EN

INSTRUCTIONS FOR USE
Single Use Laryngoscope Blades & Handles

STARKLING
MEDIZINTECHNIK

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Device(s)

1	Green System Single Patient Use Laryngoscope Blade, All Metal Construction **(MacIntosh & Miller)**
2	Green System Single Patient Use Laryngoscope Blade, Metal & Plastic Construction **(MacIntosh & Miller)**
3	Green System Single Patient Use Laryngoscope Blade, All Plastic Construction **(MacIntosh & Miller)**
4	Green System Single Patient Use Laryngoscope Handle, Metal Plastic Construction **(Medium, Small & Stubby)**

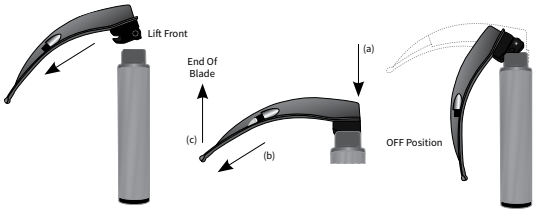
Intended Use

Starkling Laryngoscope is a two-part, hand held device consisting of a handle that contains batteries and a detachable blade. Laryngoscopes are designed to provide illumination within the larynx during the process of performing intubations. This instruction book covers both standard and fiberoptic type laryngoscopes.

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. 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 green system 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 polybag.
- 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 Starkling 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.
- Ensure that spare blades and handles are always available in case of failure or emergency.

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. (a)
2. Apply downward/forward pressure to seat securely. (b)
3. Lift the front end of blade until it clicks and locks under the bar. (c)
4. Verify the blade is lit properly.
5. Reverse the above instructions to remove the blade.

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

Compatibility

Starkling Laryngoscopes conform to current ASTM F965-99, ISO 7376:2009 standards. They are compatible with virtually all major brands of illumination hook on blades and handles. For easy visual identification, all green system models are clearly delineated by a green indicator on both handle and blade.

Disposal

Handle & 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.

Handle’s Battery

Turn bottom lid of handle counter clockwise until the lid separates from the body of the handle. Remove the battery and dispose of properly.

Classification & Applicable Standards

- Class 1 (CE – MDD 93/42/EEC & FDA)
- ISO 7376:2009
- 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% Non-Condensing
Altitude	0 - 13,123 feet (0 - 4,000 meters)
Atmospheric Pressure	50 Kpa to 106 Kpa

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.

Symbols
Symbols may be used on some package labeling for easy identification

Manufacturer
(Company responsible for a device marketed under its own name regardless of whether **"manufactured for"** or **"manufactured by"** the company.)

REF **Catalog number**

LOT **Lot number**

Not sterile

Latex Free

Do not reuse

Expiry date

Temperature limitation

Keep Dry

Do not use if package is damaged

Do not Discard, Recycle. Contact the local city or town offices for instructions on proper disposal.

CAUTION **Caution** see warnings or precautions

Rx Only **Federal (USA)** law restricts this device to sale by or on the order of physician or practitioner

Type B Equipment: Indicates equipment providing a particular degree of protection against electric shock.

Consult instructions for use

This instructions provided above have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for single-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

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