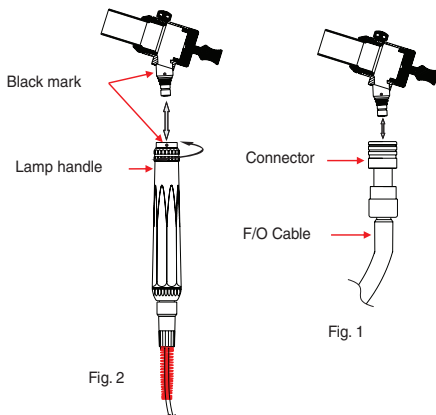


Fig. 3

Anular Fiber illumination

Apply a lubricant to the cone and insert in anal passage way. Align the black mark on the head & obturator with a similar mark on the anoscope to achieve proper unblocking. Remove the obturator by twisting left or right for locking insert the obturator anoscope black mark on the head & handle of obturator in same align insert and twist left or right as shown in Fig. 3. Remove the obturator by aligning the slot again and pull out the obturator. Now the instrument is ready for use. Turn on the light to light up the passage and perform



examination and treatment. If magnification of the object is required, insert the swivel lens in to one hole provided.

Important

Obturator can be used as a protection against any unwanted material falling inside the anoscope (Proctology Instruments). So if the examination is not being conducted and the anoscope (Proctology Instruments) is still inserted, it is highly recommended to put the obturator in tube.

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
	Unique device identifier		Temperature limit
	Limite di umidità		Atmospheric pressure limit

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.