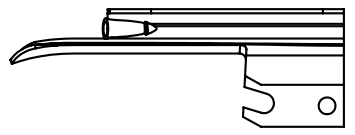
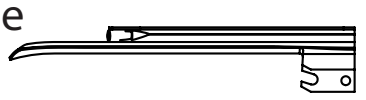
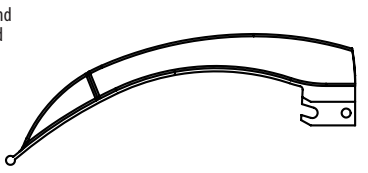
Fiberoptic Laryngoscope Blade Stellar™ Series and Helios™ Series







by Orion Concepts Inc.

www.orionconceptsinc.com

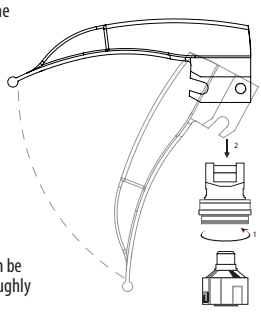
Intended use: Fiberoptic Laryngoscope Blades are used for direct endo-tracheal intubationand the Stellar™ Series and Helios™ Series are reusable devices. They conform to ISO 7376 standard and carry the green identification mark to indicate compatibility with green standard fiberoptic laryngoscopes.

PREPARATION AND USE OF INSTRUMENTS

Before use, ensure that the instrument is free from damage of any kind. Hook blade on handle and swing upwards to latch into "On" position and ensure satisfactory light output.

Flexible-tip Blades: Hook blade on handle and swing upwards to latch into "On" position. Do not hold or operate the lever while inserting laryngoscope into patient. When the tip of the blade locates in the vallecula, operate the lever carefully and no further than necessary to lift the epiglottis. Release the lever before extracting the blade.

CAUTION: Use care during intubation and hold the laryngoscope by the handle, do not operate the lever as the movable blade tip can cause injury to the patient if it is not used according to these instructions and with a normal degree of caution.



CARE AND MAINTENANCE, BLADES

To ensure maximum life and performance, the following instructions should be strictly adhered to. Great care should be taken when handling fiberoptic blades. Do not drop the blades or the fibers inside may fracture reducing output of light.

CLEANING, BLADES

Immediately after use, blades should be rinsed in clean tap water to remove any residue. The blades should then be gently scrubbed in soapy water with a soft brush, to provide a thorough physical cleaning. After cleaning, thoroughly rinse the blade and dry thoroughly with a clean towel.

All STELLAR™ SERIES & HELIOS™ SERIES Fiberoptic Laryngoscope Blades are compatible with enzymatic cleaners. Follow manufacturer's instructions for recommended solution strengths and exposure times

The fiber bundles are not field serviceable and non-replaceable.

DISINFECTION & STERILIZATION, BLADES

WARNING: Ultrasonic cleaning is not recommended.

CAUTION: Disinfection / Sterilization: (Minimum High-Level Disinfection is required)

High Level Disinfection / Sterilization (See below for accepted methods of high level disinfection / sterilization methods)

1. Autoclave (Steam) : Autoclaving may be used.
Note: Do not exceed temperature of 134°C and pressure of 28psi. A cycle time of 4 minutes and up to 20 minutes of drying time is recommended. Longer cycle times of up to 60 minutes will not be harmful to the metal blade but may cause a reduction in light **transmitted through the fiberoptic bundles. Light transmission is affected over time by repeated autoclave cycles**

WARNING: Flash autoclaving and hot air sterilization are not recommended.

2. Cold Soak Solutions : Cold soak solutions which are compatible for use with stainless steel and plastics may be used. Consult Orion Concepts Inc. regarding the use of other solutions. Follow manufacturer's instructions for recommended solution strengths and exposure times.

CAUTION: Do not use extended soak periods, e.g. overnight.

3. Steris® System 1 : STELLAR™ SERIES & HELIOS™ SERIES Fiberoptic Laryngoscope Blades are compatible

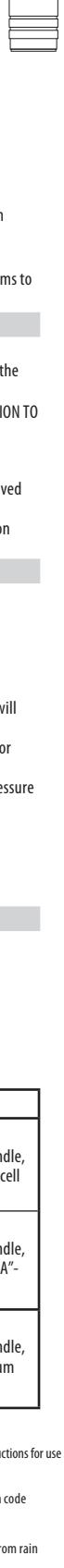
4. Steris® V-PRO® Sterilization System : STELLAR™ SERIES & HELIOS™ SERIES Fiberoptic Laryngoscope Blades are compatible.

5. STERRAD® Process :STELLAR™ SERIES & HELIOS™ SERIES Fiberoptic Laryngoscope Blades are compatible. Use in compliance with the STERRAD® system processing directions and warnings as recommended for their units.

WARNING : devices returned to ORION CONCEPTS Inc. must have been decontaminated or sterilized by the user or facility before return shipment and certified or labeled as such.

