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www.gimaitaly.com

PROFESSIONAL MEDICAL PRODUCTS

LAME FIBRE OTTICHE “GIMA MAXLITE” - “GIMA GREEN”
FIBRE OPTIC BLADES “GIMA MAXLITE” - “GIMA GREEN”
LAMES À FIBRE OPTIQUE « GIMA MAXLITE » - « GIMA GREEN »
FASEROPTISCHE KLINGE “GIMA MAXLITE” - “GIMA GREEN”
HOJAS DE FIBRA ÓPTICA “GIMA MAXLITE” - “GIMA GREEN”
LÂMINAS DE FIBRA ÓTICA “GIMA MAXLITE” - “GIMA GREEN”
ΛΕΠΙΔΕΣ ΟΠΤΙΚΩΝ ΙΝΩΝ “GIMA MAXLITE” - “GIMA GREEN”
“GIMA MAXLITE” - "GIMA GREEN" شفرات الألياف الضوئية

MANUALE D’USO E MANUTENZIONE
USE AND MAINTENANCE BOOK
INSTRUCTIONS DE FONCIONNEMENT ET ENTRETIEN
BETRIEBS UND WARTUNGS ANWEISUNGEN
MANUAL DE USO Y MANTENIMIENTO
MANUAL DE USO E MANUTENÇÃO
ΕΓΧΕΙΡΙΔΙΟ ΧΡΗΣΗΣ ΚΑΙ ΣΥΝΤΗΡΗΣΗΣ
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 باستعمال المنتج.*

CE

Teme l’umidità
Keep dry

Conservare al riparo della luce solare diretta
Keep away from sunlight

REF **58051 - 58052 - 58056 - 58057**
58058 - 58059 - 58060 - 58061
34460 - 34461 - 34462 - 34463
34464 - 34469 - 34470 - 34471
34472 - 34473 - 34474

Gima S.p.A.
Via Marconi, 1
20060 Gessate (MI) - Italy
Made in Pakistan

M58051-M-Rev.1.04.18

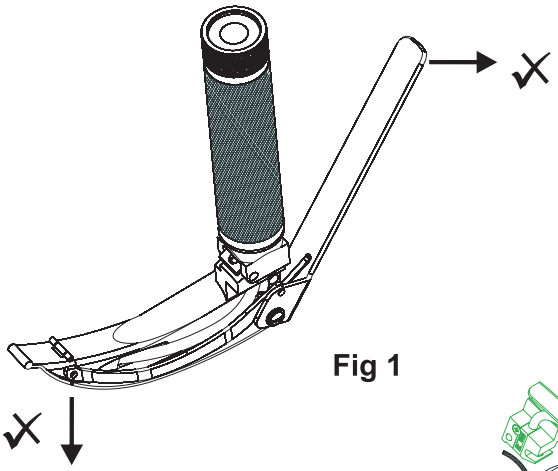


Fig 1

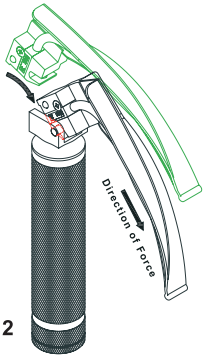


Fig 2

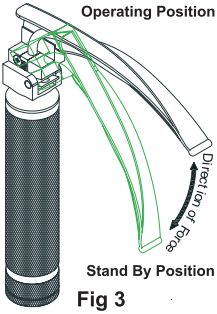


Fig 3

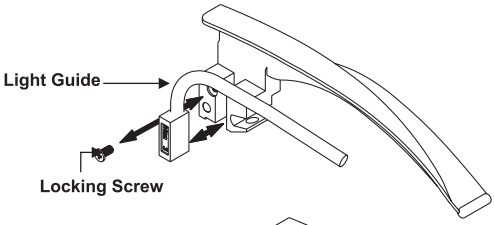
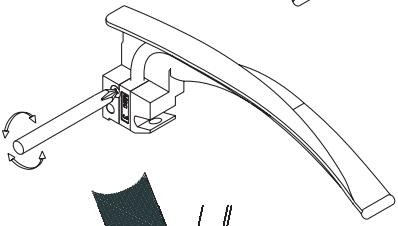


Fig 4



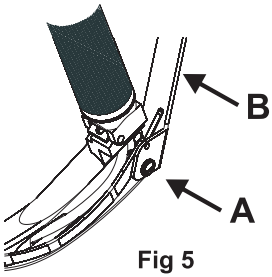


Fig 5

GIMA ENGLISH

Thank you for purchasing our product. This product meets the most stringent requirements regarding the selection of manufacturing materials and also the final control. 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.

Features

The Fiber Optic laryngoscope blades are manufactured from antimagnetic 18/8- quality stainless steel type AISI 303/304 which is highly resistant to corrosion and conform to the ISO 7376 standard.
In the Gime Green blades the fiber optic light blades stems are removable and are interchangeable with a same size blade. By unscrewing the locking side screw as shown in Fig. 4, the light guide can be disengaged and removed for cleaning, repairs or replacement. The removable light guide also has the added advantage that it enables quicker and cheaper repair to be performed should the fibers break due to rough use, or need replacing due to natural wastage.
The GIMA Maxlite F. O. Blades are built with an integrated F. O. bundle with no cavities to trap or body fluids, thus allowing the blade to be easily and decontaminates. This contributes largely to the elimination of cross infection.

