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For Order & Support

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EN

INSTRUCTIONS FOR USE

Single Use Laryngoscope Fiber Optic Blades

Device(s)

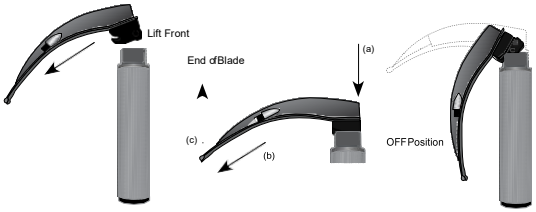
SR#	Description
1	Single Patient Use Laryngoscope Fiber Optic Blade, Metal & Plastic Assembly **(Macintosh & Miller)**

Intended Use

Laryngoscope is a two-part, hand held device consisting of a handle that contains batteries and a detachable blade. Laryngoscopes fiber optic blades are designed to visualize the larynx during the process of performing intubations by receiving illumination from the fiber optic handles. This instruction book covers fiber optic type laryngoscopes.

Positioning & Mounting of Blade to Handle

1. Attach selected blade onto properly operational handle by placing “hook” on blade-base underneath bar on handle as shown in the below figure.
2. Apply downward/forward pressure to seat securely as shown in the below figure.
3. Lift the front end of blade until it clicks and locks under the bar as shown in the below figure.
4. Verify the blade is lit properly.
5. Reverse the above instructions to remove the blade.



2. Cervical spine injury, in which the need for complete immobilization of the cervical spine makes endotracheal intubation difficult.

Warnings

A warning statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately could lead to patient injury, illness, or death.

- Please observe laws (federal law in USA) which restricts this device to sale by or on the order of a physician or licensed healthcare practitioner.
- Only trained personnel should use a laryngoscope for intubation.
- Conventional blades & handles and fiber optic blades & handles are not interchangeable with each other.

Cautions

- Not for use in vicinity of MRI equipment or other intense magnetic fields.
- Repeated testing of this device prior to use may result in a shortened operational time, reducing the life of the product and possibly resulting in operational failure.
- Ensure that the product is operated and used only under assistance of the person with the requisite training, knowledge or experience.
- Read, follow and keep the instructions for use.
- Use the product only in accordance with its intended use, (see intended use).
- Prior to use, visually check the product for bent, broken, cracked or missing component(s).
- Before using the product take off the protected packaging.
- Do not use the product if it is damaged or defective.
- Make sure that excessive force is not placed on this product. Excessive force can result in failure.

Instructions

Before Use

Use only with ISO 7376 compatible handles & blades.

- Do not sterilize, reprocess, or reuse single-use handles or blades.
- Carefully inspect device for burrs, sharp edges, or other visually discernible defects.

Note: Incorrectly mounting the blade may result in damage to blade or malfunction of device.

Contraindications

The following are only relative contraindication to tracheal intubation

1. Severe airway trauma or obstruction that does not permit safe passage of an endotracheal tube.
2. Ensure that spare blades and handles are always available in case of failure or emergency.

Compatibility

Laryngoscopes conform to current ASTM F965-99, EN ISO 7376 standards. They are compatible with virtually all major brands of illumination hook on blades and handles. For easy visual identification.

Disposal of Blade

It is the user’s responsibility to ensure that the used product is disposed of in accordance with medical waste disposal guidelines, where applicable.

Classification & Applicable Standards

- Class 1 (CE – (EU) MDR 2017/745 & FDA)
- EN ISO 7376
- ASTM F965-99

Recommended Operating Environment

Operating Temperature	50°F to 104°F / 10 °C to 40 °C
Operating Temperature	< 95% Non-Condensing
Transport/Storage Temp	-4°F to 113°F / -20 °C to 45 °C Humidity: Up to 95% Noncondensing

Warning: Operating your device outside the recommended operating temperature environment may negatively impact device performance and may cause damage to the device and/or patient or care provider.

USED SYMBOLS :

	Manufacturer		Non-sterile
	EU Authorized Representative		Consult instructions for use
	Catalogue number		Conformity mark
	Date of manufacture		Batch number
	Keep away from sunlight		Keep dry
	Humidity limitation		Temperature limitation
	Do not use if pack is opened or damaged		CAUTION! Federal (US) law restricts this device to sale by or on order of a licensed healthcare surgeon.