



GIMA

PROFESSIONAL MEDICAL PRODUCTS

LAME E MANICI MONOUSO (STERILI)
SINGLE USE BLADES AND HANDLES (STERILE)
LAMES ET POIGNÉES JETABLES (STÉRILES)
HOJAS Y MANGOS DESECHABLES (ESTÉRILES)
LÂMINAS E CABOS DESCARTÁVEIS (ESTÉREIS)
EINWEGSPATELN UND -GRIFFE (STERIL)
ΛΕΠΙΔΕΣ ΚΑΙ ΛΑΒΕΣ ΜΙΑΣ ΧΡΗΣΗΣ (ΑΠΟΣΤΕΙΡΩΜΕΝΕΣ)

شفرات ومقابض للاستخدام الواحد (معقمة)

Manuale d'uso - User manual

Manuel de l'utilisateur

Guia de uso - Guia para utilização

Gebrauchs- und instandhaltungsanleitung

Οδηγίες χρήσης - دليل الاستخدام

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.

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.

ACHTUNG: Diese Anleitung muss vor dem Einsatz des Produkts aufmerksam gelesen und vollständig verstanden werden.

ΠΡΟΣΟΧΗ: Οι χειριστές αυτού του προϊόντος πρέπει να διαβάσουν και να καταλάβουν πλήρως

τις οδηγίες του εγχειριδίου πριν από την χρήση του. تنبيه: يجب على المشغلين قراءة هذا الدليل وفهمه بالكامل قبل

استخدام المنتج

REF

810-411-00S (Gima 58001)

810-411-01S (Gima 58002)

810-401-01S (Gima 58006)

810-401-02S (Gima 58007)

810-401-03S (Gima 58008)

810-401-04S (Gima 58009)

810-401-05S (Gima 58010)

810-459-25S (Gima 58016)

810-457-25S (Gima 58017)



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STERILE EO



Single Use Blades and Handles (sterile)



Attention: The operator must read and understand this manual thoroughly in order to ensure durable and reliable product performance over a predetermined period.

After opening the packages, it is recommended to check that all the components are present and in perfect conditions

Intended use:

A laryngoscope is a device that helps perform intubation during the administration of general anaesthesia or mechanical ventilation. Any patient with respiratory problems and in need of ventilation should be intubated with the help of a laryngoscope, which allows for better visualisation and a quick procedure. Laryngoscopy can be performed to facilitate tracheal intubation during general anaesthesia or cardiopulmonary resuscitation or for surgical procedures on the larynx or other parts of the upper tracheobronchial tree. The laryngoscope is intended for temporary use.

Single use blades (fibre-optically lit laryngoscope) are used with the fibre optic handle for the single use laryngoscope. The blades of the single use laryngoscope have a lightweight acrylic guide that is used to transmit light from a light source to the distal end of the blade. The single use fibre optic handle acts as a power source for itself and a light source for the disposable blades. The LED is used in the disposable handle as a light source.

Patient population:

The laryngoscope is designed and intended to be used for intubation, to facilitate its use on all types of target patients.

Depending on necessities, the handle of the laryngoscope is used with the corresponding blade and acts as a power or light source.

Applicable norm:

ISO 7376:2020 (Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation)

Operating instruction

1. Engage the blade by aligning its slot with the hook pin of the handle. As shown in Fig. 1
2. Apply sufficient force (10N-45N) to engage. As shown in Fig. 2
3. Apply force upward to bring the blade into the operating position. As shown in Fig. 3
4. Check that the blade is correctly positioned and secured.
5. Bring the blade to its stand-by position then apply force downward.
6. Follow the instructions in reverse order to remove the blade.

Note: Fibre optic blades must be used with fibre optic handles. Fibre optic blades and handles can be identified by the “green colour”.



Fig. 1) Attach the blade to the handle



Fig. 2) Engage the blade with the handle by applying sufficient force



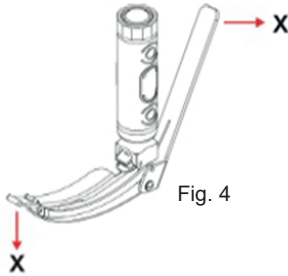
Fig. 3) Lift the blade upwards until it locks with the handle



These blades and handles are for single use only. Do not reuse or recondition these blades and handles. Check the laryngoscope operation before intubation. Always keep extra blades and handles available in case of failure or emergency

Blade using procedure (optical fibre):

The blades must be assembled to the corresponding fibre optic handle, according to the above procedure. To operate the tip, press the lever behind the handle. Do not touch the lever during initial use, until the laryngoscope tip is inserted into the vallecula. After reaching the visual range position, press the lever in the direction of the handle to raise the tip of the blade; therefore lift the epiglottis, without the need to use the force exerted by the main part of the blade. Release the lever before pulling the blade back.

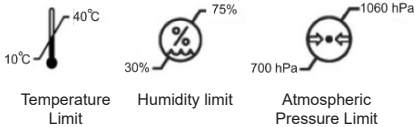


⚠ Do not grip the lever while removing the blade. Do not apply pressure in the directions shown in Fig. 4. Doing so would force the blade and lever apart. This could lead to the connection damaging, resulting in incorrect operation or a rigidity of the adjustable tip.

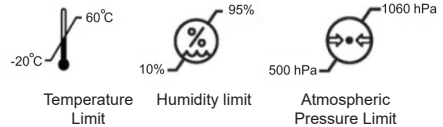
Note: The laryngoscope is intended for temporary treatment ≤ 5 minutes, with a 5 minutes interval between applications. For the fibre optic blades of the single use laryngoscope the maximum temperature at the site of application, at a room temperature of 40°C , is 44.4°C

⚠ The laryngoscope may only be used by qualified medical personnel and in professional healthcare facilities.

Operating Environment:



Storage/Transportation Conditions:



⚠ Using the device without complying to the recommended operating conditions may adversely affect performance and cause damage to the device and/or the patient or healthcare professional.

Maintenance:

The device does not require maintenance.

Support:

The device has no components that can be repaired by the end user.

General Precautions/Warnings:

These products are designed to be SINGLE USE. Do not reuse or recondition.

These products are intended as single use product that can be used on a single patient for a single episode of use within a 1 hour period.

Read the label before unpacking the product. Do not use the device if the packaging is damaged.

Do not use the equipment if it is damaged. Contact your dealer/distributor.

Repeated testing of this equipment before use could significantly reduce its service life or result in operational failure. It is possible to incorrectly mount the blade. This may cause malfunction or damage of blade and/or handle.


















Please ensure that used blades are discarded as clinical waste in accordance with local policies.

If the light is intermittent or does not turn on, check the batteries and electrical contacts.

This product must not be introduced or used in areas with strong magnetic fields, e.g. near MRI scanners.

Shelf life:

Single use blades and handles have a service life of 5 years. Only RTU handles have a service life of 3 years

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

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies