



GIMA

PROFESSIONAL MEDICAL PRODUCTS

Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com

MANICO A FIBRE OTTICHE MONOUSO FIBER OPTIC HANDLE SINGLE USE MANCHE À FIBRE OPTIQUE, À USAGE UNIQUE FIBER OPTIC HANDLE SINGLE USE MANGO DE FIBRA ÓPTICA DE UN SOLO USO CABO DE FIBRA ÓTICA DE USO DESCARTÁVEL ΛΑΒΗ FIBER OPTIC ΜΙΑΣ ΧΡΗΣΗΣ مقبض OPTIC HANDLE للاستخدام مرة واحدة

Manuale d'uso e manutenzione
Use and maintenance book
Instructions de fonctionnement et entretien
Betriebs und wartungs anweisungen
Manual de uso y mantenimiento
Manual de uso e manutenção
Εγχειρίδιο χρήσης και συντήρησης
دليل الإستعمال والرعاية

ATTENZIONE: Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.
ATTENTION: The operators must carefully read and completely understand the present manual before using the product.
AVIS: Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.
ACHTUNG: Die Bediener müssen vorher dieses Handbuch gelesen und verstanden haben, bevor sie das Produkt benutzen.
ATENCIÓN: Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.
ATENÇÃO: Os operadores devem ler e entender completamente este manual antes de usar o produto.

ΠΡΟΣΟΧΗ: Οι χειριστές αυτού του προϊόντος πρέπει να διαβάσουν και να καταλάβουν πλήρως τις οδηγίες του εγχειριδίου πριν από την χρήση του.
الحذر: على العمال قراءة وفهم هذا الدليل بكامله قبل البدء باستخدام المنتج.



REF 58012 - 58014 - 58015



Medical Devices (Pvt) Ltd.
Wazirabad Road, Ugoki,
Sialkot - Pakistan
Made in Pakistan



Obelis S.A Bd. General Wahis, 53
1030 Brussels, Belgium

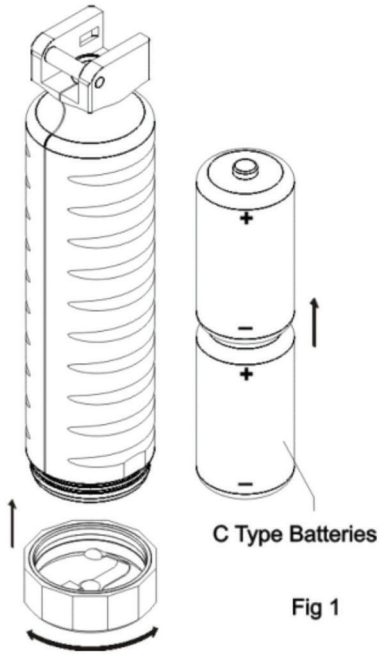


STERILE EO

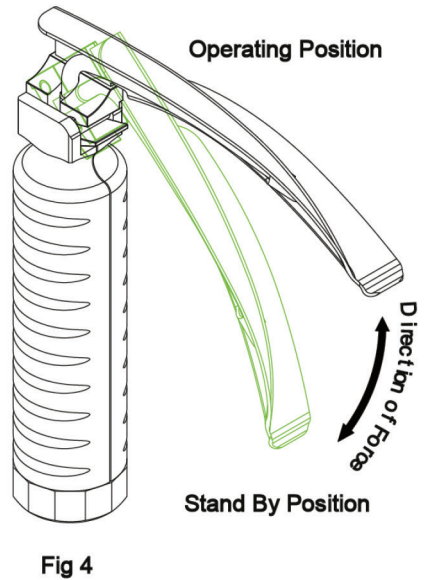
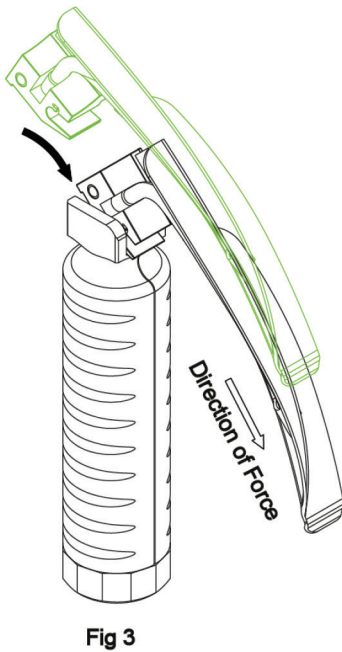
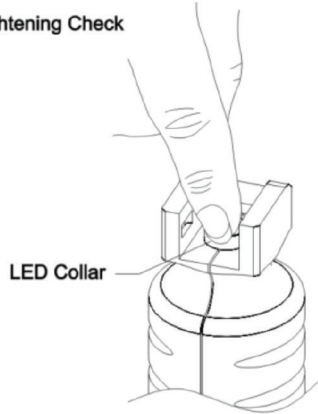


0120





LED Lightening Check



Attention

Thank you for purchasing our product. This product meets the most stringent requirements regarding the selection of manufacturing material and also the final control, Operating instruction manual relates to our brand of Laryngoscope. 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.

