PROFESSIONAL MEDICAL PRODUCTS

TESTA ILLUMINAZIONE F.O. ANO-RET-TO-PROCTOSCOPIO

ANO-RECTO-PROCTOSCOPE F.O. ILLUMINATION HEAD

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.

GIMA 25953

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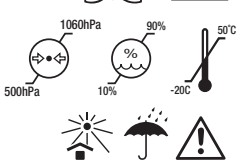
Made in Pakistan

EC REP Obelis s.a. Bd Général Wahis 53
B-1030 Brussels, Belgium

REF **819-103-01**



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Attention

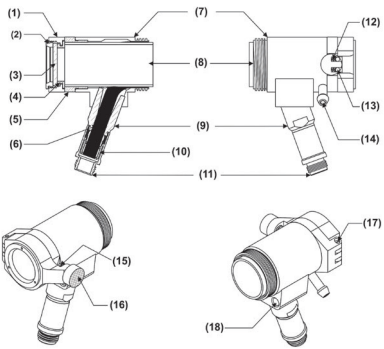
Operating instruction manual relates to F.O. Instrument Head and Disposable Tube. These instructions should be followed to ensure durability of this product. The operator must carefully read and understand this manual thoroughly to keep the product performance durable and reliable for longer period.
After opening the packages, 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.
The instrument must be used by qualified medical personnel within a professional health facility.

Features

1. Stainless steel construction making it easier to clean and disinfect with conventional solutions.
2. Annular F.O. illumination enables brighter illumination.
3. Illumination by Fiber Optic cable and projector, lamp handle or hand held power source.
4. Comes with ACMI and WOLF standard connections, STORZ connector supplied separately.
5. Air tight glass window.
6. Insufflations adaptor for pneumatic test.
7. 1.5 x swivel lens for Sigmoidoscope and 2.0 x lens for Proctoscope and Anoscope.

Product overview (see figure)

1). Glass Window
2). Glass Window Screw Ring
3). Plan Glass
4). Synthetic Seal
5). Back End
6). Fiber Loading Dia 6.00 Length 150mm
7). Main Chamber
8). Inner Tube
9). Instrument End Connector
10). Wolf Fitting Sleeve
11). Storz Adopter
12). Wire Assembling Spring
13). Stainless Steel Ball
14). Insufflation Adaptor
15). Side Screw
16). Side Screw Head
17). Window Assembly Screw
18). Hole for Swivel Lens



Intended use and operation

The F.O. Instrument is intended for examination and performance of procedure within the rectum and the anus. It should only be operated by qualified medical personnel within a professional health facility. When the tube is inserted, remove the obturator through the instrument head.
The viewing window is equipped with a face plate and can be conveniently opened and closed at any time. The instrument can be made airtight by slightly tightening the fastening screw. For an insufflation bulb without a valve, the insufflated air can be regulated by gently loosening or tightening the screw. If magnification of the area to be examined is required, insert the swivel lens into one of the two holes.

Operating instructions

Loosen the fastening screw and open the viewing window. If the swivel window isn't necessary, it can be removed by extracting it upwards out of the instrument head. Attach the instrument to a suitable power/light source. Pull the obturator out of the tube. Insert the tube with the extension piece as far as possible into the instrument head and secure this by twisting to the right. Insert the obturator through the instrument head into the tube. Apply a suitable lubricant to the tip of the obturator and the tube. The tubes should only be inserted into the patient when an obturator is fitted. Choose a tube size suitable for the patient. The instrument head can be used with the twin bellow insufflator. To do so, connect the twin bellow insufflator with the insufflation adopter/bellow nipple.

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.

Application duration

The Sigmoidoscope, Proctoscope and Anoscope are intended for transient application. The Application time should not exceed 15 minutes.

CARE AND MAINTENANCE

Cleaning Procedure

Immediately after use, the F.O. Instrument Head should be rinsed under cool running tap water until all visible soil is removed. Ensure that all hard-to-reach areas are flushed with the running tap water. Immerse sealed F.O. Instrument head in a presoak enzymatic cleaner solution, which was prepared in accordance to manufacturer's recommendations for a minimum of two minutes. Remove device from enzymatic cleaner solution and rinse with lukewarm running tap water for a minimum of one minute to remove all residues and visible soils. Then, immerse device in enzymatic detergent. Brush thoroughly using a soft-bristle brush. Dry with lint free, clean cloth or filtered pressurized air. Follow with HIGH-LEVEL DISINFECTION or STEAM STERLIZATION PROCEDURE.
The twin insufflator can treated by surface disinfection.

Disinfection

Soaking in solutions or Thermo chemically in a washer Sterilizer up to 93°C maximum may perform disinfection. Manufacturer's instruction regarding duration and concentration of solutions should be strictly adhered. After Disinfection, rinse thoroughly in sterile water and dry with a clean lint free cloth.

Cold Soak Solution

To achieve a high-level disinfection, Cidex®OPA or 2.4% Glutaraldehyde solution may be used according to manufacturer's instructions. Dry with lint free, clean cloth or filtered pressurized air. Do not immerse F.O. Instrument in Bleach, Betadine or Potassium Hydroxide solutions.

Doing so will several damage instruments also avoid metal to metal contact after soaking, the F.O. Instrument should be rinsed under sterile water to remove chemical residues and dry with lint free clean cloth or filtered pressurized air.

Sterilization

Before performing any of the procedures described below, F.O. Instrument Head should be cleaned as described in the cleaning Procedure.

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

Note:
Do not exceed temperature of 134°C and pressure of 28 psi Flash autoclaving and hot air sterilization should be avoided as these processes will damage the instrument.

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

Warnings and safety information

Check the correct operation of the device before use. Do not use the device if there are visible signs of damage. Do not use the device in fire or explosive risk area (e.g. oxygen saturated or an aesthetic environments). Do not modify the device. Use only original parts, spare parts, accessories and power sources. The device must not be placed near strong Magnetic fields, e.g. MRI units.

Electromagnetic disturbances

Warning. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Caution!
Indicates potential hazardous situations. Ignoring the corresponding instructions may lead to dangerous situations of mild to serious extent.

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
REF	Product code	LOT	Lot number
	Manufacturer		Date of manufacture
	Consult instructions for use	MD	Medical Device
UDI	Unique device identifier		Temperature limit
	Humidity limit		Atmospheric pressure limit
EC REP	Authorized representative in the European community		Imported by

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