GreenStar™ Fiberoptic Laryngoscope Handle

The battery handle consists of two sections: the main handle & head section. The LED cartridge and the battery/batteries must be removed from the instrument prior to high-level disinfection and/or sterilization.



The instrument is designed to operate in ambient temperatures of 31°C or less.

EMC compatibility: this device conforms with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices.

CLEANING, DISINFECTION & STERILIZATION PROCDEDURE, HANDLE

When hospital policy permits the laryngoscope handle may be wiped down using a suitable germicidal wipe or germicidal solution.

Main Handle Sections: Remove batteries and lamp cartridge as described in the Maintenance section before subjecting handle to any of the following processes.

LED Lamp Cartridge: The cartridge and lens must only be cleaned with a mild detergent and warm water solution. DO NOT ALLOW SOLUTION TO ENTER INTO CARTRIDGE

WARNING : The lamp cartridge MUST be removed before SOAKING OR REPROCESSING the handle.

Main Handle & Head Sections: After removing the batteries and LED lamp cartridge the main handle assembly and head may be autoclaved following the autoclave manufacturer's instructions and best practices of your facility.

The main handle assembly and head sections may also be soaked in an enzymatic detergent instructions or washed or soaked in disinfection solution following the directions supplied by the manufacturer of the detergents or solutions

CARE AND MAINTENANCE, HANDLE

Battery Replacement (Disposable)

1. Unscrew head from handle and remove Battery/batteries. **2.** Standard Handle uses 2 "C" cell batteries.

3. Replace with appropriate battery/batteries observing polarity as shown (fig. A) and replace handle head.

CAUTION : Remove batteries and store separately from handles if handles will be out of service for periods of 2 months or longer.

LED Lamp Cartridge

1. Prior to removal, allow cartridge time to cool. Unscrew handle head by turning counterclockwise. LED Lamp holder cartridge assembly will remain in head. Remove by applying finger pressure in the direction shown by the arrow.

CAUTION: Be sure cartridge lens is clean and free of any fingerprints after assembly. If necessary, the lens may be cleaned with a soft cloth or cotton ball moistened with a mild detergent and warm water solution.

2. To replace cartridge in the head, invert head. Insert the cartridge into the head until the holder exits opening on top and apply slight pressure to set the cartridge in place.

3. Replace head on handle observing polarity as shown (fig.A) and tighten by turning clockwise.

* There are no user serviceable parts in the LED lamp cartridge.

WARNING : Orion Concepts Inc., cannot guarantee that any of the recommended sterilization methods will guarantee sterility. This must be validated by the hospital and/or equipment manufacturer.

TEST PROCEDURES, BLADES & HANDLES

Laryngoscope blades and handles should always be tested after cleaning/disinfection/sterilization and prior to use. To test, connect the laryngoscope blade to the handle and swing up to the ON position. If the unit fails to light or flickers, check the batteries and the electrical contacts.

Be sure adequate supplies of batteries and replacement parts are readily available. If the problem still persists, contact ORION CONCEPTS Inc. Customer Service.

WARNING : If handle is hot to touch, immediately remove and inspect all batteries and check cartridge for proper operation.

Fiberoptic Laryngoscope Blade Reference Chart

STELLAR™ SERIES (SS) & HELIOS™ SERIES (HS), Risk Class II

Profile	Size	SS Part No.	HS Part No.	Profile	Size	SS Part No.	HS Part No.
Macintosh	1	219MA1	208MA1	Miller	00	219MI00	208MI00
	2	219MA2	208MA2		0	219MI0	208MI0
	3	219MA3	208MA3		1	219MI1	208MI1
	4	219MA4	208MA4		2	219MI2	208MI2
McCoy (Flex Tip)	3	219MCC3	208MCC3		3	219MI3	208MI3
	4	219MCC4	208MCC4		4	219MI4	208MI4

Product Code	Class	Description
GS-MED-A-NU	I	LED, Fiber Optic Laryngoscope Handle, Medium Size, "C"-cell batteries
GS-PEN-A-NU	I	LED, Fiber Optic Laryngoscope Handle, Paediatric Size, "AA"-cell batteries
GS-STU-A-NU	I	LED, Fiber Optic Laryngoscope Handle, Stubby Size, Lithium Battery

WARNING : ONLY TRAINED PERSONNEL SHALL USE A LARYNGOSCOPE FOR INTUBATION

Symbols and Definitions

"WARNING" Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device

Caution, consult accompanying documents

Consult instructions for use

Alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property.

Temperature limitation

Non-sterile

Batch code

Date of manufacture (yyyy-mm)

Keep away from rain

Catalogue number

Manufacturer

Unique device identifier

ORION CONCEPTS™

CUSTOMER SERVICE

2- 451 Enfield Rd., Burlington ON, Canada • Phone (289) 288-1448 Fax (289) 288-1450

ONLY TRAINED PERSONNEL SHALL USE A LARYNGOSCOPE FOR INTUBATION.

Use of instrument in presence of intense magnetic fields should present no problems.

Printed in Canada

IFU1603 R5