

SIGMOIDOSCOPIO

SIGMOIDOSCOPE

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 29410 - 29411 - 29412 - 29413 - 29414



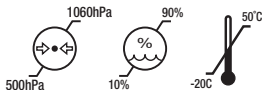
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ITALIANO

Leggere attentamente queste istruzioni prima di utilizzare il sigmoidoscopio 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 il sigmoidoscopio, per assicurarsi che tutti i componenti necessari siano presenti e che siano in perfette condizioni.

Indicazioni d'uso

Il sigmoidoscopio è uno strumento utilizzato per esaminare il passaggio anale ed è disponibile in cinque differenti misure.

Caratteristiche del prodotto

Questi sigmoidoscopi sono dotati di un'illuminazione a fibre ottiche, che consente la costante illuminazione del passaggio anale e ne facilita l'esaminazione.

Read these instructions carefully before using the sigmoidoscope 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

Sigmoidoscope is an instrument primarily used for examination and treatment of the anal passage. The sigmoidoscope is available in five different sizes.

Feature

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

These sigmoidoscope 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 sigmoidoscopes are made from 18/8 type stainless steel making them rust proof and most stable under cleaning and disinfection process.

Cautions

Sigmoidoscope must be inserted with obturator, securely locked. The cone of the obturator and the tube must be lubricated with suitable lubricant before use.

Usage

Check that all parts are correctly attached before usage. All proctoscopes 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 sigmoidoscope 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 sigmoidoscope. Align the black mark on the handle with a similar mark on the sigmoidoscope to achieve proper locking. The handle is locked onto the sigmoidoscope by twisting the knob towards right. For unlocking, twisting the knob towards left and pull down the handle.

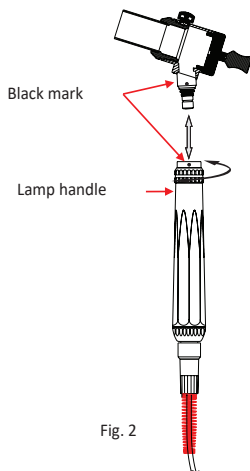


Fig. 2

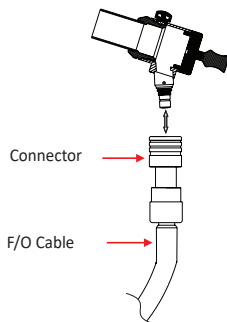


Fig. 1

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.

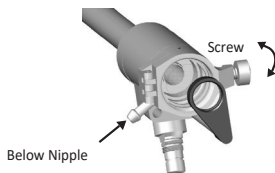
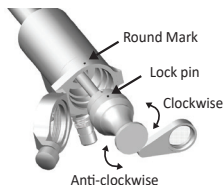


Fig. 3



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
	Authorized representative in the European community		Unique device identifier
	Imported by		Temperature limit
	Humidity limit		Atmospheric pressure limit

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.