Operating Instructions

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

Intended Note

Handle is an integral part of laryngoscope, plays vital role in providing power and acts as light source for fiber optic blades used to examine a patient's upper airway and provides aid in placement of tracheal tube while intubations. Single use laryngoscope offer safe, effective solution for total cross contamination control while eliminating the time and expense of sterilizations.

This product must only be used by a trained professional. Handle is manufactured in accordance with ISO 7376 standard and should be used only with compatible blades manufactured in accordance with ISO 7376 standards.

Features

- Made from robust, impact resistant plastic, highly reliable, corrosion/rust resistant stainless steel and electroplated brass.
- LED illumination with up to 50,000+ LUX providing Anesthetists with a better visualization while examination or intubations reducing battery consumption.
- Ergonomically designed grip ensure external textured and corrugated surface for proper grip while use.
- Simple assembling procedure facilitates the user to Prepare it for emergency use.
- "Ready to Use" versions of this handle eliminate the time loss in loading batteries in emergency situations.
- Supplied sterile, packed in clean room conditions.
- ETO sterilization is being done on the product.
- Compatible with any F.O blade manufactured in accordance with ISO 7376 standards

Battery No.	Life time of battery consumption	Total LUX capacity	Life Time
04-0198-0935 (for ready to use)	120 min (+-10%)	50.000+	3 years

NOTE: the working voltage of device is 3.0V + 0.2V.

Pre-checking parameters

Before using the handle please ensure following:

- The packaging is not ruptured or damaged.
- Fit the blade to the handle and check that the LED functions correctly.



IMPORTANT NOTE: Always keep extra blades and handles available in case of failure or emergency.

Batteries Insertion Procedure

1. In case of "C" type handle unscrew the end cap from the handle as shown in fig.1 insert two 'C' type batteries. And in case of "Ready to Use handle" there is no need to insert batteries.
2. Insert batteries with appropriate positive and negative terminals as shown in fig.1
3. After inserting batteries make sure that the LED is lightening by pressing LED collar downwards as shown in fig.2

Operating Instruction

Fitting & Removing a laryngoscope blade to a laryngoscope handle:

1. Engage the blade by aligning the slot of the blade on to the hook pin of the handle and apply a sufficient force (10-45 N) so that the heel fits on the handle producing a click. fig.3
2. Holding the blade from lip side apply a torque (0.35-1.35 Nm) in the direction as shown in the fig.4 in order to bring the blade in operating position.
3. To disengage, bring the blade in standby position by applying a force (10-45 N) at the lip and with the help of thumb push the foot part front portion

NOTE: In case the blade is engaged incorrectly; this may result in a non-functioning.

Sterilization

Disposable handle are being packed in clean room in controlled environment as per 100K class and EO (Ethylene Oxide) sterilization is being carried out in order to clear the contamination.

Precautions



Read the label before losing packing.

Do not use if packaging has been open or damaged.

Only qualified person should use it.

Handle the device with care and keep the instrument away from the range of insects and rodents.

Autoclaving is not permissible for this type of handle.

Never unscrew the end cap in case of (ready to use) handle doing this may cause the handle to be malfunction.

Ultrasonic cleaning is not recommended.

Store the device in clean environment at normal temperature

Please ensure that the blades, handles and batteries are discarded as clinical waste in accordance with local policies.

Transport and Storage

Before transporting the appliance, make sure that it is correctly packaged ensuring also that there are no risks of shocks bumps or falls during the transport itself. Damage to the appliance caused during transport and handling is not covered by the guarantee. The device must be stored in a dry, cool area away from direct sunlight. It must not be placed in contact with any substances or chemical agents which could cause damage and reduce safety characteristics.

Operation

Temperature 10°C - 40°C

Humidity 30% - 75%

Air Pressure 700 hPa - 1060 hPa

Storage & Transport



















Temperature -20°C to 60°C

Humidity 10% - 90% (without condensation)

Air Pressure 500 hPa - 1060 hPa

Product Life

The shelf life of the Disposable laryngoscope handle as mentioned on the product Label is 3 years valid from the date of manufacture.

	Caution: read instructions (warnings) carefully		Follow instructions for use
	Keep in a cool, dry place		Keep away from sunlight
	Manufacturer		Date of manufacture
	Product code		Lot number
	Medical Device complies with Directive 93/42/EEC		Authorized representative in the European community
	Disposable device, do not re-use		Non ri-sterilizzare
	Don't use if package is damaged		Sterilized using ethylene oxide
	WEEE disposal		Expiration date
	Latex free		Type B applied part



Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.*

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product. This product meets high qualitative standards both as regards the material and the production. The warranty is valid for 12 months from the date of supply of GIMA. During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons. Labor costs and personnel traveling expenses and packaging not included.

All components subject to wear are not included in the warranty.

The repair or replacement performed during the warranty period shall not extend the warranty. The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use. GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc. The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.

The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.