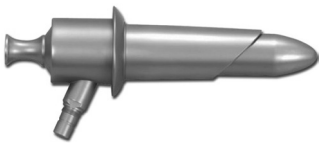
GIMA
PROFESSIONAL MEDICAL PRODUCTS

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.

M29400-M-Rev.3-07.20

REF **29400 - 29401 - 29402 - 29403**

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Made in Pakistan

MD

ITALIANO

Leggere attentamente queste istruzioni prima di utilizzare l'anoscopio e conservarle per una futura consultazione.

Attenzione

L'utilizzatore deve leggere attentamente le istruzioni contenute in questo manuale al fine di ottenere sempre prestazioni ottimali dallo strumento e per mantenere lo stesso affidabile nel tempo.
Controllare il contenuto della scatola contenente l'anoscopio, per assicurarsi che tutti i componenti necessari siano presenti e che siano in perfette condizioni.

Indicazioni d'uso

L'anoscopio è uno strumento utilizzato principalmente per esaminare il passaggio anale

Caratteristiche del prodotto

Questi anoscopi sono dotati di un'illuminazione a fibre ottiche, che consente la costante illuminazione del passaggio anale e ne facilita l'esaminazione.
Questo anoscopio può essere utilizzato sia con fonte di luce alogena da 120 watt, oppure con un più compatto ed economico manico porta luce da 6,0 volt.
Lo strumento è realizzato in acciaio inox 18/8 inossidabile ed è stato testato durante tutte le operazioni di pulizia e disinfezione standard.

Avvertenze

L'anoscopio deve essere montato con l'otturatore, fissato saldamente ad esso. Il cono di questi anoscopi deve essere lubrificato con lubrificante idoneo prima dell'uso.

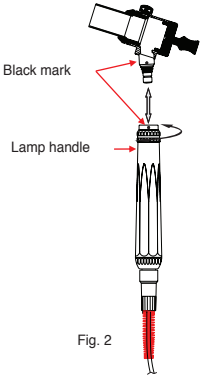

Fig. 2

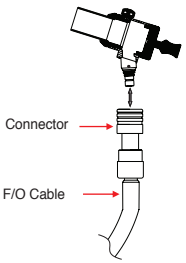

Fig. 1

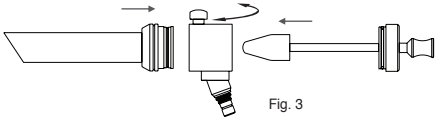

Fig. 3

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 achive 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 steriliz-er. 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	CE	Medical Device compliant with Regulation (EU) 2017/745
	Keep in a cool, dry place		Keep away from sunlight
REF	Product code	LOT	Lot number
	Manufacturer		Date of manufacture
	Consult instructions for use	MD	Medical Device

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