High quality and bigger Fiber bundles in GIMA Maxlite F. O. blade ensure excellent light trasmission. 8,000 lux with 2.5V Xenon lamp and 14,000 lux with 3.5V Xenon lamp 20,000 Lux with 2.5V LED and 40,000 Lux with 3.5V LED. The LED Handles (2.5V, 3.5V) provide 3x brighter illumination than Xenon Handles (2.5V, 3.5V).
GIMA Maxlite Blades are maintenance free and autoclavable up to 134°C / 5 min approximately for 4,000 times.

Using the Blades

Do not grip the lever when removing the blade. Do not apply any pressure, in the directions shown in the illustration Fig 1, which could force the blade and lever apart.
Damage to the linkage may occur, resulting in incorrect action, or stiffness of the adjustable tip. The blade is assembled to the handle in the normal manner. The lever to operate the tip section will then extend behind the handle.
The lever should not be touched during the initial stage of use, until the tip of the laryngoscope has been inserted into the vallecula.
Once this stage has been reached, movement of the lever towards the handle will elevate the tip of the blade, and therefore lift the epiglottis, without the need to increase the force exerted by the main part of the blade. Release the lever before withdrawing the blade.

Operating Instruction

1. Engage the blade by aligning the slot of the blade on to the hook pin of the handle and apply a sufficient force 10N-45N to make engagement as show in Fig 2.
2. Apply force upward to bring the blade in operating position as in Fig 3.
3. To bring the blade in stand by position apply force downward as in Fig 3.

Light Guide Replacement Procedure

1. Remove locking screw with a screw driver as show in Fig 4.
2. Pull out the green block and slide out the light guide.
3. Fix new light guide of similar size and replace the locking screw.
4. Be sure that the screw is properly screwed in Blades
5. To remove the light guide, first remove screw A, to allow removal of lever B as shown in Fig 5. The blade levering mechanism may require articulation, before the light guide can be detached from the blade.

Great care should be taken while performing this procedure to avoid structural damage to the fiber blade.

Care & Maintenance

1. Cleaning Procedure

Immediately after use, the laryngoscope system 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 laryngoscope system 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. Remove bottom cap and brush thoroughly using a soft-bristle brush, while ensuring that all hard to reach are reached visible soils / residue removed. Dry with lint free, clean cloth or filtered pressurized air. Follow with HIGH-LEVEL DISINFECTION or STEAM STERLIZATION PROCEDURE.

Ultrasonic cleaning is strictly prohibited

2. Disinfection
Soaking in solutions or Thermo chemically in a washer Sterilizer up to 65°C maximum may perform disinfection. Manufacturers instruction regarding duration and concentration of solutions should be strictly adhered. After Disinfection, rinse throughly in sterile water and dry with a lint free clean cloth.

3. 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. Reassemble all parts, load handle with batteries and test the system for proper function. If not functional, review battery / lamp testing instructions below.

Do not immerse Blades in Bleach, Betadine or Potassium Hydroxide solutions. Doing so will severel damage instruments also avoid metal to metal contact after soaking, the blades should be rinsed under sterile water to remove chemical residues and dry with lint free clean cloth or filtered pressurized air.

4. Sterilization
Before performing any of the procedures described below, the blade should be cleaned as described in the cleaning Procedure.
Note: Its is recommended to remove the fiber optic light guide from the blade before sterilization it effect the polishing of fiber and decreases the light output.

5. Gas Sterilization
Gas sterilization by Ethylene oxide up to a maximum temperature of 65 C and 8 p.s.i, may be performed, which is preferred especially if sterilization is to be performed regularly.

6. Steam Sterilization
Steam Sterilization can also be performed. Insert device in appropriate autoclave pouch.

	(A) GRAVITY DISPLACEMENT STEAM	(B) PRE-VACUUM STEAM
Temperature	121°C (250°F)	132°C (270°F)
Cycle Time	30 Minutes	4 Minutes
Dry Time	15 Minutes	20 Minutes

Note: Do not exceed temperature of 135°C and pressure of 28 p.s.i
Flash autoclaving and hot air sterilization should be avoided as these processes will damage the instrument.

Steris Amsco V-Pro
F/O Laryngoscope Blades and Handles are compatible with:
Amsco V-Pro 1 Low Temperature Sterilization System
Amsco V-Pro 1 Plus Low Temperature Sterilization System
Amsco V-Pro 1 Pro Max Temperature Sterilization System

Sterrad
F/O Larynogoscope Blades and Handles are compatible with:
Sterrad 100nx System (Standard and Express Cycle)
Sterrad nx System (Standard Cycle)
Sterrad 1005 and 200 System (Short Cycle Outside US)
Sterrad 50 System

Blade & Handle Test Procedure

Laryngoscope blades and handle should always be tested after cleaning/ disinfection/ sterilization and prior to use. To test connect the laryngoscope blade to handle and pull it to the ON position as in Fig 2 if the unit fails to light or flicker, check the lamp/ batteries and the electrical contacts, Be sure adequate supplies of spare lamps, batteries and replacement parts are readily available if problem still persists, contact supplier please.

Warning
The above listed sterilization Guidelines, provided by GIMA are intended as procedures compatible with specific materials. Sterilization must be performed to approved Hospital protocol. GIMA can not guarantee sterility. This will be validated by the hospital and or sterilization equipment manufacturers.

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.